P19-01 CALA MEASUREMENT UNCERTAINTY POLICY

Revision 2.0

February 12, 2020

CALA

Trust, measured accurately

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1.0 SCOPE

This policy is to be implemented by all applicants and CALA-accredited laboratories. Uncertainty is to be estimated during method validation and re-estimated when changes to operations are made that may affect sources of uncertainty and these sources have not been shown to be unaffected through method validation or other studies.

2.0 BACKGROUND

ISO/IEC 17025 requires the estimation of measurement uncertainty for testing and calibration laboratories as noted in 7.6 of ISO/IEC 17025: 2017. The standard also specifies the reporting requirements with respect to measurement uncertainty. Accredited and applicant laboratories must meet these requirements and any relevant CALA policies on measurement uncertainty.

The only exception to the requirement to estimate uncertainty for each test is explained in a subsequent note:

> *"In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions "*
>
> *—ISO/IEC 17025:2017clause7.6.3 Note 1*

Note: A well-recognized test method is taken as those published in international, national or regional standards or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by equipment manufacturer**.**

3.0 DEFINITIONS

Expanded uncertainty: (GUM 2.3.5) quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.

> Note: The fraction may be viewed as the coverage probability or level of confidence of the interval.
>
> To associate a specific level of confidence with the interval defined by the expanded uncertainty requires explicit or implicit assumptions regarding the probability distribution characterised by the measurement result and its combined standard uncertainty. The level of confidence that may be attributed to this interval can be known only to the extent to which such assumptions may be justified.

Measurand: (VIM 2.3) quantity intended to be measured.

Measurement: (VIM 2.1) process of experimentally obtaining one or more quantity values that can be reasonably attributed to a quantity.

Uncertainty of measurement: (GUM 2.2.3) parameter associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the measurand.

> Note: (GUM 2.2.3) The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.
>
> Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterised by experimental standard deviations. The other components, which can also be characterised by standard deviations, are evaluated from assumed probability distributions based on experience or other information.
>
> It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion. This definition is that of the "Guide to the expression of uncertainty in measurement" in which its rationale is detailed (see in particular 2.2.4 and Annex D to GUM).

4.0 POLICY

Applicant and accredited laboratories shall have and apply procedures for estimating measurement uncertainty for all quantitative (i.e producing a numerical result) methods on their scope of accreditation. Estimation of uncertainty is not required for qualitative methods but laboratories must identify those components contributing to the uncertainty. In cases where the nature of the test method precludes rigorous, metrological and statistically valid estimation of the measurement uncertainty, a testing laboratory shall make a reasonable attempt to estimate the uncertainties of the results based in theoretical principles or practical experience.

Where a testing laboratory performs its own calibrations, the laboratory shall have and apply a procedure for estimating uncertainty associated with its calibrations.

Laboratories shall report the expanded uncertainty estimate as part of the reported result when:

1. Requested by the customer;
2. It is relevant to the validity or application of the result; or,
3. When the uncertainty affects conformity to a specification limit.

When required, the laboratory shall report the expanded uncertainty along with the analyte concentration in the same units as the analyte concentration. The laboratory shall also report the coverage factor and the confidence level used.

For all estimates of measurement uncertainty, the required elements are:

1. Identify and document all components of uncertainty in the test (e.g. bias, sampling, sub-sampling, calibration, etc.);
2. Determine the significance of each component, eliminating any component that is insignificant (if the laboratory chooses);
3. Identify all available data that can be used in the uncertainty estimate and the component(s) to which it applies (e.g., CRMs, duplicate data, spike recovery data, etc.).
   Data used shall be adequate to cover variability within the laboratory and not based on a single day/run;
4. Identify any gaps in data; and,
5. Use the available data, and logically derived estimates where gaps exist, to calculate the expanded uncertainty. The coverage factor, k, is 2 or the appropriate (95% confidence level) Student's T distribution factor (two tailed).

4.1 Large Analytical Range

The estimation of measurement uncertainty shall be relevant to the expected concentration range of the analyte. Where applicable, the uncertainty shall be estimated at different concentration levels to account for the change in uncertainty with concentration.

4.2 Different Matrices

Laboratories shall make independent estimates of measurement uncertainty for tests performed on samples with significantly different matrices.

4.3 Uncertainty Due to Sampling/Subsampling

When laboratories select an analytical portion from a sample that may not be homogeneous, the laboratory shall include sub-sample uncertainty as part of the combined standard uncertainty calculation. When evaluating measurement uncertainty all contributions which are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

P19-02 Guidance on The Implementation of the CALA Measurement Uncertainty Policy provides information on how this policy may be met. Other documents and guides may also be used by laboratories to develop methods to fulfil these requirements.

5.0 REFERENCES

1. ISO/IEC 17025 - *General Requirements for the Competence of Testing and Calibration Laboratories*, 2017.
2. Ellison, S.L.R., M. Rosslein, and A. Williams, Editors, *Quantifying Uncertainty in analytical Measurement*, 3rd Edition, Eurachem/CITAC, available on internet at www.measurementuncertainty.org/mu/quam2.pdf, 2012.
3. *Evaluation of measurement data — Guide to the expression of uncertainty in measurement*, JCGM 100:2008 GUM 1995 with minor corrections, 2008.
4. ILAC Guide 17:2002, *Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025. 2002*, International Laboratory Accreditation Cooperation (ILAC).
5. *International Vocabulary of Metrology - Basic and general concepts and associated terms (VIM), JCGM* 200:12 3rd edition, 2008 version with minor corrections.

6.0 REVISION HISTORY

Revision Number	Revision Date	Nature of Revision
2.0	February 12, 2020	Divided the previous policy on measurement uncertainty into 2 documents: a policy document and a guidance document
		Updated references to reflect wording in ISO/IEC 17025:2017