APPENDIX G
EVALUATION OF MEASUREMENT UNCERTAINTY

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1. SCOPE

This AIHA Laboratory Accreditation Programs, LLC (AIHA LAP) Policy documents the requirements for accredited laboratories to maintain accreditation to ISO/IEC 17025:2017 regarding the evaluation of measurement uncertainty. This policy applies to all laboratories accredited by the AIHA LAP. AIHA LAP wishes to thank and acknowledge the Canadian Association for Laboratory Accreditation (CALA) for its permission to incorporate elements of CALA P19 – *CALA Policy on the Estimation of Uncertainty of Measurement in Environmental Testing* in preparing the initial version of this policy document.

2. REFERENCES

The following documents provide the basis and assist with application of the principles stated in this policy.

- **CALA P19** – *CALA Policy on the Estimation of Uncertainty of Measurement in Environmental Testing*, Canadian Association for Laboratory Accreditation
- **JCGM 100:2008 (GUM 1995 with minor corrections) Evaluation of measurement data — Guide to the expression of uncertainty in measurement,** https://www.bipm.org/en/publications/guides/gum.html
- **ILAC Guide 17:** Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025., https://ilac.org/publications-and-resources/ilac-guidance-series/
- ILAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration
- JCGM 200:2012, **International vocabulary of metrology — Basic and general concepts and associated terms (VIM)** published by (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML), https://www.bipm.org/en/publications/guides/
- **ISO/IEC 17025:2017** - General Requirements for the Competence of Testing and Calibration Laboratories
- **Quantifying Uncertainty in Analytical Measurement**, 3rd Edition, 2012, Eurachem/CITAC,

3. TERMS AND DEFINITIONS

Bias (measurement bias) (VIM 2.18 JCGM 200:2012): estimate of a **systematic measurement error**
NOTE: Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

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<u>Combined standard uncertainty (combined standard measurement uncertainty)</u> (VIM 2.31 JCGM 200:2012): **standard measurement uncertainty** that is obtained using the individual **standard measurement uncertainties** associated with the **input quantities in a measurement model**

<u>Coverage factor</u> (VIM 2.38 JCGM 200:2012): number larger than one by which a **combined standard measurement uncertainty** is multiplied to obtain an **expanded measurement uncertainty**
NOTE: A coverage factor, *k*, is typically in the range of 2 to 3.

<u>Coverage probability</u> **(**VIM 2.37 JCGM 200:2012): probability that the set of **true quantity values** of a **measurand** is contained within a specified **coverage interval**
NOTE 1 This definition pertains to the Uncertainty Approach as presented in the GUM.
NOTE 2 The coverage probability is also termed "level of confidence" in the GUM.

<u>Expanded uncertainty</u> **(expanded measurement uncertainty)** (VIM 2.35 JCGM 200:2012): product of a **combined standard measurement uncertainty** and a factor larger than the number one
NOTE 1 The factor depends upon the type of probability distribution of the **output quantity in a measurement model** and on the selected **coverage probability.**
NOTE 2 The term "factor" in this definition refers to a **coverage factor.**
NOTE 3 Expanded measurement uncertainty is termed "overall uncertainty" in paragraph 5 of Recommendation INC-1 (1980) (see the GUM) and simply "uncertainty" in IEC documents.

<u>Level of confidence</u> GUM term used for **Coverage Probability**

NOTE The value is often expressed as a percentage.

<u>Measurand</u> (VIM 2.3 JCGM 200:2012): **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 any relevant component, and the chemical entities involved.
NOTE 4 In chemistry, "analyte", or the name of a substance or compound, are terms sometimes used for 'measurand'. This usage is erroneous because these terms do not refer to quantities.

<u>Measurement</u> (VIM 2.1 JCGM 200:2012): process of experimentally obtaining one or more quantity **values** that can reasonably be attributed to a **quantity**
NOTE 1 Measurement does not apply to **nominal properties.**
NOTE 2 Measurement implies comparison of quantities or counting of entities.
NOTE 3 Measurement presupposes a description of the quantity commensurate with the intended use of a **measurement result,** a **measurement procedure,** and a calibrated **measuring system** operating according to the specified measurement procedure, including

the conditions **standard uncertainty** (VIM 2.30 JCGM 200:2012) **measurement uncertainty** as a standard deviation.

Type A evaluation of measurement uncertainty (VIM 2.28 JCGM 200:2012): evaluation of a component of **measurement uncertainty** by a statistical analysis of **measured quantity values** obtained under defined measurement conditions.
NOTE For various types of measurement conditions, see **repeatability condition of measurement, intermediate precision condition of measurement,** and **reproducibility condition of measurement.**

Type B evaluation of measurement uncertainty (VIM 2.29 JCGM 200:2012): evaluation of a component of **measurement uncertainty** determined by means other than a **Type A evaluation of measurement uncertainty**

EXAMPLES Evaluation based on information
— associated with authoritative published **quantity values,**
— associated with the quantity value of a **certified reference material,**
— obtained from a **calibration** certificate,
— about drift,
— obtained from the **accuracy class** of a verified **measuring instrument,**
— obtained from a limits deduced through personal experience.

Uncertainty of measurement (measurement uncertainty) (VIM 2.26 JCGM 200:2012): 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. BACKGROUND

Knowledge of the measurement uncertainty of test results is important for laboratories, their customers and regulators. Laboratories must understand the performance of their test methods and the uncertainty associated with test results to ensure their test results meet their customers' needs. Therefore, the measurement uncertainty process must be incorporated into method validation or verification exercises. Customers use test results to make rational, cost effective decisions and need to understand the reliability of the test results especially as they approach regulatory limits. Regulatory agencies need to understand the impact and risk of the test results reported to them.

The degree of rigor needed in an evaluation of measurement uncertainty will depend on such factors as the requirements of the test method, the requirements of the customer and the existence of narrow limits on which decisions on conformance to a specification are based. It is recognized that customers and regulatory agencies are not consistent in their knowledge or use of measurement uncertainty evaluations, however this is expected to change over time.

This AIHA LAP policy complies with the requirements of ISO/IEC 17025:2017 and the policies and guidance provided by APLAC and ILAC. The AIHA LAP provides examples for common approaches used in different disciplines in a separate guidance document. However, the examples are not exhaustive, nor can they include every valid or reasonable approach. Several organizations and groups have published guidance and worked examples on the evaluation of measurement uncertainty. Laboratories are encouraged to review many sources for examples of other statistically valid approaches that pertain to their activities. Refer to the AIHA LAP Guidance on the Evaluation of Measurement Uncertainty document for a list of sources.

5. EVALUATION OF MEASUREMENT UNCERTAINTY POLICY

The requirements which underlies this policy is given in ISO/IEC 17025:2017, Clauses 7.6 and 7.8.3.1 c).

Laboratories accredited under AIHA LAPshall fulfil the following requirements with respect to the evaluation of measurement uncertainty for tests associated with their scope of accreditation:

5.1 Laboratories shall be able to demonstrate their ability to evaluate measurement uncertainty for all accredited quantitative test methods. In those cases where a rigorous evaluation is not possible, the laboratory must make a reasonable attempt to estimate the uncertainty of test results. All approaches that provide a reasonable and valid evaluation of uncertainty are equally acceptable.

5.2 Laboratories shall make independent evaluations of uncertainty for tests performed on samples with significantly different matrices. For example, evaluations made for filter samples cannot be applied to bulk samples.

5.3 Evaluations of measurement uncertainty are not needed where the reported test results are qualitative. Laboratories are, however, expected to have an understanding of the contributors to variability of test results. Examples of such tests are those that report only organism identifications or presence/absence.

5.4 Laboratories shall have a written procedure describing the process used to evaluate measurement uncertainty, including at a minimum:

5.4.1 Definition of the measurand.
5.4.2 Identification of the contributors to uncertainly of measurement.
5.4.3 Details of the approaches used for evaluating measurement uncertainty, such as Type A and/or Type B.

When using the Type A approach, laboratories shall utilize one or more of the following options. These options are generally considered from 1) most suitable, to 4) least suitable:

1) <u>Uncertainty specified within a standard method.</u> In those cases where a well-recognized test method (such as a peer-reviewed AOAC, NIOSH, OSHA, ASTM, etc. method), specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of calculated results, laboratories need not do anything more than follow the reporting instructions as long as they can demonstrate they follow the reference method without modification and can meet the specified reliability.

2) <u>Laboratory Control Samples (LCS) and Matrix Spikes.</u> In cases where matrix specific LCS (CRM or media spikes) and/or matrix spike data are available, include uncertainty evaluated from the standard deviation of long term data collected from routine sample runs for existing test methods or from the standard deviation of the LCS or matrix spike data for method validation/verification studies for new test methods.

3) <u>Duplicate Data</u>. In cases where sub-sampling occurs and there are data over the reporting limit, include uncertainty evaluated from long term duplicate data collected from routine sample runs for existing test methods or method validation/verification studies for new test methods.

4) Proficiency Testing (PT) Sample Data. In cases where the previous options are not available and where PT samples are analyzed with sufficient data above the reporting limit, pooled PT sample data can be used to evaluate uncertainty.

5.4.4 Identification of the contributors of variability for qualitative test methods.

5.4.5 All calculations used to evaluate measurement uncertainty and bias.

5.4.6 The reporting procedure.

5.5 Laboratories are required to re-evaluate measurement uncertainty when changes to their operations are made that may affect sources of uncertainty.

5.6 Laboratories shall report the expanded measurement uncertainty, along with the reported analyte concentration, in the same units as analyte concentration, when:

- it is relevant to the validity or application of the test results, or
- a customer's instructions so requires, or
- the uncertainty affects compliance to a specification limit.

5.7 When reporting measurement uncertainty, the test report shall include the coverage factor and confidence level used in the evaluations (typically k = approximately 2 at the 95% confidence level).

5.8 When the test method has a known and uncorrected systematic bias, it shall be reported separately from the test result and measurement uncertainty, as a probable bias value.

6. ASSESSMENT FOR ACCREDITATION

During assessment and surveillance of a laboratory, the assessor will evaluate the capability of the laboratory to evaluate the measurement uncertainty for test methods included in the laboratory's scope of accreditation. The assessor will verify that the methods of evaluation applied are valid, all significant contributors to uncertainty have been considered, and all the criteria of the AIHA LAP policy are met.

7. GUIDANCE AND EXAMPLES

Refer to the AIHA LAP Guidance on the Evaluation of Measurement Uncertainty document for suggestions and examples for implementing the policies listed in this document and a list of helpful references.