Perry Johnson Laboratory Accreditation, Inc.

Policy on Measurement Uncertainty

1.0 INTRODUCTION

1.1 A Conformity Assessment Body (CAB) seeking or maintaining accreditation shall evaluate the associated measurement uncertainty.

1.2 Section 2.3 Uncertainty of Measurement for CABs Providing Accredited Calibration Services is written to comply with the requirements of ILAC-P14:09/2020.

2.0 PJLA POLICY OF UNCERTAINTY OF MEASUREMENT

2.1 UNCERTAINTY OF MEASUREMENT FOR CABS PERFORMING TESTING (OTHER THAN MEDICAL)

2.1.1 The CAB performing testing (other than medical), PT providers (using an in-house or non-accredited subcontracted laboratory for value assignment) and reference material producers (using an in-house or non-accredited subcontracted laboratory for value assignment), shall follow the uncertainty requirements of the relevant version of ISO/IEC 17025.

2.1.2 When relevant, records of the identification of contributions to and the evaluation of measurement uncertainty shall be available for accredited scope items during each assessment.

2.1.3 Reporting of Statements of Conformity for Test Reports

CABs are allowed to issue certificates that include a statement of conformity related to specifications. When the measurement result is determined (or verified) to be within a specified tolerance or limits (i.e., pass/fail, etc.), the associated uncertainty of the measurement result shall be accounted for with respect to the tolerance or limits in accordance with a documented agreement with the customer. This decision rule shall be established during contract review.

For regulatory values of the standards issued by the Japanese government and reference values of standards issued by standard owners, the standard values agreed upon between the CAB and the standard owner are used, so there is no need to use uncertainty in a statement of conformity.

2.1.3.1 The CAB shall meet and maintain appropriate records for the following requirements (criteria ISO/IEC 17025:2017) when making statements of conformity:

Clause 3.7 defines a decision rule as:

“A rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement.”

By this definition, the inclusion of measurement uncertainty is inherent to a decision rule when making a statement of conformity. However, the application of decision rules and measurement

uncertainty must consider the context of the testing being performed.

Application of Measurement Uncertainty:

For most testing and calibration activities, measurement uncertainty is a critical element in determining conformity. However, there are circumstances where its explicit inclusion may not be required.

Regulatory Testing in the US Economy:

In the US economy, testing in support of regulatory requirements may not typically require the use of measurement uncertainty when making statements of conformity. In these cases, a statement such as the following may be used:

"Measurement uncertainty is not applied when providing statements of conformity; decision rules are not identified in regulation."

In such circumstances, Clause 7.8.6.1 may not apply, but all other relevant clauses related to decision rules must be met.

Qualitative and Sensory Testing:

For qualitative testing (e.g., identity, presence/absence, classifications, tally counts, sensory evaluations such as visual, olfactory, and touch-based assessments), traditional uncertainty analysis may not apply. Variability in these tests is typically addressed through standardized procedures, personnel training, or controlled testing conditions.

In these cases, the CAB must document its approach to addressing variability or justify the exclusion of measurement uncertainty during contract review, as required by Clause 7.1.3.

Customer-Specific Requirements:

When testing is performed to customer-specific or specified methods, the determination of conformity may depend on the customer’s instructions. In such instances, the CAB must clearly define the decision rule or specify that no decision rule is applied, in accordance with the agreement established during contract review (Clause 7.1.3).

Relevant ISO/IEC 17025:2017 Requirements:

The following clauses must be adhered to when making statements of conformity:

Clause 6.2.6(b): Personnel must be authorized to perform "analysis of results, including statements of conformity or opinions and interpretations."

Clause 7.1.3: When a customer requests a statement of conformity to a specification or standard (e.g., pass/fail, in-tolerance/out-of-

tolerance), the specification or standard and the decision rule must be clearly defined, communicated, and agreed upon with the customer.

Clause 7.8.3.1(b) and (c): Where relevant, the statement of conformity must include measurement uncertainty if it affects the validity or application of results or is required by the customer.

Clause 7.8.4.1(a) and (e): Measurement uncertainty must be presented where relevant, and statements of conformity must clearly specify the requirements or specifications met.

Clause 7.8.6.1: When providing a statement of conformity, the laboratory must document and apply the decision rule, taking into account the associated risks.

Clause 7.8.6.2: The laboratory's statement of conformity must clearly identify:

a) The results to which the statement applies,

b) The specifications, standards, or parts thereof met or not met, and

c) The decision rule employed.

Documenting Variations:

The CAB shall ensure that any deviations or exceptions to the standard requirements (e.g., regulatory exclusions or qualitative testing approaches) are documented in the laboratory's management system, with sufficient justification provided to demonstrate conformance to ISO/IEC 17025:2017.

2.1.3.2 If the above conditions cannot be agreed upon by the CAB and its customer, the CAB should consider reporting the results and related measurement uncertainty, and let the customer determine the conformity to a specification.

2.2 Uncertainty of Measurement for CABs Performing Medical Testing

2.2.1 The CAB shall follow the uncertainty requirements of the relevant version of ISO 15189.

2.2.2 When relevant, records of the evaluation of measurement uncertainty shall be available for accredited scope items during each assessment.

2.3 Uncertainty of Measurement for CABs Providing Accredited Calibration Services

2.3.1 Uncertainty Report on the Scope of Accreditation

2.3.1.1 Accredited CABs shall evaluate, estimate, and maintain expanded uncertainties to be identified as the Calibration and Measurement Capability (CMC) for each line item in their scope of accreditation using a coverage probability of approximately 95%.

The unit of the CMC uncertainty shall always be the same as that of the measurand or in a term relative to the measurand.

2.3.1.1.1 Uncertainties shall be reevaluated when contributors have changed (e.g., changes in personnel, recalibration, or repair of equipment, etc.) or where contributions differ in magnitude from those defined in a current estimation (environmental conditions are out of ranges anticipated through original estimate).

2.3.1.2 The scope of accreditation of an accredited calibration laboratory shall include the 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.

2.3.1.3 There shall be no ambiguity in the expression of the CMC on the scopes of accreditation and, consequently, on the smallest measurement uncertainty 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 measurement uncertainty shall be applied:

a) A single value, which is valid throughout the measurement range.

b) A measurement range. In this case a calibration laboratory shall ensure that linear interpolation is appropriate in order to find the uncertainty at intermediate values.

c) An explicit function of the measurand and/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 digits for the uncertainty.

2.3.1.4 The CMC identified shall include the contribution from a best existing device to be calibrated such that the CMC claimed is achievable.

2.3.1.5 Where the CAB offers 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 artifact effects, interferences, etc. shall be considered).

2.3.2 Reporting of Measurement Uncertainty on Calibration Certificates

2.3.2.1 CABs shall report the measurement uncertainty (MU) on all accredited certificates and reports, when the end use of the item under calibration is for calibrations furthering metrological traceability.

2.3.2.2 The measurement uncertainty shall include all significant contributors including those attributed to the item under test.

2.3.2.3 The measurement uncertainty reported shall follow requirements of the *Guide to the expression of Uncertainty in Measurement*, the GUM.

2.3.2.4 The measurement result shall 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.

2.3.2.5 A statement of the measurement result and the associated uncertainty must be accompanied by an explanation of the coverage probability and coverage factor (k).

Example: “The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k=2, which for a normal distribution corresponds to a coverage probability of approximately 95%.”

2.3.2.6 Expanded uncertainties reported on calibration certificates and reports shall be limited to two significant digits. However, it is preferable that rounding to two significant digits should not be performed in the budget sheet but should be performed after multiplying by the coverage factor k=2.

For the process of rounding, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided (i.e., Section 7 of the GUM).

2.3.2.7 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.

2.3.2.8 The CAB shall not report a smaller uncertainty of measurement on their accredited certificates than the uncertainty of the Calibration

and Measurement Capability (CMC) identified on the scope of accreditation of the CAB.

2.3.2.9 The unit of measure for the MU reported on calibration certificates and reports shall be the same as that of the measurand or relative to the measurand.

2.2.2.10 CABs shall not report measurement data with significant digits beyond the resolution of the instruments' reported uncertainty of measurement

2.3.2.11 When the end use of the item under calibration is not for calibrations furthering metrological traceability, (e.g., when a calibration laboratory calibrates measuring instruments for a client's in-house use), the CAB's customer may request a report to be issued in a simplified manner. Evidence of the request shall be available for review at the time of an assessment.

2.3.2.11.1 Regardless of if a CAB's customer wants the uncertainty of measurement reported, the CAB shall retain records of the measured quantity values and uncertainty of measurement. These are to be available upon request.

2.3.3 Reporting of Statements of Conformity for Calibration

CABs are allowed to issue certificates that include a statement of conformity related to specifications. When the measurement result is determined (or verified) to be within a specified tolerance or limits (i.e., pass/fail, etc.), the associated uncertainty of the measurement result shall be accounted for with respect to the tolerance or limits in accordance with a documented agreement with the customer. This decision rule shall be established during contract review.

2.3.3.1 The CAB shall meet and maintain appropriate records for the following requirements (criteria ISO/IEC 17025:2017) when making statements of conformity:

Clause 3.7: a decision rule is defined as a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement.

By this definition, the CAB must consider and address measurement uncertainty when making the statement of conformity. The inclusion of measurement uncertainty is inherent to a decision rule.

Clause 6.2.6 b) requires that the laboratory shall authorize personnel to perform "analysis of results, including statements of conformity or opinions and interpretations."

Clause 7.1.3 requires that "When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g., pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision

rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer."

Clause 7.8.3.1b) states "where relevant, a statement of conformity with requirements or specifications" and clause 7.8.3.1c) states "where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent), when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the measurement uncertainty affects conformity to a specification limit."

Clause 7.8.4.1a) states "the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent)."

Clause 7.8.4.1e) also states "where relevant, a statement of conformity with requirements or specifications."

Clause 7.8.6.1 states "When a statement of conformity to a specification or standard for test or calibration is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule."

Clause 7.8.6.2 requires that "the laboratory shall report on the statement of conformity, such that the statement clearly identifies:

a) to which results the statement of conformity applies;

b) which specifications, standard or parts thereof are met or not met;

c) the decision".

2.2.3.1 If the above conditions cannot be agreed upon by the CAB and its customer, the CAB should consider reporting the results and related measurement uncertainty, and let the customer determine the conformity to a specification.