Perry Johnson Laboratory Accreditation, Inc.

Policy on Measurement Uncertainty

1.0 INTRODUCTION

1.1 The following paragraphs define the responsibilities of organizations seeking accreditation by PJLA regarding the estimation of CMC (Calibration and Measurement Capability) and measurement uncertainty. The requirement to estimate CMC applies to calibration organizations only. This policy is based on the requirements outlined in ISO/IEC 17025:2017, ISO 15189:2012, ISO 17034:2016, ISO/IEC 17011:2017 and ILAC P-14:09/2020 and applies only to calibrations or tests for which an accredited result is to be reported. The GUM and its accompanying documents [8] establish general rules for evaluating and expressing uncertainty in measurement that can be followed in most fields of measurements. In accordance with ILAC P14, laboratories will be required to determine measurement uncertainty in accordance with the GUM.

Criteria in regard to the establishment of CMC can be located in PL-4 Policy on Scopes of Accreditation for Calibration Laboratories.

2.0 TERMS

2.1 **The Calculation of Uncertainty for a Measurement:** Is an effort to set reasonable bounds for the measurement result according to standardized rules. These rules are established in the GUM (ISO/IEC Guide **98:2008** The Guide to the Expression of Uncertainty in Measurement).

2.2 **Calibration and Measurement Capabilities:** Is an effort to express "The smallest uncertainty which an organization can attain when performing a more or less routine calibration of a nearly ideal device under nearly ideal conditions". 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 published in the BIPM key comparison database (KCDB) of the CIPM MRA or;

b) as described in the organization's scope of accreditation granted by a signatory to the ILAC Agreement.

As implied in the definition of CMC above, accredited calibration laboratories shall not report a smaller measurement uncertainty than the uncertainty described by the CMC for which the laboratory is accredited.

For further information in regard to the term CMC, refer to Appendix A ILAC P P14:09/2020*."* A paper by the joint BIPM/ILAC working group**.**

3.0 PRIOR TO ACCREDITATION

3.1 The applicant calibration organization shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all

contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis. The organization must estimate the CMC for every measured quantity, instrument or gauge listed in its desired scope of accreditation in accordance with its documented procedure.

3.1.1 Note: Although the requirements in 3.1 specifically to applicant *organizations* it is understood that the requirement continues to apply after accredited status has been attained by the organization.

3.2 These evaluations shall identify all sources of uncertainty, identify the manner in which the source is distributed and make a reasonable estimation of the contribution of each identified source. The organization must define the method by which it classifies sources as significant or insignificant. The organization shall then prepare an uncertainty budget *(where applicable and appropriate)* containing all relevant information related to the identified significant sources of uncertainty. The budget shall be used to process the information it contains in a mathematically and statistically appropriate method producing as output the expanded uncertainty of measurement for the calibration or test performed. The coverage factor (k) and the confidence level must be stated as components of the output from the uncertainty budget. In addition, the budget shall be organized in such a way and contain sufficient annotation to easily permit independent review and analysis during assessment or at other times as requested.

3.2.1 Sources of uncertainty will include but not be limited to those items listed below:

- reference standards or reference materials; e.g., a gage block, a pH standard
- methods and equipment used-e.g., a super micrometer, a pipette
- environmental conditions-e.g., temperature, relative humidity, air currents
- properties and condition of the unit under test-e.g., reflectance, hardness, unit exhibits wear
- Operator- e.g. skill, reproducibility.

4.0 CALIBRATION

4.1 When using the uncertainty budget to estimate CMC for inclusion on its desired scope of accreditation, the calibration organization shall consider the performance of the “best existing device” available for each calibration sub-discipline. This means that for sources which can be expected to vary from calibration to calibration, identify the smallest contribution, which will occur when the conditions, which cause it, are at optimum and use these values in the estimate of CMC. For sources, which by their nature remain constant, the organization may use the smallest values they may reasonably expect to encounter.

4.1.1 Examples of sources whose value is variable: (not inclusive)

repeatability of the unit under test;

temperature and temperature related effects, and;

relative humidity and humidity related effects.

4.1.2 Examples of sources whose value is constant: (not inclusive)

resolution, and;

uncertainty of a standard obtained from the certificate of a current calibration, the results of which have been determined to be traceable.

4.2 CALIBRATION REPORTING AND CMC

4.2.1 As entered on the scope and uncertainty as reported on the calibration certificate, test report, or reference material certificate shall be expressed using no more than 2 significant digits and no insignificant digits. For guidance on methods to identify significant and insignificant digits as well as rules for rounding of numbers used to express the CMC or uncertainty refer to PJLA PL-4. When CMC is expressed as a Relative Uncertainty Equation it is permissible to employ a greater number of significant digits to preserve accuracy during computation of specific CMC values. This is done with the understanding that when the equation is solved for specific values of the variable, the solution will be reduced to not more than 2 significant digits prior to recording the result. When the stated CMC is the result of conversion from one system of units to another (SI to USC as an example), the resulting stated value will typically require a larger number of significant digits in order to retain numerical equivalence. The number of significant digits to be used in CMC expressions resulting from conversion shall be no greater than that which produces a stated value that will, upon conversion back to the original system of units and rounded appropriately, generate the original value.

4.2.2 The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a coverage probability of approximately 95 %. The unit of the uncertainty shall always be the same as the measurand or in a term relative to the measurand, e.g., percent, µV/V or part per 10_6. Because of the ambiguity of definitions, the use of terms “PPM” and “PPB” are not acceptable. Refer to PL-4 for additional requirements concerning calibration lab’s scope of accreditation.

5.0 CALIBRATION OR TESTING ORGANIATION PERFORMING THEIR OWN CALIBRATIONS (IN-HOUSE CALIBRATIONS)

5.1 In house calibration facilities shall use the appropriate uncertainty budget to estimate uncertainty of measurement for all calibrations performed. The values assigned for identified sources of uncertainty shall be those that apply to the specific unit under test, the equipment used to perform the calibration, environmental and environmental related conditions and personal influences as they exist at the time the calibration is performed.

6.0 TESTING

6.1 The applicant testing organization shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method. On those occasions when the nature of the test method precludes this type o f rigorous, metrologically and statistically valid calculation of uncertainty of measurement, the organization shall at least attempt to identify all the components of uncertainty and make a reasonable estimation. The organization shall ensure that the form of reporting does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data as referenced in ISO/IEC 17025:2017 clause 7.6.3. When rigorous, mathematically, and statistically valid estimate of the measurement uncertainty may not be possible, so the requirements in ISO/IEC 17025:2017 7.6.3 would apply. In such cases the organization must identify all the components of uncertainty and make a “reasonable estimation”. The “reasonable estimation” is to be based on knowledge of the performance of the method and on the measurement. It also shall make use of, for example, previous experience and validation data. This is especially applicable in the biological, chemical, environmental and sensory evaluation fields. 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 organization is considered to have satisfied ISO/IEC 17025:2017 clause 7.6.3 or ISO 15189:2012, Section 5.5.1.3. by following the test method and reporting instructions. Examples include ASTM, AOAC, BAM, USP, FDA, EPA, etc. methods as well as regulatory, legal methods – US CFR, EU/EC methods and associated reporting.

7.0 REFERENCE MATERIAL PRODUCERS (RMPS) AND CERTIFIED REFERENCE MATERIAL PRODUCERS (CRMS)

7.1 As required by ISO 17034:2016(E) 7.13 the RMP shall have documented procedures for the assigning property values and their uncertainties. Reference material producers shall carry out an assessment of the measurement uncertainties to be included in the assignment of the property values in accordance with the requirements of the GUM, ISO/IEC Guide 98-3:2008/SUPPL 2:2011 or equivalent when appropriate and applicable. When estimating uncertainties of the property values of interest, any uncertainties resulting from between-unit variations and/or from possible stability (both during storage and during transportation) shall be assessed and shall be included in the assigned uncertainty. ISO Guide 35:2017 Reference Materials, Guidance for the characterization and assessment of homogeneity and stability provides guidance on the determination of certified values and their uncertainties. Other procedures and methods for determining property values and their uncertainties may be appropriate but they must be defined and documented. More considerations for

RMPs are contained in APAC TEC1-008 APAC Guidance on RM Use and Production Ver 1.0 (20190508). A statement of uncertainty is mandatory for CRMs and is recommended for RM(s). ISO Guide 35:2017, is an extensive, recognized guidance document for the statistical techniques appropriate for the characterization and assignment of property values and their uncertainties, as well as the assessment of homogeneity (within batch and batch to batch) and stability Another reference for uncertainties in analytical measurements is Eurachem/CITAC guide: Quantifying Uncertainty in Analytical Measurement, Third edition, (2012).

8.0 MEDICAL/CLINICAL LABORATORIES (15189)

8.1 *According to ISO 15189: 2012, Section 5.5.1.4, the laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples and shall define the performance requirements for the measurement uncertainty of each measurement procedure. The laboratory shall consider the measurement uncertainty when interpreting measured quantity values. Measurement uncertainties may be calculated using quantity values obtained by the measurement of quality control materials under intermediate conditions including as many routine changes possible in the standard operation of a measurement procedure. When examinations do not report a measured quantity value the laboratory should calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.*

Another source for determining the estimation of measurement uncertainty is *ISO/TS 20914:2019 - Medical laboratories — Practical guidance for the estimation of measurement uncertainty.*

9.0 MAINTAINING COMPLIANCE

9.1 Upon achieving accreditation, the uncertainty budgets and the decisions regarding sources of uncertainty shall be periodically reviewed and updated by the organization to reflect changes in the organization, its equipment, procedures or personnel that might influence the ability of the organization to perform specific calibrations or tests for which they are accredited. These changes shall be documented. Additionally, for calibration organizations, CMCs shall be recalculated based on any changes to the related uncertainty budgets or the underlying information contained within them. This information must be provided to the PJLA assessor during subsequent surveillance and reassessments or to PJLA staff upon request. The process of review established by the organization must take into account all initially identified sources of uncertainty as well as any additional sources that might result from the potential changes mentioned above.

9.2 Any additions to an existing Scope of Accreditation will not be made until the previously stated requirements are fulfilled with regard to a documented procedure for the estimation of uncertainty of measurement and (for calibration organizations) CMC. This procedure and (for calibration organizations) the estimated CMC produced from it shall be made available to the PJLA assessor or to PJLA staff upon request. Upon review, the organization's procedure must be

found to be reasonable and the calibration organization's CMC estimated from its use must be a reasonable value. If the CMC is stated as a relative value, then the results obtained from solving the relationship for any value between the minimum and maximum must be determined to be reasonable as well.

9.3 The combined and expanded uncertainties and the CMC (for calibration organizations) must be meaningful for any item that the organization intends to list on the scope of accreditation. A CMC or uncertainty of measurement estimate may be not meaningful if it is less than can reasonably be expected, and its magnitude cannot be defended on the basis of a thorough, rigorous method of determination. PJLA reserves the right to reject any CMC or uncertainty estimates proposed by applicant or accredited organizations if in the opinion of PJLA the magnitude or the manner of estimation is not meaningful or appropriate. Should a CMC or uncertainty of measurement estimate be determined to unmeaningful and therefore rejected, PJLA will initiate its policy for removal of the affected conformity assessment (i.e., test, calibration, rmp) activity from the scope of accreditation of the organization involved. The organization has the right to dispute this decision as outlined in PJLA's Dispute and Appeal Procedure (SOP-10).

9.4 ISO/IEC 17025:2017 (clause 7.8.4.1 a) requires calibration certificates to report 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 (i.e., percent). Any deviation from this requirement would need to come under the realm of simplified reporting as specified in ISO/IEC 17025:2017(clause 7.8.1.3). This is only permissible, if agreed to by the customer during the contract review process. This agreement shall be documented. Also, during contract review, the laboratory is required as per ISO/IEC 17025:2017 (clause 7.1.3) to define and capture the customer agreement as to the decision rule which will be employed when making statements of compliance. The decision rule is defined as a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. If a statement of compliance is being made on calibration reports, the agreed to decision rule is required as per ISO/IEC 17025:2017 (clause 7.8.6.1) to document the calibration report. For guidance in determining and selecting appropriate decision rules to meet these requirements specified in ISO/IEC 17025:2017, PJLA encourages the usage of ILAC G 8 "Guidance on Decision Rules and Statements of Conformity

9.5 For instances when the underlying distribution is asymmetrical or when uncertainty is estimated using Monte Carlo simulations or logarithmic units, presentations other than y +/-U may be needed. Acceptability of alternative methods of presenting the measurement result and its associated uncertainty of measurement will be considered by PJLA on a case-by-case basis.

9.6 Although PJLA assessors are not permitted to perform the calculations for the estimation of measurement uncertainty, several resources are available to assist organizations in satisfying the measurement uncertainty requirements of the relevant standard being assessed to and this policy including its requirements related to CMCs or uncertainties in general.

REFERENCE SOURCES

- *NIST Technical Note 1297, 1994 Edition: Guidelines for Evaluating and Expressing Uncertainty of NIST Measurement Results*
- *ANSI/NCSL Z540-2-1997: U.S. Guide to the Expression of Uncertainty in Measurement*
- *Journal of Research of National Institute of Standards and Technology Volume 102, Number 6, November- December 1997 (647) Uncertainty and Dimensional Calibrations*
- *ILAC G8:09/2019 Guidelines on the Reporting of Compliance with Specification*
- *ISO 17034:2016 General Requirements for the Competence of Reference Material Producers*
- ISO Guide 35:2017 *Reference materials — Guidance for characterization and assessment of homogeneity and stability.*
- ISO Guide 31:2015(E) *Reference Materials, -Contents of certificates labels and accompanying documents*
- APAC TEC1-008 APAC Guidance on RM Use and Production Ver 1.0 (20190508)
- Eurachem/CITAC guide*: Quantifying Uncertainty in Analytical Measurement, Third edition, (2012)*
- *NISTIR 6919 Recommended Guide for Determining and Reporting Uncertainties for Balances and Scales*
- *ILAC P14:09/2020 ILAC Policy for Uncertainty in Calibration*
- ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*
- JCGM 100:2008, GUM 1995 with minor corrections, *Evaluation of measurement data – Guide to the expression of uncertainty in measurement. Also includes a suite of guides on Evaluation of measurement data* (Available fromhttps://www.bipm.org/en/publications/guides/)
- *International Vocabulary of Basic and General Terms in Metrology (VIM), 3rd edition, JCGM 200:2012 (JCGM 100:2008 with minor corrections) available from the BIPM homepage www.bipm.org or ISO/IEC Guide 99:2007 available from ISO.*
- *ISO 15189:2012 Medical Laboratories Requirements for Quality and Competence*
- ISO/TS 20914:2019 - Medical laboratories — Practical guidance for the estimation of measurement uncertainty