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 with regard to 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 17025:2005, ISO 15189:2012, Guide 34, ISO/IEC 17011:2004 and ILAC P-14:12/2013 and applies only to calibrations or tests for which an accredited result is to be reported.

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 **The Calculation of CMC:** 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". The CMC is a "special case" of uncertainty estimated for the "best existing device" within a calibration discipline or sub-discipline. By its nature it is the lower limit of uncertainty of measurement. 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.

By definition the organization can never perform a calibration for which the uncertainty is less than their stated CMC.

3.0 PRIOR TO ACCREDITATION

3.1 The applicant calibration organization shall have and shall apply a documented procedure for estimating CMC and uncertainty of measurement. 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.

3.2 The applicant testing and RMP organizations shall have and shall apply a documented procedure for estimating uncertainty of measurement for the tests it performs.

3.2.1 Note: Although the requirements in 2.1 and 2.2 apply specifically to applicant *organizations* it is understood that the requirement continues to apply after accredited status has been attained by the organization.

3.3 These procedures 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.

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.

CALIBRATION-CMC

4.2 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.

5.0 CALIBRATION ORGANIZATIONS OR TESTING ORGANIZATIONS PERFORMING THEIR OWN CALIBRATIONS

5.1 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 have and shall apply a documented procedure for estimating uncertainty of measurement comparable to the requirements for calibration organizations listed above when it is appropriate to do so. 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 17025:2005 clause 5.4.6.2. When rigorous, mathematically, and statistically valid estimate of the measurement uncertainty may not be possible, so the requirements in ISO/IEC 17025:2005 5.4.6.2 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 17025:2005 clause 5.4.6.2 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 Guide 34:2009(E) 5.16.1* the RMP shall have procedures as outlined in *ISO Guide 35:2006(E) General and statistical principles for certification*, for the assigning the uncertainties to the property values. 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 (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 in accordance with ISO Guide 35 and shall be included in the assigned uncertainty. More requirements for RMPs are contained in *APLAC TC 008: rev 5 (2015) Requirements and Guidance on the Accreditation of a Reference Material Producer, section 5.16*. A statement of uncertainty is mandatory for CRMs and is recommended for RMs. *ISO Guide 35:2006(E) Reference Materials, General and statistical principles for certification*, is an extensive normative 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 *The Eurachem/CITAC guide: Quantifying Uncertainty in Analytical Measurement, Third edition, (2012*) .

8.0 MEDICAL/CLINICAL LABORATORIES (15189)

8.1 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.

(Reference: (ISO 15189:2012, Section 5.5.1.4 Measurement uncertainty of measured quantity values)

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, CMC's 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 reaccreditation assessments 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 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. This also applies for RMPs with regard to the scopes developed in accordance with APLAC TC 008 Issue 5 (March 2015), section 6.

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 through, 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 be *not* meaningful and therefore rejected, PJLA will initiate its policy for removal of the affected calibration or test 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 17025:2005 (clause 5.10.4.1 b) and ILAC-P14:12/2010 (section 6.1) establish three options which apply to calibration organizations when reporting the results of calibrations performed. These options are as follows:

(a) Report the measurement result and its associated uncertainty of measurement.

(b) Report the measurement result and a statement of compliance with an identified metrological specification or clauses thereof.

(c) Report the measurement result, its associated uncertainty of measurement and a statement of compliance with an identified metrological specification or clauses thereof.

9.5 Certificates issued by PJLA accredited organizations have potential worldwide distribution as a result of PJLA's status as an ILAC and APLAC signatory. On that basis and in order to be more consistent with international practices, PJLA strongly encourages organizations to exercise either option (a) or (c) only. Although option (b) is acceptable under the standard, its use is strongly discouraged by PJLA. Calibration laboratories (during contract review) are required to determine if items submitted to them for calibration will themselves be used in performing further calibrations. If the item will itself be used to perform further calibrations then (per ILAC P14-01-2013 section 6.1) the certificate of calibration must contain the uncertainty of measurement regardless of the option selected. The organization must document that this determination was made and this documentation must be available for review by the PJLA assessor during assessments or at other times as requested by PJLA headquarters staff.

9.6 When making the statement that the measurement is in compliance with an "identified metrological specification or clauses thereof" the calibration organization is required per ISO/IEC17025:2005 (clause 5.10.4.2) to have accounted for the associated uncertainty of measurement in reaching its decision. This requirement applies when the organization exercises either option (b) or (c). Clause 5.4.6 of the standard contains the requirement that calibration and testing laboratories have and apply a procedure defining the manner by which they estimate the uncertainty of measurement for calibrations and test performed. Additionally for calibration laboratories, PJLA requires that this procedure also define the manner by which uncertainty is accounted for when making a statement of compliance with a specification.

9.6.1 If the laboratories uncertainty procedure does not address the manner in which uncertainty is accounted for PJLA will require that it be accounted for using the method suggested in ILAC G8 03 2009.

9.6.2 If taking uncertainty into account would result in a possible failure where the measured value actually passes, the following example compliance statement can be used. "*It is not possible to state compliance using a 95 % coverage probability for the expanded uncertainty although the measurement result falls within specified limits.* Optionally, if the organization wishes, it can simply state "*It is not possible to state compliance".*

10.6.2.1 *PJLA defines this condition as* ***Pass-Indeterminate****.*

9.6.3 If taking uncertainty into account would produce a possible pass where the measured value actually failed, the following example compliance statement can be used. "*It is not possible to state noncompliance although the measurement result falls outside specified limits using a 95 % coverage probability for expanded uncertainty may produce values*

within specified limits." Optionally, if the organization wishes, it can simply state "*It is not possible to state noncompliance".*

10.6.3.1 *PJLA defines this condition as* ***Fail-Indeterminate****.*

9.7 In the instances when it is necessary for testing organizations to make "a statement of compliance / non-compliance with requirements and/or specifications" or "a statement on the estimated uncertainty of measurement" as detailed in ISO/IEC 17025:2005, clause 5.10.3.1 b) and c), the requirements in 10.8, 10.9 and 10.10 will apply for test reports issued.

9.8 RMP organizations are required to include uncertainties for the assigned property values for certified reference materials in their certificates in compliance with ISO Guide 31: 200(E) sections 5.11 and 6 and Guide 34:2009(E) section 5.17.

9.9 ISO/IEC 17025:2005 (clause 5.10.1) provides for calibration and test results to be reported in a simplified manner for internal customers. Simplified reporting to external customers is only permitted when authorized by the customer by means o f a written agreement to that effect.

9.10 In the event that a written agreement exists between the organization and its customer instructing the organization to report only the measurement result, PJLA requires that the organization include a statement on the certificate issued indicating that the uncertainty of measurement associated with the measurement result contained in the calibration certificate (or test report when it is appropriate to do so) is available from the organization upon request.

10.10.1 An example of an acceptable statement follows. "The uncertainty of measurement associated with the measurement result reported in this certificate is available from the organization upon request". This statement is intended only as an example and other statements, which express the same intent, would be acceptable.

9.11 In the event that a written agreement exists between the organization and its customer instructing the organization to report only the measurement result and a statement of compliance with an identified metrological specification or clauses thereof, PJLA requires that the organization include a statement on the certificate issued indicating that the uncertainty of measurement associated with the measurement result contained in the calibration certificate is available from the organization upon request. Additionally the statement must indicate that the uncertainty of measurement was accounted for in making the decision that the calibrated device was or was not in compliance with an identified metrological specification or clauses thereof.

9.11.1 An example of an acceptable statement follows. "The uncertainty of measurement associated with the measurement result reported in this certificate is available from the organization upon request and was accounted for in making the decision of compliance or noncompliance with the relevant specification identified above". This statement is intended only as an example and statements, which express the same intent, would be acceptable.

9.12 When the organization chooses or is required to exercise option (a) or (c) above, the measurement result and its associated uncertainty of measurement shall be reported as y +/- U where y is the value of the measured quantity and U is the associated expanded uncertainty. The units of y and U shall be included. A tabular presentation of the measurement result may be used and the relative expanded uncertainty may be used if appropriate to do so. The coverage factor (k) and the coverage probability shall be stated on the calibration certificate. To this an explanatory note shall be added. An example of an acceptable note is shown below.

9.12.1 "*The reported expanded uncertainty of measurement is stated as the combined standard uncertainty of measurement multiplied by the coverage factor k (k =2) such that the coverage probability corresponds to approximately 95 %".* This statement is intended only as an example and other statements which express the same intent would be acceptable.

9.13 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.

9.14 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 ISO/IEC 17025:2005 and/or ISO Guide 34:2009 and this policy including its requirements related to CMCs or uncertainties in general.

EXCELLENT SOURCES OF REFERENCE INFORMATION IN ADDITION TO THE GUM INCLUDE:

[1] *NIST Technical Note 1297, 1994 Edition: Guidelines for Evaluating and Expressing Uncertainty of NIST Measurement Results*

[2] *ANSI/NCSL Z540-2-1997: U.S. Guide to the Expression of Uncertainty in Measurement*

[3] *Journal of Research of National Institute of Standards and Technology Volume 102, Number 6, November- December 1997 (647) Uncertainty and Dimensional Calibrations*

[4] *ILAC G8:03/2009 Guidelines on the Reporting of Compliance with Specification*

[5] ISO Guide 34:2009(E) *General requirements for the competence of reference material producers.*

[6] ISO Guide 35:2006(E) *Reference Materials, General and statistical principles for certification*

[7] ISO Guide 31:2000(E) *Reference Materials, -Contents of certificates and labels*

[8] APLAC TC 008:rev 5 (2015) *Requirements and Guidance on the Accreditation of a Reference Material Producer*

[9] Eurachem/CITAC guide*: Quantifying Uncertainty in Analytical Measurement, Third edition, (2012)*

[10] *NISTIR 6919 Recommended Guide for Determining and Reporting Uncertainties for Balances and Scales*

[11] *ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration*

[12] ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*

[13] *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.*

[14] *ISO 15189: 2012 Medical Laboratories Requirements for Quality and Competence*