PL 008 -02

NiNAS POLICY ON UNCERTAINTY OF MEASUREMENTS

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1. Purpose/Scope

According to ILAC-P14, ISO/IEC 17025:2017 requires calibration and testing laboratories to have and apply procedures for the estimation of uncertainty of measurement. Both ISO 15189 and ISO 17034 have similar requirements for reference measurement laboratories and reference material producers. Measurement uncertainty estimation is required for the comparison of measurement results. The purpose of this policy is to describe NiNAS policy on the evaluation and reporting of measurement uncertainty for calibration and testing (including medical testing) laboratories.

2. References/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: (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: (GUM 2.2.3) parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributes to the measurand.

Measurand: quantity intended to be measured.

International System of Units (SI): system of units based on the International System of Quantities adopted by the General Conference on Weights and Measures (CGPM).

Accuracy: closeness of agreement between a measured quantity value and a true quantity value of a measurand.

Trueness: closeness of agreement between the averages of an infinite number of replicate measured quantity values and a reference quantity value.

Precision: closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions.

Error: the difference between the measured quantity value and the reference quantity value.

Uncertainty: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

3. General

3.1. NiNAS requires both accredited and applicant laboratories to meet the requirements of clause 7.6 of ISO/IEC 17025:2017 in estimating measurement uncertainty in testing and calibration. The standard also specifies the reporting requirements with respect to measurement uncertainty that laboratories must meet in addition to any other NiNAS' applicable requirements.

3.2 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 that contribute to the uncertainty.

3.3 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 result based on theoretical principles or practical experience.

3.4 When using a standard test method, there are three cases to consider by testing laboratories:

- When using a standardized test method, which contains guidance to the uncertainty evaluation, testing laboratories are not expected to do more than to follow the uncertainty evaluation procedure as given in the standard;
- If a standard gives a typical uncertainty of measurement for test results, laboratories are allowed to quote this figure if they can demonstrate full compliance with the test method;

- If a standard implicitly includes the uncertainty of measurement in the test results there is no further action necessary.

3.5 Calibration laboratories shall report their measurement uncertainty on all calibration certificates as required by ISO/IEC 17025:2017.

3.6 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. The uncertainty affects conformity to a specification limit.

3.7 For all estimates of measurement uncertainty, the required elements include:

i. Identify and document all components of uncertainty in the test (e.g. bias, sampling, sub-sampling, calibration, etc.);
ii. Determine the significance of each component, eliminating any component that is insignificant (if the laboratory chooses);
iii. 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;
iv. Identify any gaps in data; and
v. 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).

3.8 The procedures used to estimate measurement uncertainty 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 laboratory shall then prepare an uncertainty budget (where applicable and appropriate) containing all relevant information related to the identified significant sources of uncertainty.

3.9 The uncertainty budget shall be used to process the information it contains in a mathematical 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.

3.10 Sources of uncertainty will include but not be limited to the following items:

i. Reference standards or reference materials; e.g., a gauge block, a pH meter;
ii. Methods and equipment used, e.g. a super micrometer, a pipette;
iii. Environmental conditions, e.g., temperature, relative humidity, air currents;
iv. Properties and condition of the unit under test (UUT), e.g. reflectance, hardness;
v. Operator, e.g. skill, reproducibility.

3.11 Applicable requirements of ILAC P14

A calibration and measurement capability (CMC) is a capability (calibration and measurement) available to customers under normal conditions:

a) As described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement; or
b) As published in the BIPM key comparison database (KCDB) of the CIPM MRA.

3.11.2 The scope of accreditation of an accredited calibration laboratory shall include the calibration and measurement capability (CMC) expressed in terms of:

a) Measurand or reference material;
b) Calibration/measurement method/procedure and/or type of instrument/material to be calibrated/measured;
c) Measurement range and additional parameters where applicable, e.g., frequency of applied voltage;
d) Uncertainty of measurement

3.11.3 The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a specific coverage probability of approximately 95 %. The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand, e.g., percent.

3.11.4 An accredited laboratory is not permitted to report an uncertainty smaller than its accredited CMC. The magnitude of the uncertainty reported on a certificate of calibration depends on properties of the device being calibrated.

4.0 Forms

Table: 8-1 Forms in use with Policy 8	
Form Number	Title

5.0 Document History

Modification No/Date	Proposed by	Page No.	Summary of Modification