Contents

1. Purpose

1.1 This document describes the ENAS requirements regarding evaluation of uncertainty of measurement in calibration, testing and measurement, and the reporting of uncertainty on the certificates of calibration and test/measurement reports.

2. Scope

2.1 This document is applicable to all testing, medical and calibration laboratories seeking ENAS accreditation (applicants and accredited) as per the relevant requirements from ISO/IEC 17025 and ISO 15189 Standards. These requirements may also be applied to other conformity assessment activities where testing and/or calibration is involved such as inspection (ISO/IEC 17020) and product certification (ISO/IEC 17065).

2.2 Relevant sections of these requirements shall also be applicable to conformity assessment bodies (CABs) that perform their own calibrations (known as internal calibrations or “In-house” calibrations).

3. Definitions

3.1 For the purpose of this document, the relevant terms and definitions given in the “International Vocabulary of Metrology – Basic and General Concepts and Associated Terms” (VIM) [5][7] and the following apply:

Calibration and Measurement Capability (CMC)

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 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.

4. ENAS Requirements to Measurement Uncertainty of Calibration

4.1 Calibration laboratories shall have up-to-date documented procedure for the estimation of measurement uncertainty for all calibrations and measurements covered by the scope of accreditation and including the calibrations of their own equipment (internal or “In-house” calibrations). The procedure shall include identification of sources of error and magnitudes of influence, including those arising from sampling where applicable, and uncertainty budget with estimation of the contributions considered to calculate the expanded uncertainty of measurement.

4.2 Estimation of uncertainties of measurement shall be carried out in compliance with the ISO/IEC Guide 98-3, “Guide to the Expression of Uncertainty in Measurement (GUM)”.

4.3 Calibration laboratories shall provide documented evidence that they can provide calibrations to customers so that measurement uncertainties equal those covered by the CMC showed in their scopes of accreditation. Requirements in ENAS document ETR 08 apply.

4.4 Calibration laboratories shall report the measurement uncertainty of the measurement results in their calibration certificates meeting the requirements in the Section 6 of this document.

4.5 ENAS assessment team shall evaluate the procedure developed by the laboratory to assess proper consideration of magnitudes of influence, estimation of uncertainty contributions, calculations leading to uncertainty of measurement and CMC, and reporting of measurement uncertainty in calibration certificates.

5. ENAS Requirements to Measurement Uncertainty of Testing

5.1 The testing and medical laboratory shall evaluate measurement uncertainty for all tests and measurements in the scope (or proposed scope) of accreditation. The following aspects shall be taken into consideration when evaluating measurement uncertainty:

a) Where a test produces numerical results (or the reported result is based on a numerical result), the uncertainty of those numerical results shall be estimated.

b) 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 (e.g. quality control charts, validation, internal quality control activity, round-robin tests, participation on relevant proficiency testing, CRM, etc.).

Example: Qualitative or semi-qualitative tests that require no uncertainty budgets (tests that are exposure or environmental simulation only such as Salt Spray as per ASTM B117 etc., tests where the result is numerically rated by judgement, such as Tap Adhesion as per ASTM D3359 or tests where results are a comparison from a reference plaque such as Microstructure as per ASTM A247).

Example: Physical, chemical, environmental or biological/microbiological test methods based on published regulatory or consensus methods: such as APHA, AOAC, ASTM, BS for which uncertainty is not defined in the method. Uncertainty may be estimated using the standard deviation of laboratory control samples for more than 50 points for these types of test.

c) Where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, it shall be considered that the laboratory satisfies this requirement by providing evidence of following the test method and reporting instructions.

Example: Tensile Properties of Plastics as per ASTM D638.

Example: Compression Properties of metals as per ASTM E9.

Example: Tension Testing of Metals as per ASTM E8.

Example: Power frequency withstand electrical voltage dry test as per IEC 62271-1, the test voltage level applied to the device under test has to be measured with an uncertainty within ± 3.0 %. After applying the test voltage for 1 minute, the result of the test is qualitative: Pass/Fail. It shall be considered that the laboratory meets the uncertainty requirements to the test if it provides evidence of following the method and estimation of the uncertainty to the measurements involved are consistent with the limits defined.

d) Where, for a particular well-recognized method, the measurement uncertainty of the results has been established and verified, the laboratory shall not need to evaluate the measurement uncertainty for each result as long as it can demonstrate that the identified critical influencing factors (magnitudes of influence) are under control.

5.2 Policies/procedures covering this requirement shall be documented and updated records maintained for individual tests. Documented procedures for the estimation of measurement uncertainty shall include suitable analysis of magnitudes of influence and sources of error affecting the measurements and test results, proper estimation of their contribution to the uncertainty, estimation/calculation of the overall (expanded) uncertainty of measurement as per the ISO/IEC Guide 98-3 “Guide to the Expression of Uncertainty in Measurement (GUM)”. Where applicable, the overall uncertainty of measurement should be consistent with the given requirements.

5.3 The laboratory shall document under what circumstances measurement uncertainty shall be presented in test reports. Uncertainty estimates shall be reported where it is relevant to the validity or application of the test results; where required by the customer, or where the measurement uncertainty affects conformity to a specification limit.

5.4 ENAS assessment team shall evaluate policies/procedures developed by the laboratory to assess proper consideration of uncertainty of measurement in testing and reporting activity.

6. Requirements on Expression of Uncertainty of Measurement in Calibration Certificates and Test Reports

6.1 Measurement uncertainty of measurement results shall be presented in calibration certificates and test reports, where applicable, in the same unit as that of 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.).

6.2 Accredited calibration laboratories and testing laboratories, where applicable, shall report the measured quantity value and the uncertainty of measurement, in compliance with the requirements described in the following:

6.2.1 The measurement result shall normally include the measured quantity value y and the associated expanded uncertainty U. In calibration certificates and test reports the measurement result should be reported as $y \pm U$ associated with the units of y and U. Tabular presentation of the measurement result may be used and the relative expanded uncertainty $U/|y|$ may also be provided if appropriate. The coverage factor and the coverage probability shall be stated on the calibration certificate/test report. To this an explanatory note shall be added, which may have the following content:

"*The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %.*"

Note: For asymmetrical uncertainties other presentations than y ± U may be needed. This also concerns cases when uncertainty is determined by Monte Carlo simulations (propagation of distributions) or with logarithmic units.

6.2.2 The numerical value of the expanded uncertainty shall be given to, at most, two significant figures. For the process of rounding, the usual rules for rounding of numbers shall be used. In reporting final results, it may sometimes be appropriate to round uncertainties up rather than to the nearest digit, subject to the guidance on rounding provided i.e. in Section 7 of the GUM (JCGM 100).

Note: *For further details on rounding, see the GUM and ISO 80000-1*

6.3 Contributions to the uncertainty stated on calibration certificates shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer's device. Where applicable the uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except that uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device. Therefore, reported uncertainties tend to be larger than the uncertainty covered by the CMC. Contributions that cannot be known by the laboratory, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory anticipates that such contributions will have significant impact on the uncertainties attributed by the laboratory, the customer should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.

6.4 As the definition of CMC implies, accredited calibration laboratories shall not report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited.

7. Reference

[1] ILAC-P14:09 – ILAC Policy for Measurement Uncertainty in Calibration.

[2] ENAS ETR 08 – ENAS Technical Requirement for CMC and Calibration Scope of Accreditation.

[3] EA-4/02 M, Evaluation of the Uncertainty of Measurement in Calibration.

[4] ISO/IEC Guide 98-3- Uncertainty of measurement – Part 3, Guide to the expression of uncertainty in measurement (GUM).

[5] ISO/IEC Guide 99 International vocabulary of metrology - Basic and general concepts and associated terms (VIM).

[6] ISO 80000-1, Quantities and units - Part 1: General.

[7] JCGM 200- International vocabulary of metrology – Basic and general concepts and associated terms (Available from www.BIPM.org).

8. Change History

8.1 The following provides a summary of the changes made to this document:

Rev. No	Date	Changes
01	28.03.2021	1. Whole document is reviewed to incorporate ILAC P14:09/2020 requirement. 2. Year of publications removed from the reference standards given. 3. Sections 6.1 is reworded; Note is added to section 6.2.2 4. Typo is corrected in section and word “Random” is removed from section 6.3.