WEST AFRICAN ACCREDITATION SYSTEM (SOAC)

ESTIMATION OF THE UNCERTAINTY OF MEASUREMENT BY LABORATORIES
(C11.01)

Approval		Effective Date
Date	01/11/19	01/11/19

SUMMARY

1 PURPOSE AND SCOPE

This document defines the policy for the estimation of uncertainty of measurement by laboratories and the determination and specification of the Calibration and Measurement Capability.
It is applicable to all accredited calibration laboratories and testing laboratories performing their own calibration.

2 REFERENCES

- ISO / IEC 17011, Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
- C08-TRACEABILITY OF MEASUREMENTS
- EA-4/02, Evaluation of the Uncertainty of Measurement in Calibration
- EA 4/16, EA guidelines on the expression of uncertainty in quantitative testing
- ILAC P14, ILAC Policy for uncertainty in calibration
- ISO 5725-1, Accuracy (trueness and precision) of measurement methods and results – Part 1: General principles and definitions
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- ISO 80000-1, Quantities and Units – Part 1: General
- JCGM 100, GUM 1995 with minor corrections, Evaluation of measurement data - Guide to the expression of uncertainty in measurement
- JCGM 200, International Vocabulary of Metrology – Basic and General concepts and associated terms (VIM)

3 EFFECTIVE DATE AND REVIEW

This document is applicable from the date specified on the cover page. It will be updated as necessary.

4 SUMMARY OF CHANGES

Version 00: creation.
Version 01: revision and update for new dispositions addressed.

5 TERMS AND DEFINITIONS

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

Measurand: The measurand is defined as the “particular quantity subject to measurement.

Best existing device: The term “best existing device” is understood as a device to be calibrated that is commercially or otherwise available for customers, even if it has a special performance (stability) or has a long history of calibration.

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

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

ILAC P14 sets out calibration and measurement capability (CMC) expressed in terms of:

- measurand or reference material;
- calibration/measurement method/procedure and/or type of instrument/material to be calibrated/measured;
- measurement range and additional parameters where applicable, e.g., frequency of applied voltage;
- uncertainty of measurement.

Standard uncertainty: uncertainty of the result of a measurement expressed as a standard deviation

Combined standard uncertainty: standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model.

Coverage Factor: numerical factor used as a multiplier of the combined standard uncertainty in order to obtain an expanded uncertainty.
Note that a coverage factor k is typically in the range 2 to 3.

Expanded Uncertainty: 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.

Type A Evaluation of Uncertainty: method of evaluation of uncertainty by the statistical analysis of series of observations.

Type B Evaluation of Uncertainty: Method of evaluation of uncertainty by means other than the statistical analysis of series of observations.

6 UNCERTAINTY OF MEASUREMENT

6.1 All calibration laboratories and testing laboratories shall have and apply a procedure for the estimation of the uncertainty of measurement.

6.2 Measurement units and measurement standards shall be traceable to an unbroken chain of comparisons stating appropriate uncertainties of measurement. (Refer to C08 and ILAC P 10).

6.3 The estimation of the uncertainty of measurement shall include the identification of, and analysis of all known components of importance. The degree of rigor applied to the estimation of the measurement uncertainty should be appropriate to the intended purpose of the calibration based on the customer requirements.

6.4 In general laboratories shall use the guidelines as specified in the GUM as the basis for the preparation of their procedure on the estimation of the uncertainty of measurement. In exceptional cases, other internationally recognized methodologies as those described in parts 1 to 6 of ISO 5725 and E4/16 may be applied.

The exceptional cases accepted and considered by SOAC include but are not limited to :

- the alternative of Proficiency Testing participation outcome to estimate the uncertainty for testing activities,
- the guidance is given in ISO 19036 to estimate the uncertainty for microbiology laboratories, (as well as the different possible microbiological approaches)
- cases where uncertainties approved by testing standards;
- the uncertainties calculated according to ISO 5725 regarding interlaboratory comparison.

6.5 It is recommended that the data relevant to the determination of the uncertainty of measurement including quantities, standard uncertainties, and sensitivity coefficients be available in clear, unambiguous format such as in a spreadsheet or tabular format.

6.6 Laboratories may elect to perform uncertainty of measurement calculations using computerized spreadsheets. In such cases, the laboratory shall ensure that the spreadsheets are suitably **documented, validated and protected** against unauthorized changes.

6.7 Certain electronic calculators used in the statistical model are prone to errors due to rounding; this may become evident in the calculation of standard deviation when the calculation returns an incorrect result. Appropriate methods shall be applied to circumvent these calculation errors.

6.8 The uncertainty of measurement shall not be reported to more than **02 significant digits.** In reporting final results, it may sometimes be appropriate to round uncertainties up rather than to the nearest digit. However, common sense should prevail. Output and input estimates should be rounded to be consistent with their uncertainties. Correlation coefficients should be given with **03-digit accuracy** if their absolute values are near unity.

Rounding should always be carried out at the end of the process in order to avoid the effects of cumulative rounding errors.

7 SOAC POLICY ON MEASUREMENT OF UNCERTAINTY FOR CALIBRATION LABORATORIES

7.1 Estimation of Measurement Uncertainty for Calibration Laboratory

7.1.1 The Calibration and Measurement Capability (CMC) are consulted in the SOAC technical annex of accreditation. The CMC is 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.

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. Usually, the inclusion of the relevant unit gives the necessary explanation.

7.1.2 The uncertainty of measurement represented as part of the CMC represents the smallest uncertainty of measurement that a laboratory can claim for any measurement or calibration performed and reported in a certificate that makes reference to accreditation and/or includes the accreditation symbol.

7.1.3 Estimation of measurement uncertainty is a crucial part of ensuring traceability. Where it is possible to calculate uncertainty, the calculations must be performed in accordance with ILAC P14 latest version and the ISO Guide to the Expression of Uncertainty in Measurement (also known as GUM). This document can be obtained as an ISO document, or as an OIML document [OIML G 1-100].

7.1.4 Expanded uncertainties are typically reported in two significant digits using a coverage factor of k = 2 to approximate the 95 percent level of confidence.

Calibration certificates must provide statements of the measurement results and the associated uncertainty. Such statements must include the coverage factor and confidence level.

7.1.5 The laboratory must use appropriate methods to develop their uncertainty estimates. The method used to develop the uncertainty estimate must be defined and documented. All readings, observations, calculations, and derived data must be maintained.
Developing an uncertainty estimate generally requires statistical analysis of experimental data. Laboratories shall analyze the data in accordance with good statistical practice and methodology.

7.1.6 All components contributing significantly to the uncertainty of measurement including the drift between subsequent calibrations of the measurement standard shall be taken into account when evaluating the measurement capability.

7.1.7 The determination of the uncertainty of measurement for the purposes of the establishment of the CMC uncertainty shall include at least the uncertainty contribution from a “best existing device” to be calibrated.

7.1.8 When the scope of accreditation of the laboratory includes a range of measurements for a specified parameter, the laboratory shall be capable of achieving the CMC uncertainty throughout the specified range. In instances where this is not possible sub-ranges, single values or a matrix shall be introduced with separate CMC’s specified for the individual sub-ranges or single values or matrix entries.

7.1.9 Applicant laboratories and laboratories wishing to have changes made to their laboratories CMC's shall submit an Uncertainty of Measurement calculation in support of the requested CMC.

7.2 Measurement Uncertainties for On-Site Calibrations in the Scopes of Accreditation

7.2.1 It is important that the scopes of accredited laboratories that perform calibrations on customers' sites do not contain potentially misleading values for on-site capabilities.

The following points shall be observed:

SOAC staff shall ensure that Best Uncertainty is clearly defined on scopes of accreditation. This may be accomplished with the following footnote:
"**The uncertainty given in the calibration and measurement capability (CMC) is the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation when performing more or less routine calibrations of nearly ideal measurement standards or of nearly ideal measuring instruments. Best uncertainties represent expanded uncertainties expressed at approximately the 95 % level of confidence, usually using a coverage factor of k = 2. The measurement uncertainty of a specific calibration performed by the laboratory may be greater than the best uncertainty due to the behavior of the customer's device, to the environment (if the calibration is performed in the field), and to influences from the circumstances of the specific calibration**."

7.2.2 In addition, when the best uncertainty is cited for a calibration offered in the field, this uncertainty should be further qualified to emphasize that uncertainties obtained in the field are typically larger than uncertainties obtained in a stable laboratory environment. This may be accomplished with the following footnote:

"On-site calibration service is available for this calibration. Best uncertainty is for calibration at the laboratory's permanent facility; as noted above, uncertainties obtained in the field will typically be larger than the best uncertainty."

However, it is often easier for the laboratory to specify environment tolerances outside of which no work will be done and to base the best uncertainty estimates on those tolerances. The assessor should check these tolerances to see that they are reasonable and consistent with equipment specifications. In these cases, further qualification of the best uncertainty is unnecessary.

7.2.3 SOAC assessors shall ensure that the scope of an accredited laboratory **clearly indicates which parameters are offered on-site**. The laboratory that performs calibrations on a client's site maintains a full list of all the equipment that is transported.

8 SOAC POLICY ON MEASUREMENT UNCERTAINTY FOR TESTING LABORATORIES.

8.1 An understanding of the concept of the uncertainty of measurement is important in order to be able to choose testing methods that are fit for purpose. The uncertainty of measurement should be consistent with the given requirements.

8.2 According to ISO/IEC 17025:2017, test reports shall include, 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;
- a customer's instruction so requires, or
- the measurement uncertainty affects conformity to a specification limit.

8.3 In any case, laboratories shall know and document the uncertainty associated with a measurement whether it is reported or not. When a laboratory does not document its measurement uncertainty, it will have to justify that in writing, especially testing activities in areas where an estimation of measurement uncertainty based on statistical validation data is relevant.

8.4 As a general rule, the implementation of the concept of measurement uncertainty should be in line with the implementation of ISO/IEC 17025:2017. SOAC may agree on exceptions for technical areas where the uncertainty of measurement is difficult to apply.
For those areas, SOAC will promote and support the development of guidance documents and worked examples.

8.5 SOAC considers that a statement on the measurement uncertainty in testing reports, where relevant and necessary, will be common practice in the future. Some tests are purely qualitative and consideration is still being given as to how the measurement uncertainty applies in such cases. One approach is to estimate the probability of false-positive or false-negative results. The issue of estimating the measurement uncertainty in regard to qualitative results is recognized as an area in which further guidance is required.

8.6 Testing laboratories shall have and apply procedures for evaluating 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.

Note 1 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 laboratory is considered to have satisfied this clause by following the test method and reporting instructions.

Note 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

8.7 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

Note 1 Sources of uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

Note 2 The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating measurement uncertainty.

9 TABLE OF MODIFICATIONS

No.	Source	Modification in brief (Relevant changes)
C11.00- 25 July 2019		
Creation		
C11.01- 12 September 2019		
1	§ 2	Update of the references
2	§ 5	- Definitions revised to the latest version of VIM and ILAC P14 - 4 definitions have been completely removed from this section
3	§ 6.1	This section has been revised to the general context of the uncertainty estimation
4	§ 6.2	This section has been updated
5	§ 6.4	This section revised to specify the exceptional cases considered and accepted by SOAC
6	§ 6.8 and 6.9	These 2 sections have been withdrawn. And § 6.10 became § 6.8 and has been revised
7	§ 7.1.1	Further details added to this section to address the expression of the uncertainty
8	§ 7.1.5	The last paragraph of this section removed
9	§ 7.1.6	Withdrawn. And § 7.1.7 became § 7.1.6 and so forth
10	§ 7.1.8	This section has been revised
11	§ 7.2.1	This section has been revised in its wording
12	§ 7.2.3	The last sentence of this section removed
13	§ 8.1	The first sentence of this section removed
14	§ 8.2	The first sentence of this section removed and technically revised
15	§ 8.3	The verbal form ''should'' replaced by ''shall''
16	§ 8.5	The words in brackets in this section removed
17	§ 8.6	This section has been technically revised: the first paragraph and Note 1 removed. Note 2 became Note 1. And a new Note 2 added.
18	§ 8.7	Note 3 removed.
19	§ 8.8	This section removed from this document