ILAC Policy for
Measurement Uncertainty in Calibration

ILAC-P14:09/2020

About ILAC

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among Accreditation Bodies (ABs). The data and test results issued by laboratories, and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via this Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of "accredited once, accepted everywhere".

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.

Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at www.publicsectorassurance.org.

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PREAMBLE

In order to enhance the harmonisation in the expression of measurement uncertainty on calibration certificates and on scopes of accreditation of calibration laboratories, ILAC approved a resolution at its third General Assembly meeting in Rio de Janeiro in 1999 that ILAC would develop criteria for the determination of measurement uncertainty (see below)*. Since then ILAC members have implemented documents on measurement uncertainty based on the “Guide to the expression of uncertainty in measurement” (GUM). ILAC and the International Bureau of Weights and Measures (BIPM) have signed a Memorandum of Understanding (MOU) and issued Joint Declarations aiming at cooperation on various issues. In recent years ILAC and the BIPM have agreed to harmonise the terminology, namely the “Best Measurement Capability (BMC)” previously used on scopes of accreditation of calibration laboratories with the “Calibration and Measurement Capability (CMC)” of the Appendix C of the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA).

This policy document addresses the evaluation of measurement uncertainty and its expression on calibration certificates of accredited laboratories and the evaluation of the CMC on the scopes of accreditation in line with the principles agreed upon between ILAC and the BIPM (see annex).

> **3.7.6 ILAC Arrangement Signatories shall have and implement criteria for the determination of uncertainty of measurements in calibration by June 2000. The signatories shall demonstrate that such documents are equivalent to the GUM Guide. The document EAL-R2 “Expression of the Uncertainty of Measurements in Calibration”* [1] *will be used as the measuring stick for such documents as a temporary measure pending the development of an ILAC document. Later versions of that EA document remain relevant and are now numbered EA-4/02*[1].

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2[2]

PURPOSE

This policy sets out the requirements for the statement of Calibration and Measurement Capabilities (CMCs) and for the evaluation of measurement uncertainty in calibration certificates or reports. In the context of this document, “calibration laboratory” implies all organisations performing calibration activities – i.e., testing, calibration and medical laboratories; inspection bodies; biobanks; reference material producers and proficiency testing providers. This policy has been developed in order to ensure a harmonised interpretation of the GUM and the consistent use of CMCs by ILAC member bodies to strengthen the credibility of the ILAC Arrangement. While this policy covers calibration of a reference material (RM), it does not cover the assignment of uncertainty to a property value of an RM in any area.
Organisations other than calibration laboratories are not expected to evaluate their CMC but should pay attention to CMC’s covered by the ILAC Arrangement in Calibration and the CIPM MRA.

This document is effective six months after the date of publication.

AUTHORSHIP

This publication was prepared by the ILAC Accreditation Committee (AIC) and endorsed by the ILAC membership.

PROCEDURE

1. Introduction

ISO/IEC 17025 [3] requires laboratories to evaluate the measurement uncertainty for all calibration activities.

ISO 15195 [4] and ISO 17034 [5] have similar requirements for reference measurement laboratories and reference material producers.

Specific advice on the evaluation of measurement uncertainty can be found in the "Guide to the expression of uncertainty in measurement" (GUM) [6][8], first published in 1993 in the name of BIPM, International Electrotechnical Commission (IEC), International Federation of Clinical Chemistry (IFCC), International Laboratory Accreditation Cooperation (ILAC), International Organization for Standardization (ISO), International Union of Pure and Applied Chemistry (IUPAC), International Union of Pure and Applied Physics (IUPAP) and International Organization of Legal Metrology (OIML). 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. The GUM describes an unambiguous and harmonised way of evaluating and stating the measurement uncertainty. Many Accreditation Bodies, as well as regional co-operations, have published mandatory criteria documents and guidance on measurement uncertainty, aligned with the GUM, to help laboratories implement the criteria and guidance. Some examples of guidance documents are listed in Section 7 of this Policy.

2. Terms and Definitions

For this document, the relevant terms and definitions given in the "International Vocabulary of Metrology – Basic and General Concepts and Associated Terms" (VIM) [9] and the following apply:

2.1. Calibration and Measurement Capability

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.

See the appendix A for further explanation of the term CMC.

3. ILAC Policy on the Evaluation of Measurement Uncertainty

The Accreditation Body shall ensure that the accredited calibration laboratories evaluate measurement uncertainty in compliance with the GUM.

To ensure evaluation of the measurement uncertainty is aligned with the GUM, the Accreditation Body may use documents published by other organisations or publish its own document containing practical guidance and mandatory requirements. Any mandatory requirements shall be in accordance with this policy and the reference documents.

4. ILAC Policy on Scopes of Accreditation of Calibration Laboratories

4.1 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 or measurement method or procedure and type of instrument or material to be calibrated or measured;
c) measurement range and additional parameters where applicable, e.g. frequency of applied voltage;
d) measurement uncertainty.

4.2 There shall be no ambiguity in the expression of the CMC on the scopes of accreditation and, consequently, on the smallest measurement uncertainty that can be expected to be achieved by a laboratory during a calibration or a measurement. Where the measurand covers a value, or a range of values, one or more of the following methods for expression of the measurement uncertainty shall be applied:

a) A single value, which is valid throughout the measurement range.
b) A measurement range. In this case a calibration laboratory shall ensure that linear interpolation is appropriate in order to find the uncertainty at intermediate values.
c) An explicit function of the measurand and/or a parameter.
d) A matrix where the values of the uncertainty depend on the values of the measurand and additional parameters.
e) A graphical form, providing there is sufficient resolution on each axis to obtain at least two significant digits for the uncertainty.

Open intervals ((example 1) “$0 < U < x$”, or (example 2) for a resistance interval of 1 to 100 ohms, the uncertainty stated as “less than 2 μΩ/Ω”) are incorrect in the expressions of CMCs.

4.3 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 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.

The CMC quoted shall include the contribution from a best existing device to be calibrated such that the CMC claimed is demonstrably realisable.

Note 1: 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.

Note 2: When it is possible that the best existing device can have a contribution to uncertainty from repeatability equal to zero, this value may be used in the evaluation of the CMC. However other fixed uncertainties associated with the best existing device shall be included.

Note 3: In exceptional instances, such as evidenced in very limited number of CMCs in the KCDB, it is recognized that a “best existing device” does not exist and/or contributions to the uncertainty attributed to the device may significantly affect the uncertainty. If such contributions to uncertainty from the device can be separated from other contributions, then the contributions from the device may be excluded from the CMC statement. For such a case, however, the scope of accreditation shall clearly identify that the contributions to the uncertainty from the device are not included

4.4 Where laboratories offer services such as reference value provision, the uncertainty covered by the CMC shall include factors related to the measurement procedure as it will be carried out on a sample, i.e., typical matrix effects, interferences, etc. shall be considered. The uncertainty covered by the CMC will not generally include contributions arising from the instability or inhomogeneity of the material. The CMC shall be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

Note: *The uncertainty described by the CMC for the reference value measurement is not identical with the uncertainty associated with a reference material provided by a reference materials producer. The expanded uncertainty of a certified reference material will in general be higher than the uncertainty described by the CMC of the reference measurement on the reference material.*

5. ILAC Policy on Statement of Measurement Uncertainty on Calibration Certificates

5.1 The Accreditation Body shall ensure that an accredited calibration laboratory reports the measurement uncertainty in compliance with the GUM.

5.2 The measurement result shall include the measured quantity value y and the associated expanded uncertainty U. In calibration certificates 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. To this an explanatory note shall be added, which may have the following content:

“The reported expanded measurement uncertainty is stated as the standard measurement uncertainty 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 concerns also cases when uncertainty is determined by Monte Carlo simulations (propagation of distributions) or with logarithmic units.*

5.3 The numerical value of the expanded uncertainty shall be given to, at most, two significant digits. Where the measurement result has been rounded, that rounding shall be applied when all calculations have been completed; resultant values may then be rounded for presentation. For the process of rounding, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided i.e in Section 7 of the GUM.

Note: *For further details on rounding, see the GUM and ISO 80000-1:2009* [6].

5.4 Contributions to the uncertainty stated on the calibration certificate 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.

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

5.6 As required in ISO/IEC 17025, accredited calibration laboratories shall present the measurement uncertainty in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent).

6. References

[1] EA-4/02 M:2013, *Evaluation of the Uncertainty of Measurement in Calibration*

[2] ISO/IEC Directives, Part 2, Principles to structure and draft documents intended to become International Standards, Technical Specifications or Publicly Available Specifications, Eight Edition 2018

[3] ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

[4] ISO 15195:2018, *Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures*

[5] ISO 17034:2016, *General requirements for the competence of reference material producers* 2019.

[6] The International System of Units (SI). Bureau International des Poids et Mesures. 9th Edition

[7] ISO 80000-1:2009, *Quantities and units - Part 1: General*

[8] 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 from https://www.bipm.org/en/publications/guides/)

[9] JCGM 200:2012 *International vocabulary of metrology – Basic and general concepts and associated terms* (Available from www.BIPM.org)

7. Example of guidance documents

— UKAS M3003, Edition 4: October 2019, available from www.ukas.com

— IPAC OGC10 Avaliacao de incerteza de medicao em calibracao 2015

— COFRAC document LAB REF 02, Exigences pour l'accréditation des laboratoires selon la Norme NF EN ISO/IEC 17025:2017, available from www.cofrac.fr

APPENDIX A - Informative

CALIBRATION AND MEASUREMENT CAPABILITIES.

A paper by the joint BIPM/ILAC working group.

1. Background

1. After the "Nashville meeting" of the Regional Metrology Organisations and ILAC in 2006, the BIPM/ILAC working group received a number of comments on its proposals for a common terminology for Best Measurement Capability (BMC) and Calibration and Measurement Capability (CMC). It also received comments on its proposal to harmonise on the term "measurement capability" (MC). Some commentators, primarily from the RMO and National Metrology Institute (NMI[1]) community, wished, however, to retain the term CMC. They argued that it had become widely accepted for use in describing, evaluating, promoting, and publishing the capabilities listed in the Calibration and Measurement Capability part of the Key Comparison Data Base of the CIPM MRA. Other commentators from both communities considered that the two terms were applied and interpreted differently according either to established practice or to poor or inconsistent interpretation. They considered that this was itself an adequate justification for a harmonized definition. All, however, agreed that there should be further work to follow up the "Nashville statement" (NS).

2. A further proposal was discussed between the BIPM and the ILAC in a bilateral meeting on 8 March 2007 when ILAC representatives volunteered to move away from the term BMC and to harmonise on CMC. The issue was presented to a meeting between the Regional Metrology Organisations (RMO) and the Regional Accreditation Bodies (RAB) on 9 March 2007. The RMO/RAB meeting welcomed the text. Small modifications were made at the Joint Committee of the Regional Metrology Organisations and the BIPM (the JCRB) on 3 May 2007 in Johannesburg. A presentation was then made on 10 May 2007 to the Accreditation Issues Committee of ILAC which accepted the document. This text was circulated to the members of the working group on 1 June, in advance of its planned meeting during the NCSLI conference in St Paul, USA, on 1 August 2007 so that there could be further regional consultations. During that period, a small working group developed "Notes 5a and b" aimed at the reference material community.

3. The BIPM/ILAC working group finalised the text during the St Paul meeting and now presents it for approval by the ILAC General Assembly in October 2007 and by the International Committee for Weights and Measures (CIPM) in November 2007. The working group suggested that, after approval, BIPM and ILAC should draft a joint statement on the subject. It also recommended that ILAC should adapt its current draft policy on estimation of uncertainty in calibration so as to take account of the recommendations and the outcome of the working group. The working group will continue to collaborate on other joint documents, which might include additional guidance to laboratories or bodies which produce reference materials. Other documents could include any agreed actions as a result of the ILAC survey of Accreditation Bodies on their experience of accrediting NMIs and a similar survey of

[1] Where the term NMI is used it is intended to include Designated Institutes (DIs) within the framework of the CIPM MRA

the NMIs' experiences. These documents will be discussed in the RMO/RAB meeting in March 2008.

4. The Definition.
"In the context of the CIPM MRA and ILAC Arrangement, and in relation to the CIPM-ILAC Common Statement, the following shared 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 laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement. "

5. The Notes to accompany the definition are of crucial importance, and aim to clarify issues of immediate relevance to the definition. They do not claim to cover every implication, or to address related issues. They may, however, be developed further, either in the current draft ILAC policy document on the evaluation of uncertainty in calibration, or in any guidance subsequently developed by the JCRB, for approval by the CIPM.

NOTES

N1 The meanings of the terms Calibration and Measurement Capability, CMC, (as used in the CIPM MRA), and Best Measurement Capability, BMC, (as used historically in connection with the uncertainties stated in the scope of an accredited laboratory) are identical. The terms BMC and CMC should be interpreted similarly and consistently in the current areas of application.

N2 Under a CMC, the measurement or calibration should be:

- performed according to a documented procedure and have an established uncertainty budget under the management system of the NMI or the accredited laboratory;
- performed on a regular basis (including on demand or scheduled for convenience at specific times in the year); and
- available to all customers.

N3 The ability of some NMIs to offer "special" calibrations, with exceptionally low uncertainties which are not "under normal conditions," and which are usually offered only to a small sub-set of the NMI's customers for research or for reasons of national policy, is acknowledged. These calibrations are, however, not within the CIPM MRA, cannot bear the equivalence statement drawn up by the JCRB, and cannot bear the logo of the CIPM MRA. They should not be offered to customers who then use them to provide a commercial, routinely available service. Those NMIs which can offer services with a smaller uncertainty than stated in the database of Calibration and Measurement Capabilities in the KCDB of the CIPM MRA, are, however, encouraged to submit them for CMC review in order to make them available on a routine basis where practical.

N4 Normally there are four ways in which a complete statement of uncertainty may be expressed (range, equation, fixed value and a matrix). Uncertainties should always comply with the *Guide to the Expression of Uncertainty in Measurement* (GUM) and should include the components listed in the relevant key comparison protocols of the

CIPM Consultative Committees. These can be found in the reports of comparisons published in the CIPM MRA KCDB as a key or supplementary comparison.

N5 Contributions to the uncertainty stated on the calibration certificate and which are caused by the customer's device before or after its calibration or measurement at a laboratory or NMI, and which would include transport uncertainties, should normally be excluded from the uncertainty statement. Contributions to the uncertainty stated on the calibration certificate include the measured performance of the device under test during its calibration at the NMI or accredited laboratory. CMC uncertainty statements anticipate this situation by incorporating agreed-upon values for the best existing devices. This includes the case in which one NMI provides traceability to the SI for another NMI, often using a device which is not commercially available.

N5a Where NMIs disseminate their CMCs to customers through services such as calibrations or reference value provision, the uncertainty statement provided by the NMI should generally include factors related to the measurement procedure as it will be carried out on a sample, i.e., typical matrix effects, interferences etc. must be considered. Such uncertainty statements will not generally include contributions arising from the stability or inhomogeneity of the material. However, the NMI may be requested to evaluate these effects, in which case an appropriate uncertainty should be stated on the measurement certificate. As the uncertainty associated with the stated CMC cannot anticipate these effects, the CMC uncertainty should be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

N5b Where NMIs disseminate their CMCs to customers through the provision of certified reference materials (CRMs) the uncertainty statement accompanying the CRM, and as claimed in the CMC, must indicate the influence of the material (notably the effect of instability, inhomogeneity and sample size) on the measurement uncertainty for each certified property value. The CRM certificate should also give guidance on the intended application and limitations of use of the material.

N6 The NMI CMCs which are published in the KCDB provide a unique, peer-reviewed traceability route to the SI or, where this is not possible, to agreed - upon stated references or appropriate higher order standards. Assessors of accredited laboratories are encouraged always to consult the KCDB (http://kcdb.bipm.org) when reviewing the uncertainty statement and budget of a laboratory in order to ensure that the claimed uncertainties are consistent with those of the NMI through which the laboratory claims traceability.

N7 National measurement standards supporting CMCs from an NMI or DI are either themselves primary realizations of the SI or are traceable to primary realizations of the SI (or, where not possible, to agreed - upon stated references or appropriate higher order standards) at other NMIs through the framework of the CIPM MRA. Other laboratories that are covered by the ILAC Arrangement (i.e. accredited by an ILAC Full Member Accreditation Body) also provide a recognized route to traceability to the SI through its realizations at NMIs which are signatories to the CIPM MRA, reflecting the complementary roles of both the CIPM MRA and the ILAC Arrangement.

N8 Whereas the various parties agree that the use of the definitions and terms specified in this document should be encouraged, there can be no compulsion to do so. We believe that the terms used here are a significant improvement on those used before and provide additional guidance and help so as to ensure consistency in their use, understanding, and application worldwide. We therefore hope that, in due course, they will become commonly accepted and used.

APPENDIX B

Revision Table – The table provides a summary of the key changes to this document from the previous version.

Section	Amendment
About ILAC introductory text	Replaced with new version
Copyright text	Replaced with new version
Purpose and Scope	The document is now prepared to be applied to all CAB's performing calibrations.
4. ILAC Policy	The policy is clarified and restricted to calibrations. Thus the inclusion of requirements to RMP has been reduced.
5.1	The policy is updated to comply with the recent ISO/IEC 17011:2017.
5.3	Minor changes to requirements to expanded uncertainty and removal of requirements for not using ppm and ppb.
5.4	The former clause 5.4 has been deleted and one sentence has been added to 5.3 to cover the content of the former clause 5.4.
6.1	The disclaimer allowing for not reporting uncertainties in calibrations has been removed due to changes in ISO/IEC 17025:2017.
6.3	The rounding of numbers has been changed.
6.6	Requirements for reporting have been updated to be in compliance with ISO/IEC 17025:2017.
7. References and 8. Examples of guidance documents	Updated
Appendix B	Revision table added