ILAC Policy for Uncertainty in Calibration

ILAC-P14:01/2013

ILAC – International Laboratory Accreditation Cooperation

ILAC is the international authority on laboratory and inspection body accreditation, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

ILAC provides the infrastructure that supports the world-wide demonstration of competence and equivalence of testing (including medical) and calibration laboratories, inspection bodies and other types of bodies serving or supporting laboratories and inspection bodies through accreditation. Accreditation of laboratories and inspection bodies supports activities within and between economies including trade, protection of health, safety and the environment for the public benefit. Its fundamental purpose is to provide confidence in the competence of bodies supporting these activities.

The ILAC Arrangement is an international, multilateral mutual recognition arrangement for accreditation bodies. Participating accreditation bodies agree to promote acceptance of the equivalence of calibration, test and inspection reports produced by accredited facilities. Each accreditation body undergoes peer evaluation according to ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

ILAC values the critical complementary and supportive activities of its Regional Cooperation Body members in the realisation of its vision, mission, goals and associated strategies. The Regional Cooperation Body members through the implementation of their multilateral mutual recognition arrangements provide all of the peer evaluation resources and much of the technical inputs to ILAC documents.

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PREAMBLE

In order to enhance the harmonisation in the expression of uncertainty of measurement 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 will develop criteria for the determination of uncertainty of measurement (see below)*. Since then ILAC members have implemented documents on uncertainty of measurement based on the "Guide to the Expression of Uncertainty of Measurement" (GUM). ILAC and the 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)" used on scopes of accreditation of calibration laboratories with the "Calibration and Measurement Capability (CMC)" of the Appendix C of the CIPM MRA.

This policy document addresses the estimation of uncertainty of measurement 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.*

PURPOSE

This policy sets out the requirements and guidelines for the estimation and statement of uncertainty in calibration and measurement, which apply to accreditation bodies and their accredited laboratories and reference material producers that perform calibration and measurement, in order to ensure a harmonised interpretation of the GUM and the consistent use of CMC by ILAC member bodies to strengthen the credibility of ILAC Arrangement.

This document is effective from the date of publication.

AUTHORSHIP

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

An amendment to clarify Clause 6.1 was proposed by the ILAC AIC and endorsed by the ILAC membership in January 2013.

PROCEDURE

1. Introduction

ISO/IEC 17025 requires calibration laboratories and testing laboratories to have and apply procedures for the estimation of uncertainty of measurement.

ISO 15195 [2] and ISO Guide 34 [3] have similar requirements for reference measurement laboratories and reference material producers.

Specific advice on the evaluation of uncertainty can be found in the "Guide to the Expression of Uncertainty in Measurement" (GUM), first published in 1993 in the name of BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML [4][8]. The GUM establishes general rules for evaluating and expressing uncertainty in measurement that can be followed in most fields of physical measurements. The GUM describes an unambiguous and harmonised way of evaluating and stating the uncertainty of measurement and provides several options to estimate and state uncertainty of measurement. Similarly, ISO Guide 35 [5] provides specific advice on determining the contributions to uncertainty from reference materials, including instability, inhomogeneity, and sample size, but several options are allowed. This may result in various interpretations of the GUM and ISO Guide 35, and hence calibration/reference measurement laboratories and reference material producers accredited by ILAC member bodies may report uncertainty of measurement in an inconsistent way. For this reason, many accreditation bodies, as well as regional co-operations, have published mandatory criteria documents and guidance on uncertainty of measurement, in line with the GUM and ISO Guide 35, to help laboratories implement the criteria and guidance. Some examples of guidance documents are listed in Section 8 of this Policy.

2. Scope

This document sets forth the ILAC policy regarding the requirements for the evaluation of the uncertainty of measurement in calibration and measurement, evaluation of the calibration and measurement capability (CMC), and the reporting of uncertainty on the certificates of calibration and measurement.

This document is applicable to calibration laboratories, reference measurement laboratories for laboratory medicine, and producers of certified reference materials that provide calibration and measurement services that refer to their accredited status under the ILAC MRA.

Relevant sections of this policy may also be applicable to testing laboratories that perform their own calibrations.

3. Terms and Definitions

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) [6][9] and the following apply:

3.1 Calibration Laboratory

In this policy, "calibration laboratory" further means a laboratory that provides calibration and measurement services.

3.2 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 annex for further explanation of the term CMC.

4. ILAC Policy on the Estimation of Uncertainty of Measurement

4.1 Accreditation bodies that are full members of or are applicants to the ILAC Mutual Recognition Arrangement (the ILAC MRA) shall require their accredited calibration laboratories to estimate uncertainties of measurement for all calibrations and measurements covered by the scope of accreditation.

4.2 Calibration laboratories accredited by the accreditation bodies shall estimate uncertainties of measurement in compliance with the "Guide to the Expression of Uncertainty in Measurement" (GUM), including its supplement documents and/or ISO Guide 35. To make sure that its accredited calibration laboratories estimate uncertainty of measurements in line with the GUM and/or ISO Guide 35, the accreditation body may use documents published by other organisations or publish its own document containing practical guidance and mandatory requirements. These mandatory requirements should be in accordance with the reference documents mentioned above.

5. ILAC Policy on Scopes of Accreditation of Calibration Laboratories

5.1 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/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.

5.2 There shall be no ambiguity on the expression of the CMC on the scopes of accreditation and, consequently, on the smallest uncertainty of measurement that can be expected to be achieved by a laboratory during a calibration or a measurement. Particular care should be taken when the measurand covers a range of values. This is generally achieved through employing one or more of the following methods for expression of the uncertainty:

a) A single value, which is valid throughout the measurement range.
b) A range. In this case a calibration laboratory should have proper assumption for the interpolation to find the uncertainty at intermediate values.
c) An explicit function of the measurand 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 figures for the uncertainty.

Open intervals (e.g., "$U < x$") are not allowed in the specification of uncertainties.

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

5.4 Calibration laboratories shall provide evidence that they can provide calibrations to customers in compliance with 5.1 b) so that measurement uncertainties equal those covered by the CMC. In the formulation of CMC, laboratories shall take notice of the performance of the "best existing device" which is available for a specific category of calibrations.

A reasonable amount of contribution to uncertainty from repeatability shall be included and contributions due to reproducibility should be included in the CMC uncertainty component, when available. There should, on the other hand, be no significant contribution to the CMC uncertainty component attributable to physical effects that can be ascribed to imperfections of even the best existing device under calibration or measurement.

It is recognized that for some calibrations a "best existing device" does not exist and/or contributions to the uncertainty attributed to the device 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.

NOTE: 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.

5.5 Where laboratories provide services such as reference value provision, the uncertainty covered by the CMC 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. 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 should be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

Note: *The uncertainty covered 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 covered by the CMC of the reference measurement on the reference material.

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

6.1 ISO/IEC 17025 requires calibration laboratories to report, in the calibration certificate, the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

Accredited calibration laboratories shall report the measured quantity value and the uncertainty of measurement, in compliance with the requirements in 6.2 – 6.5 of this section.

By exception, and where it has been established during contract review that only a statement of compliance with a specification is required, then the measured quantity value and the measurement uncertainty may be omitted on the calibration certificate. The following shall however apply:

- The calibration certificate is not intended to be used in support of the further dissemination of metrological traceability (i.e. to calibrate another device);
- As specified in ISO/IEC 17025:2005 clause 5.10.4.2, the laboratory shall determine the uncertainty and take that uncertainty into account when issuing the statement of compliance; and
- The laboratory shall retain documentary evidence of the measured quantity value and the uncertainty of measurement, as specified in ISO/IEC 17025 clauses 5.10.4.2 and 4.13, and shall provide such evidence upon request.

6.2 The measurement result shall normally 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 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 $y \pm U$ may be needed. This concerns also cases when uncertainty is determined by Monte Carlo simulations (propagation of distributions) or with logarithmic units.*

6.3 The numerical value of the expanded uncertainty shall be given to, at most, two significant figures. Further the following applies:

a) The numerical value of the measurement result shall in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result.

b) 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 ISO 80000-1:2009* [7].

6.4 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. Random 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.

6.5 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. References

[1] EA-4/02:1999, *Expressions of the Uncertainty of Measurements in Calibration* (including supplement 1 to EA-4/02) (previously EAL- R2)

[2] ISO 15195:2003, *Laboratory medicine - Requirements for reference measurement laboratories*

[3] ISO Guide 34:2009, *General requirements for the competence of reference material producers*

[4] ISO/IEC Guide 98-3:2008 – *Uncertainty of measurement – Part 3, Guide to the expression of uncertainty in measurement* (GUM:1995).

[5] ISO Guide 35:2006, *Reference materials – General and statistical principles for certification*

[6] ISO/IEC Guide 99:2007, *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)*

[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.* (Available from www.BIPM.org)

[9] JCGM 200:2008 *International vocabulary of metrology – Basic and general concepts and associated terms* (Available from www.BIPM.org)

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

8. Example of guidance documents

— UKAS M3003, edition 2: January 2007, available from www.ukas.com

— DAkkS-DKD-3 Angabe der Messunsicherheit bei Kalibrierungen

— COFRAC document LAB REF 02, paragraph 9.2

— ENAC CEA-ENAC-LC/02 Expresión de la incertidumbre de medida en las calibraciones
31-01992/Amd1:2005

ANNEX - 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 estimation 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.

BIPM/RMO-ILAC/RAB WORKING PARTY

V1 AJW, 17 April 2007.

V2 Changes agreed during the JCRB meeting (Johannesburg) in May 2007. included by AJW1 June 2007. This version was presented to and agreed by the ILAC AIC on 10 May in Vienna.

V3. Including "Note 5". 16 July 2007.

V4 25 July with changes from LM/JMcL/MK.

V5 1 August 2007 agreed during the meeting at St Paul.

V6 Drafted by AJW 07 September 2007as a result of comments received on v5.

Proposed path for endorsement is by:

1. BIPM,
2. JCRB (for recommendation to the CIPM for approval)
3. ILAC General Assembly
4. The CIPM