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RULES FOR THE EVALUATION OF MEASUREMENT UNCERTAINTY

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1. SUBJECT AND SCOPE

The purpose of these rules is to define the policy for the evaluation of measurement uncertainty, as well as the reporting of uncertainty in statements of conformity issued by testing/calibration laboratories and medical laboratories.

These rules are intended for ATCG staff and ATCG assessors involved in the accreditation process of testing/calibration laboratories in accordance with the requirements of standards MEST EN ISO/IEC 17025:2018 and MEST EN ISO 15189:2023, and they also apply to conformity assessment bodies that use measurements in conformity assessment activities.

2. ABBREVIATIONS AND DEFINITIONS

2.1 Abbreviations

SI – International System of Units
EA – European co-operation for Accreditation
ILAC – International Laboratory Accreditation Cooperation

2.2 Definitions

For the purposes of this document and the implementation of activities prescribed therein, the terms and definitions given in the International Vocabulary of Metrology (VIM – International Vocabulary of Metrology: Basic and General Concepts and Associated Terms, JCGM 200) shall be used.

Only selected definitions are provided in this document:

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

CMC (Calibration and Measurement Capability) calibration and measurement capability available to customers under normal conditions:
(a) as stated in the laboratory's scope of accreditation, or
(b) as published in the BIPM Key Comparison Database (KCDB)

3. RELATION TO OTHER DOCUMENTS

~~VIM 4 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms~~ ~~VIM (fourth edition)~~ International Vocabulary of Metrology – Basic and General Concepts and Associated Terms, JCGM 2021
GUM – Evaluation of Measurement Data: Guide to the Expression of Uncertainty in Measurement, JCGM 100:2008, BIPM
EA-4/02 M:2022 – Evaluation of the Uncertainty of Measurement in Calibration
EA-4/16 G – EA Guidelines on the Expression of Uncertainty in Quantitative Testing

ILAC-P14:~~01~~/2020 – ILAC Policy for Uncertainty in Calibration
ILAC G17:01/2021 – ILAC Guidelines for Measurement Uncertainty in Testing
~~ILAC-P14:01/2013 ILAC Policy for Uncertainty in Calibration~~
MEST EN ISO/IEC 17025:2018 – General requirements for the competence of testing and calibration laboratories
MEST EN ISO 15189:2023 – Medical laboratories – Requirements for quality and competence

- ~~*Where the above documents are not indicated with a year of publication, the latest valid editions/versions shall apply, in accordance with the updated list ZPR.02.04 – Register of External Documents*~~ *Amendment 1 dated 03 July 2023.*

4. DESCRIPTION OF ACTIVITIES AND RESPONSIBILITIES

The Accreditation Body of Montenegro accepts the principles for the evaluation of measurement uncertainty contained in the documents EA-4/02 M:2022 Evaluation of the Uncertainty of Measurement in Calibration, ILAC-P14:~~01~~/2020 ILAC Policy for Uncertainty in Calibration, and ILAC G17:01/2021 ILAC Guidelines for Measurement Uncertainty in Testing.

These documents are available at: www.european-accreditation.org and www.ilac.org

4.1 Evaluation of Measurement Uncertainty in Testing Laboratories, Including Medical Laboratories

Laboratories shall identify contributions to measurement uncertainty. When evaluating measurement uncertainty, all significant contributions, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

A testing laboratory shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation, an estimate shall be made based on understanding of the theoretical principles or practical experience of the method.

Medical laboratories shall determine measurement uncertainty for each measurement procedure used to report quantitative results of patient samples. The laboratory shall define performance requirements for measurement uncertainty for each procedure and regularly review the uncertainty estimates.

Compliance with MEST EN ISO/IEC 17025:2018 and MEST EN ISO 15189:2023 is demonstrated by:
a) the existence and application of a document for evaluation of measurement uncertainty (e.g. procedure or instruction), or inclusion of the evaluation method within the test method; and
b) records of performed evaluations, including calculations and final results of (expanded) measurement uncertainty.

Testing laboratories, including medical laboratories, shall provide documented evidence of measurement uncertainty evaluation during assessment.

The evaluation process shall comply with ILAC G17:01/2021 ILAC Guidelines for Measurement Uncertainty in Testing .

Where necessary for interpretation of results and when applicable, test reports shall include measurement uncertainty:
– when it affects validity or application of results;
– when required by the customer;
– when it affects compliance with specification limits.

Medical laboratories shall consider measurement uncertainty when interpreting results and make it available upon request.

4.2 Evaluation of Measurement Uncertainty in Calibration Laboratories

Laboratories shall identify all contributions to measurement uncertainty, including sampling where relevant.

Calibration laboratories, including those performing internal calibration, shall evaluate measurement uncertainty for all calibrations.

Compliance with MEST EN ISO/IEC 17025:2018 is demonstrated by:
a) documented procedures including example calculations for uncertainty evaluation; or
b) documented calibration procedures including uncertainty evaluation and example calculations.

Calibration laboratories shall provide documented evidence of uncertainty evaluation during assessment.

The evaluation shall comply with ILAC-P14:~~01~~ 2020 ILAC Policy for Uncertainty in Calibration i EA 4/02:2022 M Evaluation of the Uncertainty of Measurement in Calibration.

Calibration laboratories shall, in accordance with the principles of EA-4/02 M:2022 and ILAC-P14:~~01~~/2020, define and document their Calibration and Measurement Capabilities (CMC).

ATCG ensures that accredited laboratories evaluate uncertainty in accordance with GUM Evaluation of measurement data - Guide to the expression of uncertainty in measurement, JCGM 100 :2008 BIPM.

The scope of accreditation shall include CMC expressed in terms of:
– measurand or reference material;
– method/procedure and/or instrument type;
– measurement range and relevant parameters;
– measurement uncertainty.

To avoid ambiguity in the expression of Calibration and Measurement Capabilities (CMC) within the scope of accreditation, and consequently the smallest measurement uncertainty that can be expected to be achieved by the laboratory during calibration or measurement, where the measurand covers a value or a range of values, one or more of the following methods shall be used to express measurement uncertainty:

- a single value valid over the entire measurement range;
- a range of measurement uncertainty values; in this case, the laboratory shall ensure that linear interpolation is appropriate for determining the uncertainty within the measurement range;
- a defined function of the measurand or a parameter used to determine the measurement uncertainty;
- a matrix where the value of measurement uncertainty depends on the value of the measurand and additional parameters;
- a graphical representation, ensuring sufficient resolution on each axis so that at least two significant digits of the expanded measurement uncertainty can be read from the graph.

Open intervals (e.g. "0 < U < x" or, for example, for a resistance measurement range from 1 Ω to 100 Ω, uncertainty stated as "less than 2 μΩ/Ω") are not acceptable for the expression of CMC.

To avoid ambiguity in definitions, the use of expressions such as ppm (parts per million) and ppb (parts per billion) is not acceptable.

The stated CMC shall include contributions from the "best" available device to be calibrated, in such a way that the claimed CMC can be achieved.

When laboratories provide services such as assigning reference values, the measurement uncertainty covered by the CMC shall include factors associated with the measurement procedure applied to the sample. The measurement uncertainty covered by the CMC typically does not include contributions arising from instability and inhomogeneity of the material. The CMC shall be based on the analysis of the inherent performance characteristics of the method for typical stable and homogeneous samples.

The measurement result includes the measured value y and the associated expanded measurement uncertainty U. In a calibration certificate, the measurement result shall be reported as $y \pm U$, together with the associated units for y and U. Tabular presentation of results may also be used, as well as relative expanded measurement uncertainty $U/|y|$.

In the calibration certificate, the coverage probability and the coverage factor shall be stated, together with an explanation such as:
"Expanded measurement uncertainty is stated as the combined standard measurement uncertainty multiplied by a coverage factor k corresponding to a coverage probability of approximately 95%."

Measurement uncertainty shall generally be expressed using two significant digits, unless there is a valid technical reason for using a different format.

Note: Details on rounding numerical values of measurement results can be found in GUM and ISO 80000-1.

Contributions to the measurement uncertainty stated in the calibration certificate shall include relevant short-term influences during calibration as well as influences originating from the customer's device. Where applicable, the measurement uncertainty shall include the same contributions that were considered in the evaluation of the CMC uncertainty components, except that the uncertainty components estimated for the "best" available device shall be replaced by those related to the customer's device. Consequently, the uncertainties reported in the calibration certificate tend to be greater than the uncertainties covered by the CMC. Contributions that the laboratory cannot reasonably know, such as uncertainties arising from transport, should normally be excluded from the statement of measurement uncertainty. However, if the laboratory anticipates that such contributions could have a significant impact on the measurement uncertainty, the customer shall be informed accordingly (review of requests, tenders and contracts, MEST EN ISO/IEC 17025:2018).

The calibration certificate shall include the measurement uncertainty of the result, expressed in the same unit as the measurand or as a relative value with respect to the measurand.

In a calibration certificate issued by an accredited calibration laboratory, the stated measurement uncertainty shall not be smaller than the uncertainty defined in the CMC for the respective calibration method specified in the scope of accreditation.

5. FORMS

This document has no associated records.