ILAC Guidelines for Measurement Uncertainty in Testing

ILAC-G17:01/2021

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 (ABs) 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 AB. 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 2000 ILAC issued ILAC G17 "Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025" and the task for that document was to provide guidance on the implementation of the uncertainty concept in testing as required by ISO/IEC 17025 which was first issued in 1999.

ISO/IEC 17025 specifies detailed requirements concerning the evaluation of measurement uncertainty and how it should be stated in the test reports. At that time the test result and the uncertainty were regarded as two partly independent quantities. Over the years this concept has changed and in the "International Vocabulary of Metrology – Basic and General Concepts and Associated Terms" [4], VIM 3, a measurement result is made up of a measured quantity value and the measurement uncertainty.

Evaluation of measurement uncertainty has further been a topic dealt seriously within several sectors of testing and a huge number of guidelines have been developed during the last twenty years. Still measurement uncertainty is debated intensely in many fields of testing as well as in governmental institutions around the world and evaluation of measurement uncertainty has still not matured equally well in all areas of testing. This fact has been essential for the development of this ILAC document. The aim of this document is to provide guidance and related references for the evaluation of measurement uncertainty in testing, as well as to encourage the customary reporting of measurement uncertainty in order to fulfil expectations of relevant clauses from ISO/IEC 17025:2017 [5]. The document also aims to assist laboratories in understanding the common approach taken by accreditation bodies when performing assessments against these requirements.

PURPOSE

The purpose of this document is to provide guidance and related references for the evaluation of measurement uncertainty and its reporting in test reports. It is applicable to all areas of testing covered by the ILAC Arrangement in Testing. This document is also relevant in some parts of medical examination (ISO 15189:2012 [14]) as well as other kinds of conformity assessment where testing is performed. Some guidance notes are also provided in this document for AB to assess reporting of measurement uncertainty.

AUTHORSHIP

This procedure was prepared by the ILAC Accreditation Committee (AIC) and endorsed by the ILAC membership in 2020.

PROCEDURE

1. Introduction

Knowledge of the measurement uncertainty of test results is fundamentally important for laboratories, their customers and all parties using and interpreting these results.

When measurements are repeated or compared, it is important that measurement uncertainty is taken into account. This is especially the case when results are reported against a specification limit. Comparability of results can usually be determined when measurement uncertainty is considered. This is the case when more laboratories have measured the same parameter of a test item (sample) or when a laboratory regularly measures a parameter which is being monitored.

Specific advice on the evaluation of measurement 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 [3]. The GUM establishes general rules for evaluating and expressing uncertainty in measurement that can be followed in most fields of physical measurements. For chemical quantities EURACHEM/CITAC published a guide, Quantifying Uncertainty in Analytical Measurement [1], which is a more relevant reference in chemistry and related fields.

Although the GUM and the EURACHEM/CITAC document describe an unambiguous and harmonised way of evaluating measurement uncertainty, it has proved necessary to produce sector specific guidance taking due care to the nature of the specific sector. For this reason, many laboratory organisations, accreditation bodies (AB) and regional co-operations, have published guidance on evaluation of uncertainty in testing. Some example of guidance documents are listed in Section 5 of this document.

2. Terms and Definitions

For the purpose of this document, relevant terms and definitions given in the "International Vocabulary of Metrology – Basic and General Concepts and Associated Terms" (VIM) [4] and other references are included below.

2.1 Measurement result (VIM 2.9)
Set of quantity values being attributed to a measurand together with any other available relevant information.

Note 2: A measurement result is generally expressed as a single measured quantity value and a measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single measured quantity value. In many fields, this is the common way of expressing a measurement result.

2.2 Measurement uncertainty (VIM 2.26)
Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

2.3 Expanded measurement uncertainty (VIM 2.35)
Product of a combined standard measurement uncertainty and a factor larger than the number one

2.4 Coverage interval (VIM 2.36)
Interval containing the set of true quantity values of a measurand with a stated probability, based on the information available

2.5 Coverage probability (VIM 2.37)
Probability that the set of true quantity values of a measurand is contained within a specified cover-age interval

2.6 Coverage factor (VIM 2.38)
Number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

2.7 Target measurement uncertainty (VIM 2.34)
Measurement uncertainty specified as an upper limit and decided on the basis of the intended use of measurement results

2.8 Decision rule (ISO/IEC 17025:2017 3.7)
Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

2.9 Testing laboratory
Laboratory that performs testing according to ISO/IEC 17025.

3. Guidance on evaluation of Measurement Uncertainty in Testing

While some laboratories may use the Guide to Uncertainty in Measurement (GUM), ISO/IEC Guide 98-3 [3], or equivalent documents such as EA 4/02 and guidance documents published by individual AB [27-31], it is recognized that there is a large spectrum of application documents for evaluation of measurement uncertainty in testing [1-2, 7-13, 15-16] that are particular to an area of testing on an international or national level. For example, EURACHEM/CITAC, EUROLAB and Nordtest, have some documents about measurement uncertainty, including measurement uncertainty arising from sampling [24 & 25]. Other areas such as microbiology have documents about measurement uncertainty [20 & 21].

In some areas of testing in which uncertainty cannot be expressed as an expanded uncertainty for the test result (e.g. qualitative testing or examinations) [22 & 23], other means for evaluation of measurement uncertainty, such as a probability for false positive or false negative test results, may be more relevant.

For quantitative measurements where the final results are expressed in a qualitative way (e.g. pass/fail), evaluation of measurement uncertainty is still applicable.

4. Guidance on the reporting of Measurement Uncertainty in Testing

Evaluation of measurement uncertainty has developed hugely over the last twenty years and is now well implemented across the world and in most areas of testing.

In order to ensure a harmonised level of reporting, the guidelines in this part will focus on providing examples and suggestions for the clauses in ISO/IEC 17025:2017 related to reporting of measurement uncertainty

ISO/IEC 17025:2017 requires laboratories to:

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:
…
c) 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.*

The wording has not changed from the previous version of ISO/IEC 17025. The foundational expectations from the previous ISO/IEC 17025:2005, section 5.10.3.1.c, still exist. These guidelines will clarify that it is a strict requirement that testing laboratories "shall, where necessary for the interpretation of the test results" report measurement uncertainty. Laboratories are encouraged to evaluate carefully the situations where reporting measurement uncertainty can help the interpretation of test results, in order to conform to 7.8.3.1 c).

In the following examples, it will normally be necessary to report measurement uncertainty in order to comply with 7.8.3.1 c), if the laboratory is not required to report a statement of conformity:

- Environmental tests conducted regularly and where conformity to a specification limit is assessed by the customers. Such cases may be mandated by legislation or be voluntary. In order for customers to assess if a test parameter is subject to change and poses a risk for not complying with the regulation, the measurement uncertainty needs to be known. The measurement uncertainty is necessary for the customers to make a qualified decision, e.g., on changes to their water or waste water treatment facilities.

- Product tests where a product is tested for conformity to a specification. In such cases the test result may be quantitative as well as pass/fail. In both cases the reporting of measurement uncertainty should be important for a customer to assess the risk of product failure for an item near the specification limit. This is particularly relevant if the customer is the product manufacturer.

It is however recognized that there are situations where the requirement for reporting of measurement uncertainty may not be obvious, e.g., the laboratory cannot be sure about the end use of the test results and the customer also does not explicitly require MU to be reported. In such cases, customary reporting of measurement uncertainty in testing can help the laboratory to fulfil its responsibility under ISO/IEC 17025:2017. Customary reporting of measurement uncertainty in testing has several advantages:

- Only after taking measurement uncertainty into account, a deviation between two test results can objectively be judged to be compliant or non-compliant.

- Reporting measurement uncertainty allows users to assess if the test results are fit for purpose (i.e. if measurement uncertainty is adequately low or smaller than the target measurement uncertainty).

- The need for repetitive and redundant tests is reduced when reported measurement uncertainties are initially taken into account.

- Reported measurement uncertainties provide information of the performance of a test method both in a laboratory and across laboratories and allows for development and improvement of standardized methods.

- Laboratories will not on a case-by-case basis be asked by their customers for additional information of measurement uncertainties and will not have to determine when the measurement uncertainty is necessary for interpretation of test results and when it is not.

- Customary reporting consolidates measurement uncertainty evaluation.

When customary reporting is not made, AB should assess how the laboratory ensures conformity with ISO/IEC 17025:2017 clause 7.8.3.1 c) and how the borderlines between reporting and non-reporting of measurement uncertainty are established. Such borderlines may be connected to a decision rule [10, 12, 17-19] (refer to ILAC G8).

The following issues should be taken into account by ABs:

- The AB should encourage the proper use of measurement uncertainty by stakeholders and regulators, including establishing decision rules. Laboratories in turn should be encouraged to discuss with their stakeholders and regulators the intended use of the reported results and the relevance of evaluating and/or reporting measurement uncertainty.

- The AB may consider the appropriateness to encourage their accredited laboratories to include a disclaimer that whenever either a component of measurement uncertainty, including that arising from sampling, cannot be reasonably evaluated or the relevant requirement is not applicable then this should be clarified in the test report. For example, in the case of sampling, the disclaimer may be: "*The measurement uncertainty arising from sampling is not included in the expanded measurement uncertainty*".

- When measurement uncertainty is reported, it should normally be the expanded measurement uncertainty based on the coverage probability of approximately 95% and the coverage factor *k* needed to achieve the probability. It is understood that coverage probabilities other than 95% may be better suited to particular circumstance. To this, an explanatory note should be added, which may have the following content: *"The reported expanded measurement uncertainty is stated as the combined standard measurement uncertainty multiplied by the coverage factor k = [value used] such that the coverage probability corresponds to approximately [the desired coverage probability]%."*.

- When reporting the test result and its measurement uncertainty, the use of excessive numbers of digits should be avoided [26]. Unless specifically identified in the method reporting requirement, it usually suffices to have at most two significant digits of measurement uncertainty as is required for calibration in ILAC P14.

5. References

[1] EURACHEM / CITAC Guide CG 4 (2012), *Quantifying Uncertainty in Analytical Measurement, Third Edition* (available from www.eurachem.org)

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

[3] 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)
Note: this document is also available as ISO/IEC Guide 98-3:2008

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

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

[6] EA-4/02 M: 2013, *Evaluation of the Uncertainty of Measurements in Calibration* (available from www.european-accreditation.org)

[7] EA-4/16 G: 2003 *EA guidelines on the expression of uncertainty in quantitative testing* (available from www.european-accreditation.org)

[8] ISO 21748:2017, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation*

[9] Nordtest Technical Report 537 (2017) *Handbook for Calculation of Measurement Uncertainty in Environmental Laboratories* (available from www.nordtest.info)

[10] JCGM 106:2012 *Evaluation of measurement data – The role of measurement uncertainty in conformity assessment* (available from www.BIPM.org)
Note: this document is also available as ISO/IEC Guide 98-4:2012

[11] IEC GUIDE 115:2007, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

[12] ILAC G-8:09/2019 *Guidelines on Decision Rules and Statements of Conformity* (available from https://ilac.org/)

[13] ILAC P14-09/2020 *ILAC Policy for Uncertainty in Calibration* (available from https://ilac.org/)

[14] ISO 15189:2012 *Medical Laboratories – Requirements for Quality and Competence*

[15] EURACHEM/CITAC Guide (2015) *Setting and Using Target Uncertainty in Chemical Measurement, First Edition* (available from www.eurachem.org)

[16] EUROLAB Technical Report No. 1/2006 *Guide to the Evaluation of Measurement Uncertainty for Quantitative Test Results* (available from https://www.eurolab.org)

[17] EUROLAB Technical Report No. 1/2017 *Decision rules applied to conformity assessment* (available from https://www.eurolab.org)

[18] EURACHEM/CITAC Guide (2007) *Use of uncertainty information in compliance assessment* (available from www.eurachem.org)

[19] Guide OIML G 19:2017 *The role of measurement uncertainty in conformity assessment decisions in legal metrology* (available from www.oiml.org)

For measurement uncertainty of microbiological tests, the following references are useful:

[20] ISO 29201:2012 *Water Quality – The Variability of Test Results and the Uncertainty of Measurement of Microbiological Enumeration Methods*

[21] ISO 19036:2019 *Microbiology of the Food Chain – Estimation of Measurement Uncertainty for Quantitative Determinations*

For uncertainty of qualitative tests, the following references are useful:

[22] *Quality assurance of qualitative analysis in the framework of the European project 'MEQUALAN',* Accred Qual Assur (2003) 8:68-77

[23] IFCC-IUPAC Recommendations 2017 *Vocabulary on nominal property, examination, and related concepts for clinical laboratory sciences,* Pure Appl. Chem. 90 (2018) 913–935

For sampling measurement uncertainty, the following two references are useful:

[24] EURACHEM/EUROLAB/CITAC/Nordtest/AMC Guide (2019) *Measurement uncertainty arising from sampling: A guide to methods and approaches, Second Edition* (available from www.eurachem.org)

[25] Nordtest Technical Report 604 (2020) *Uncertainty from sampling - A Nordtest Handbook for Sampling Planners on Sampling Quality Assurance and Uncertainty Estimation* (available from www.nordtest.info)

The following reference for the management of significant digits for reporting of measurement uncertainty is useful:

[26] http://mechem.rd.ciencias.ulisboa.pt/ms-excel-spreadsheet-for-automatic-selection-of-significant-digits/

6. Example of guidance documents

[27] UKAS M3003, edition 4: October 2019 (available from www.ukas.com)

[28] DAkkS-DKD-3 Angabe der Messunsicherheit bei Kalibrierungen

[29] COFRAC document LAB GTA 86, paragraph 7.8.3

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

[31] General Accreditation Guidance. Estimating and reporting measurement uncertainty of chemical test results, NATA, 2018 (available from www.nata.com.au)

APPENDIX A

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

Not needed here – total rewrite of document.