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ACC-CD-42-01

Criteria for Estimation of Measurement Uncertainty in Testing Laboratories.

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1 Background Information

1.1 Purpose

The purpose of this document is to describe how KENAS assesses the application of measurement uncertainty within the requirements of ISO/IEC 17025 –Requirements for the competence of testing and calibration Laboratories.

1.2 Scope

It applies to Testing and Calibration Laboratories that are accredited or seeking accreditation under KENAS.

2 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 shall apply. Other 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 Acronyms and Abbreviations

CEO	Chief Executive Officer
KENAS	Kenya Accreditation Service

2.2 Definition of Terms

2.2.1 Measurement result (VIM 2.9)

Set of quantity values being attributed to a measurand together with any other available relevant information.

2.2.2 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

2.2.3 Expanded measurement uncertainty (VIM 2.35)

Product of a combined standard measurement uncertainty and a factor larger than the number one ILAC-G17:01/2021 ILAC Guidelines for Measurement Uncertainty in Testing.

2.2.4 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

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2.2.5 Coverage probability (VIM 2.37)

Probability that the set of true quantity values of a measurand is contained within a specified cover-age interval

2.2.6 Coverage factor (VIM 2.38)

Number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

2.2.7 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

2.2.8 Decision rule (ISO/IEC 17025:2017 3.7)

Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

2.2.9 Testing laboratory

Laboratory that performs testing according to ISO/IEC 17025

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3 Criteria

3.1 Guidance on evaluation of Measurement Uncertainty in Testing

3.1.1 While some laboratories may use the Guide to Uncertainty in Measurement (GUM), ISO/IEC Guide 98-3. it is recognized that there is a large spectrum of application documents for evaluation of measurement uncertainty in testing

3.1.2 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:

a) it is relevant to the validity or application of the test results;
b) a customer's instruction so requires, or
c) the measurement uncertainty affects conformity to a specification limit.

3.1.3 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).

3.1.4 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.

3.1.5 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:

a) Only after taking measurement uncertainty into account, a deviation between two test results can objectively be judged to be compliant or non-compliant.
b) 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).
c) The need for repetitive and redundant tests is reduced when reported measurement uncertainties are initially taken into account.
d) 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.

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e) 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.
f) Customary reporting consolidates measurement uncertainty evaluation.

3.1.6 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:

a) KENAS 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.

b) KENAS will 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”.

c) 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]%.”.

d) 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 1` is required for calibration in ILAC P14

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3.2 Guidance on the reporting of Measurement Uncertainty in Testing

3.2.1 KENAS does not prescribe a specific formula for estimating uncertainty of measurement. Laboratories should consider available references and consult with their own experts to determine the most applicable method for developing an estimation of uncertainty of measurement.

3.2.2 The estimate of uncertainty must have an empirical basis where the laboratory complies with the following;

a) Specify what is being tested
b) Specify the test method and the instrument(s) used.
c) Construct and document an appropriate measurement uncertainty budget, identifying and listing all potential sources of uncertainty.
d) The estimate must be based on those parameters that significantly impact the results. Laboratories may dismiss any potential sources which do not impact the uncertainty of measurements based on previous experience. This will have to be documented and justified based on the degree of insignificance.
e) Gather sufficient measurement data or identify existing recent analytical data on replicate measurements which may be available in the laboratory. Sources could include but not limited to: method validation, Quality Control, Proficiency Testing, replicate-testing data. Other sources of data may include calibration certificates or reviewed & published scientific literature.
f) Calculate the estimated uncertainty of the measurement method and have the result and supporting data available in the laboratory for reference.
g) Maintain or recalculate the estimated uncertainty of measurement as the need arises (i.e. when a significant change occurs in the budget).

3.2.3 The purpose of specific tests and use of the test results should be considered when estimating uncertainty of measurement. Consideration must be given to the impact of the process on the laboratory's time and resources. However, good science and the needs of the customer(s) will be the determining factors.

3.2.4 Records must be maintained to describe the process used to develop the estimation of uncertainty. These records must include the elements of the budget, data gathered, calculations to arrive at the estimate, and the estimated uncertainty associated with the measurement method. The records must be available at the laboratory during assessments and, when requested by a customer of the Laboratory testing services.

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3.2.5 In testing, understanding and reporting measurement uncertainty is crucial for accurate and reliable results. The guidance involves identifying all potential sources of uncertainty, estimating the size of each, combining these into an overall uncertainty figure, and then reporting the result along with the uncertainty. This helps to determine the range within which the true value is likely to fall. Here's a more detailed breakdown:

3.2.5.1 Identifying Sources of Uncertainty:

- **Test method:** The chosen method itself can introduce errors.
- **Equipment:** Calibration, accuracy, and limitations of the instruments used can contribute to uncertainty.
- **Reference materials:** The uncertainty associated with reference standards used for calibration can affect the measurement.
- **Sample handling:** How samples are collected, prepared, and stored can impact the final results.
- **Environmental factors:** Temperature, humidity, and other environmental conditions can influence the measurement.
- **Analyst:** The skill and experience of the person performing the test can affect the outcome.
- **Method validation:** Data from method validation studies can help estimate uncertainty.

3.2.5.2 Estimating Uncertainty:

Type A evaluation (statistical):

This involves analyzing the spread of results from multiple measurements, often using statistical methods like standard deviation or standard error of the mean.

Type B evaluation (non-statistical):

This relies on knowledge of the instrument's specifications, the uncertainty of reference materials, or other expert knowledge to estimate uncertainty.

3.2.5.3 Combining Uncertainties:

Combined uncertainty:

The various uncertainty components are combined mathematically to calculate a combined standard uncertainty.

Expanded uncertainty:

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The combined uncertainty is multiplied by a coverage factor (usually 2) to provide an interval within which the true value is expected to lie with a certain level of confidence (e.g., 95%).

3.2.5.4 Reporting Uncertainty:

- **Report the measured value and its expanded uncertainty** .
- **Include an uncertainty statement**: explaining how the uncertainty was determined and what it means in terms of the measurement.
- **Round the measurement result and uncertainty appropriately** .

3.2.5.5 Key Considerations:

GUM:

The "Guide to the Expression of Uncertainty in Measurement" provides the framework for evaluating and expressing measurement uncertainties.

ILAC:

The International Laboratory Accreditation Cooperation (ILAC) provides guidance on measurement uncertainty in testing, including ILAC P14, which focuses on calibration.

ISO/IEC 17025:2017

This standard requires laboratories to determine and express measurement uncertainty.

Decision rules:

When stating conformity with a specified requirement (e.g., Pass/Fail), a decision rule should be used that accounts for the measurement uncertainty.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	GUM	Guide to the expression of uncertainty in measurements
2.	ILAC P14	ILAC Policy for uncertainty in Calibration
3.	VIM	International Vocabulary for Metrology
4.	ILAC-G17:01/2021	ILAC Guidelines for Measurement Uncertainty in Testing
5.	ILAC G-8:09/2019	Guidelines on Decision Rules and Statements of Conformity
6.	ISO 15189	Medical Laboratories – Requirements for Quality and Competence

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Revision/Amendment Records

Date	Ver	Revised By	Reason for Revision
30/05/2026	01	QRM	Newly developed document

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