# TN 1.0: GAC Technical Note 1

**Uncertainty of measurement**



## 1. Purpose / Scope:

As per ISO/IEC 17025 and ISO 15189, when reporting the result of a measurement of a physical quantity, it is obligatory that some quantitative indication of the quality of the result be given in order to assess its reliability: this is the measurement uncertainty.
Without uncertainty estimation, measurement results cannot be compared, either among themselves or with reference values given in a specification or standard.
The purpose of this technical note is to provide GAC policy on the evaluation and reporting of measurement uncertainty for calibration and testing (including medical) laboratories.

## 2. References:

- JCGM 200:2012: International vocabulary of metrology – Basic and general concepts and associated terms (VIM) - 3rd edition [1]
- JCGM 100:2008 (GUM): Evaluation of measurement data — Guide to the expression of uncertainty in measurement [2]
- EA-4/02 M:2013: Evaluation of the uncertainty of measurement in calibration [3]
- EA-4/16 G:2003: EA guidelines on the expression of uncertainty in quantitative testing [4]
- ILAC G17:2002: Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025 [5]
- ILAC P14:2013: ILAC Policy for Uncertainty in Calibration [6]
- ILAC P15:2016: Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies [7]
- APLAC TC 005: Issue No.4, Interpretation and guidance on the Estimation of Uncertainty of Measurement in Testing [8]

## 3. Terms / Definitions *[Ref 1]*:

- Quantity: property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference.
- Measurand: quantity intended to be measured.
- International System of Units SI: system of units, based on the International System of Quantities, their names and symbols, including a series of prefixes and their names and symbols, together with rules for their use, adopted by the General Conference on Weights and Measures (CGPM).
- Accuracy: closeness of agreement between a measured quantity value and a true quantity value of a measurand.
- Trueness: closeness of agreement between the averages of an infinite number of replicate measured quantity values and a reference quantity value.
- Precision: closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions.
- Error: measured quantity value minus a reference quantity value (systematic and random).
- Uncertainty: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

- **Combined standard uncertainty ($u_c$):** standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model.
- **Expanded uncertainty (U):** product of a combined standard measurement uncertainty and a factor larger than the number one.
- **Coverage factor (k):** number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty.
- **Calibration:** operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.
- **Verification:** provision of objective evidence that a given item fulfils specified requirements.
- **Metrological traceability:** property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

## 4. GAC Policy *[Ref 5]*:

- ✓ The GUM, ISO 5725 and ISO/IEC 17025 form the basic documents but sector specific interpretations may be needed;
- ✓ The basis for the estimation of uncertainty of measurement is to use existing experimental data (quality control charts, validation, round robin tests, PT, CRM, handbooks etc.);
- ✓ Calibration and testing laboratories shall document fully their procedures for the estimation of measurement uncertainty and shall be able to show records of it being implemented for a period of at least 3 months prior to the assessment;
- ✓ Calibration laboratories shall report their CMC on the accreditation schedule as detailed in ILAC document P14. This requirement is applicable for testing/medical laboratories performing in-house calibrations but without publishing the capabilities in their accreditation schedule,
- ✓ Calibration laboratories shall report their measurement of uncertainty on all calibration certificates as per ISO/IEC 17025. This requirement is applicable for testing/medical laboratories performing in-house calibrations;
- ✓ When using a standard test method there are three cases:
  - when using a standardized test method, which contains guidance to the uncertainty evaluation, testing laboratories are not expected to do more than to follow the uncertainty evaluation procedure as given in the standard;
  - if a standard gives a typical uncertainty of measurement for test results, laboratories are allowed to quote this figure if they can demonstrate full compliance with the test method;
  - if a standard implicitly includes the uncertainty of measurement in the test results there is no further action necessary.
- ✓ The required depth of the uncertainty estimations may be different in different technical fields. Factors to be taken into account include:
  - Common sense;
  - Influence of the uncertainty of measurement on the result;

- Appropriateness;
- Classification of the degree of rigor in the determination of uncertainty of measurement.

✓ In certain cases, it can be sufficient to report only the reproducibility;

✓ When information about estimation of the uncertainty of measurement is limited, any report of the uncertainty should make this clear.

The acceptable approaches for estimating measurement uncertainties for calibration and testing are detailed in the following paragraphs.

## 5. Calibration Laboratories:

### 5.1. GUM approach:

The basic concepts in uncertainty evaluation are:

- the knowledge about any quantity that influences the measurand is in principle incomplete and can be expressed by a probability density function (PDF) for the values attributable to the quantity based on that knowledge ,
- the expectation value of that PDF is taken as the best estimate of the value of the quantity,
- the standard deviation of that PDF is taken as the standard uncertainty associated with that estimate,
- the PDF is based on knowledge about a quantity that may be obtained from repeated measurements—Type A evaluation,
- Scientific judgement based on all the available information on the possible variability of the quantity—Type B evaluation.

Hereinafter, the typical steps for calculating the uncertainty of measurement based on GUM approach:

a. Express in mathematical terms the dependence of the measurand (output quantity) $Y$ on the input quantities $X_i$ according to equation $Y = f(X_1,..., X_N)$. In the case of a direct comparison of two standards the equation may be very simple, e.g. $Y = X_1+X_2$ ,
b. Identify and apply all significant corrections,
c. Enumerate all sources of uncertainty in the form of an uncertainty analysis,
d. Calculate the standard uncertainty for repeatedly measured quantities: Type-A evaluation,
e. For single values, e.g. resultant values of previous measurements, correction values or values from the literature, adopt the standard uncertainty where it is given or can be calculated according to paragraph 4.3 of GUM [Ref 2]. If no data are available from which the standard uncertainty can be derived, state a value of $u(x_i)$ on the basis of scientific experience: Type-B evaluation,
f. Calculate the combined uncertainty $u_c(y)$ according to the following equation:

$$u_C^2(y) = \sum_{i=1}^{n}\left[\frac{\partial f}{\partial x_i}\right]^2 .u^2(x_i) + 2.\sum_{i=1}^{n-1}\sum_{j=i+1}^{n}\frac{\partial f}{\partial x_i}.\frac{\partial f}{\partial x_j}.u(x_i, x_j)$$

If input quantities are known to be non-correlated, apply the following simple form:

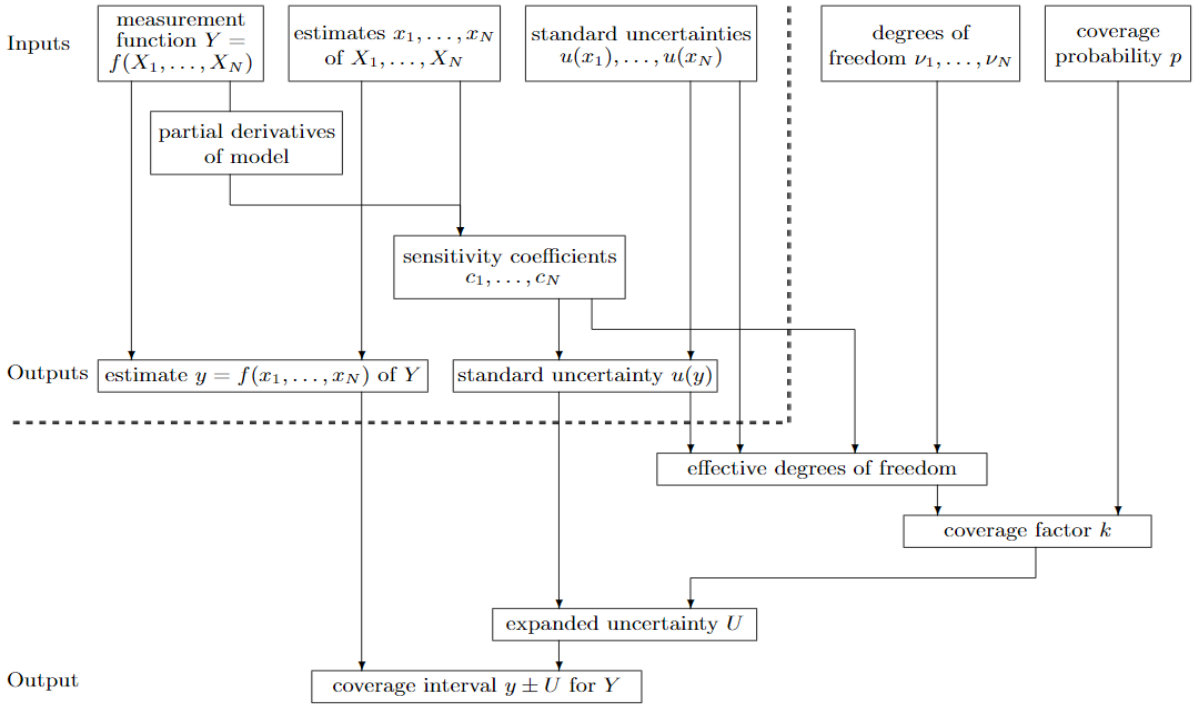
$$u_C^2(y) = \sum_{i=1}^{n} \left[ \frac{\partial f}{\partial x_i} \right]^2 .u^2(x_i)$$

g. Calculate the expanded uncertainty $U$ by multiplying the standard uncertainty $u_c(y)$ associated with the output estimate by a coverage factor $k$ chosen in accordance with paragraph 6 of GUM **[Ref 2]**

$$y - U \leq Y \leq y + U \quad or \quad Y = y \pm U$$

h. Report the result of the measurement comprising the estimate $y$ of the measurand, the associated expanded uncertainty $U$ and the coverage factor $k$ in the calibration certificate in accordance with Section 6 of ILAC P14 **[Ref 6]** and of ILAC P15 **[Ref 7]**.

i. Determine compliance with a specification: decision on when and how to report compliance or non-compliance with a specification vary according to the requirements of the client and other interested parties. However, the laboratory should consider measurement uncertainty appropriately, when making compliance decisions, and clients should not be misled in relation to the reliability of such decisions.




— **Measurement uncertainty evaluation using the GUM uncertainty framework, where the top-left part of the figure (bounded by broken lines) relates to obtaining an estimate $y$ of the output quantity $Y$ and the associated standard uncertainty $u(y)$, and the remainder relates to the determination of a coverage interval for $Y$**

## 5.2. Applicable requirements of ILAC P14:

- 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.

- 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.

- 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.
- An accredited laboratory is not permitted to report an uncertainty smaller than its accredited CMC. The magnitude of the uncertainty reported on a certificate of calibration depends on properties of the device being calibrated.
  No device is perfect and so the concept of a “best existing device” is used in association with the evaluation of a CMC. CMC uncertainty statements therefore incorporate agreed values for the best existing devices. Where necessary, the laboratory's schedule of accreditation includes remarks that describe the conditions under which the CMC can be achieved.

### 5.3. Other information:

The BIPM JCGM (Joint Committee for Guides in Metrology) is publishing a series of documents to accompany the GUM, such as:

- JCGM 101:2008: Evaluation of measurement data – Supplement 1 to the "Guide to the expression of uncertainty in measurement" – Propagation of distributions using a Monte Carlo method,
- JCGM 102:2011: Evaluation of measurement data – Supplement 2 to the "Guide to the expression of uncertainty in measurement" – Extension to any number of output quantities,
- JCGM 106:2012: Evaluation of measurement data – The role of measurement uncertainty in conformity assessment.

## 6. Testing Laboratories *[Ref 4]*:

A quantitative test result is considered to be a measurement result in the sense used in the GUM. The important distinction is that a comprehensive mathematical model, which describes all the effects on the measurand, is less likely to be available in testing. The evaluation of uncertainty in testing may therefore require the use of validation and method performance studies as described hereinafter.

The observed performance characteristics of test methods are often essential in evaluating the uncertainty associated with the results. This is particularly true where the results are subject to important and unpredictable effects, which can best be considered as random effects, or where the development of a comprehensive mathematical model is impractical. Method performance data also includes the effect of several sources of uncertainty simultaneously and its use may accordingly simplify considerably the process of uncertainty evaluation. Information on test method performance is typically obtained from:

- Data accumulated during validation and verification of a test method prior to its application in the testing environment;
- Interlaboratory studies according to ISO 5725;
- Accumulated quality control data
- Proficiency testing schemes.

This section provides general guidance on the application of data from each of these sources.

## 6.1. Data accumulated during validation and verification of a test method prior to application in the testing environment:

In practice, the fitness for purpose of test methods applied for routine testing is frequently checked through method validation and verification studies. The data so accumulated can inform the evaluation of uncertainty for test methods. Validation studies for quantitative test methods typically determine some or all of the following parameters:

- Precision,
- Bias,
- Linearity,
- Capability of detection,
- Selectivity and specificity,
- Robustness or ruggedness.

## 6.2. Interlaboratory study of test methods performance according to ISO 5725:

Interlaboratory studies according to ISO 5725 typically provide the repeatability standard deviation $s_r$ and reproducibility standard deviation $s_R$ (both as defined in ISO 3534-1) and may provide an estimate of trueness (measured as bias with respect to a known reference value). The general principles are:

a. Establishing the relevance of method performance data to measurement results from a particular measurement process;
b. Establishing the relevance of method performance data to the test item by identifying differences in sample treatment, sampling, or expected level of response between the laboratory's test item and those test items examined in a collaborative study;
c. Identifying and evaluating the additional uncertainties associated with factors not adequately covered by the interlaboratory study;
d. Using the principles of the GUM to combine all the significant contributions to uncertainty, including the reproducibility standard deviation, any uncertainty associated with the laboratory component of bias for the test method, and uncertainties arising from additional effects identified in c).

These principles are applicable to test methods that have been subjected to interlaboratory study. For these cases, reference to ISO TS 21748 is recommended for details of the relevant procedure.

The additional sources (mentioned in c)) that may need particular consideration are:

- Sampling: Collaborative studies rarely include a sampling step. If the method used in-house involves sub-sampling, or the measurand is a bulk property of a small sample, the effects of sampling should be investigated and their effects included,
- Pre-treatment: In most studies, samples are homogenized, and may additionally be stabilized, before distribution. It may be necessary to investigate and add the effects of the particular pre-treatment procedures applied in-house,
- Method bias: Method bias is often examined prior to or during interlaboratory study, where possible by comparison with reference methods or materials. Where the bias itself, the standard uncertainties associated with the reference values used, and the standard uncertainty associated with the estimated bias are all small compared with the reproducibility standard deviation, no additional allowance need be made for the uncertainty associated with method bias. Otherwise, it will be necessary to make such allowance.
- Variation in conditions: Laboratories participating in a study may tend to steer their results towards the means of the ranges of the experimental conditions, resulting in underestimates of the ranges of results possible within the method definition. Where such effects have been investigated and shown to be insignificant across their full permitted range, however, no further allowance is required;
- Changes in sample type: The uncertainty arising from samples with properties outside the range covered by the study will need to be considered.

### 6.3. Test or measurement process quality control data:

Many test or measurement processes are subject to control checks based on periodic measurement of a stable, but otherwise typical, test item to identify significant deviations from normal operation. Data obtained in this way over a long period provide a valuable source of data for uncertainty evaluation. The standard deviation of such a data set provides a combined estimate of variability arising from many potential sources of variation. It follows that if applied in the same way as method performance data (above), the standard deviation provides the basis for an uncertainty evaluation that immediately accounts for the majority of the variability that would otherwise require evaluation from separate effects.

Quality control (QC) data of this kind will not generally include sub-sampling, the effect of differences between test items, the effects of changes in the level of response, or inhomogeneity in test items. QC data should accordingly be applied with caution to similar materials, and with due allowance for additional effects that may reasonably apply.

### 6.4. Proficiency testing data:

Proficiency tests are intended to check periodically the overall performance of a laboratory. A laboratory's results from its participation in proficiency tests can accordingly be used to check the evaluated uncertainty, since that uncertainty should be compatible with the spread of results obtained by that laboratory over a number of proficiency test rounds.

In general, proficiency tests are not carried out sufficiently frequently to provide good estimates of the performance of an individual laboratory's implementation of a test method. Additionally, the nature of the test items circulated will typically vary, as will the expected result. It is thus difficult to accumulate representative data for well-characterized test items. Furthermore, many schemes use consensus values to assess laboratory performance, which occasionally lead to apparently anomalous results for individual laboratories. Their use for the evaluation of uncertainty is accordingly limited. However, in the special case where:

- the types of test items used in the scheme are appropriate to the types tested routinely
- the assigned values in each round are traceable to appropriate reference values, and
- the uncertainty associated with the assigned value is small compared with the observed spread of results,

The dispersion of the differences between the reported values and the assigned values obtained in repeated rounds provides a basis for an evaluation of the uncertainty arising from those parts of the measurement procedure within the scope of the scheme.
Systematic deviation from traceable assigned values and any other sources of uncertainty must also be taken into account.

### 6.5. Microbiological analysis:

GUM approach does not apply satisfactorily in the case of the microbiological analysis of food, where it is difficult to build a really comprehensive model of the measurement process. Because of the possibility of overlooking a significant source of uncertainty, there is a high risk of underestimating the true measurement uncertainty value. Furthermore, it appears difficult to quantify accurately the contribution of each individual step of the analytical process in food microbiology, where:

- The analyte is a living organism, whose physiological state can be largely variable, and
- The analytical target includes different strains, different species or different genera.

In other words, the microbiological analyses do not enable a metrologically rigorous and statistically valid estimation of MU.
Therefore a "top-down" or "global" approach to MU, which is based on a standard deviation of reproducibility of the final result of the measurement process, is judged more suited. This is an approach based on experimental results (with replication of the same analysis) which, in the case of microbiology, seems more meaningful than the step-by-step approach.
ISO/TS 19036 gives guidance for the estimation and expression of measurement uncertainty associated with quantitative results in food microbiology.
It is applicable to the quantitative analysis of products intended for human consumption and the feeding of animals, and of environmental samples in the area of food production and food handling, typically carried out by enumeration of microorganisms using a colony-count technique, but applicable also to quantitative analysis by alternative instrumental methods.