



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Guidelines for Estimation and Expression of Uncertainty in Measurement

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1. DEFINITIONS OF RELATED TERMS AND PHRASES

The guide explains explicitly a large number of metrological terms which are used in practice. A few terms of general interest have been taken from the “International Vocabulary of Basic and General terms in Metrology”

- 1.1. **Accepted Reference Value** - A value that serves as an agreed upon reference for comparison
- 1.2. **Arithmetic Mean** - The sum of values divided by the number of values
- 1.3. **Combined Standard Measurement Uncertainty / Combined Standard Uncertainty** - Standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model
- 1.4. **Conventional quantity value / Conventional value of a quantity / Conventional value** -Quantity value attributed by agreement to a quantity for a given purpose
- 1.5. **Correction** - Compensation for an estimated systematic effect
- 1.6. **Coverage Factor** - Number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty
- 1.7. **Coverage probability or confidence level** -The value of the probability associated with a confidence interval or a statistical coverage interval
- 1.8. **Coverage Probability / Confidence Level** - Probability that the set of true quantity values of a measurand is contained within a specified coverage interval
- 1.9. **Degree of freedom** - The number of terms in a sum minus the number of constraints on the terms of the sum
- 1.10. **Estimates** - The value of a statistic used to estimate a population parameter
- 1.11. **Estimation** - The operation of assigning, from the observations in a sample, numerical values to the parameters of a distribution chosen as the statistical model of the population from which this sample is taken
- 1.12. **Expanded measurement uncertainty / Expanded uncertainty** - Product of a combined standard measurement uncertainty and a factor larger than the number one
- 1.13. **Expectation** - The expectation of a function $g(z)$ over a probability density function $p(z)$ of the random variables z is defined by

$$E[g(z)] = \int g(z)p(z)dz$$

The expectation of the random variable z , denoted by μ_z and which is also termed as the expected value or the mean of z . It is estimated statistically by $\bar{z}$, the arithmetic mean or average of n independent observations z_i of the random variable z , the probability density function of which is $p(z)$

$$\bar{z} = \frac{1}{n} \sum_{i=1}^n z_i$$

- 1.14. Experimental standard deviation** - For a series of n measurements of the same measurand, the quantity $s(q_j)$ characterizing the dispersion of the results and given by the formula :

$$s(q_j) = \sqrt{\frac{\sum_{j=1}^n (q_j - \bar{q})^2}{n-1}}$$

q_j being the result of the j^{th} measurement and $\bar{q}$ being the arithmetic mean of the n results considered

- 1.15. Measurand** - Quantity intended to be measured
- 1.16. Measurement Accuracy / Accuracy of Measurement / Accuracy** - Closeness of agreement between a measured quantity value and a true quantity value of a measurand
- 1.17. Measurement Error / Error of Measurement / Error** - Measured quantity value minus a reference quantity value
- 1.18. Measurement Repeatability / Repeatability** - Measurement Precision under a set of Repeatability Conditions of Measurement
- 1.19. Measurement Reproducibility / Reproducibility** - Measurement Precision under reproducibility conditions of measurement
- 1.20. Measurement Result / Result of Measurement** - Set of quantity values being attributed to a measurand together with any other available relevant information
- 1.21. Measurement Uncertainty / Uncertainty of Measurement / Uncertainty** - Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used
- 1.22. Probability density function** - The derivative (when it exists) of the distribution function

$$f(x) = dF(x) / dx$$

$f(x)dx$ is the probability element

$$f(x) dx = \Pr(x < X < x + dx)$$

- 1.23. Probability distribution** - A function giving the probability that a random variable takes any given value or belongs to a given set of values
- 1.24. Probability function** - A function giving for every value x , the probability that the random variable X takes value x :
- $$p(x) = \Pr(X = x)$$
- 1.25. Random Measurement Error / Random Error of Measurement / Random Error** - Component of measurement error that in replicate measurements varies in an unpredictable manner
- 1.26. Random Variable** - A variable that may take any of the values of a specified set of values and with which is associated a probability distribution
- 1.27. Reference quantity value / Reference value** - Quantity value used as a basis for comparison with values of quantities of the same kind
- 1.28. Repeatability Condition of Measurement / Repeatability Condition** - Condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time
- 1.29. Reproducibility Condition of Measurement / Reproducibility Condition** - Condition of Measurement, out of a set of conditions that includes different locations, operators, measuring systems, and replicate measurements on the same or similar objects
- 1.30. Result of measurement** - Value attributed to a measurand, obtained by measurement
- Note: Complete statement of the result of a measurement includes information about uncertainty in measurement
- 1.31. Standard Deviation** - The positive square root of the variance
- 1.32. Standard Measurement Uncertainty / Standard Uncertainty of Measurement/ Standard uncertainty** - Measurement Uncertainty expressed as a standard deviation
- 1.33. Sensitivity coefficient associated with an input estimate** - The differential change in the output estimate generated by the differential change in that input estimate
- 1.34. Sensitivity of a Measuring System / Sensitivity** - Quotient of the change in an indication of a measuring system and the corresponding change in a value of a quantity being measured

- 1.35. Systematic Measurement Error / Systematic Error of Measurement / Systematic Error** - Component of measurement error that in replicate measurements remains constant or varies in a predictable manner
- 1.36. True Quantity Value / True Value of a Quantity / True Value** - Quantity Value consistent with the definition of a Quantity
- 1.37. Type A Evaluation of Measurement / Uncertainty Type A Evaluation** - Evaluation of a component of measurement uncertainty by a statistical analysis of measured quantity values obtained under defined measurement conditions
- 1.38. Type B evaluation of measurement / Uncertainty Type B evaluation** - Evaluation of a component of measurement uncertainty determined by means other than a Type A evaluation of measurement uncertainty
- 1.39. Variance** - A measure of dispersion, which is the sum of the squared deviations of observations from their average divided by one less than the number of observations

2. INTRODUCTION

2.1. Purpose

The international standard ISO / IEC 17025 for testing and calibration laboratories as well as ISO 15189 for medical laboratories requires the laboratories to estimate the uncertainties of measurement results. The laboratory's customers use the results for taking important business decisions. Laboratories therefore select and control the measurement methods to ensure that the overall variability, an indication of uncertainty is small enough for the end result to be appropriate for customer's requirement. Too large an uncertainty may affect the reliability of the decision and too small uncertainty may make the situation complex and costly. So, an appropriable estimate of measurement uncertainty is an important task performed by laboratories.

Calibration laboratories estimate and report the uncertainties in the calibration certificates. Regarding testing laboratories APLAC TC 010 states that most laboratories have until now chosen not to state measurement uncertainty in their test reports, instead such information has been given only when the customer has asked for it. In future information about the measurement uncertainty may appear more frequently in test reports endorsed with accreditation symbol.

The bible on measurement uncertainty “Evaluation of Measurement data — Guide to the Expression of Uncertainty in Measurement” is usually referred as GUM. The GUM approach usually emphasizes on identifying the many factors that have a functional relationship with the measurand and contribute to the variation of measurement results. The variances of each of these factors are characterized and combined to describe the uncertainty of final measurement results. The GUM approach is also described as the “bottom up” approach. To estimate uncertainty using this approach one needs a reasonable understanding of statistics. Many laboratory professionals do not feel comfortable with GUM approach as it requires a mathematical model and associated statistics, for them the application of “top-down” approach is more appropriate. In this approach, the uncertainty of measurement is derived from the estimates of the variations which come directly from the experimental data such as method validation experiments or routine quality control data. Both approaches are scientifically valid and give reasonable estimates of measurement uncertainty.

2.2. Scope

- 2.2.1. The document may be used by laboratories as a guidance document while estimating measurement uncertainty in varieties of laboratories such as calibration, testing and medical laboratories. Measurements which can be treated as outputs of several correlated inputs have been excluded from scope of this document. The document covers the following topics
- 2.2.1.1. Uncertainty – basic concepts and probability distributions
 - 2.2.1.2. Definition of related terms;
 - 2.2.1.3. Uncertainty estimation using GUM approaches
 - 2.2.1.4. Degree of freedom;
 - 2.2.1.5. Uncertainty estimation using approaches other than GUM
 - 2.2.1.5.1. Use of repeatability, reproducibility and bias estimates
 - 2.2.1.5.2. Use of control charts
 - 2.2.1.5.3. Test for which measurement uncertainties do not apply
 - 2.2.1.5.4. Measurement uncertainty estimation in medical laboratories

3. ESTIMATION OF UNCERTAINTY USING GUM APPROACH

3.1. Concept

Conformity assessment is the process of assessing whether a product complies with the requirement of a technical regulation or its specification. Measurement results are used for taking compliance decision on products. The objective of measurement is to determine the value of measurand. The measurement uncertainty is the quality attribute of a measurement results. It is therefore essential that the uncertainty value is such that the measurement result is fit for the intended purpose. This will ensure that risks associated with compliance decision are within acceptable limits. Therefore, correct estimation of measurement result and its associated uncertainty is essential

Quality of measurements has assumed great significance in view of the fact that measurement results provide the very basis of all control actions.

3.2. Sources

3.2.1. The objective of measurement is to find the value of measurand (traditionally also referred to as true value and defined as value consistent with definition of a given particular quantity). The measurement result having corrected for systematic effect, can at the best be called the best estimation of the value of measurand. Since measurement results are always indeterminate there is always an uncertainty associated with it. The uncertainty of result of measurement reflects the inexact knowledge of the value of measurand. The word measurement should be understood to mean both a process and the output of that process.

3.2.2. In general, a measurement has imperfections that give rise to error in the measurement result. Traditionally an error is viewed as having two components, namely a random component and a systematic component.

3.2.3. Random errors arise from unpredictable and spatial variation of influence quantities, which affect the outcome of a measurement process. These may include:

3.2.3.1. The way measurement method is employed,

3.2.3.2. The variation in environment conditions in the laboratory,

3.2.3.3. Inherent instability of measuring equipment,

3.2.3.4. Personal judgment of test engineer / analyst

- 3.2.4. An influence quantity has been defined as quantity that is not itself the measurand but one that affect the result of measurement. Few examples may be as follow
- 3.2.4.1. Temperature of a micrometer used to measure length,
 - 3.2.4.2. Frequency in the measurement of the amplitude of an alternating electric potential difference
 - 3.2.4.3. Bilirubin concentration in the measurement of haemoglobin concentration in a sample of human blood plasma
- 3.2.5. The effects of such variations give rise to variation in repeat observations of the measurand. Although it is not possible to compensate for the random errors of a measurement result, it can usually be reduced by increasing the number of observations. The influence of random effect can also be reduced by exercising appropriate control on the measurement process.
- 3.2.6. Systematic error, like random error, cannot be eliminated but it can often be reduced. These errors may include:
- 3.2.6.1. Errors reported in the calibration certificate of a measuring equipment / measurement standard.
 - 3.2.6.2. Errors due to different influence conditions at the time measurements that are being carried out compared to those errors when equipment was calibrated.
- 3.2.7. If a systematic error of a measurement result can be quantified e.g. from a calibration certificate and it is significant in size relative to required accuracy of measurement, a correction can be applied to compensate for the systematic effect. It is assumed that after correction, the expected value of error arising from systematic effect will be zero. The known systematic error is also called bias.

However, applying correction to a measurement result to compensate for systematic effect does not make the result totally error free. Instead, there is a measure of uncertainty of the result due to incomplete knowledge of required value of correction. The error arising from imperfect compensation of a systematic effect cannot be exactly known.

It should be pointed out that errors, which can be recognized as systematic and can be isolated in one case, may simply pass of as random in another case.

3.2.8. Hence, it is necessary that the result of measurement should be corrected for all recognized significant effects and that every effort has been made to identify such effects. The measuring equipment and measurement systems are calibrated using measurement standards and reference materials to eliminate systematic effects, nonetheless the uncertainties associated with these standards and reference materials should always be taken into account.

Hence, the result of measurement after correction for recognized systematic effects is still only an estimate of the value of measurement because of the uncertainty arising from random effects and from imperfect correction of the result for the systematic effects. Whereas, the exact values of contributions to the error of a result of measurement are unknown and unknowable, the uncertainties associated with random and systematic effects that give rise to error can be evaluated. If the correction due to systematic effect is overlooked and even if the evaluated uncertainties are small, there is still no guarantee that the error in measurement result is small. So, applying correction for systematic effect is very important.

3.2.9. Uncertainty of measurement is thus an expression of the fact that, for a given measurand and a given result of measurement of it, there is not one value but an infinite number of values dispersed about the result that are consistent with all the observations and data and one's knowledge of the physical world and that with varying degrees of creditability can be attributed to the measurand. The International Standard ISO / IEC Guide 99-12: 2007, International Vocabulary of Metrology-Basic and General Concepts and Associated Terms VIM has defined measurement uncertainty as "non negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used."

The definition is supplemented with four notes

Note 1: Measurement Uncertainty includes components arising from systematic effects, such as components associated with corrections and assigned quantity value of measurand standard as well as definitional uncertainty. Some times estimated systematic effects are not corrected for but, instead associated measurement uncertainly components are incorporated.

Note 2: The parameter may be for example, a standard deviation called standard measurement uncertainty or a specified multiple of it or the half width of an interval having a stated coverage probability.

Note 3: Measurement uncertainty comprises in general many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components which may be evaluated by Type B evaluation of measurement uncertainty can also be characterized by standard deviations, evaluated from probability density functions based on experience or further information.

Note 4: In general, for a given set of information, it is understood that measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in modification of the associated uncertainty.

A measurement results is therefore expressed as a single measured quantity value and a measurement uncertainty with its units.

3.3. Evaluation of Standard Uncertainty

The standard uncertainty of the measurand depends upon the standard uncertainties of the input quantities and also upon their correlation (if any). The standard uncertainty of input quantities is evaluated by Type A evaluation or type B evaluation or a combination of both.

The Type A evaluation of standard uncertainty is the method of evaluating the uncertainty by the statistical analysis of a series of observations. In this case the standard uncertainty is the experimental standard deviation of the mean of the repeat measurements.

The Type B evaluation of standard uncertainty is the method of evaluating the uncertainty by means other than the statistical analysis of the repeat measurements. In this case the standard uncertainty is evaluated by scientific

judgment based on all available information on possible variability of the input quantities.

3.3.1 Modeling the Measurement

3.3.1.1 In most cases, a measurand Y is not measured directly, but is determined from N other quantities $X_1, X_2, \dots, X_N$ through a functional relationship f :

$$y = f(X_1, X_2, \dots, X_N) \quad (1)$$

3.3.1.2 The input quantities $X_1, X_2, \dots, X_N$ upon which the output quantity Y depends may themselves be viewed as measurands and may themselves depend on other quantities, including corrections and correction factors for systematic effects.

3.3.1.3 The set of input quantities $X_1, X_2, \dots, X_N$ may be categorized as:

3.3.1.3.1 quantities whose values *and uncertainties* are directly determined in the current measurement. These values and uncertainties may be obtained from, for example, a single observation, repeated observations or judgement based on experience, and may involve the determination of corrections to instrument readings and corrections for influence quantities, such as ambient temperature, barometric pressure, and humidity;

3.3.1.3.2 quantities whose values *and uncertainties* are brought into the measurement from external sources, such as quantities associated with calibrated measurement standards, certified reference materials, and reference data obtained from handbooks.

3.3.1.4 An estimate of the measurand Y , denoted by y , is obtained from Equation (1) using input estimates $x_1, x_2, \dots, x_N$ for the values of the N quantities $X_1, X_2, \dots, X_N$. Thus, the output estimate y , which is the result of the measurement, is given by

$$y = f(x_1, x_2, \dots, x_N) \quad (2)$$

Note:

In some cases, the estimate y may be obtained from

$$y = \bar{Y} = \frac{1}{n} \sum_{k=1}^n Y_k = \frac{1}{n} \sum_{k=1}^n f(X_{1,k}, X_{2,k}, \dots, X_{N,k})$$

That is, y is taken as the arithmetic mean or average of n independent determinations Y_k of Y , each determination having the same uncertainty and each being based on a complete set of observed values of the N input quantities

X_i obtained at the same time. This way of averaging, rather than $y = f(\bar{X}_1, \bar{X}_2, \dots, \bar{X}_N)$, where

$$\bar{X}_i = \frac{1}{n} \sum_{k=1}^n X_{i,k}$$

is the arithmetic mean of the individual observations $X_{i,k}$, may be preferable when f is a nonlinear function of the input quantities $X_1, X_2, \dots, X_N$ but the two approaches are identical if f is a linear function of the X_i .

3.3.1.5 The estimated standard deviation associated with the output estimate or measurement result y , termed combined standard uncertainty and denoted by $u(y)$, is determined from the estimated standard deviation associated with each input estimate x_i , termed standard uncertainty and denoted by $u(x_i)$.

3.3.1.6 Each input estimate x_i and its associated standard uncertainty $u(x_i)$ are obtained from a distribution of possible values of the input quantity X_i . This probability distribution may be frequency based, that is, based on a series of observations $X_{i,k}$ of X_i , or it may be an *a priori* distribution. Type A evaluations of standard uncertainty components are founded on frequency distributions while Type B evaluations are founded on *a priori* distributions. It must be recognized that in both cases the distributions are models that are used to represent the state of our knowledge.

3.3.2 Type A evaluation of standard uncertainty

Type A evaluation of standard uncertainty applies to situation when several independent observations have been made for any of the input quantities under the same conditions of measurement. If there is sufficient resolution in the measurement process, there will be an observable scatter or spread in the values obtained.

3.3.2.1 In most cases, the best available estimate of the expectation or expected value μ_q of a quantity q that varies randomly, and for which n independent observations q_k have been obtained under the same conditions of measurement, is the arithmetic mean or average $\bar{q}$ of the n observations:

$$\bar{q} = \frac{1}{n} \sum_{k=1}^n q_k \quad (3)$$