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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(qj) characterizing the dispersion of the results and given by the formula :

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

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 exits) 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, repeatability 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 result~~s~~. 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 ...., X_N through a functional relationship *f* :

$$y = f\,(X_1, X_2 \ldots\ldots\ldots, X_N) \qquad (1)$$

3.3.1.2 The input quantities X1, X2 ...., XN 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 X1, X2 .... ,XN 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 x1, x2 .... xN for the values of the N quantities X1, X2 ...., XN. Thus, the output estimate y, which is the result of the measurement, is given by

$$y = f\,(x_1, x_2, \ldots\ldots x_n) \qquad (2)$$

Note:

In some cases, the estimate *y* may be obtained from

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

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

Xi obtained at the same time. This way of averaging, rather than $y = f(\bar{X}_1, \bar{X}_2, \ldots.., \bar{X}_N)$, 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 ...., 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 uc(y), is determined from the estimated standard deviation associated with each input estimate xi, termed standard uncertainty and denoted by u(xi).

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:

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

Thus, for an input quantity X_i estimated from n independent repeated observations $X_{i,k}$, the arithmetic mean X_i obtained from Equation (3) is used as the input estimate x_i in Equation (2) to determine the measurement result y; that is, $x_i = \overline{X_i}$. Those input estimates not evaluated from repeated observations must be obtained by other methods, such as those indicated in the second category of 3.3.1c.

3.3.2.2 The individual observations qk differ in value because of random variations in the influence quantities, or random effects. The experimental variance of the observations, which estimates the variance σ^2 of the probability distribution of q, is given by

$$s^2(q_k) = \frac{1}{n-1}\sum_{j=1}^{n}(q_j - \bar{q})^2 \qquad (4)$$

This estimate of variance and its positive square root $s(q_k)$, termed the experimental standard deviation characterize the variability of the observed values q_k , or more specifically, their dispersion about their mean $\bar{q}$.

3.3.2.3 The best estimate of $\sigma2(\bar{q})=\sigma2 / n$, the variance of the mean, is given by

$$s^2(\bar{q}) = \frac{s^2(qk)}{n} \qquad (5)$$

The experimental variance of the mean $s^2(\bar{q})$ and the experimental standard deviation of the mean $s(\bar{q})$, equal to the positive square root of $s^2(\bar{q})$, quantify how well $\bar{q}$ estimates the expectation μ_q of q, and either may be used as a measure of the uncertainty of $\bar{q}$.

Thus, for an input quantity X_i determined from n independent repeated observations $X_{i,k}$, the standard uncertainty $u(x_i)$ of its estimate $x_i = \bar{X}_i$ is $u(x_i) = s(\bar{X}_i)$, with $s^2(\bar{X}_i)$ calculated according to Equation (5). For convenience, $u^2(x_i) = s^2(\bar{X}_i)$ and $u(x_i) = s(\bar{X}_i)$ are sometimes called a *Type A variance* and a *Type A standard uncertainty*, respectively.

Note: 1

The number of observations n should be large enough to ensure that $\bar{q}$ provides a reliable estimate of the expectation μ_q of the random variable q and that $s^2(\bar{q})$ provides a reliable estimate of the variance

$\sigma^2(\bar{q}) = \sigma^2/n$

Note: 2

Although the variance $s^2(\bar{q})$ is the more fundamental quantity, the standard deviation $s(\bar{q})$ is more convenient in practice because it has the same dimension as *q* and a more easily comprehended value than that of the variance.

3.3.2.4 The degrees of freedom v_i of $u(x_i)$, equal to *n-1* in the simple case where $x_i = \bar{X_i}$ and $u(x_i) = S(\bar{X}_i)$ are calculated from *n* independent observations as in 3.3.2.1 and 3.3.2.2, should always be given when Type A evaluations of uncertainty components are documented.

3.3.2.5 If the random variations in the observations of an input quantity are correlated, for example, in time, the mean and experimental standard deviation of the mean as given in 3.3.2.1 and 3.3.2.2 may be inappropriate estimators of the desired statistics. In such cases, the observations should be analyzed by statistical methods specially designed to treat a series of correlated, randomly-varying measurements.

3.3.3 Type B evaluation of standard uncertainty

3.3.3.1 For an estimate x_i of an input quantity X_i that has not been obtained from repeated observations, the associated estimated variance $u^2(x_i)$ or the standard uncertainty $u(x_i)$ is evaluated by scientific judgment based on all of the available information on the possible variability of X_i . The pool of information may include

3.3.3.1.1 previous measurement data;

3.3.3.1.2 experience with or from general knowledge of the behavior and properties of relevant materials and instruments;

3.3.3.1.3 manufacturer's specifications;

3.3.3.1.4 data provided in calibration and other certificates;

3.3.3.1.5 uncertainties assigned to reference data taken from handbooks

For convenience, $u^2(x_i)$ and $u(x_i)$ evaluated in this way are sometimes called a *Type B variance* and a *Type B standard uncertainty*, respectively.

3.3.3.2 The proper use of the pool of available information for a Type B evaluation of standard uncertainty calls for insight based on experience and general knowledge, and is a skill that can be learned with practice. It should be recognized that a Type B evaluation of standard uncertainty can be as reliable as a Type A evaluation, especially in a measurement situation where a Type A evaluation is based on a comparatively small number of statistically independent observations.

3.3.3.3 If the estimate x_i is taken from a manufacturer's specification, calibration certificate, handbook, or other source and its quoted uncertainty is stated to be a particular multiple of a standard deviation, the standard uncertainty $u(x_i)$ is simply the quoted value divided by the multiplier, and the estimated variance $u^2(x_i)$ is the square of that quotient.

3.3.3.4 Examples of Type B estimation of standard Uncertainty

3.3.3.4.1 From the calibration certificate:

A calibration certificate normally quotes an expanded uncertainty ‘U’ at a specified high level of confidence, A cover factor ‘k’ will be used to obtain this uncertainty from the combination of standard uncertainties. It is therefore necessary to divide the expanded uncertainty by the same coverage factor to obtain standard uncertainty

u(xi) = U / k

3.3.3.4.2 From manufacturer’s Specification:

Manufacturers specifications are generally quoted at a given confidence level e.g. 95% or 99%, In such cases, normal distribution can be assumed and the tolerance limit is divided by coverage factor ‘k’ for the stated confidence level.

For a confidence level of about 95%, the value of k is 2 and for a confidence level of 99%, the value of k is 2.58.

If a confidence level is not stated then a rectangular distribution shall be used.

3.3.3.5 The quoted uncertainty of xi is not necessarily given as a multiple of a standard deviation as in 3.3.3c. Instead, one may find it stated that the quoted uncertainty defines an interval having a 90, 95, or 99 percent level of confidence. Unless otherwise indicated, one may assume that a normal distribution was used to calculate the quoted uncertainty, and recover the standard uncertainty of xi by dividing the quoted uncertainty by the appropriate factor for the normal distribution. The factors corresponding to the above three levels of confidence are 1.64; 1.96; and 2.58.

3.3.3.6 In other cases, it may be possible to estimate only bounds (upper and lower limits) for X_i, in particular, to state that “the probability that the value of X_i lies within the interval a_- to a_+ for all practical purposes is equal to one and the probability that X_i lies outside this interval is essentially zero”. If there is *no* *specific knowledge* about the possible values of X_i within the interval, one can only assume that it is equally probable for X_i to lie anywhere within it (a uniform or rectangular distribution of possible values). Then $\bar{x}_i$, the expectation or expected value of X_i, is the midpoint of the interval,

$\bar{x}_i = (a_- + a_+) / 2$, with associated variance

$u^2 (\bar{x}_i) = (a_+ - a_-)^2 / 12$ (6)

If the difference between the bounds, $a_+ - a\_$ is denoted by 2*a*, then Equation (6) becomes

$u^2 (\bar{x}_i) = a^2 / 3$ (7)

Note:

When a component of uncertainty determined in this manner contributes significantly to the uncertainty of a measurement result, it is prudent to obtain additional data for its further evaluation.

3.3.3.7 Examples of Type B evaluation of standard uncertainty:

3.3.3.7.1 Standard uncertainty due to resolution of measuring equipment – A digital thermometer has a least significant digit of 0.1°C. The numeric rounding caused by finite resolution will have a semi range limit of 0.05°C. Thus, the corresponding uncertainty of + / - 0.05°C can be assumed to have rectangular or uniform distribution. Thus, the corresponding standard uncertainty will be

$u(xi) = a_i / \sqrt{3}$

$= 0.05 / 1.732$

$= 0.029$°C

3.3.3.7.2 Uncertainty of reference standard - Reference standards are used for calibrating measuring equipments in calibration laboratories. An uncertainty statement about the measured value of a reference standard is contained in the calibration certificate of the standard. Sometimes uncertainty statement is not qualified by a statement of confidence level, it can be assumed that the uncertainty is given as maximum bounds within which all values of reference standard are likely to lie with equal probability, rectangular or uniform distribution can be assumed, if ±U is the uncertainty of reference standard, the standard uncertainty $u(x_i)$ due to the above uncertainty is given by

$$u(x_i)= U/\sqrt{3}$$

3.3.3.8 In 3.3.3.6, because there was no specific knowledge about the possible values of Xi within its estimated bounds a− to a+, one could only assume that it was equally probable for Xi to take any value within those bounds, with zero probability of being outside them. Such step function discontinuities in a probability distribution are often unphysical. In many cases, it is more realistic to expect that values near the bounds are less likely than those near the midpoint. It is then reasonable to replace the symmetric rectangular distribution with a symmetric trapezoidal distribution having equal sloping sides (an isosceles trapezoid), a base of width a+ -a- = 2a, and a top of width 2aβ, where $0 \le \beta \le 1$. As $\beta \rightarrow 1$, this trapezoidal distribution approaches the rectangular distribution of 3.3.3.6, while for β.0, it is a triangular distribution. Assuming such a trapezoidal distribution for Xi, one finds that the expectation of Xi is xi = (a− + a+) / 2 and its associated variance is

$$u^2 (x_i) = a^2 (1+ \beta^2) / 6 \qquad (8)$$

Which becomes for the triangular distribution, β=0

$$u^2 (x_i) = a^2 / 6 \qquad (9)$$

3.3.3.9 Examples of Type B evaluation of standard uncertainty:

3.3.3.9.1 A tensile testing machine is used in a testing laboratory where the ambient temperature can vary randomly but does not depart from nominal value more than 3ºC. The machine has a large thermal mass and is therefore most likely to be at the mean air temperature with no probability of being outside the 3ºC limit. It is reasonable to assume a triangular distribution, therefore the standard uncertainty for its temperature is

$u(x_i)=a / \sqrt{6}$

$=3 / 2.449 = 1.2$ºC

3.3.3.9.2 The uncertainty of assigned volume of volumetric flask also follows triangular distribution. The manufacturer quotes a volume for the flask of 100ml ± 0.1ml. Here the standard uncertainty is calculated assuming triangular distribution

$u(x_i)=0.1 / \sqrt{6}$

$=0.1 / 2.449 = 0.04$ml

A triangular distribution is chosen because in an effective production process the nominal value is more likely than extremes. The resulting distribution is better represented by triangular distribution rather than rectangular distribution.

3.3.3.10 Another distribution used in specialized situation for type B evaluation is U-distribution. For example, a mismatch uncertainty associated with the calibration of RF power sensor has been evaluated as having semi range limits of 1.3%. Thus, the corresponding standard uncertainty will be

$u(x_i) = a / \sqrt{2}$

$= 1.3 / 1.414 = 0.92\%$

3.3.3.11 It is important not to “double-count” uncertainty components. If a component of uncertainty arising from a particular effect is obtained from a Type B evaluation, it should be included as an independent component of uncertainty in the calculation of the combined standard uncertainty of the measurement result only to the extent that the effect does not contribute to the observed variability of the observations. This is because the uncertainty due to that portion of the effect that contributes to the observed variability is already included in the component of uncertainty obtained from the statistical analysis of the observations.

3.3.3.12 The discussion of Type B evaluation of standard uncertainty in 3.3.3a to 3.3.3h is meant only to be Indicative. Further, evaluations of uncertainty should be based on quantitative data to the maximum extent possible.

3.4. Evaluation of combined standard uncertainty

3.4.1. Uncorrelated input quantities

3.4.1.1. The standard uncertainty of y, where y is the estimate of the measurand Y and thus the result of the measurement, is obtained by appropriately combining the standard uncertainties of the input estimates x_1, x_2, ..., x_N . This *combined standard uncertainty* of the estimate y is denoted by $u_c(y)$.

3.4.1.2. The quantities x_i that affects the measurand may not have a direct one to one relationship with it. Indeed, they may be entirely different unit altogether. For example, a dimensional laboratory may use Steel gauge block for calibrating measuring tools. A significant influence quantity is temperature. Because the gauge blocks have a significant coefficient of expansion, there is an uncertainty arises in their length due to uncertainty in temperature units. In order to translate the temperature uncertainty into uncertainty in length units, it is necessary to know how sensitive the length of the gauge blocks is to temperature. In other words, a sensitivity coefficient is required.

3.4.1.3. The combined standard uncertainty $u_c(y)$ is the positive square root of the combined variance

$u_c{}^2(y)$,which is given by

$$u_c^2(y)=\sum_{i=1}^{N}\left(\frac{\partial y}{\partial xi}\right)^2 u^2(x_i) \qquad (10)$$

Where *f* is the function given in Equation (1). Each $u(x_i)$ is a standard uncertainty evaluated as described in 3.3.2 (Type A evaluation) or as in 3.3.3 (Type B evaluation). The combined standard uncertainty $u_c(y)$ is an estimated standard deviation and characterizes the dispersion of the values that could reasonably be attributed to the measurand *Y*

Equation (10) is based on a first-order Taylor series approximation of $Y = f(X_1, X_2, ..., X_N)$, and is termed as the *law of propagation of uncertainty*.

3.4.1.4. The partial derivatives $\partial f / \partial x_i$ are equal to $\partial f / \partial X_i$ evaluated at $X_i = x_i$. These derivatives, often called sensitivity coefficients, describe how the output estimate *y* varies with changes in the values of the input estimates x_1, x_2, ..., x_N. In particular, the change in *y* produced by a small change Δxi in input estimate *xi* is given by $(\Delta y)_i = (\partial f/\partial x_i)(\Delta x_i)$. If this change is generated by the standard uncertainty of the estimate x_i, the corresponding variation in *y* is $(\partial f/\partial x_i)u(x_i)$. The combined variance $u_c^2(y)$ can therefore be viewed as a sum of terms, each of which represents the estimated variance associated with the output estimate *y* generated by the estimated variance associated with each input estimate x_i. This suggests writing Equation (10) as

$$u_c^2(y)=\sum_{i=1}^{N}[c_i u(x_i)]^2 \equiv \sum_{i=1}^{N} u_i^2(y) \qquad (11)$$

Where

$$c_i \equiv \frac{\partial f}{\partial x_i}, \; u_i(y) \equiv |c_i| \, u(x_i) \qquad (12)$$

3.4.1.5. The calculations required to obtain sensitivity coefficients by partial differentiation can be a lengthy process particularly when there are many input contributions and uncertainty estimates are needed for a range of values.

3.4.1.6. Instead of being calculated from the function *f*, sensitivity coefficients $\partial f / \partial x_i$ are sometimes determined experimentally: one measures the change in *Y* produced by a change in a particular X_i while holding the remaining input quantities constant. In this case, the knowledge of the function *f* (or a portion of it when only several sensitivity coefficients are so determined) is accordingly reduced to an empirical first-order Taylor series expansion based on the measured sensitivity coefficients.

3.5. Expanded uncertainty in measurement

3.5.1. **Introduction**

Although $u_c(y)$ can be universally used to express the uncertainty of a measurement result, in some commercial, industrial, and regulatory applications, and when health and safety are concerned, it is often necessary to give a measure of uncertainty that defines an interval about the measurement result that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.

3.5.2. **Expanded uncertainty**

3.5.2.1. The additional measure of uncertainty that meets the requirement of providing an interval of the kind indicated in 3.5.1 is termed *expanded uncertainty* and is denoted by *U*. The expanded uncertainty *U* is obtained by multiplying the combined standard uncertainty $u_c(y)$ by a *coverage factor k*:

$$U=ku_c(y) \tag{13}$$

The result of a measurement is then conveniently expressed as $Y=y\pm U$, which is interpreted to mean that the best estimate of the value attributable to the measurand *Y* is *y*, and that $y-U$ to $y+U$ is an interval that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to *Y*. Such an interval is also expressed as $y-U \le Y \le y+U$.

3.5.2.2. The GUM recognizes the need for providing high level of confidence associated with an uncertainty and uses the term expanded uncertainty. Specifically, U is interpreted as defining an interval about the measurement result that encompasses a large fraction p of the probability distribution characterized by that result and its combined standard uncertainty, and p is the coverage probability or level of confidence of the interval.

3.5.3. **Choosing a coverage factor**

3.5.3.1. The value of the coverage factor *k* is chosen on the basis of the level of confidence required of the interval $y-U$ to $y+U$. In general, *k* will be in the range 2 to 3. However, for special applications *k* may be outside this range. Extensive experience with and full knowledge of the uses to which a measurement result will be put can facilitate the selection of a proper value of *k.*

3.5.3.2. Ideally, one would like to be able to choose a specific value of the coverage factor *k* that would provide an interval $Y=y+U = y \pm ku_c(y)$ corresponding to a particular level of confidence *p*, such as 95 or 99 percent; equivalently, for a given value of *k*, one would like to be able to state unequivocally the level of confidence associated with that interval.

It is often adequate in measurement situations where the probability distribution characterized by *y* and $u_c(y)$ is approximately normal and the effective degree of freedom of u_c(y) is of significant size. When this is the case, which frequently occurs in practice, one can assume that taking *k=2* produce an interval having a level of confidence of approximately 95 percent.

3.6. Statement of uncertainty in measurement

3.6.1. In calibration certificates the complete result of the measurement consisting of the estimate y of the measurand and the associated expanded uncertainty U shall be given in the form (y ±U). To this an explanatory note must be added which in the general case should have the following content: The reported expanded uncertainty in measurement is stated as the combined standard uncertainty in measurement multiplied by the coverage factor k = 2, which for a normal distribution corresponds to a coverage probability of approximately 95 %. In test reports where measurement uncertainty is reported, the uncertainty estimates should also be reported as above.

3.6.2. However, in cases where the procedure of Appendix B has been followed, the additional note should read as follows: The reported expanded uncertainty in measurement is stated as the combined standard uncertainty in measurement multiplied by the coverage factor k which for a t-distribution with ν_{eff} effective degrees of freedom corresponds to a coverage probability of approximately 95 %.

3.6.3. The numerical value of the uncertainty in measurement should be given to at most two significant figures. The numerical value of the measurement result should in the final statement normally be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result. For the process of rounding, the usual rules for rounding of numbers have to be used. However, if the rounding brings the numerical value of the uncertainty in measurement down by more than 5 %, the rounded-up value should be used.

3.7. Apportionment of standard uncertainty

3.7.1. The uncertainty analysis for a measurement-sometimes called the Uncertainty Budget of the measurement-should include a list of all sources of uncertainty together with the associated standard uncertainties of measurement and the methods of evaluating them. For repeated measurements the number n of observations also has to be stated. For the sake of clarity, it is recommended to present the data relevant to this analysis in the form of a table. In this table all quantities should be referenced by a physical symbol X_i, or a short identifier. For each of them at least the estimate x_i, the associated standard uncertainty in measurement u (x_i), the sensitivity coefficient c_i and the different uncertainty contributions $u_i(y)$ should be specified. The degrees of freedom have to be mentioned. The dimension of each of the quantities should also be stated with the numerical values in the table.

Table 3.7.1: Schematic view of an Uncertainty Budget

Source of Uncertainty X_i	**Estimates x_i**	**Limits $\pm \Delta x_i$**	**Probability Distribution - Type A or B**	**Standard Uncertainty $u(x_i)$**	**Sensitivity coefficient c_i**	**Uncertainty contribution $u_i(y)$**	**Degree of freedom ν_i**
X_1	x_1	Δx_1	-Type A or B	$u(x_1)$	c_1	$u_1(y)$	ν_1
X_2	x_2	Δx_2	-Type A or B	$u(x_2)$	c_2	$u_2(y)$	ν_2
X_3	x_3	Δx_3	-Type A or B	$u(x_3)$	c_3	$u_3(y)$	ν_3
-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-
X_N	x_N	Δx_N	-Type A or B	$u(x_N)$	c_N	$u_N(y)$	ν_N
Y	y					$u_c(y)$	ν_{eff}

3.7.2. A formal example of such an arrangement is given as Table (3.7.1) applicable for the case of uncorrelated input quantities. The standard uncertainty associated with the measurement result $u_c(y)$ given in the bottom right corner of the table is the root sum square of all the uncertainty contributions in the outer right column. Similarly, ν_{eff} has to be evaluated as mentioned in Appendix –B.

4. STEP BY STEP PROCEDURE FOR ESTIMATING THE UNCERTAINTY IN MEASUREMENT

The steps to be followed for evaluating and expressing the uncertainty of the result of a measurement may be summarized as follows:

4.1. Step 1

Express mathematically the relationship between the measurand Y and the input quantities X_i on which Y depends: $Y = f\ (X_1,\ X_2 ...\ X_N)$. The function f should contain every quantity, including all corrections and correction factors that can contribute a significant component of uncertainty to the result of the measurement

4.2. Step 2

Identify all uncertainty source, some of the possible source of uncertainty are

4.2.1. Contribution from calibration of the measuring equipment including contribution from reference and working standards.

4.2.2. Uncertainty related to loading applied and measurement of it.

4.2.3. Stability and resolution of digital measuring equipment.

4.2.4. Resolution of analogue instruments.

4.2.5. Approximation and assumptions incorporated in measurement method.

4.2.6. Uncertainly due to procedure used to prepare the sample for test and actually testing it.

4.2.7. Rounded values of constants and other parameters used for calculations.

4.2.8. Effect of environmental conditions e.g. Ambient temperature and humidity variation.

4.2.9. Variability of power supply source.

4.2.10. Personal bias in reading analogue instruments.

4.2.11. Most of the times the testing laboratories test the sample given to it. However, in many situations laboratories are involved in sampling and the result reported is extrapolated for the bulk. In such a situation sampling error could be a major source of uncertainty.

4.2.12. Changes in the characteristics or performance of measuring equipment or reference material since the last calibration.

4.2.13. Variation in repeat observations made under similar situations due to random effects such as electrical noise in measuring instruments, fluctuations in environmental conditions and power supply, variability in homogeneity of test samples, variability in performance of persons carrying out the tests etc.

4.3. Step 3

Determine x_i, the estimated value of input quantities X_i, either on the basis of the statistical analysis of series of observations or by other means

4.4. Step 4

Determine sensitivity coefficients as given in 3.4.1.4.

4.5. Step 5

Evaluate the *standard uncertainty* $u(x_i)$ of each input estimate x_i. For an input estimate obtained from the statistical analysis of series of observations, the standard uncertainty is evaluated as *Type A evaluation of standard uncertainty*. For an input estimate obtained by other means, the Standard uncertainty $u(x_i)$ is evaluated as *Type B evaluation of standard uncertainty*

4.6. Step 6

Calculate the result of the measurement, that is, the estimate y of the measurand Y, from the functional relationship f using for the input quantities X_i the estimates x_i obtained in step 2

4.7. Step 7

4.7.1. Determine the *combined standard uncertainty* $u_c(y)$ of the measurement result y from the standard uncertainties associated with the input estimates (as described in Clause 4) using law of propagation of uncertainty equation (10)

Alternately combined standard uncertainty can also be evaluated as given below:

4.7.1.1. If the mathematical model involves only sum and / or difference of input quantities eg. y=(p+q+r----) the combined standard uncertainty Uc=(y) is given by

$$Uc(y) = \sqrt{u(p)^2 + u(q)^2 + u(r)^2 + --}$$

Where u(p) etc are standard uncertainty of p,q,r, ---- etc

4.7.1.2. If the mathematical model involves only a product or quotient eg. y=(pxqxrx-----) or y=(qxq / r---) the combined standard uncertainty Uc (y) is given by

$$Uc\ (y) = y\sqrt{\left(\frac{u(p)}{p}\right)^2 + \left(\frac{u(q)}{q}\right)^2 + \left(\frac{u(r)}{r}\right)^2} + - - -$$

Where y=measurement result derived from measurement of input quantities p,q,r,etc. and u(p) / p etc. are the uncertainties in the parameters expressed as relative standard deviations.

4.7.2. For the purpose of combined uncertainty components, it is most convenient to break the original mathematical model down to expressions which consists solely of operations covered by rules given in (a) and (b) above.

For example, the expression (o+p) / (q+r) can be broken down to two elements (o+p) and (q+r). The interim uncertainties for each of these can be calculated using rule (a) above, these interim uncertainties can then be combined by using rule (b) to give the combined standard uncertainty.

4.8. Step 8

Determine the effective degree of freedom from the formula given in equaltion Welch–Satterthwaite equation.

4.9. Step 9

If it is necessary to give an expanded uncertainty U, whose purpose is to provide an interval y -U to y+U that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand Y, multiply the combined standard uncertainty $u_c(y)$ by a coverage factor k, typically in the range 2 to 3, to obtain U= $ku_c(y)$. Select k on the basis of the level of confidence required of the interval

Report the result of the measurement y together with its combined standard uncertainty $u_c(y)$ or expanded uncertainty U along with confidence level

5. UNCERTAINTY ESTIMATION USING METHODS OTHER THAN GUM APPROACH

ISO / IEC 17025 has referred to two ISO documents viz Guide to the Expression of Uncertainty in Measurement (GUM) and ISO: 5725, Accuracy (trueness and precision) of measurement method and results, with reference to estimation of measurement uncertainty therefore leading to two approaches. GUM approach is more rigorous and universally acceptable approach irrespective of technological area of measurement. It provides the current international consensus method for estimating measurement uncertainty. It is also equally applicable to calibration and test results. The methodology given so far is based on GUM approach.

However, GUM approach supposes that mathematical model is available or can be derived that describes the functional relationship between the measurand and the influence quantities. In the absence of this model, GUM approach does not apply very well and in certain cases, the validity of results from a particular mathematical model may need to be verified e.g. through inter-laboratory comparison tests. Many laboratory professionals do not feel comfortable with GUM approach, they prefer to compute standard deviation as a traditional reference to estimate variability of measurement results.

5.1. Use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation

5.1.1. Many laboratories perform tests on items based on standard test methods, certain attributes of the test methods such as repeatability, reproducibility and trueness which relates to their performance are arrived at based on inter laboratory collaborative studies. A number of laboratories participate in such collaborative programs during the course of method validation. Examples of such methods are ASTM test methods, methods published by AOAL International, ISO, IUPAC etc.

5.1.2. Many professionals do not feel comfortable in applying GUM approach, if a mathematical model cannot be formulated easily. In such a situation measurement uncertainty can be estimated based on international standard ISO 21748:2010 "Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation" as a guidance document. The standard uses the information available on estimates of repeatability, reproducibility and trueness of test methods published by professional bodies.

These methods provide estimates of intra and inter laboratory components of variance together with an estimate of uncertainty associated with the trueness of the method.

5.1.3. Measurement uncertainty relates to individual results whereas repeatability, reproducibility and bias by contrast relate to performance of test method. It is therefore important that test process performance figures derived from method performance studies are relevant to all individual measurement results produced by the testing process.

5.1.4. The general approach used in estimation of measurement uncertainty by this method requires that

5.1.4.1. Estimates of repeatability, reproducibility and trueness of test methods in use are available from published information about the test method in use.

5.1.4.2. The laboratory confirms that its implementation of test method is consistent with the established performance of test method by checking its own bias and precision. This confirms that the published data are applicable to the results obtained by the laboratory.

5.1.4.3. Any influence on measurement results that were not adequately covered by collaborative study be indentified and the variance associated with the results that could arise from these effects be quantified or they must be demonstrably negligible

5.2. Procedure for evaluating Measurement Uncertainty using ISO 21748:2010.

5.2.1. **Step 1**

Obtain estimates of repeatability, reproducibility and trueness in use from published information about the method

5.2.2. **Step 2**

Establish whether the laboratory bias for measurement is within that expected on the basis of data obtained as per step1.

A laboratory should demonstrate that while implementing the test method, its bias is under control i.e. the laboratory component of bias is within the range expected from collaborative study. For this purpose, certified reference material or measurement standard is needed. It is assumed that the bias checks are performed on materials with reference values closely similar to the items actually under routine test. The laboratory should perform a number of replicate measurements on the reference material or reference standards under repeatability conditions. The bias is estimated as the laboratory mean minus the certified value. In addition to the mean of laboratory replicate, within laboratory standard deviation (s_W) of the replicate measurements also is also calculated. The information on repeatability standard deviation (s_r) and reproducibility standard deviation (s_R) is obtained from published information about the method as given in step1.

The between laboratory standard deviation (s_L) is derived from (s_R) and (s_r) by equation $s_L^2 = s_R^2 - s_r^2$. A reference value of standard deviation (s_D) is also calculated by

$s_D = [s_L^2 + s_w^2 / n]^{1/2}$

where 'n' is replicate number of measurements taken on certified reference material or measurement standard.

The measurement process is considered to be performing adequately if $|\Delta| < 2s_D$ where Δ is the bias as calculated. If above equation is satisfied it is a demonstration that the laboratory component of the bias is under control.

5.2.3. **Step 3**

Establish whether the precision attained by current measurement is within that expected on basis of repeatability and reproducibility estimates obtained from step1.

For this the laboratory should show that its repeatability is consistent with repeatability standard deviation obtained in the course of collaborative exercise.

The demonstration of consistency can be achieved by taking replicate measurements on suitable test material to obtain repeatability standard deviation s_l with preferably replicate measurements of more than 15. The repeatability standard deviation s_l so obtained based on replicate measurements taken by the laboratory is compared with repeatability standard deviation s_r obtained from published information about the test method. The comparison is a statistical comparison to see whether the two values are significantly different or not. This is done using F test at a 95% level of confidence.

If s_l is found to be significantly greater than s_r, the laboratory should either identify the cause or use s_l in place of s_r in all uncertainty estimates. This will involve an increase in the estimated value of reproducibility standard deviation as $s_R=\sqrt{s_L^2+s_r^2}$ will now be replaced by $s_R'=\sqrt{s_l^2+s_L^2}$ where s_R' is the adjusted estimate of reproducibility standard deviation and s_L has already been defined in step 2. Conversely where s_l is significantly smaller than s_r, the laboratory may also use s_l in place of s_r thereby giving a smaller estimate of uncertainty

5.2.4. **Step 4**

Identify any influence on the measurement that were not adequately covered in collaborative studies based on which estimates as given in step1 were obtained.

Quantify the variances that could arise from these effects, taking into account the sensitivity coefficients and the uncertainty for each influence, However the collaborative studies based on which repeatability, reproducibility and trueness of the method are estimated are done very exhaustively, this step may rarely need to be performed by a normal laboratory in routine operations.

5.2.5. **Step 5**

Where the bias and precision are under control as demonstrated by step 2 and step 3, combine the reproducibility estimate from step1 or step3 with the uncertainty associated with trueness to form a combined uncertainty estimate. If necessary, uncertainty associated with step 4 may also be used to obtain combined uncertainty estimate

5.3. Continued verification of performance

In order to use ISO 21748:2010 as a guidance document for estimating measurement uncertainty based on repeatability, reproducibility and trueness estimates certain pre conditions are to be met by the laboratory. In addition to preliminary estimation of bias and precision, the laboratory should take due measures to ensure that the measurement process remains in a state of statistical control. In particular this will involve the following

5.3.1. Appropriate quality control including regular checks on bias and precision. These checks may use any relevant stable, homogeneous test items or material, use of quality control charts is a good tool to monitor that measurement process remains in a state of statistical control. The details of control charts are given in subsequent paras.

5.3.2. Quality assurance measures including the use of appropriately trained and qualified staff operating with a suitable quality systems compliance to the requirement of ISO / IEC 17025 will be advantageous.

5.4. Uncertainty estimation

In a simplest case if it could be demonstrated that laboratory component of bias is under control as given in step2 above and the uncertainty of bias is negligible, the reproducibility standard deviation s_R obtained from step1 or s_R obtained from step3 represents the combined standard uncertainty $u_C(y)$ of the measurement result. In order to obtain the expanded uncertainty 'U' at an approximate confidence level of 95%, $u_C(y)$ is multiplied by coverage factor k=2.

However, if influence factors as given in step4 are to be taken into consideration, reference can be made to ISO 21748:2010.

The general principle of using reproducibility data in uncertainty evaluation is sometimes called a "top-down" approach in contrast of GUM approach a "bottom-up" approach

5.5. Use of control charts for estimation of measurement uncertainty

5.5.1. ISO / IEC 17025: 2017 clause 7.7.1 requires that the laboratories should have regular use of certified reference material and / or internal quality control using secondary reference material as a quality control measure. The standard also requires that data should be recorded in such a way that trends are detectable and statistical techniques shall be applied to the reviewing of results. This requirement is met by the use of control charts as a quality control measures. The technique is based on use of control sample which is similar to sample under test and the control sample is tested along with the routine sample under test. The use of control chart for estimating measurement uncertainty is based on the following:

5.5.1.1. The control sample should have a certified or otherwise known or accepted value. Thus, any bias in the measurement process can be corrected for.

5.5.1.2. The value of measurand represented by control sample should be close to the value of measurand actually obtained during routine testing. Generally, the uncertainty of measurement will be some function of the level of the test or value of measurand. It may therefore be necessary to track several control samples at different levels of measurand in order to properly assess the measurement uncertainty for various levels of measurand encountered.

5.5.1.3. The measurement process for control sample should be the same as for routine sample.

5.5.1.4. The control procedure is applicable where stable control materials are available and are analyzed repeatedly over long periods of time. Control data are displayed on control charts and are in use in many laboratories. The application differs from laboratory to laboratory such as control based on single measurement or replicate measurements. For replicate measurements, mean and range charts are used. However, most laboratories use single measurements for day to day control applications.

5.5.1.5. The first step is to study the measurement process that is to be controlled and characterize its performance. Repeat measurements are made on control samples which are stable. Variability of repeat measurements characterizes the imprecision of measurement process. It is assumed that distribution of these data is Gaussian and can be described by its mean ($\bar{x}$) and standard deviations. These statistics are calculated from replication study generally over a 20-25-day period on each level of control sample per day.

5.5.1.6. A control chart is prepared for each level of control material. The chart displays measured value on the y-axis versus the time or run number on the x-axis. Horizontal lines are drawn for the mean and for upper and lower control limits which are calculated from the standard deviation.

5.5.1.7. Mean(x) and standard deviation(s) are calculated. Initial estimates are made from a data set n approximately 20-25. When n is low these statements may not be reliable. These estimates should be revised when more control observations are accumulated by using cumulated data obtained from subsequent rounds of 20-25 days. The cumulative totals for these terms can be obtained by adding the value of different data sets.

5.5.1.8. These totals could then be used to get cumulative estimates of $\bar{x}$ and s

5.5.1.9. Using the estimate of population standard deviation, warning limits are established at ±2 sigma and action limits at ±3 sigma. If the accepted value of control sample has known uncertainty, root sum square it with population standard deviation to get standard deviation that should be used for control chart.

5.5.1.10. The measurement process must be in statistical control and that must be demonstrated by control charts. Measurement processes that are not in statistical control must be brought in control before control chart can be properly constructed.

5.5.1.11. With a properly constructed control chart the warning limits provides estimate of measurement uncertainty at approximately 95% confidence level. Control chart is therefore most direct way of estimating measurement uncertainty.

6. TEST FOR WHICH MEASUREMENT UNCERTAINTY ESTIMATION DOES NOT APPLY

6.1. When a test produces a numerical result or reported result is a numerical value, the testing laboratory shall estimate the uncertainty of those numerical results. Most of the results reported by testing laboratories in their test reports fall in this category. There are certain situations when results of test are not numerical or are not based on numerical data, such tests are called qualitative tests e.g. pass / fail or positive / negative etc. For such tests the laboratories are not required to estimate uncertainty of test results.

6.2. Note 2 under ISO / IEC 17025: 2017, Clause 7.6.3 states that in those cases where a well-recognized test method specifies the limits to the values of major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions.

6.3. In such a situation laboratory is not required to estimate the uncertainty of test results. However, a laboratory intending to apply this note 2 should demonstrate that the condition detailed above are satisfied. The laboratory should also demonstrate that in operating the test methods, all such measurements and factors are controlled with in specified limits.

6.4. Well recognized test methods should generally be taken as those meeting the conditions stated in clause 7.2.1.4 of ISO / IEC 17025: 2017. Specific limits to the values of major source of uncertainty means that the test method specifies the minimum allowable uncertainty or maximum permissible limits for each required measurement and specifies limits for environmental conditions or other factors that are known to have significance influence on the outcome of tests. Specifies the form of presentation of calculated results means that the standard includes a specific statement regarding number of significant figures to be reported, the rounding procedure or other specific form for expression of results. Where all these conditions are met, no further work in estimating measurement uncertainty is needed and no statement of measurement uncertainty needs to be reported.

6.5. Examples of such methods are a number of test methods given by committee of testing laboratories (CTL) of International Electro technical Commission (standard) for Electrical Equipment (IECEE) Scheme. For example, one such test stipulates the following conditions

6.5.1. Input power source to be maintained: voltage ±2.0 percent, Frequency ± 5.0 percent, Total harmonic distortion- minimum 3.0 percent.

6.5.2. Ambient temperature: 23 ± 2 degree C

6.5.3. Relative Humidity: 93 ± 2 percent

6.5.4. Personnel: documented technical competency requirement for the tests

6.5.5. Procedure: documented laboratory procedure

6.5.6. Equipment accuracy-voltage and current ± 1.5%,

6.5.7. Power - ± 3% , frequency ± 0.2%, temperature ± 2ºC .

Appendix A

Probability distribution

A.1 Normal distribution

The probability density function p(x) of the normal distribution is as follows:

$$P(x) = \frac{1}{\sigma\sqrt{2\pi}} \exp\left[-(x-\mu)^2 / 2\sigma^2\right], \qquad -\infty < x < +\infty$$

(A.1)

Where μ is the mean and σ is the standard deviation. Figure (A.1) represents such a distribution.

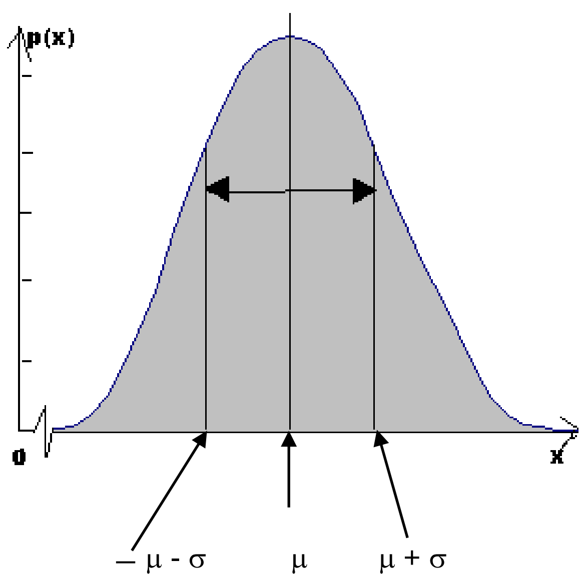

Figure A.1: Schematic view of the normal (Gaussian) distribution

A.1.1 When to use normal distribution

In some situation, the quoted uncertainty in an input or output quantity is stated along with level of confidence. In such cases, one has to find the value of coverage factor so that the quoted uncertainty may be divided by this coverage factor to obtain the value of standard uncertainty. The value of the coverage factor depends upon the distribution of the (input or output) quantity. In the absence of any specific knowledge about this distribution, one may assume it to be normal. Values of the coverage factor for various level of confidence for a normal distribution are as follows:

Table A.1: Confidence Level and the corresponding Coverage factor (k)

Confidence level	68.27 %	90 %	95 %	95.45 %	99 %	99.73 %
Coverage factor (k)	1.000	1.645	1.960	2.000	2.576	3.000

If based on available information, it can be stated that there is 68% chance that the value of input quantity X_i lies in the interval of a_- and a_+; and also it is assumed that the distribution of X_i is normal, then the best estimate of X_i is :

$$x_i = a, \text{ with } u(x_i) = a \qquad \text{(A.2)}$$

A.2 Rectangular distribution

The probability density function p(x) of rectangular distribution is as follows:

$$P(x) = \frac{1}{2a}, a_- < x < a_+, \; where \; a = (a_+ - a_-)/2$$

(A.3)

Figure (A.2) represents such a distribution. The expectation of X_i is given as x_i

$$E(X_i) = x_i = (a_+ + a_-)/2$$

(A.4)

and its variance is

$$Var(X_i) = a^2/3, \; where \; a = (a_+ - a_-)/2$$

(A.5)

A.2.1 When to use rectangular distribution

In cases, where it is possible to estimate only the upper and lower limits of an input quantity X_i and there is no specific knowledge about the concentration of values of X_i within the interval, one can only assume that it is equally probable for X_i to lie anywhere within this interval . In such a situation rectangular distribution is used.

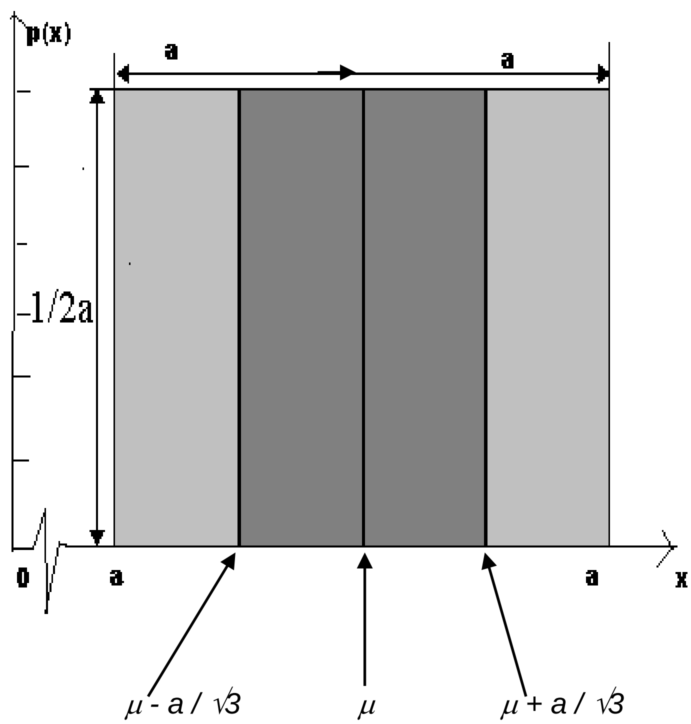

Figure A.2: Schematic view of the rectangular distribution

A.3 **Symmetrical Trapezoidal Distribution**

The above rectangular distribution assumes that X_i can assume any value within the interval with the same probability. However, in many realistic cases, it is more reasonable to assume that X_i can lie anywhere within a narrower interval around the midpoint with the same probability while values nearer the bounds are less and less likely to occur. For such cases, the probability distribution is represented by a symmetric trapezoidal distribution function having equal sloping sides (an isosceles trapezoid), a base of width $a_+ - a_- = 2a$, and a top of width $2\beta a$, where $0 \le \beta \le 1$ is used .

The expectation of X_i is given as:

$$E(X_i) = (a_+ + a_-)/2 , \qquad \text{(A.6)}$$

and its variance is

$$Var(X_i) = a^2(1 + \beta)^2 / 6 \qquad \text{(A.7)}$$

When $\beta \rightarrow 1$, the symmetric trapezoidal distribution is reduced to a rectangular distribution.

A.3.1 Triangular Distribution

When β = 0, the symmetric trapezoidal distribution is reduced to a triangular distribution. Figure (A.3) shows such a distribution. When the greatest concentration of the values is at the center of the distribution, then one must use the triangular distribution.

The expectation of X_i is given as,

$$E(X_i) = (a_+ + a_-)/2, \quad \text{(A.8)}$$

and its variance is

$$Var(X_i) = a^2/6 \quad \text{(A.9)}$$

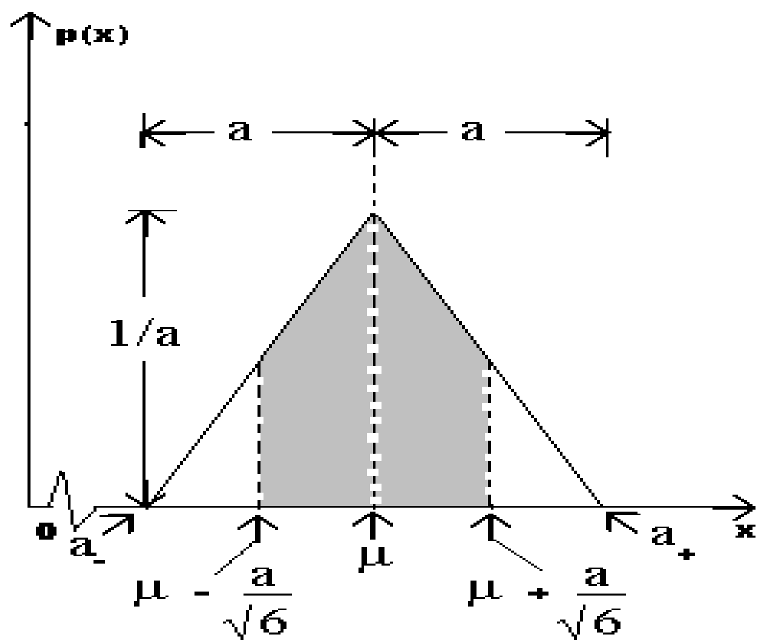

Figure A.3: Schematic view of the triangular distribution

A.4 U-Shaped Distribution

This U-shaped distribution is used in the case of mismatch uncertainty in radio and microwave frequency power measurements (shown in figure (A.4). At high frequency the power is delivered from a source to a load, and reflection occurs when the impedances do not match. The mismatch uncertainty is given by $2\Gamma_s\ \Gamma_L$ where Γ_s and Γ_L are the reflection coefficients of the source and the load respectively. The standard uncertainty is computed as:

$$u^2\,(x_i) = (2\ \Gamma_S\ \Gamma_L)^2 / 2 \qquad \text{(A.10)}$$

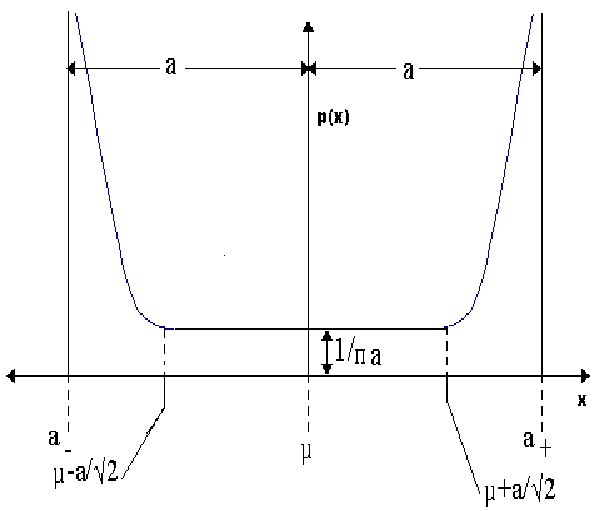

Figure A.4: Schematic view of the U-shaped distribution

Appendix B

Coverage factor derived from effective degrees of freedom

B.1 To estimate the value of a coverage factor k corresponding to a specified coverage probability requires that the reliability of the standard uncertainty u(y) of the output estimate y is taken into account. That means taking into account how well u(y) estimates the standard deviation associated with the result of the measurement. For an estimate of the standard deviation of a normal distribution, the degrees of freedom of the estimate, which depends on the size of the sample on which it is based, is a measure of the reliability. Similarly, a suitable measure of the reliability of the standard uncertainty associated with an output estimate is its effective degrees of freedom ν_{eff}, which is approximated by an appropriate combination of the ν_i for its different uncertainty contributions $u_i(y)$.

B.2 The procedure for calculating an appropriate coverage factor k :

Step 1

Obtain the standard uncertainty associated with the output estimate.

Step 2

Estimate the effective degree of freedom ν_{eff} of the standard uncertainty u(y) associated with the output estimate y from the Welch-Satterthwaite formula.

Step 3

Obtain the coverage factor k from the table of values of student "t" distribution. If the value of ν_{eff} is not an integer, it is truncated to the next lower integer and the corresponding coverage factor k is obtained from the table.

B.3 Welch-Satterthwaite formula is as follows:

$$\nu_{eff} = \frac{u^4(y)}{\sum_{i=1}^{N} \frac{u_i^4(y)}{\nu_i}} \qquad \text{(B.1)}$$

where $u_i(y)$ (i = 1,2,3,……..N) defined in Eqs. (11) and (12), are the contributions to the standard uncertainty associated with the output estimate y resulting from the standard uncertainty associated with the input estimate x_i which are assumed to be mutually statistically independent, and the ν_i is the effective degrees of freedom of the standard uncertainty contributions $u_i(y)$.

Note: The calculation of the degrees of the freedom ν for Type A and Type B of the evaluation may be as follows:

Type A Evaluation

For the results of direct measurement (Type A evaluation), the degree of freedom is related to the number of observations (n) as,

$\nu_i = n - 1$ (B.2)

Type B Evaluation

For this evaluation, when lower and upper limits are known

$\nu_i \rightarrow \infty$ (B.3)

It is suggested that ν_i should always be given when Type A and Type B evaluations of uncertainty components are documented.

Where high precision measurements are undertaken, the accredited calibration laboratories shall be required to follow ISO Guide to the expression of uncertainty in Measurement (1995). Concerned laboratories should refer to Annexure – G (with special emphasis on table G-2) and Annexure –H for related examples.

However, assuming that $\nu_i \rightarrow \infty$ is not necessarily unrealistic, since it is a common practice to chose a_- and a_+ in such a way that the probability of the quantity lying outside the interval a_- to a_+ is extremely small.

Interpretation on Effective Degrees of Freedom

“Whilst the reason for determining the number of degrees of freedom associated with an uncertainty component is to allow the correct selection of value of student’s t, it also gives an indication of how well a component may be relied upon. A high number of degrees of freedom is associated with a large number of measurements or a value with a low variance or a low dispersion associated with it. A low number of degrees of freedom corresponds to a large dispersion or poorer confidence in the value.

Every component of uncertainty can have an appropriate number of degrees of freedom, ν, assigned to it. For the mean, $\bar{x}$, for example ν = n - 1, where n is a number of repeated measurements. For other Type A assessments, the process is also quite straightforward. For example, most spreadsheets provide the standard deviation of the fit when data is fitted to a curve. This standard deviation may be used as the uncertainty in the fitted value due to the scatter of the measurand values. The question is how to assign components evaluated by Type B processes.

For some distributions, the limits may be determined so that we have complete confidence in their value. In such instances, the number of degrees of freedom is effectively infinite. The assigning of limits, which are worst case, leads to this instance, namely infinite degrees of freedom, and simplifies the calculation of effective degrees of freedom of the combined uncertainty.

If the limits themselves have some uncertainty, then a lesser number of degrees of freedom must be assigned. The ISO Guide to the expression of uncertainty in measurement (GUM) gives a formula that is applicable to all distributions. It is equation G.3 that is:

$$\nu \approx ½ \, [\, \Delta u(x_i) \,/\, u(x_i) \,]^{-2} \qquad \text{……… 1}$$

Where $\Delta u(x_i) / u(x_i)$ is the relative uncertainty in the uncertainty

This is a number less than 1, but may for convenience be thought of as a percentage or a fraction. The smaller the number, the better defined is the magnitude of the uncertainty.

For example, if relative uncertainty is 10%, i.e.

$$\Delta u(x_i) / u(x_i) = 0.1$$

Then it can be shown that the number of degrees of freedom is 50. For a relative uncertainty of 25 % then ν = 8 and for relative uncertainty of 50 %, ν = is only 2.

Rather than become seduced by the elegance of mathematics, it is better to try to determine the limits more definitely, particularly if the uncertainty is a major one. It is of the interest to note that equation (1) tells us that when we have made 51 measurements and taken the mean, the relative uncertainty in the uncertainty of the mean is 10%. This shows that even when many measurements are taken, the reliability of the uncertainty is not necessarily any better than when a type B assessment is make. Indeed, it is usually better to rely on prior knowledge rather than using an uncertainty based on two or three measurements. It also shows why we restrict uncertainty to two digits. The value is usually not reliable enough to quote to better than 1 % resolution.

Once the uncertainty components have been combined, it remains to find the number of degrees of freedom in the combined uncertainty. The degrees of freedom for each component must also be combined to find the effective number of degrees of freedom to be associated with the combined uncertainty. This is calculated using the Welch-Satterthwaite equation, which is:

$$\nu_{eff} = [u_c^4 (y) / \sum_{1}^{n} \{ u_i^4 (y) / \nu_i\}] \qquad \text{...... 2}$$

Where:

ν_{eff} is the effective number of degrees of freedom for u_c the combined uncertainty

ν_i is the number of degrees of freedom for u_i, the i^{th} uncertainty term

$u_i (y)$ is the product of $c_i u_i$

"The other terms have their usual meaning".

Table B.1: Student t-distribution for degrees of freedom ν. The t-distribution for ν defines an interval $-t_p(\nu)$ to $+t_p(\nu)$ that encompasses the fraction p of the distribution. For p = 68.27%, 95.45%, and 99.73%, k is 1, 2, and 3, respectively.

Degrees Freedom	**Fraction p in percent**					
(ν)	**68.27**	**90**	**95**	**95.45**	**99**	**99.73**
1	1.84	6.31	12.71	13.97	63.66	235.80
2	1.32	2.92	4.30	4.53	9.92	19.21
3	1.20	2.35	3.18	3.31	5.84	9.22
4	1.14	2.13	2.78	2.87	4.60	6.62
5	1.11	2.02	2.57	2.65	4.03	5.51
6	1.09	1.94	2.45	2.52	3.71	4.90
7	1.08	1.89	2.36	2.43	3.50	4.53
8	1.07	1.86	2.31	2.37	3.36	4.28
9	1.06	1.83	2.26	2.32	3.25	4.09
10	1.05	1.81	2.23	2.28	3.17	3.96
11	1.05	1.80	2.20	2.25	3.11	3.85
12	1.04	1.78	2.18	2.23	3.05	3.76
13	1.04	1.77	2.16	2.21	3.01	3.69
14	1.04	1.76	2.14	2.20	2.98	3.64
15	1.03	1.75	2.13	2.18	2.95	3.59
16	1.03	1.75	2.12	2.17	2.92	3.54
17	1.03	1.74	2.11	2.16	2.90	3.51
18	1.03	1.73	2.10	2.15	2.88	3.48
19	1.03	1.73	2.09	2.14	2.86	3.45
20	1.03	1.72	2.09	2.13	2.85	3.42
25	1.02	1.71	2.06	2.11	2.79	3.33
30	1.02	1.70	2.04	2.09	2.75	3.27
∞	1.000	1.645	1.960	2.000	2.576	3.000

Normative References:

This document has been prepared based on references from the following documents:

1. ISO/IEC Guide 98-3:2008 - "Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM: 1995)".
2. ISO/IEC Guide 99:2007, International vocabulary of metrology - Basic and general concepts and associated terms (VIM)
3. ISO 3534-1 Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability
4. IEC GUIDE 115:2007 - Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector
5. UKAS M3003 edition 3 November 2012- The expression of uncertainty and confidence in measurement
6. EURACHEM / CITAC Guide quantifying uncertainty in analytical measurements (edition 3 - 2012)
7. ISO 21748:2010 Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation
8. The Uncertainty of measurement - Physical and Chemical Metrology Impact and Analysis, S.K. Kimothi, American society for quality (ASQ) 2002
9. ISO / IEC 17025: 2017, General requirements for the competence of testing and calibration laboratories
10. ISO 15189: 2012, Medical laboratories -- Requirements for quality and competence

National Accreditation Board for Testing and Calibration Laboratories (NABL)
NABL House
Plot No. 45, Sector 44,
Gurugram - 122003, Haryana
Tel. no.: 91-124-4679700 (30 lines)
Fax: 91-124-4679799
Website: www.nabl-india.org