Evaluation of Measurement Uncertainty for Testing & Calibration Laboratories as Per ISO/ IEC 17025:2017

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Abstract

Measurement uncertainty is a qualitative measure of measurand in addition to precision and accuracy. Estimation of uncertainty in measurement is one of the most important characteristics for demonstration of competence for testing and calibration laboratories accredited on ISO/ IEC 17025 standards. To ensure the metrological traceability, to have confidence in measurements, and to produce valid results, the laboratory must estimate uncertainty from all significant sources. Consequently, measurement uncertainty can impact decision rules, statements of conformity, and risks associated with making decisions regarding a standard or specification. This paper presents a concise guideline for the estimation of measurement uncertainty for testing and calibration laboratories with a focus on electrical whether accredited on ISO/ IEC 17025:2017 standards or planned to achieve accreditation in the future. Non-accredited electrical testing and calibration laboratories may adopt the procedure/ process to enhance acceptability, ensure confidence in measurement results, and as a part of good laboratory practices. Finally, the authors presented their way of budgeting measurement uncertainty as an example which is being implemented in an electrical testing laboratory.

Index Terms— ISO/ IEC 17025:2017, Measurement Uncertainty, Testing, Calibration, Metrological traceability, Normal/ Gaussian Distribution, Decision Rules, Statement of Conformity, Risk assessment

I. INTRODUCTION

ESTIMATION of measurement uncertainty is one of the key requirements for the demonstration of competence in testing and calibration laboratories. It has a direct impact on the validity of measurement results. ISO/ IEC 17025:2017 [1] sets out the requirements for the development of a Quality Management System (QMS) for demonstration of competence. Laboratories accredited on ISO/ IEC 17025:2017 are also referred to as Conformity Assessment Bodies (CABs). Accredited laboratories, either testing or calibration shall estimate measurement uncertainty for its measurement results. ISO/IEC 17025:2017 standard has addressed the requirement for calibration laboratories to estimate and report the measurement uncertainty for each of the measurement results.

However, for testing laboratories, the question remains open as standard has required evaluating measurement uncertainty and reporting shall be made when it can affect the validity of test results or as required by a customer or any other requirement. The paper will discuss the procedure/ process that may be followed so that the ambiguities in the estimation of measurement uncertainty may be resolved with a focus on application to electrical testing and calibration laboratories. The procedure can be extended to other laboratories with little/ minor modifications.

II. LITERATURE REVIEW

Measurement uncertainty is not a new concept. It has been widely used to quantify the spread or possible deviation in measurement. Measurement uncertainty is defined in Vocabulary of Metrology (VIM) [2] as a non-negative number, which is attributed to the measured quantity (measured quality is also referred to as measurand) so that its possible spread can be estimated. Measurement uncertainty is reported in the format as 'X±U', where 'X' is the best estimate under controlled environmental conditions and 'U' is expanded uncertainty at coverage factor 'k=2', with confidence levels no less than 95 %. As VIM defined measurement uncertainty as a non-negative number, it means measurement uncertainty would always be a positive number or zero in a special case when estimation is not possible under certainty circumstances i.e., for some testing results, where quality is important i.e., PASS/ FAIL, etc., it might not be possible to estimate the measurement uncertainty for the process.

As discussed in [14] and [18], many authors present their work which includes the evaluation of measurement uncertainty concerning the GUM method, Fuzzy variables, Monte Carlo Simulation, and others. However, in laboratories complying with ISO/ IEC 17025:2017 standard, it is neither a requirement nor feasible to pay too much attention to the evaluation of measurement uncertainty as it might compromise other areas including general, process, resource, and/ or management system requirements. Moreover, the author only discussed the literature presented and did not include which method to use. In addition, the author has no recommendation for the evaluation of measurement uncertainty. Similarly, the authors in [15], [18] presented a details Mathematical model about the estimation of measurement uncertainty. However, it lacks a demonstration of practical evaluation of measurement uncertainty. The author in [16] presented about evaluation of measurement uncertainty in a Biochemistry laboratory. However, it does not comply with the requirements of international standards i.e., the significance of measurement uncertainty components was not evaluated. Authors in [17] presented their thoughts and research on measurement uncertainty, including conformity assessment but it lacks practical demonstration.

The author in [19] presented an estimation of measurement uncertainty using Bayesian statistics using the concept of conditional probability and area under the curve, but then again it lacks a demonstration of how measurement uncertainty has to be evaluated.

In totality, the authors presented their way of estimating measurement uncertainty and its mathematical, probabilistic, and statistical models. However, none of the authors comply or consider the requirements of international standards i.e., ISO/ IEC 17025:2017 standard. Moreover, the majority of authors are unable to demonstrate the evaluation of measurement uncertainty in real-world scenarios. This research gap has been filled in this research paper by presentation and demonstration of practical evaluation of measurement uncertainty for appliance testing as an example, which is accredited under ISO/ IEC 17025:2017 standard.

A) ISO/ IEC 17025:2017 requirements for estimation of measurement uncertainty

As per requirements of ISO/ IEC 17025:2017, a laboratory either performing accredited testing or calibration should estimate measurement uncertainty associated as follows:

I. Identify all possible contributions, if applicable.

II. While estimation, all contributing factors must be considered which are significant. If a laboratory is implanting sampling, the uncertainty in measurement due to sampling contribution should also be included. Appropriate analysis technique may be used and is open to laboratory.

III. Calibration labs are bound to estimate measurement uncertainty for all its measurements or calibrations.

IV. Testing laboratories are also directed to estimate the measurement uncertainty; however, the standard does not bond estimation of measurement uncertainty for each testing/ measurement result. Moreover, the standard made estimation of measurement uncertainty easy by providing the provision of estimation based on the theoretical principles and understanding if testing methods include the method or procedure for estimation. As an alternative, practical experience can also be utilized for the estimation of measurement uncertainty in this case. For testing laboratories, if a well-renowned test method gives the limits of sources to be included in measurement uncertainty, then there is no need to consider additional contributors if the laboratory has followed all the instructions of the test method including reporting format, etc. Moreover, the laboratory does not need to repeat the estimate of measurement uncertainty if control of critical factors has been demonstrated.

As illustrated above, the requirements for calibration laboratories are more stringent when compared to testing. It will be illustrated and discussed in the next sections. Measurement uncertainty can be expressed in the same unit as of measurand or as a unit-less quantity i.e., percentage of measurement point, etc.

B) ISO/ IEC 17025:2017 requirements for reporting of measurement uncertainty

This section will cover all the requirements for testing and/ or calibration laboratories for reporting measurement uncertainty in calibration and/ or test reports. As per standard requirements:

Testing laboratories will be required to report measurement uncertainty if it can impact the validity of test results or requested by customers or can have an impact on conformity to a standard or specification. Otherwise, there is no need to report measurement uncertainty. If sampling has been done, its uncertainty is required to be separately reported.

Calibration laboratories are required to report the measurement uncertainty for all its measurement results irrespective of the condition. If sampling has been done, its uncertainty is required to be separately reported.

It may be noted that for most of the modern equipment and processes, the spread of measurement uncertainty is symmetrical i.e., the same amount of spread towards the lower and upper sides of measurand. Measurement uncertainty spread might be unsymmetrical i.e., 'X+U1' and 'X-U2', where 'U1'and 'U2'are lower and upper spread of measurement uncertainty. In this paper, we assume measurement uncertainty to be symmetrical and thus can be represented as 'X ± U'. Therefore, the estimation of measurement uncertainty, where one or more contributors are unsymmetrical is not covered under the scope of this research.

C) Proposed model for Evaluation of Measurement Uncertainty

As seen from the above discussion, it is clear that ISO/ IEC 17025:2017 sets out the requirements for estimation of measurement uncertainty and reporting. On the other hand, ISO/ IEC 17025:2017 is open to estimating uncertainty using any appropriate means or method. Beginners guide to measurement uncertainty (GUM) [2], [3], has been considered to be one of the most appropriate and standardized practices that have been followed by most calibration and testing laboratories worldwide. The following approach might be used in order to estimate the measurement uncertainty in the form of a measurement uncertainty budget as follows:

1. Enlist all the possible measurement uncertainty contributors. For instance, possible measurement uncertainty components when estimation of measurement uncertainty for testing would be:

I. Manufacturer specifications/equipment-related components
    i. Accuracy of tester/ calibrator
    ii. Resolution of tester/ calibrator
    iii. Drift of tester/ calibrator
    iv. Stability of tester
    v. Bias or systematic error in the tester
II. Calibration service provider-related components
    i. Measurement Uncertainty from calibration Certificate
    ii. Stability of calibration standard
III. Measurement process-related components
    i. Repeatability of the measurement process
    ii. Reproducibility of measurement process
    iii. Hysteresis of measurement process
    iv. Sampling uncertainty (if applicable)
IV. Environmental and facilities-related components
    i. Temperature variation
    ii. Humidity variation

   - iii. Power supply, frequency variation, and stability
   - iv. Contamination or dust particles etc.

2. Assign the type of uncertainty i.e., type A being estimated using statistical techniques or methods (μA1, μA2, …, μAn). It generally consists of repeatability and reproducibility. Repeatability is necessary for both testing and calibration laboratories. Reproducibility is recommended in case of strict practices, for instance, microbiological laboratories, sampling, method verification, and validation require strict practice to estimate measurement uncertainty due to reproducibility. Type B (μB1, μB2, …, μBn), estimated other than statistical methods used. Usually, all components other than reproducibility and repeatability can be classified as type B components. It is a general rule of thumb and may vary from situation and laboratory to laboratory.
3. Convert all the sources of uncertainty in standard form using the knowledge of the probabilistic distribution of each source.
   - I. For instance, measurement uncertainty reported in calibration certificates is generally reported at more than 95 % confidence intervals with a coverage factor of k = 2 (Normal or Gaussian distribution probability), so it will be converted to standard form by dividing it by factor or divisor of "2".
   - II. If no knowledge of probability distribution of any source of measurement uncertainty is given, it may be taken as rectangular or uniform distributed probability i.e., equally likely to happen at all points and gives maximum area under the curve or contribution of measurement uncertainty. For rectangular distribution, the divisor factor would be "$2\sqrt{3}$"
   - III. For resolution, standard uncertainty may be estimated by taking half of the resolution of the tester/ calibrator.
   - IV. It may also be noted that generally type A uncertainties are already estimated in standard form, so there is no need to do this further. Take a square of the contributor's type A:

$$\mu_A = \sqrt{\mu_{A1} + \mu_{A2} + \ldots + \mu_{An}} \qquad (1)$$

and type B

$$\mu_B = \sqrt{\mu_{B1} + \mu_{B2} + \ldots + \mu_{Bn}} \qquad (2)$$

Then take square root to estimate the overall root mean squared of type A and type B uncertainty individually.

4. Finally, find out the combined uncertainty sum using

$$\mu_C = \sqrt{\mu_A^2 + \mu_B^2} \qquad (3)$$

5. Find out the sources whose impact is significant. For instance, if a contributor of measurement uncertainty is less than 1 % of the total estimate (combined uncertainty), it may be excluded from the overall budget. It may also be noted that contribution from repeatability should not be removed from the overall estimate irrespective of its significance as per International Laboratory Accreditation Cooperation's Policy P14 [4] i.e., ILAC Policy for Measurement Uncertainty in Calibration. [5]
6. Testing laboratories may also adopt it as a part of good practices and to have the opportunity to enhance the scope of accreditation in calibration as well.
7. After the determination of significance, non-significant sources may be excluded from the overall estimate using the same process from "2 to 5".
8. Finally, estimate expanded measurement uncertainty from combined uncertainty estimated in"7"having significant sources only, i.e.,μE=2μC, with coverage factor "k=2" corresponding to a confidence level of more than 95 % (probability of measurement uncertainty normally distributed).
9. For testing laboratories, record the measurement uncertainty and make it a part of documented evidence as per requirements of Technical Records to be maintained by ISO/ IEC 17025:2017 accredited Conformity Assessment Bodies (CABs). report of this measurement uncertainty is up to customer requirement, or when it can affect the validity of test results. Testing laboratories may also report irrespective of the requirements as a part of good laboratory practices. It is dependent on testing laboratory policy or practice too. For calibration laboratories, report it against each measurement result and retain the documented evidence for re-assessment, surveillance, improvement, training, and quality assurance purposes.

III. PROBABILISTIC DISTRIBUTIONS

A) Normal or Gaussian Distribution

It is a type of probabilistic distribution in which the maximum probability of occurrence lies close to the mean. As we go away from the mean, the probability starts decreasing exponentially. Eventually, the probability of values far away from means becomes horizontal asymptotes and never touches the horizontal or x-axis, i.e., far values have still some probability of occurrence, but it is very low and may be assumed zero for practical and measurement processes. This type of probabilistic distribution due to its realistic nature is most widely used for several components of measurement uncertainty depending on the type and information. Its beauty lies in the fact that when several components are summed together, they always approach normal or Gaussian distribution. This fact has been utilized by the GUM approach and is readily acceptable worldwide. So, after combining the measurement uncertainty from different sources, the sum is always normally distributed.

Another beauty of Gaussian distribution is that it can be completely described with mean and coverage factors. It is a universally recommended practice to report measurement uncertainty as expanded measurement uncertainty at coverage factor 'k=2', which

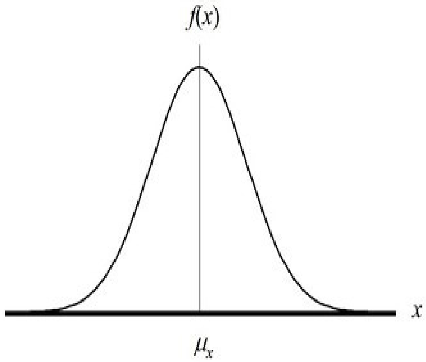

Fig. 1 Normal or Gaussian Distribution (Source: ISO Budgets) [11]

corresponds to more than 95 % confidence level (also denoted as C.L.). case must be taken while estimating measurement uncertainty of normally distributed origin as all random or natural processes follow Gaussian distribution (weather sample or population). Randomness may be ensured in case of sample is taken so that it can have all the characteristics of a population. The typical normal distribution curve is illustrated in Fig. 1. The maximum probability lies at the mean value while the probability decreases significantly as we go away from the mean value.

B) Rectangular or Uniform Distribution

It is another useful type of distribution that is widely used. It is not realistic but used when there is an equally likely probability of measurement results. For instance, the drift of the standard cannot be modeled with precision and hence can be assumed to have the same probability at all intervals. Similarly, uncertainty due to resolution is also modeled as a rectangular or uniform distribution. This distribution is more popular since it gives the maximum area under the curve when compared with other probabilistic distributions and hence can cover the worst-case scenario with maximum contribution of measurement uncertainty. A general rectangular distribution curve is shown in Fig. 2. It is clear from the figure that the probabilistic distribution is uniform within the range and is zero outside the range.

C) Other Probabilistic Distributions

Several probabilistic distributions are being used by mythologists and testing operators. Some other commonly used examples are quadratic distribution, U-shaped distribution, and triangular distribution. The details are discussed in [10]. The factors for normalization or divisor for some of the common types of distributions are tabulated below:

IV. RESULTS AND DISCUSSION

This paper provides an easy guideline for the estimation of measurement uncertainty for electrical calibration and testing laboratories. This paper integrates the requirements of the ISO/ IEC 17025:2017 standard and the GUM approach. This paper also provides a systematic way for estimation of measurement uncertainty for electrical calibration and testing laboratories i.e., by making measurement uncertainty budget. The following are the conclusions and results of this paper:

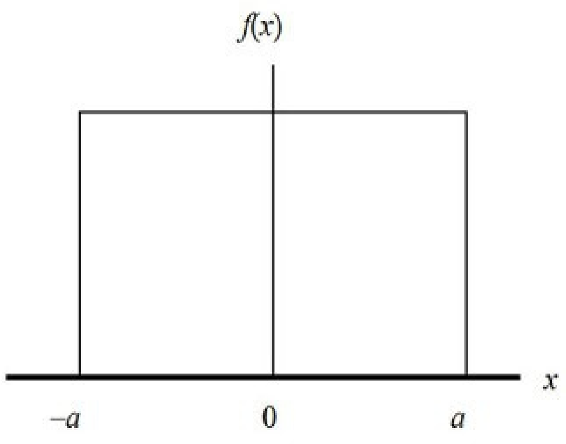

Fig. 2 Rectangular or Uniform Distribution (Source: ISO Budgets) [11]

TABLE I. NORMALIZATION FACTORS FOR PROBABILISTIC DISTRIBUTIONS

Distribution Types	**Nature of curve/ Shape**	**Normalization factor**
Normal or Gaussian	Bell-shaped curve	‘K’ or coverage factor
Uniform or Rectangular	Constant	$\overline{3}$
U-Shaped	U shaped curve	$\overline{2}$
Quadratic	Parabolic Shaped	$\overline{3}$
Triangular	Linear increasing and decreasing	$\overline{5}$

A) Example Line Leakage Testing (LLT) of Electric fan

Line leakage testing (LLT), also known as touch current testing is one of the tests that is required for every product to have minimum safety requirements for every electronic/ electrical product. The same applies to biomedical products/ equipment with more stringent requirements. The testing is being conducted by an electrical safety compliance analyzer. Here, we are going to apply the line leakage test requirements for electrical appliances i.e., electric fans. The testing has been performed concerning Clause 16 of IEC 60335-2-80:2015 and Clause 16.1 & 16.2 of IEC 60335-1:2020. As shown in Fig. 3, the unit under test i.e., bracket fan was set to undergo LLT. The fan was classified as a Class-0I appliance as there is an accessible metallic part corresponding to power circuitry. However, there is no provision for earthing in the supply cord or plug. As per the above-mentioned clauses, the line leakage test will be conducted at 1.06 times the working voltage i.e., 1.06*230 V = 243.8 V. The average value of the best estimate of the line leakage test for a fan (consumer appliance) is measured to be 26.2 µA.

B) Quantification of sources and determination of significance for LLT test

As discussed in the earlier section, we have to first quantify the measurement uncertainty sources. The possible quantifiable measurement uncertainty sources would be:

I. Manufacturer specifications/equipment-related components including Accuracy, Resolution, Drift, Stability, and Bias or systematic error in the tester

TABLE II. SYSTEMATIC COMPARISON OF GUIDES ON EVALUATION OF MEAUSREMENT UNCERTAI

Source of knowledge	**ISO/ IEC 17025:2017**	**GUM**	**Testing & Calibration**	**ILAC P14**	**Significance**	**Budgeting**
ISO/ IEC 17025:2017	Yes	No	Yes	No	No	No
GUM	No	Yes	Yes	No	No	No
ILAC P14	No	No	No	Yes	No	No
This guide research	Yes	Yes	Yes	Yes	Yes	Yes
ISO/ IEC 17025:2017	Yes	No	Yes	No	No	No

Fig. 3 Class-01 Appliance for Line Leakage Testing

II. Calibration service provider-related components including Measurement Uncertainty from Calibration certificate and Stability of calibration standard

III. Measurement process-related components, Repeatability, and/ or Reproducibility of the measurement process

IV. Environmental and facilities-related components including Temperature variation, Humidity variation, Power supply, frequency variation, and stability

The contribution from sources would be determined by the following table:

From the above table, it is clear that sources including resolution, stability of tester, bias, stability of reference standard, and uncertainty from calibration certificate are no longer significant for the current scenario. However, we must include uncertain sources of repeatability and calibration certification in the budget as these sources are required to comply with the requirement of ILAC P14 and Metrological traceability (Clause of ISO/ IEC 17025:2017 standard). The graphical representation of sources of measurement is shown in the figure below.

TABLE III. QUANTIFICATION AND DETERMINATION OF THE SIGNIFICANCE OF MEASUREMENT UNCERTAINTY SOURCES

Source(s) of uncertainty	Base/ Measurement point	Standard uncertainty	Normalized uncertainty (percentage)	Relative Contribution of Source
Accuracy	26.20	0.40	1.53%	20.93%
Resolution	26.20	0.03	0.11%	1.51%
Drift	26.20	0.20	0.76%	10.46%
Stability Tester	26.20	0.12	0.44%	6.04%
Bias	26.20	0.10	0.38%	5.23%
Calibration Report	30.00	0.08	0.25%	3.43%
Stability (Standard)	30.00	0.02	0.05%	0.69%
Repeatability	26.20	1.20	4.58%	62.78%
Temperature	25.00	0.77	3.06%	42.00%
Humidity	50.00	1.91	3.81%	52.23%
Power supply	230.00	4.60	2.00%	27.42%
Frequency	50.00	0.50	1.00%	13.71%

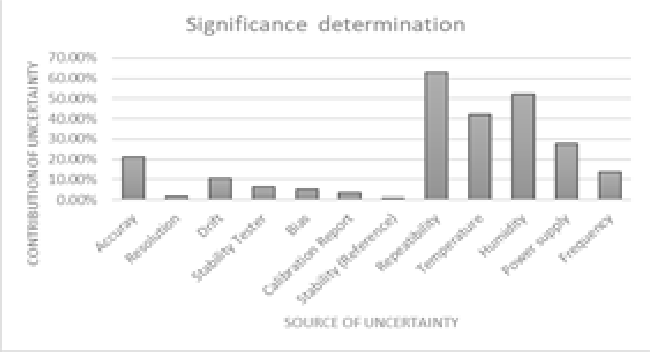

Fig. 4 Graphical interpretation of contributions from different types of measurement uncertainty sources

The final measurement uncertainty budget is shown in Table IV. It may be noted that the over-measurement uncertainty is estimated to be 7.30 % when all sources are considered. However, it becomes 7.27 % when only significant sources are considered. The decrease in overall measurement uncertainty is only 0.33 % which is very small. Moreover, as per the requirement of ISO/ IEC 17025:2017 standard, only significant contributions are required to be considered.

Therefore, the line leakage current for the fan (appliance under test) can be reported as a 26.2μ*A* ± 7.27% or 26.2 ± 1.90 μ*A*. The appliance under test can be reported as "PASS" for the line leakage test as the measurement result is fairly within the acceptable range i.e., line leakage current for Class-0I appliance should be less than 0.5*mA*.

The novelty of this research can be summarized as below:

I. In literature, authors presented their way of estimation of measurement uncertainty. However, authors are unable to comply with the requirements of international standards i.e., ISO/ IEC 17025:2017 standard. This research manuscript provided a simple guideline for the evaluation of measurement uncertainty including a demonstration of real-world problems in electrical appliance testing.

TABLE IV. FINAL MEASUREMENT UNCERTAINTY BUDGET WITH ALL SIGNIFICANT CONTRIBUTORS ONLY

Source(s) of uncertainty	Base/ Measurement point	Standard uncertainty	Normalized uncertainty (percentage)
Accuracy	26.20 µA	0.40 µA	1.53%
Drift	26.20 µA	0.20 µA	0.76%
Calibration Report	30.00 µA	0.08 µA	0.25%
Repeatability	26.20 µA	1.20 µA	4.58%
Temperature	25.00 ℃	0.77 ℃	3.06%
Humidity	50.00 % RH	1.91 % RH	3.81%
Power supply	230.00 V	4.60 V	2.00%
Frequency	50.00 Hz	0.50 Hz	1.00%
Total	---	---	7.27%

II. The research presented an estimation of measurement uncertainty from several sources having different units. Firstly, measurement uncertainty is expressed as a percentage i.e., unitless quantity, and then combined using the root mean square method. Standard permits laboratories or conformity assessment bodies to express or evaluate measurement uncertainty as a relative unit (percentage) or unit in which quantity or parameter has been measured. After combining and expanding measurement uncertainty, the uncertainty has been expressed in the same unit for better understanding and more comprehensive guidelines in this research manuscript.

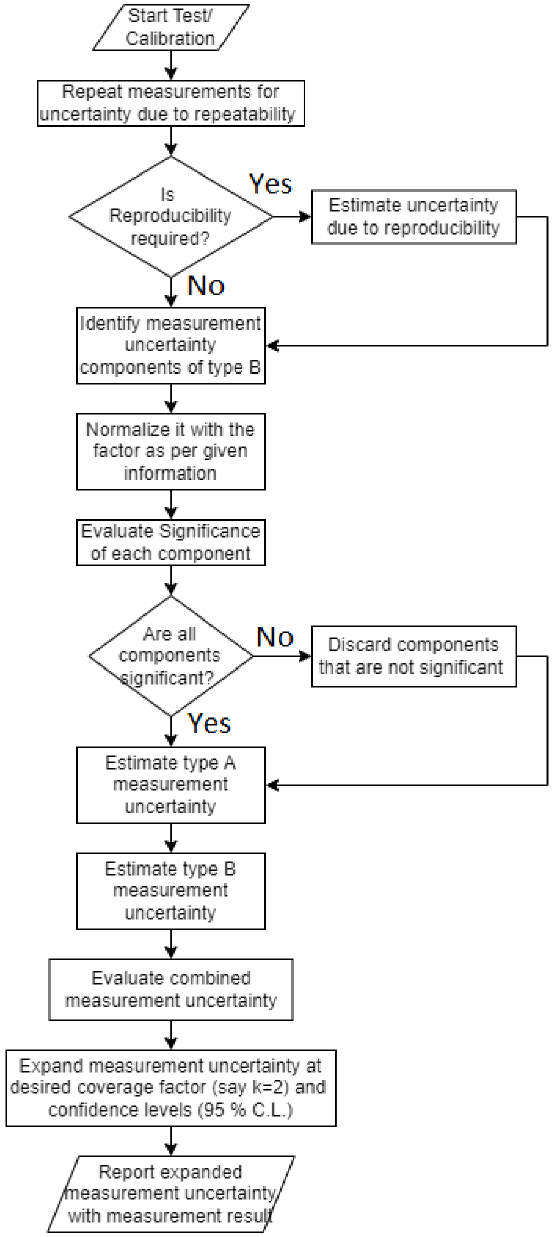

Fig. 5. Flow chart of measurement uncertainty evaluation to ensure metrological traceability of measurement results to System International of units and to conform with the requirements of ISO/ IEC 17025:2017

III. More than 90 % of the authors do not describe or demonstrate how measurement uncertainty can be evaluated. This research article also fills this gap of demonstration in the light of internally acceptable practices.

For ease, and better standing, the whole process of evaluation of measurement uncertainty as per the requirements of ISO/ IEC 17025:2017 international standards is illustrated in the flow chart as shown in Fig. 5. The flow chart summarizes the process of evaluation of measurement uncertainty which is one of the key requirements of international standard implementation and maintenance, to ensure metrological traceability to System International of units and for grant of accreditation for worldwide recognition and acceptance of testing and calibration results.

V. CONCLUSION & FUTURE WORK

Measurement uncertainty estimation is one of the key requirements to be met to get accreditation on the ISO/ IEO 17025:2017 standard. This paper provides a system approach to estimate measurement uncertainty while meeting all the requirements of ISO/ IEC 17025:2017 requirements, GUM approach, estimation of measurement uncertainty by making a budget while considering the significant sources i.e., provides an integrated and simplified approach for estimation of measurement uncertainty. The same approach can be utilized by other testing and calibration laboratories (including chemical, biological, mechanical, nuclear, etc.) with ease. Similarly, uncertainty can be utilized for reporting statements of conformity while making decisions and considering measurement uncertainty. Decision Rules, Risk and measurement uncertainty, and reporting statements of conformities [4] along with opinions and interpretations are not covered under the scope of this publication. This paper also provides a demonstration of the evaluation of measurement uncertainty by addressing a real-world problem that is covered under the ISO/ IEC 17025:2017 accreditation scope of the laboratory.

The current research work provides a thorough guideline and easy footprints for a testing laboratory to evaluate measurement uncertainty as per ISO/ IEC 17025:2017 standard, Guide to Measurement Uncertainty and Policies of International Laboratory Accreditation Cooperation (ILAC), etc. However, quantification of measurement risk i.e., global and/ or local risk(s), consumer and/ or producer risk(s), and making decisions or reporting statements of conformity while considering measurement uncertainty are beyond the scope of this research study.

VI. ACKNOWLEDGMENT

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Inspiring Words from Famous Writers

1) "You can make anything by writing." - C.S. Lewis
2) "Writing is like driving at night in the fog. You can only see as far as your headlights, but you can make the whole trip that way." - E.L. Doctorow
3) "Writing well means never having to say, 'I guess you had to be there.'" - Jef Mallett
4) "The best time for planning a book is while you're doing the dishes." - Agatha Christie
5) "The scariest moment in writing is just before the start." - Stephen King
6) "If there's a book that you want to read, but it hasn't been written yet, then you must write it." - Toni Morrison
7) "No tears in the writer, no tears in the reader. No surprise in the writer, no surprise in the reader." - Robert Frost
8) "Writing is an act of faith, not a trick of grammar." - E.B. White
9) "Fill your paper with the breathings of your heart." - William Wordsworth
10) "To write is human, to edit is divine." - Stephen King