EGAC Guidelines on Calculation of Measurement Uncertainty for Testing Laboratories
PB13L

Prepared by: Testing Laboratories Accreditation Manager
Rasha Toni

Reviewed by: EGAC Accreditation Director
Mohamed Osman

Authorized by: EGAC Executive Director
Hany El Desouki

Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
3.1/May 2016	Quality Department	All	Update clauses and issuing of some documents & Standards

INDEX

1. INTRODUCTION

2. OBJECTIVE

3. SCOPE OF APPLICATION

4. UNCERTAINTY OF MEASUREMENT IN THE STANDARDS

5. DEFINITIONS

6. FACTORS CONTRIBUTING TO UNCERTAINTY OF MEASUREMENT

7. POLICY ON THE IMPLEMENTATION OF UNCERTAINTY CONCEPTS

8. GUIDANCE ON IMPLEMENTATION

9. PROCEDURES FOR THE EVALUATION OF THE RESULT UNCERTAINTY

10. REFERENCES:

EGAC Guidelines on Calculation of Measurement Uncertainty for Testing Laboratories

1. INTRODUCTION

Knowledge of the uncertainty of measurement of testing results is fundamentally important for laboratories, their clients and all institutions using these results for comparative purposes.
Competent laboratories know the performance of their testing methods and the uncertainty associated with the results. Uncertainty of measurement is a very important measure of the quality of a result or a testing method. Other such measures are reproducibility, repeatability, robustness and selectivity.
Clients should be able to make the best possible use of a laboratory's services. An accredited testing laboratory has developed appropriate procedures for collaboration with its clients. Depending on the situation, clients are interested in:

- How reliable the results are and if they can be complemented by a statement about their uncertainty;
- Knowing with what certainty a conformity statement can be made about the tested product;
- Whether the test reports are factually correct, useful and comprehensive for the laboratory's clients.

The reporting of the uncertainty of measurements may be of concern to some clients and public authorities who are not familiar with the uncertainty concept. The level of uncertainty that is acceptable has to be decided on the basis of fitness for purpose, the decision having been reached in consultation with the client. Sometimes a large uncertainty may be acceptable, sometimes a small uncertainty is required.
The understanding of the concept of uncertainty of measurement in testing has considerably changed in recent years. The standards ISO/IEC 17025 Latest version and ISO 15189 Latset version specifies detailed requirements concerning the estimation of uncertainty of measurement and how it should be stated in the test reports.
This document describes how the concept of uncertainty of measurement should be introduced taking into account present state of the art understanding. It is realized that during the course of the implementation of ISO/IEC 17025and ISO 15189: suitable sector-specific guidance will be needed. However, the harmonization of the application of the principles of uncertainty of measurement in testing between different disciplines, industry sectors, medical laboratories, and economies should remain the main goal.

2. OBJECTIVE

This guideline produces a common understanding of the definition and of the procedure for the evaluation and the statement of the uncertainty of a test result. It should rise and support a better comparability of quality in testing.
The notion "Uncertainty of a test result" will be explained and defined as the "result uncertainty". General advice, which should be taken into consideration, will be given to this specific problem and different procedures for the evaluation of the result uncertainty will be pointed out. Procedures specific for technical sectors and related to tests methods, as well as

representative examples for the evaluation and the statement of the result uncertainty, should be elaborated by bodies of respective expert associations or accreditation bodies while taking into consideration this document.
This document aims also at bringing the ideas submitted therein in the discussion about an international standard or guide concerning the evaluation and statement of the *result uncertainty*.

3. SCOPE OF APPLICATION

This document should support the assessors in the statement of the competence of a testing laboratory during its assessment procedure with regard to the evaluation and statement of the result uncertainty. This guideline is also intended for testing laboratories, who want to fulfill the requirements set out in ISO/IEC 17025:2005 and ISO 15189 concerning the evaluation and statement of the result uncertainty. The concepts given should demonstrate to the testing laboratories and customers the principal and practical possibilities for evaluation and statement of the result uncertainty.

4. UNCERTAINTY OF MEASUREMENT IN THE STANDARDS

ISO/IEC 17025:2005 and ISO 15189 allow for a variety of approaches for estimating the uncertainty of measurement in testing:

- Laboratories have to use appropriate methods of evaluation;
- All components that can influence uncertainty of measurement have to be considered, (at least an attempt must be made to identify the sources and if possible estimate them);
- A reasonable estimation based on existing knowledge of the method (including, for example, validation data) shall be made;
- Well-recognized methods specifying limits of the major sources of uncertainty require no special action from the laboratory;
- Accumulated experience of the method and measurement scope may serve as a basis;
- It is not always necessary to use metrologically rigorous and statistically valid calculations.

5. DEFINITIONS

According to the "*International vocabulary of metrology – Basic and general concepts and associated terms*", **Uncertainty of measurement** is a parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. This parameter could be a standard deviation or another part of an interval indicating a certain confidence range.
It is important that one does not only consider the single measurement but also the overall result of a test. In this case uncertainty of measurement embraces all components of a test. Some of them may be obtained by interpreting the statistical spread of results of a series of measurements. Other components have to be worked out from complementary methods (sampling plans, experience).
Testing results should be the best approximation to the true value. Statistical random and systematic factors effects contribute to the uncertainty of measurement of the testing results. If possible, the latter should be eliminated by using for instance correction factors.

Test
It is the technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure.
Examination
Set of operations having the object of determining the value or characteristics of a property
NOTE: In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or measurements.
Test method
It is the specified technical procedure for performing a test.
Post-Examination procedures (Post-analytical Phase)
Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples of the examinations
Pre-Examination procedures (Pre-analytical phase)
steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins
Result of determination
It is the attribute value identified by use of a determination procedure
Note 1: The determination procedure is a procedure for judgment, procedure for observation, procedure for measurement, procedure for calculation or procedure for statistical estimation or a combination of them. The statement is a judgment, observation, measurement, calculation or a combination of them. According to the manner of the determination procedure the result of the determination has the name result of judgment, of observation, of measurement, of calculation or of statistical estimation.
Note 2: In general the result of determination is only complete, if it comprises a statement of an uncertainty of the result."
Uncertainty of the result
It is the estimated amount for the marking of the range of values, within which the reference value is located, in doing so this value may be the true value or the estimate of mean according to the prescription or provision.
Note 3: The uncertainty of a result of a measuring procedure is called uncertainty of measurement. Corresponding designations are possible with respect to other determination procedures as quoted in annotation 1 to the notion ´result of determination´. In the following the notions "test result" and "uncertainty of a test result" will be explained and defined by the use and combination of the previously mentioned definitions.
Test result (Result of a test method)
A test result is an attribute value determined by application of a test method. The attribute value may be of a quantitative or a qualitative nature (quantitative or qualitative test result).
Uncertainties of Results in Testing
Uncertainty of a quantitative test result
It is the estimated amount for the characterization of the range of values (e.g. interval of confidence), within which the reference value is located; in doing so this value may be the true value or the estimate of mean according to the prescription or provision.
In an analogous extension the *result uncertainty* of a qualitative test is defined as follows:
Uncertainty of a qualitative test result
Estimate of the probability value of the incorrectness of the result or estimate of the probability value that the result belongs to any other class except the designated class (the simplest case:

division into two classes).

Uncertainty of measurement

Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

6. FACTORS CONTRIBUTING TO UNCERTAINTY OF MEASUREMENT

Consideration should be given to the different factors which may contribute to the overall uncertainty of a measurement (not all are relevant in all cases). Some examples are given below:

- Definition of the measurand.
- Sampling.
- Transportation, storage and handling of samples.
- Preparation of samples.
- Environmental and measurement conditions.
- The personnel carrying out the tests.
- Variations in the test procedure.
- The measuring instruments.
- Calibration standards or reference materials.
- Software and/or, in general, methods associated with the measurement.
- Uncertainty arising from correction of the measurement results for systematic effects.

7. POLICY ON THE IMPLEMENTATION OF UNCERTAINTY CONCEPTS

EGAC's policy states that, testing laboratories shall report uncertainty estimates where specified by the method, where required by the client and/or where the interpretation of the result could be compromised by a lack of knowledge of the uncertainty. This should at least be the case where testing results have to be compared to other testing results or other numerical values, such as specifications. In any case laboratories shall know the uncertainty associated with a measurement whether it is reported or not.

EGAC considers that a statement on uncertainty of measurement in testing reports where relevant and necessary will be common practice in the future (keeping in mind ISO/IEC 17025 5.10.3.1 c). Refer to EGAC publication-PB05L "EGAC Policy on Measurement Uncertainty for Testing Laboratories".

8. GUIDANCE ON IMPLEMENTATION

The implementation of the concept of uncertainty of measurement has to be in line with implementation of the standard. To start with it is necessary to agree on the following fundamental points:

A. The statement of uncertainty of measurement should contain sufficient information for comparative purposes;
B. The GUM and ISO/IEC 17025: form the basic documents but sector specific interpretations may be needed;
C. Only uncertainty of measurement in quantitative testing is considered for the time being. A strategy on handling results from qualitative testing is yet to be developed by the scientific community;
D. The basic requirement should be either an estimation of the overall uncertainty, or

identification of the major components followed by an attempt to estimate their size and the size of the combined uncertainty;

E. The basis for the estimation of uncertainty of measurement is to use existing knowledge. Existing experimental data should be used (quality control charts, validation, round robin tests, PT, CRM, handbooks etc.);

F. When using a test method there are three cases:
   - When using a standardized test method, which contains guidance to the uncertainty evaluation, testing laboratories are not expected to do more than to follow the uncertainty evaluation procedure as given in the standard;
   - If a standard gives a typical uncertainty of measurement for test results, laboratories are allowed to quote this figure if they can demonstrate full compliance with the test method;
   - If a standard implicitly includes the uncertainty of measurement in the test results there is no further action necessary. Testing laboratories should not be expected to do more than take notice of, and apply the uncertainty-related information given in the standard, i.e. quote the applicable figure, or perform the applicable procedure for uncertainty estimation. Standards specifying test methods should be reviewed concerning estimation and statement of uncertainty of *test results*, and revised accordingly by the standards organization;

G. The required depth of the uncertainty estimations may be different in different technical fields. Factors to be taken into account include:
   - Common sense;
   - Influence of the uncertainty of measurement on the result (appropriateness of the determination);
   - Classification of the degree of rigor in the determination of uncertainty of measurement.

H. In certain cases it can be sufficient to report only the reproducibility;

I. When the estimation of the uncertainty of measurement is limited any report of the uncertainty should make this clear;

J. There should be no development of new guides where usable guides already exist.

9. PROCEDURES FOR THE EVALUATION OF THE RESULT UNCERTAINTY

The *result uncertainty* has to be evaluated independent of the kind of the test result (qualitative or quantitative attribute value). A good, yet easy to follow, guide for that is in the ***References (item 10.H)***

9.1. Quantitative test result

The *result uncertainty* has to be estimated and reported by means of the usual statistical procedures according to the existing guides (see ***References***). Deviations from the concepts given in the guides, which are usual or necessary in some branches or even required by special peculiarities, are admissible (e. g. one sided 3σ-interval in construction engineering, special procedures for the evaluation of the mean and the mean error of the fatigue limit). Suitable procedures can be found in/from ***References*** (item 10).

9.2. Qualitative result

9.2.1. Based on quantitative attribute values

In that case the test consists essentially of keeping limits or threshold values. The test result is a qualitative one, but it is based (among others things) on previously determined quantitative attribute values. This is a case frequently occurring in practice.

The statements of the results uncertainties have to be made alternatively in the following manners:

a. Statement of a probability according to the definition in item 5 of this guideline. The evaluation has to be made on the basis of statistical quantities and analyses (e. g. level of confidence of the quantitative attribute values, the use of operational characteristics in case of an evaluation of random samples).
b. Statement of the corresponding quantitative attribute value in conjunction with the respective uncertainty. The uncertainty of a quantitative attribute value has to be evaluated according to item 9.1 of this guidance.

Applicable methods and procedures can be found in/from ***References*** (item 10).

9.2.2. Based on qualitative attribute values

In that case the test result exclusively consists of qualitative attribute values (attribute property/ ordinal property). The uncertainty of the qualitative test result has to be expressed as a statement of a probability according to the definition in (item 5) of this guideline. Suitable methods for the evaluation of uncertainty are for example procedures from system theory, fault-tree analysis, or suitable statistical methods (see procedures mentioned in the ***References*** of item 10).

10. REFERENCES:

A. ISO "*International vocabulary of metrology – Basic and general concepts and associated terms - VIM* 3rd ed. 2012, ISBN 92-67-10175-1
B. ISO "Guide to the Expression of Uncertainty in Measurement" (GUM): 1993 (revised 1995), ISBN 92-67-10188-9
C. ISO 5725 (Part 1 – 6):1994 Accuracy (trueness and precision) of measurement methods and results (n.b. Part 5 is 1998)
D. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
E. ILAC G17: Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025. (www.ilac.org).
F. CITAC / Eurochem "Guide to Quality in Analytical Chemistry": 2002. (see www.eurachem.org)
G. EA-4/16: "Guidelines on the expression of Uncertainty in Quantitative Testing". (see www.european-accreditation.org)
H. APLAC TC 005:2010 "Interpretation and guidance on the estimation of uncertainty of measurement in testing"; Asian Pacific Lab. Acc. Cooperation. (see www.aplac.org)
I. UKAS LAB 34: 2002: The Expression of Uncertainty in EMC Testing; United Kingdom Accreditation Service. (see www.ukas.org)
J. Traceability and Uncertainty of Measurement for Medical Laboratories, Quality Management Program – Laboratory Services (QMP–LS), Ontario Laboratory Accreditation Division (OLA).

(see http://www.qmpls.org/ola/ola_educational.html#traceability)