

EGAC Technical Guidelines for Calibration and Testing Laboratories PB15TCL

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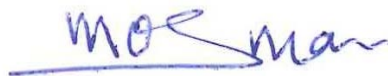


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INDEX

Part I . Guide for Measurement and Calibration Systems

Part II. Policy on Measurement of Uncertainty for Calibration Laboratories Scope

Part III. Policy on Measurement Uncertainty for Testing Labs

Part IV. Guidelines on Calculation of Measurement Uncertainty for Testing Labs

Part V. Applicable Guidelines

Part I. Guide for Measurement and Calibration Systems

1. Introduction

EGAC requirements for the competence of calibration and testing laboratories (ISO/IEC 17025:2017), contains requirements for measurement traceability and calibration. This requirements document has been prepared to ensure that laboratories comply with both the measurement and traceability requirements of ISO/IEC 17025:2017 and also the relevant requirements for calibration and testing equipment.

This document also applies to Inspection Bodies in regard of ISO/IEC 17020:2012 It also applies as a guide for the Certification Bodies in their audit against the relevant standard (e.g. ISO 9001:2015).

The requirements of this document shall be met by all EGAC accredited calibration laboratories and testing laboratories when calibrating their own equipment at an external laboratory, or performing in-house calibrations.

For the purposes of this Appendix, use the terminology of ISO/IEC 17025:2017.

General

The Laboratory shall have a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards and measuring/test equipment used in the performance of accredited calibrations and tests. Measurements performed by the Laboratory and any sub-contractors that it uses shall be covered by this system.

The system shall be designed to ensure that the Laboratory has the necessary procedures and resources to carry out calibrations and tests and supporting measurements within the required time-scales and designated limits. The Laboratory shall set these limits and they shall be consistent with the Laboratory's schedule of accreditation, the relevant calibration or test specification and/or the requirements of the Client. The system shall also ensure that any measuring and test equipment, and any reference material used, performs as intended.

The system shall include arrangements to prevent errors that are outside specified limits of permissible error, and to provide for rapid detection of deficiencies and immediate corrective action as required by ISO/IEC 17025:2017.

The policies and procedures for this system shall be documented in the Laboratory's quality manual and associated quality documentation. They shall clearly define the responsibilities and duties of each member of staff involved in the activities listed in one of this document.

The Quality Manager shall ensure that the measurement and calibration system used by the Laboratory is included in the program for quality system audits, and that the results of such audits are evaluated at the Laboratory's periodic review of the quality system.

Laboratory staff shall have the qualifications, training, experience and skill to perform the tasks referred to in this document. Training shall be maintained up-to-date.

As required by ISO/IEC 17025 :2017, the Laboratory shall maintain records of training, competency, and staff authorized to use equipment and reference materials or to perform calibrations, tests, in-house calibrations and checks.

Planning and the selection of equipment/reference.

The Laboratory shall review the requirements of the Client, and of any relevant technical specification, before commencing calibration or testing. If the work is within the capability of the Laboratory it shall, before commencing, establish a program to ensure that measurement standards/reference materials, measuring/test equipment and environmental conditions necessary for the performance of the work are available to achieve the accuracy, stability, range and resolution required. The Laboratory shall also ensure that it has the staff resources needed.

The Laboratory shall ensure that all items of measuring equipment needed for the work, including reference measurement standards, meet the requirements of ISO/IEC 17025 :2017

The Laboratory shall also ensure that, where required by EGAC, it uses reference materials as measurement standards to assist in the estimation of uncertainties of measurement, to calibrate measuring and test equipment, to monitor laboratory performance and to validate methods. Where required, reference materials shall also be used as transfer standards to compare methods.

Wherever possible, the Laboratory should use both primary pure reference materials and reference materials that have matrices matching those of the calibration/test items to take account of matrix effects.

The Laboratory shall also, wherever possible, use reference materials that have been certified as having been produced and characterized in a technically valid manner. The use of organizations operating to the ISO 9000 series of standards for the production of reference materials, which also perform their analysis or testing activities in accordance with ISO/IEC 17025:2017, would provide assurance of the quality of reference materials. The certificate shall, wherever possible, also provide evidence of traceability to national or international standards of measurement, or to national or international standard reference materials.

Where a certified reference material is not available, reference materials with suitable properties and stability shall be used. The properties required of these materials shall, wherever possible, be characterized by acceptable procedures such as those as recommended in ISO Guide 35:2017, Reference materials - General and statistical principles for certification. These procedures may include: analysis/testing by a definitive method; analysis/testing by a number of methods based on different physical or chemical principles, or analysis/testing by a number of laboratories using either the same or different methods.

Where the Laboratory prepares standards from materials of known properties, or purchases uncertified standards such as chemical standards, the Laboratory shall verify that the standards are of acceptable quality and suitable for the purpose. Standards should be purchased, where possible, from suppliers as detailed in 3.5 of this document.

Uncertainty of measurement

The Laboratory is required to produce an estimate of the uncertainty of its measurements, to include the estimation of uncertainty in its methods and procedures for calibration and testing, and to report the uncertainty of measurement in calibration certificates and in test certificates and test reports, where relevant.

Estimates of uncertainty of measurement shall take into account all significant identified uncertainties in the measurement and testing processes, including those attributable to measuring equipment, reference measurement standards (including material used as a reference standard), staff using or operating equipment, measurement procedures, sampling and environmental conditions.

In estimating uncertainties of measurement, the Laboratory shall take account of data obtained from internal quality control schemes and other relevant sources, (see ISO/IEC 17025:2017). The Laboratory shall also ensure that any requirements for the estimation of uncertainty and for the determination of compliance with specified requirements as stated in the relevant EGAC publications, are complied with at all times.

In setting the acceptance limits for the calibration of measuring and testing equipment, the Laboratory shall ensure that the limits chosen allow for the conditions under which the equipment or reference material is to be used. Such limits may be significantly different to those applicable during the calibration process.

Calibration procedures

The Laboratory shall use methods and procedures for the calibration of measuring equipment, reference measurement standards (including reference materials) and test equipment used in calibration and testing laboratories that comply with the requirements of ISO/IEC 17025:2017. The methods and procedures shall include, but not be limited to:

- Identification of the instrument, gauge or test equipment, or group of such items to which the procedure is applicable;
- Identification of all measurement standards/reference materials and associated equipment used to perform the calibration;
- the procedures to be adopted for handling, transporting, storing and using measuring equipment and reference materials used for calibration, including details of shelf life and measures to prevent contamination or loss of determinant;
- the procedures to be adopted for handling, transporting, storing and preparing items for calibration;
- the environmental conditions that must be used, the limits applicable, the procedure for any corrections that may have to be made as a result of the environmental conditions and, where relevant, the minimum period of stabilization before calibration;
- the method or procedure for calibration in the form of written instructions and diagrams where appropriate;
- details of the measurement or calibration data to be recorded and the method for presentation and analysis of this data;
- the limits of acceptance for the calibration data for the item or type of item being calibrated;
- the estimation of the uncertainty of measurement of the calibration process;
- the procedures to be adopted for selecting calibration intervals when the equipment/reference material is being used by the Laboratory to perform calibrations or tests;
- the procedures for checking equipment and reference materials between calibrations;

- an identification number, number of pages, date of issue and name of person authorizing issue and use of the procedure.

In its procedures for estimating the uncertainty of the calibration process, the Laboratory shall take into account the cumulative effect of the uncertainties of measurement of each successive stage in the chain of calibrations for each measurement standard and item of equipment calibrated. The Laboratory shall take action when the total uncertainty of measurement is such that it significantly compromises its ability to make measurements within the limits of permissible error.

Where the Laboratory uses the services of an external organization to calibrate measuring and test equipment, the requirements of ISO/IEC 17025:2017 shall be met. If the services of a EGAC accredited calibration laboratory are not available, and after considering EGAC's policy on traceability PB04L, the Laboratory shall ensure that the calibration certificate provided contains the following information:

- An unambiguous identification of the item calibrated;
- A description of the measurement standard(s) used and its calibration status;
- A statement indicating how traceability to national standards has been achieved;
- The method of calibration;
- A statement of compliance with any relevant specification;
- The calibration results;
- The uncertainty of measurement;
- The environmental conditions, where relevant;
- The date of calibration;
- The signature of the person under whose authority the certificate was issued;
- The name and address of the issuing organization and the date of the certificate.

Records

The Laboratory shall maintain records for each item of measuring equipment, including reference measurement standards and reference material standards and test equipment, used in the performance of calibrations or tests. The records shall show, either through in-house documentation or calibration certificates from external organizations, that each calibration in the chain of traceability has been carried out.

The Laboratory shall ensure that the records contain detailed information of the equipment/reference material used for calibrations, and that there is also a full and up-to-date history of the calibration of this equipment/reference material (see ISO/IEC 17025:2017).

The records shall provide sufficient information to demonstrate the measurement capability and traceability of each item of measuring equipment and the range of use of each reference material, its shelf life and required storage conditions.

Each record shall include or refer to:

- The date on which each calibration was performed;
- The calibration results obtained after and, where relevant, before any adjustment and repair;
- The specified calibration interval;
- Reference to the calibration method or procedure used and any relevant standard or specification;
- The specified limits of permissible error;
- Calibration certificates, (bearing the EGAC logo), from EGAC accredited calibration laboratories of appropriate measurement capability, from the Laboratory holding the national standard for the reference measurement standards used, or from a laboratory meeting the requirements for traceability specified in the EA document EA 5/01, Traceability of Measurement;
- Certificates, or other documentation, for all reference materials used for calibration, providing evidence of characterization of the material, and evidence of traceability to national or international standards of measurement, or to national or international standard reference materials;
- The environmental conditions at the time of calibration and the corrections made, where necessary, for such conditions;
- A statement of the uncertainties of measurement involved in the calibration and of their cumulative effect;
- Any design or performance specifications met;
- Name of persons performing the calibration and checking the results;
- Any limitations in use resulting from the calibration data obtained;
- Details of any maintenance carried out in accordance with the requirements of ISO/IEC 17025:2017 and of any servicing, adjustment, repair or modification, particularly at the time of calibration.

Similar records, as appropriate, shall be maintained for any checks carried out on equipment or reference materials between calibrations.

Calibration intervals

The Laboratory shall have documented criteria for the selection of calibration intervals for all measuring and test equipment used.

Reference measurement standards shall be calibrated at lab approved intervals. Reference materials shall be checked for deterioration and, if necessary, replaced.

All other measuring and test equipment should be calibrated see the following

- the requirements of any relevant standard specifications for the measurements /tests involved;

- the recommendation of the equipment manufacturer;
- the type and stability of the equipment;
- the extent and severity of use;
- the influence of the environmental conditions (eg; temperature, humidity, vibration and dust);
- the accuracy of measurement needed for the calibration or test concerned;
- trends determined by examination of records of previous calibrations;
- evidence obtained from service and maintenance records;
- any known or observed tendency for the equipment to exhibit wear or to drift in performance;
- the frequency of, and information from, in-house checks, using known standards.

When selecting intervals for the maintenance and calibration of measuring and test equipment, the Laboratory shall take into account all of the relevant factors in 7.3 of this document. It shall do so in such a way as to minimize the risk that the results of any calibrations/tests performed between calibrations may be affected because some of the measuring or test equipment used has failed to perform to specified requirements. For certain types of measurement, such as chemical analysis using chromatographs or spectrometers, calibration is necessary as part of normal operations using appropriate chemicals or certified reference materials.

When selecting intervals for the maintenance and calibration of new measuring and test equipment, the Laboratory shall ensure that, where only limited information is available, the interval initially selected is shorter than the expected eventual interval. The interval may then be adjusted at a later date as a result of information obtained from further calibrations and checks.

The Laboratory shall have procedures for the periodic review of maintenance and calibration intervals to take into account the variation in the type, frequency and conditions of use of any measuring or test equipment. When the performance of measuring and test equipment deviates from the specified requirements, the requirements of ISO/IEC 17025 shall be met and the maintenance and calibration intervals shall be reviewed immediately and modified where necessary. Such equipment shall not be returned to service until the reason for the deviation has been eliminated and the equipment has been re-calibrated.

The Laboratory shall shorten the intervals between calibrations (and maintenance where appropriate) when the results of preceding calibrations or intermediate checks indicate that the measuring and test equipment is no longer performing in accordance with the specified requirements.

The Laboratory shall increase the interval between calibrations only when the results of preceding calibrations, and any intermediate checks or quality control data, indicate that the performance of the measuring and test equipment is likely to remain within the specified requirements throughout the new period between calibrations.

Sealing of calibrated equipment

The Laboratory shall have procedures to prevent adjustable devices on measuring and test equipment (other than those intended for the user), whose setting affects the performance, being altered by unauthorized staff. Where seals (labels, solder, wire, paint etc) are used, they shall be designed to indicate clearly when unauthorized adjustment has been made. The procedures shall ensure that, where a seal has been damaged or broken, the requirements of ISO/IEC 17025:2017 are met.

Labeling of calibrated equipment and reference materials

The requirements for labeling, codifying, or otherwise identifying the status of calibration of measuring and test equipment used by the Laboratory are given in ISO/IEC 17025:2017

When equipment has been calibrated, or reference materials certified by an external organization, the Laboratory shall ensure that the equipment/reference material is fit for use, is labeled, and that it has a certificate (or notification, where a certificate might be delayed) to indicate the results of the calibration.

Labels, or other methods of codifying or identifying the equipment/reference material, shall, as well as indicating calibration status, clearly indicate to the staff using the equipment/reference material, any limitations of the calibration and/or any restrictions on the use of the equipment/reference material.

Any item of measuring or test equipment, or any reference material, that is not calibrated, shall not be used for accredited calibration/testing. If there is any possibility that staff might at any time use such equipment or material for accredited calibration/testing before it has been calibrated, it shall be appropriately labeled and, if possible, segregated.

Part II. EGAC Policy on Measurement of Uncertainty for Calibration Laboratories

Scope

This part defines the policies for calibration laboratories (internal or external), for the estimation of measurement uncertainty.

The concept of measurement uncertainty is relatively new for testing laboratories. Therefore practical means to implement the measurement uncertainty requirements found in ISO/IEC 17025 :2017 are necessary.

The terms “calibration laboratory” and “calibration provider” as used in this document refer to both internal labs and external providers including calibration programs within testing labs.

Estimation of Measurement Uncertainty for Calibration Laboratory

Estimation of measurement uncertainty is a crucial part of ensuring traceability. Where it is possible to calculate uncertainty, the calculations must be performed in accordance with ILAC P14 Latest version and the ISO Guide to the Expression of Uncertainty in Measurement (also known as GUM). This document can be obtained as an ISO document, or as an OIML document [OIML G 1-100].

Expanded uncertainties are typically reported in two significant digits using a coverage factor of $k = 2$ to approximate the 95 percent level of confidence.

Calibration certificates must provide statements of the measurement results and the associated uncertainty. Such statements must include the coverage factor and confidence level.

The laboratory must use appropriate methods to develop their uncertainty estimates. The method used to develop the uncertainty estimate must be defined and documented. All readings, observations, calculations, and derived data must be maintained.

Developing an uncertainty estimate generally requires statistical analysis of experimental data. Laboratories shall analyze the data in accordance with good statistical practice and methodology.

Sometimes, statistical studies cannot be performed for various reasons. In cases where statistical studies cannot be performed, an estimation of uncertainties is still required. See the Guide to the Expression of Uncertainty in Measurement for specific guidance on developing uncertainty budgets in such cases.

Measurement Uncertainties for On-Site Calibrations in the Scopes of Accreditation

It is important that the scopes of accredited laboratories that perform calibrations on customers' sites do not contain potentially misleading values for on-site capabilities. The following points shall be observed:

EGAC staff shall ensure that Best Uncertainty is clearly defined on scopes of accreditation. This may be accomplished with the following footnote:

“Best uncertainty (was referred to as best measurement capability BMC and now as calibration and measurement capability CMC, see item 4 below) is the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation when performing more or less routine calibrations of nearly ideal measurement standards or of nearly ideal measuring instruments. Best uncertainties represent expanded uncertainties expressed at approximately the 95 % level of confidence, usually using a coverage factor of $k = 2$. The measurement uncertainty of a specific calibration performed by the laboratory may be greater than the best uncertainty due to the behavior of the customer's device, to the environment (if the calibration is performed in the field), and to influences from the circumstances of the specific calibration.”

In addition, when best uncertainty is cited for a calibration offered in the field, this uncertainty should be further qualified to emphasize that uncertainties obtained in the field are typically larger than uncertainties obtained in a stable laboratory environment. This may be accomplished with the following footnote:

“On-site calibration service is available for this calibration. Best uncertainty is for calibration at the laboratory's permanent facility; as noted above, uncertainties obtained in the field will typically be larger than the best uncertainty.”

However, it is often easier for the laboratory to specify environment tolerances outside which no work will be done and to base best uncertainty estimates on those tolerances. The assessor should check these tolerances to see that they are reasonable and consistent with equipment specifications. In these cases, further qualification of the best uncertainty is unnecessary.

EGAC assessors shall ensure that The scope of an accredited laboratory clearly indicates which parameters are offered on-site. The laboratory that performs calibrations on a customer's site maintains a full list of all the equipment that is transported. For each parameter, the laboratory shall define the best uncertainty that it can achieve with each type of transported equipment.

Moving To Calibration and Measurement Capability (CMC)

Background:

Metrological traceability is disseminated to the market by accredited calibration laboratories via the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and by National Metrology Institutes (NMIs- like NIS in Egypt) under the Comité International des Poids et Mesures (CIPM) MRA. This traceability provides reliability in measurements around the world.

Currently, the services provided by many accredited calibration laboratories are described using the term “Best Measurement Capability” (BMC). This terminology is in widespread use in accreditation programs around the world.

NMIs (NIS in Egypt) have a similar description of the services provided to their customers; but use the term “Calibration and Measurement Capability” (CMC).

Change of terminology

In order to address this inconsistency in terminology the Bureau International des Poids et Mesures (BIPM) and the Regional Metrology Organizations (RMOs- like AFRMET in Africa) have, in cooperation with ILAC and the Regional (Accreditation) Cooperation Bodies (like AFRAC in Africa and EA in EU), arrived at the following conclusion:

"In the context of the CIPM MRA and ILAC Arrangement, and in relation to the CIPM-ILAC Common Statement, the following shared definition is agreed upon:

CMC is a calibration and measurement capability available to customers under normal conditions:

- (a) as published in the BIPM key comparison database (KCDB) of the CIPM MRA; or
- (b) as described in the laboratory’s scope of accreditation granted by a signatory to the ILAC Arrangement.”

As a consequence, this means that BMC and CMC shall be considered equal by accreditation bodies (like EGAC in Egypt), laboratories, their customers, the market and regulators. (The definitions used by the NMIs and the accreditation community were already aligned, but the terminology used to describe them was not.)

ILAC has therefore decided to make a change in terminology and in the future all references to BMC will be changed to CMC (see ILAC 2009-08-20 BMC to CMC Circular).

Implications for accredited calibration laboratories

This change in terminology does not mean your current uncertainties need to be re-calculated. The current uncertainty of measurement quoted on your calibration certificates or reports will remain unchanged as a result of this change in terminology. If, however, a calibration laboratory currently use the term BMC on its calibration certificates, marketing material or documentation this will need to be changed to CMC. (Note: The term ‘uncertainty of measurement’ remains unchanged.)

All EGAC accredited laboratories should be using the CMC terminology. The concept of “using all the contributions from best existing devices under calibration in the calculation of the measurement uncertainty budget of the laboratory” is already used by the laboratories, reviewed by EGAC assessors, and displayed in the laboratories’ scopes on EGAC’s website. A workshop and awareness for both the laboratories and EGAC assessors were conducted on June 2009 to

explain the difference between BMC & CMC and instruct the laboratories to use the CMC terminology. The use of the CMC terminology was conducted and reviewed by EGAC ever since. The Calibration laboratories should make this clear to their customers according to this document.

Greater Harmonization

The intention is to achieve world-wide harmonization of terminology in the dissemination of metrological traceability. Progress towards this goal and also providing clarity in the market place will be greatly assisted by accredited calibration laboratories and NMIs using the same terminology.

Whilst this terminology change will improve the dissemination of metrological traceability through-out the world, the on-going technical issues relating to measurement capability (eg contribution from device under test to the measurement uncertainty) continue to be addressed in-conjunction with BIPM. Future policy documents on these issues will be published in due course.

Part III. EGAC Policy on Measurement Uncertainty for Testing Labs.

Introduction

EGAC policy on measurement uncertainty allows testing laboratories enough time to upgrade their capabilities towards estimation of measurement uncertainty through training of their staff members in addition to development and application of procedures dedicated for measurement uncertainty.

EGAC Policy On Testing Measurement Uncertainty

EGAC applicant and accredited testing laboratories can satisfy the requirements of ISO/IEC:2017 by submitting a documented implementation plan with their 30-day corrective action response. The implementation plan must contain the steps the laboratory will take to write and implement their procedures for estimating measurement uncertainty prior to the lab's next on-site surveillance (for new labs) or annual review (for renewal labs).

EGAC Policy On The Implementation Of The Concept Of Uncertainty

Uncertainty of measurement has to be taken into account when testing results are compared with each other or against specifications. An understanding of the concept of uncertainty of measurement is important in order to be able to choose testing methods that are fit for purpose. The uncertainty of measurement should be consistent with the given requirements.

The economic aspects related to the methods have to be taken into consideration. According to ISO/IEC 17025:2017, testing laboratories must 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 should know and document the uncertainty associated with a measurement whether it is reported or not. When a laboratory does not document its measurement uncertainty, it will have to justify that in writing, especially testing activities in areas where an estimation of measurement uncertainty based on statistical validation data is relevant.

As a general rule, the implementation of the concept of uncertainty of measurement should be in line with the implementation of ISO/IEC 17025 :2017 EGAC may agree on exceptions for technical areas where uncertainty of measurement is difficult to apply.

For those areas EGAC will promote and support the development of guidance documents and worked examples.

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 :2017). Some tests are purely qualitative and consideration is still being given as to how uncertainty of measurement applies in such cases. One approach is to estimate the probability of false positive or false negative results. The issue of estimating uncertainty of measurement in regard to qualitative results is recognized as an area in which further guidance is required. EGAC will, as a first step, concentrate on the introduction of uncertainty of measurement for quantitative test results.

Procedure

A. The assessor(s) must identify and document in the method review matrix the applicable measurement uncertainty category (i – iii below) for the tests identified on the lab's proposed scope of accreditation:

- i. Qualitative tests for which measurement uncertainty budgets will not be required.
- ii. Well-recognized test methods that specify limits to the values of the major sources of uncertainty of measurement and specify the form of presentation of calculated results. In such cases, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions. (ISO/IEC 17025:2017)
- iii. Test methods that require uncertainty estimates calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement".

Note that in order to determine compliance with a specification limit (ISO/IEC 17025:2017) uncertainty must be estimated for Category III tests.

B. Objective evidence of compliance, including the procedure for estimating measurement uncertainty, the resulting documented uncertainty estimates, the trained personnel on measurement uncertainty, and supporting information, where relevant, will be reviewed before the assessment & verified in accordance with the following schedule:

- For new laboratories, compliance will be verified by the assessor during the laboratory's on-site assessment.
- For renewal labs, compliance will be verified by the assessor during the annual review process (or sooner at the laboratory's request).

This policy will be updated periodically by EGAC. Additional guidance, including examples of methods that fit the categories (I-III) listed above, will be developed as labs are assessed and information is collected.

Applicable ISO/IEC 17025 clauses on measurement uncertainty for testing labs:

ISO/IEC 17025,

Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

Note 1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as the requirements of the test method, the requirements of the client, and the existence of narrow limits on which decisions on conformance to a specification are based.

Note 2: In those cases where a well-recognized test method specifies limits to the values of the 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.

When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

Note 1: Sources of uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

Note 2: The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating measurement uncertainty.

Note 3: For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement.

[Please contact EGAC to obtain reference documents that describe acceptable methods of estimating measurement uncertainty.]

[Test reports shall, where necessary for the interpretation of the test results, include the following:]

Where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instructions so requires, or when the uncertainty affects compliance to a specification limit.

Part IV. EGAC guidelines on calculation of measurement uncertainty for testing labs.

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 :2017 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 17025:2017 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.

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.

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 17025:2017 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.

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 measure and. 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.

UNCERTAINTY OF MEASUREMENT IN THE STANDARDS

ISO/IEC 17025:2017 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.

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.

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".

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:

- The statement of uncertainty of measurement should contain sufficient information for comparative purposes;

- The GUM and ISO/IEC 17025: form the basic documents but sector specific interpretations may be needed;
- 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;
- 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;
- 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.);
- 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;
- 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.
- In certain cases it can be sufficient to report only the reproducibility;
- When the estimation of the uncertainty of measurement is limited any report of the uncertainty should make this clear;
- There should be no development of new guides where usable guides already exist.

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)*

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).

Qualitative result

a. 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).

b. 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).

Part V. Applicable Guidelines

An accredited laboratory working in the Calibration field should endeavor to use the following international standards as applicable in the specific field:

General Metrology Publications

- **From OIML organization site** (<http://www.oiml.org/publications>)
 - Evaluation of measurement data – Guide to the expression of uncertainty in measurement (OIML G 1-100) which is the same as (ISO GUM-Guide to the expression of uncertainty in measurement)

- Evaluation of measurement data - Supplement 1 to the "Guide to the expression of uncertainty in measurement" - Propagation of distributions using a Monte Carlo method (OIML G 1-101)
- International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM) (OIML V 2 – 200) same as (ISO VIM).
- **From EURAMET organization site** (<http://www.euramet.org/index.php?id=calibration-guides>) **or from EA (European co-operation for Accreditation)** (<http://www.european-accreditation.org/content/publications/pub.htm>)
 - Traceability of Measuring and Test Equipment to National Standards (EAL-G12)
 - Expression of the Uncertainty of Measurement in Calibration (EA-4/02)
- **From NIST organization site** (<http://physics.nist.gov/cuu/Uncertainty/basic.html>) (<http://physics.nist.gov/cuu/Units/index.html>)
 - Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results (NIST Technical Note 1297)
 - The Use of the International System of Units (SI)
- **From NPL organization site** (http://publications.npl.co.uk/npl_web/pdf/mgpg11.pdf) (http://publications.npl.co.uk/npl_web/pdf/mgpg8.pdf)
 - A beginner's guide to uncertainty in measurement (Guide No. 11)
 - Human factors in measurement and calibrations (Guide No. 8)
- **From A2LA Accreditation Body site** (http://www.a2la.org/guidance/est_mu_testing.pdf)
 - Estimation of Measurement Uncertainty in Testing (A2LA G104)

Publications in the field of Dimensional Metrology:

- **From EOS organization site** (<http://www.eos.org.eg/Public/ar-eg/Egyptian+Standards>)
 - ISO Geometrical Product Specifications (GPS) - Acceptance and re-verification tests for coordinate measuring machines (CMM) (ISO 10360-1 to 6)
- **From EURAMET organization site** (<http://www.euramet.org/index.php?id=calibration-guides>)
 - Coordinate Measuring Machine Calibration (EAL-G17)
 - Calibration of Gauge Block Comparators (EURAMET/cg-02)
 - Extent of Calibration for Cylindrical Diameter Standards (EURAMET/cg-06)
 - Determination of Pitch Diameter of Parallel Thread Gauges by Mechanical Probing (EURAMET/cg-10)
 - Calibration of Stylus Instruments for Measuring Surface Roughness (EAL-G20)
- **From NPL organization site** (http://publications.npl.co.uk/npl_web/pdf/mgpg43.pdf) (http://publications.npl.co.uk/npl_web/pdf/mgpg42.pdf) (http://publications.npl.co.uk/npl_web/pdf/mgpg41.pdf) (http://publications.npl.co.uk/npl_web/pdf/mgpg40.pdf) (http://publications.npl.co.uk/npl_web/pdf/mgpg39.pdf)

- CMM probing (Guide No. 43)
- CMM verification (Guide No. 42)
- CMM measurement strategies (Guide No. 41)
- Calipers and micrometers (Guide No. 40)
- Dimensional measurement using vision systems (Guide No. 39)
- From the UKAS Accreditation Body site (<http://www.ukas.com/library/Technical-Information/Pubs-Technical-Articles/Pubs-List/LAB36%20Edition%203.pdf>)
 - Laboratory Accommodation and Environment in the Measurement of Length, Angle and Form (UKAS-LAB 36)
 - Publications in the field of Temperature Metrology:
- From BIPM organization site (www.bipm.org)
 - Supplementary information for the international temperature scale 1990 (ITS-90)
- From OIML organization site (<http://www.oiml.org/publications>)
 - Liquid-in-glass thermometers, (OIML R 133)
 - Tungsten ribbon lamps for the calibration of radiation thermometers, (OIML R 48)
 - Glass capillary viscometers for the measurement of kinematic viscosity - Verification method, (OIML R 69)
- From EURAMET organization site (<http://www.euramet.org/index.php?id=calibration-guides>)
 - Calibration of Thermocouples (EURAMET/cg-08)
 - Guidelines on the calibration of Temperature Indicators and Simulators by Electrical Simulation and Measurement (EURAMET/cg-11)
 - Calibration of Temperature Block Calibrators (EURAMET/cg-13)
 - Calibration of Thermocouples (EAL-G31)
- From NIST organization site (<http://ts.nist.gov/MeasurementServices/Calibrations>)
 - The Calibration of Thermocouple and Thermocouple Materials, NIST Spec. Publ. 250-35
 - Liquid-in-Glass Thermometer Calibration Service , NIST Spec. Publ. 250-23
 - Platinum Resistance Thermometer Calibrations , NIST Spec. Publ. 250-22
 - Radiance Temperature Calibrations, NIST Spec. Publ. 250-43
- From DKD Accreditation Body site (<http://www.dkd.eu/inhalt.php?id=28>)
(choose English language)
 - Calibration of Resistance Thermometers (DKD-R 5-1)
 - Publications in the field of Pressure Metrology:
- From EURAMET organization site (<http://www.euramet.org/index.php?id=calibration-guides>)
 - Guidelines on the Calibration of Electromechanical Manometers (EURAMET/cg-17)
 - Calibration of Pressure Balances (EA-4/17)
- From OIML organization site (<http://www.oiml.org/publications>)
 - Barometers (OIML R97)
 - Indicating and recording Pressure Gauges, Vacuum Gauges and Pressure-Vacuum Gauges with Elastic Sensing Elements (Ordinary Instruments) (OIML R101)

- Pressure Gauges and Vacuum Gauges with Elastic Sensing Elements (Standard Instruments) (OIML R109)
- From DKD Accreditation Body site (<http://www.dkd.eu/inhalt.php?id=28>) (choose English language)
 - Calibration of Pressure Gauges (DKD-R 6-1)
 - Calibration of Measuring Devices for Vacuum (DKD-R 6-2 part1 to 5)
 - Publications in the field of Force Metrology:
- From EURAMET organization site (<http://www.euramet.org/index.php?id=calibration-guides>)
 - Guidelines on the Calibration of Static Torque Measuring Devices (EURAMET/cg-14)
 - Guidelines on the Estimation of Uncertainty in Hardness Measurements (EURAMET/cg-16)
 - Guidelines on the Calibration of Non-automatic Weighing Instruments (EURAMET/cg-18)
 - Uncertainty of Calibration Results in Force Measurements (EAL-G22)
- From NPL organization site (http://publications.npl.co.uk/npl_web/pdf/mgpg71.pdf)
(http://publications.npl.co.uk/npl_web/pdf/mgpg20.pdf)
(http://publications.npl.co.uk/npl_web/pdf/mgpg107.pdf)
 - The measurement of mass and weight (Guide No. 71)
 - Mechanical testing of hard metals (Guide No. 20)
 - Guide to the calibration and testing of torque transducers (Guide No. 107)
 - Publications in the field of Electrical Metrology (DC & Low Frequency):
- From EURAMET organization site (<http://www.euramet.org/index.php?id=calibration-guides>)
 - Measurement and Generation of Small AC Voltages with Inductive Voltage Dividers (EURAMET/cg-09)
 - Guidelines on the Calibration of Digital Millimeters (EURAMET/cg-15)
 - Calibration of Oscilloscopes (EAL-G30)
 - Publications in the field of Electrical Metrology (Microwave & High Frequency):
- From EURAMET organization site (<http://www.euramet.org/index.php?id=calibration-guides>)
 - Guidelines on the Evaluation of Vector Network Analyzers (VNA) (EURAMET/cg-12)
- From NPL organization site (http://publications.npl.co.uk/npl_web/pdf/mgpg68.pdf)
 - Phase Noise measurement (Guide No. 68)

References:

- ILAC 2009-08-20_BMC to CMC Circular is available from <http://www.ilac.org/publicationsandresources.html>
- Calibration and Measurement Capabilities – A Paper by the Joint BIPM/ILAC working group available from <http://www.ilac.org/publicationsandresources.html>
- PB06G “EGAC Policy on Measurement Uncertainty for Calibration Laboratories”. <http://www.egac.gov.eg/www/InfoCenter.aspx?InfoCenterTypeID=2>

Part VI. Guidelines Concerning the Validity of Calibration Certificates

General

This guidelines defines for legal purposes the circumstances under which the Calibration Certificates issued by EGAC accredited calibration laboratories become invalid.

ISO/IEC 17025:2017 clause 7.8.4.3 (A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.) In spite of the above requirement, circumstances may exist where the validity of a calibration certificate is curtailed.

Expiry date: The expiry date of a Calibration Certificate is the date after which it is no longer valid. (Reference should be made to ILAC-G24 Latest version calibration interval)

Validity

A calibration certificate issued by a EGAC accredited calibration laboratory is a legal document. Under certain circumstances it becomes immediately invalid. These include:

If the instrument or gauge is tampered with, adjusted or abused in any way;

If accidentally dropped or exposed to excessive shock of any kind (mechanical, thermal, etc.)

If it is repaired;

When an expiry date included on the certificate of calibration or calibration label, in terms of ISO/IEC 17025 requirements, has been passed.