Requirements on test laboratories and accreditation bodies concerning the estimation of the measurement uncertainty according to ISO/IEC 17025 (5.4.6 / 5.10.3) (version November 2001) *)

1) Introduction

Competent laboratories that work in accordance with DIN EN ISO/IEC 17025 are required to dispose of a procedure for the determination of the measurement uncertainty of the test results provided by the laboratory. Concerning the subject of measurement uncertainty, a number of guidelines and technical regulations exists, which in regard to the treatment of measurement uncertainties for the area of chemical analyses are only partly harmonised with each other and which sometimes address only specific or individual aspects of this problem. Therefore, the requirements for a mutual understanding and harmonisation are quite high on a national as well as an international basis.

The foundation for the estimation of the measurement uncertainty is provided by the “Guide to the Expression of Uncertainty in Measurement”, “GUM” [1]. A first step in the direction of a harmonised modus operandi for the determination and indication of measurement uncertainties is the position paper [2] prepared by PLG (Permanent Liaison Group of EA, EUROLAB and EURACHEM) with regard to the introduction of a measurement uncertainty concept in connection with the introduction of ISO/IEC 17025. The position paper is supported by both EA and ILAC. Good instructions for laboratories on how to handle measurement uncertainties are also provided by the document "A2LA Interim Policy on Measurement Uncertainty for Testing Laboratories" of August 2000 [3] published by the American accreditation body A2LA.

The present document provides the test laboratories and customers with basic and practical possibilities for the determination and indication of the measurement uncertainty following the strategy of the PLG paper and the A2LA document. At the same time, it helps assessors and accreditation bodies with the assessment of test laboratory proceedings concerning the determination and indication of measurement uncertainties within the scope of the identification of competences.

The following basic principles apply to the practical implementation of the measurement uncertainty concept:

- The laboratories have to dispose of practical methods for the estimation of the measurement uncertainty on the basis of the current state of knowledge.
- For the estimation, the laboratories can make use of already existing data in the laboratory (e.g. the available data in the scope of the quality management).
- A strict mathematic-statistical procedure is not always necessary.
- If possible, all components of the measurement uncertainty have to be observed. The components that have the greatest share in the measurement uncertainty must always be taken into account for the estimation of the measurement uncertainty.
- These components may be defined on the basis of existing values, i.e. they do not require additional measures of the laboratory.
- Methods, which can only be used for the estimation of the overall uncertainty (e.g. characteristics of interlaboratory comparisons), are permissibly as well.
- Know-how and experience may also be taken as a basis.

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*) Translation for information purposes only. The German version is authoritative.

2) Strategy of the introduction of the measurement uncertainty estimation

In general, measurements and the respective measurement uncertainty should not be as exact as possible but as exact as necessary, i.e. commercial aspects have to be considered as well. The depth (exactness) of the measurement uncertainty depends on the requirements of the customer and the method.

It is the task of the laboratory to decide on a case to case basis which procedure is best suited for the situation. Amongst other things, the sample composition and the sample preparation have to be taken into account. In some cases, simplifications are necessary and/or the estimation may be incomplete. At the moment, the sample taking in particular can only be considered in some cases. Therefore, it is especially important to give an approximate indication of the procedure for the determination.

Determining the measurement uncertainty, the laboratory should assume the currently available data. If no other data for the estimation of the measurement uncertainty is available, repeated measurements may be used as well (repeat precision, e.g. with certified reference material (CRM). Estimation on the basis of experience can be suitable as well.

3) Practical procedures to meet the requirements of the measurement uncertainty estimation according to ISO/IEC 17025

1. In the following cases, the laboratory does not have to take measures concerning the estimation of measurement uncertainties:

   1.1 So far, an estimation of the measurement uncertainty is not required for qualitative and semi-quantitative methods.

   1.2 Using standard methods that require the indication of results and measurement uncertainties in the norm, it is sufficient to indicate the results as described in the norm, if all steps of the method have been carried out in compliance with the norm. Standard methods that guarantee the observance of limit values, i.e. ensure that the measurement uncertainty is small enough, do not require the laboratory to carry out additional estimations. In these cases, the laboratory must have proven by verification or validation that it masters the respective method.

2. If it is necessary to estimate measurement uncertainties, the following estimation methods on the basis of the GUM [1] may be used depending on which data is available in the laboratory:

   2.1 Using standard methods that do not require a measurement uncertainty in the norm, the measurement uncertainty for the whole method can be estimated with little effort using standard deviations from precision data (e.g. results from interlaboratory comparisons, control cards, calibrations, repeated measurements with certified reference material, etc.). Results from interlaboratory comparisons, for example, directly provide comparative standard deviations for the whole method (see ISO 5725).

   Here, sector or method-specific recommendations can be fruitful (e.g. environmental analyses, biological analyses, food, etc.).

2.2 Using in-house methods, the existing data can be used respectively: especially validation data, internal and external data for the quality assurance, e.g. interlaboratory comparisons, calibration data, etc.

2.3 The measurement uncertainty can be determined from the contributing individual components, also if the strict mathematic connection is not known. If only little information is available, it is sufficient to estimate the measurement uncertainty from the relevant and most contributing components.

2.4 Due to its complexity, the complete mathematic-statistical procedure of strict derivation of the basic function considering all examined individual components and the knowledge of the detailed mathematical connection will be used in a laboratory only very rarely.

2.5 It is also permissible to estimate the measurement uncertainty on the basis of know-how and experience.

Measurement uncertainties as well as test methods should be customer-oriented and practical. If a higher measurement uncertainty is sufficient for the purpose, it is not required to carry out cost-intensive measures in order to determine an unnecessary low measurement uncertainty. However, this requires most of all the understanding and information of the customer.

4) Indication of the measurement uncertainty

According to ISO/IEC 17025, 5.10.3.1 c, the measurement uncertainty is only to be indicated in the test report, if:

- it is of importance for the validity or application of the test result,
- it is required by the costumer
- or if the uncertainty questions the compliance with limit values.

If indicated in the test report, it should be stated what the uncertainty is based upon (e.g. result from interlaboratory comparisons). In this way, it is possible for the customer to identify differences in the determination of the measurement uncertainty.

Furthermore, it must be indicated, whether it concerns a simple standard deviation or an extended measurement uncertainty and what the confidence level is. In many cases, it proved practical to work with an extension factor of k=2 (i.e. on the level of a double standard deviation) for the indication of the measurement uncertainty U. In this case, the confidence level amounts to 95% (assuming a normal distribution).

5) Awareness training at the customer's

Besides the requirements on the laboratory, the information of the customer plays an important role for the acceptance of the measurement uncertainty.
The Swedish test and research institute (SP) has created an information leaflet that explains the measurement uncertainty in a simple way in order to support the information of the customers. In the meantime, this paper, which is supported by many international organisations, is available in German and published on the DAR homepage [4] and the EUROLAB-D homepage.

6) Requirements on the test laboratory for the accreditation

Introducing the measurement uncertainty estimation, a simple and progressive development should be acknowledged and it should be left to the laboratory to select a suitable estimation method.

Appropriate requirements for the monitoring should allow for the introduction of the measurement uncertainty in test laboratories. During the first assessment according to ISO/IEC 17025, the implementation of the following requirements should be inspected in the laboratory:

- Are work instructions available for
  a) the estimation of the measurement uncertainty?
  b) the indication of measurement uncertainties in the test report?
- Is qualified personnel appointed for the estimation of the measurement uncertainty and are trainings scheduled?

During subsequent monitoring, it can be assumed that the handling of the measurement uncertainty is established in the laboratory. The following points are inspected subsequently:

- Application of the procedures (e.g. described in point 3) for the estimation of the measurement uncertainty and application to the accredited scope.
- Availability of examples for the estimation of the measurement uncertainty for the main application area of the laboratory.
- Random verification of the indication of
  - provided measurement uncertainties and the practical application (actual method used),
  - compliance with the stated measurement uncertainty,
  - measurement uncertainties in interlaboratory comparisons, if required.

It should be the laboratory's ambition to continuously improve its measurement uncertainty estimation with the increasing state of knowledge.

Literature

[1] Guide to the Expression of Uncertainty in Measurement, "GUM", BIPM, ISBN 92 67 10188 9,1993 / 1995

[2] Strategy to introduce the concept of measurement uncertainty in testing in connection with the introduction of the standard ISO/IEC 17025, PLG (Permanent Liaison Group of EA, EUROLAB and EURACHEM), 2000; to be published as strategy by ILAC (www.ilac.org) and EA (www.european-accreditation.org).

[3] A2LA Interim Policy on Measurement Uncertainty for Testing Laboratories, A2LA, 2000, (www.a2la.org)

[4] SP leaflet “Important information to our customers concerning the quality of measurement” in the German translation “Qualität von Messungen” (www.dar.bam.de)

Further information:

[5] Expression of the Uncertainty of Measurement in Calibration, EA-4/02, EA (www.european-accreditation.org)

[6] Quantifying Uncertainty in Analytical Measurement, EURACHEM /CITAC Guide, Eurachem / CITAC, 1995 / 2000 (www.eurachem.bam.de/guides/quam2.pdf), German translation is available.

[7] Guidelines for evaluating and expressing uncertainty of NIST measurement results, Barry N. Taylor and Chris E. Kuyatt, NIST, 1993 (http://physics.nist.gov/Pubs/contents.html)