Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025

ILAC-G17:2002

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PREAMBLE

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 standard ISO/IEC 17025 specifies detailed requirements concerning the estimation of uncertainty of measurement and how it should be stated in the test reports.

PURPOSE

This document describes how the concept of uncertainty of measurement should be introduced taking into account present state of the art understanding. It is realised that during the course of the implementation of ISO/IEC 17025, suitable sector-specific guidance will be needed. However, the harmonisation of the application of the principles of uncertainty of measurement in testing between different disciplines, industry sectors and economies should remain the main goal.

AUTHORSHIP

This publication was developed by the ILAC committee on Technical Accreditation Issues, and approved for publication by the ILAC General Assembly in 2001.

1. Uncertainty of measurement in ISO/IEC 17025

ISO/IEC 17025 provides greater detail and information on uncertainty of measurement than its predecessor, ISO/IEC Guide 25. It allows a variety of approaches for estimating the uncertainty of measurement in testing:

- laboratories have to use appropriate methods of evaluation;
- all components able to 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-recognised 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.

2. Definitions

According to the international "vocabulary of basic and general terms in metrology", uncertainty of measurement is a parameter, associated with the result of a measurement, that characterises 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.

3. 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:

1. definition of the measurand
2. sampling
3. transportation, storage and handling of samples
4. preparation of samples
5. environmental and measurement conditions
6. the personnel carrying out the tests
7. variations in the test procedure
8. the measuring instruments
9. calibration standards or reference materials
10. software and/or, in general, methods associated with the measurement
11. uncertainty arising from correction of the measurement results for systematic effects.

4. Policy on the implementation of the concept of uncertainties

Uncertainty of measurement has to be taken into account when testing procedures and/or 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 overall uncertainty of measurement should be consistent with the given requirements. The economic aspects related to the methods have always to be taken into consideration. According to ISO/IEC 17025, 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 the uncertainty associated with a measurement whether it is reported or not.

As a general rule, the implementation of the concept of uncertainty of measurement should go in line with the implementation of ISO/IEC 17025. ILACmay agree on exceptions for such technical areas where uncertainty of measurement is difficult to apply. For those areas ILAC will promote and support the development of guidance documents and worked examples.

ILAC 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). 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 recognised as an area in which further guidance is required. ILAC will, as a first step, concentrate on the introduction of uncertainty of measurement for quantitative testing results.

5. 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:

1. The statement of uncertainty of measurement should contain sufficient information for comparative purposes;
2. The GUM and ISO/IEC 17025 form the basic documents but sector specific interpretations may be needed;
3. Only uncertainty of measurement in quantitative testing is considered for the time being. A strategy on handling results from qualitative testing has to be developed by the scientific community;
4. 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;
5. The basis for the estimation of uncertainty of measurement is to use existing knowledgeExisting experimental data should be used (quality control charts, validation, round robin tests, PT, CRM, handbooks etc.);
6. When using a standard test method there are three cases:
   - when using a standardised 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 organisation.
7. 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);
   - appropriateness;
   - classification of the degree of rigour in the determination of uncertainty of measurement.
8. In certain cases it can be sufficient to report only the reproducibility;
9. When the estimation of the uncertainty of measurement is limited any report of the uncertainty should make this clear;
10. There should be no development of new guides where usable guides already exist.

6. Bibliography

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ISO/IEC 17025:1999 *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 25: 1990 *General requirements for the competence of calibration and testing laboratories*

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The International Laboratory Accreditation Cooperation (ILAC) is the principal international forum for the exchange of ideas and information on laboratory accreditation.

Established in the late 1970s, ILAC membership has grown rapidly and includes representatives from the world's major laboratory accreditation systems in Europe, Asia, North America, Australia and the Pacific. Countries that are developing their own laboratory accreditation systems are also welcome to participate and contribute.

ILAC operates a series of committees which investigate issues such as the harmonisation of international laboratory accreditation practices, the effectiveness of mutual recognition agreements in facilitating trade and the promotion of the aims and awareness of laboratory accreditation around the world.

There are regular meetings of individual ILAC committees as well as a major plenary meeting of all ILAC members.

The activities of ILAC affect a diverse range of areas including standardisation, accreditation, certification, testing, calibration, and regulation in both the public and private sectors.

ILAC has a comprehensive website at www.ilac.org which contains a wealth of information regarding accreditation, testing, trade related publications and other information of interest to industry, regulators, government, trade bodies, laboratories, accreditation bodies, and users of testing and calibration services.

The following ILAC publications are available free of charge on the ILAC website at www.ilac.org:

Brochures
ILAC Information Brochure
Why Use An Accredited Laboratory?
Why Become An Accredited Laboratory?
How Does Using an Accredited Laboratory Benefit Government & Regulators?
The Advantages of Being An Accredited Laboratory (86 kb)

Information Documents (I Series)

ILAC-I1:1994	Legal Liability in Testing
ILAC-I2:1994	Testing, Quality Assurance, Certification and Accreditation
ILAC-I3:1996	The Role of Testing and Laboratory Accreditation in International Trade
ILAC-I4:1996	Guidance Documents for the Preparation of Laboratory Quality Manuals

Guidance Documents (G Series)

ILAC-G2:1994	Traceability of Measurement
ILAC-G3:1994	Guidelines for Training Courses for Assessors
ILAC-G4:1994	Guidelines on Scopes of Accreditation
ILAC-G7:1996	Accreditation Requirements and Operating Criteria for Horseracing Laboratories
ILAC-G8:1996	Guidelines on Assessment and Reporting of Compliance with Specification
ILAC-G9:1996	Guidelines for the Selection and Use of Certified Reference Materials
ILAC-G10:1996	Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories
ILAC-G11:1998	Guidelines on Assessor Qualification and Competence
ILAC-G12:2000	Guidelines for the Requirements for the Competence of Reference Material Producers
ILAC-G13:2000	Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
ILAC-G14:2000	Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status
ILAC-G15:2001	Guidance for Accreditation to ISO/IEC 17025
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Secretariat Documents (S Series)

ILAC-S1:2000	Guidelines for the Proposal, Drafting, Approval and Publication of ILAC Documents
ILAC-S2:1998	Rules

Procedural Documents (P Series)

ILAC-P1:2000	ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies
ILAC-P2: 2000	ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Regional Cooperation Bodies for the Purpose of Recognition
ILAC-P3: 2002	ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Unaffiliated Bodies for the Purpose of Recognition
	ILAC Mutual Recognition Arrangement (Arrangement): Terms of Reference and Composition of the Arrangement Management Committee
	ILAC Mutual Recognition Arrangement (Arrangement)
	ILAC Mutual Recognition Arrangement (Arrangement): Policy Statement