EGAC Policy on Measurement Uncertainty for Testing Laboratories
PB05L

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Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
5.1/Oct 2011	Quality Manager	5/5	Adding a new standard for medical laboratories
5.2/Aug 2016	Quality Manager	All	- Updating the new clauses according to new standards - Modification in F07WI04G the reviewer & receiver

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1. INTRODUCTION

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 Latest version items 5.4.6 and 5.10.3.1 c and ISO 15189 Latest version items 5.3.1.4 and 5.5.3 (m) are necessary.

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.

2. EGAC POLICY ON MEASUREMENT UNCERTAINTY

EGAC applicant and accredited testing laboratories can satisfy the requirements of section 5.4.6 of ISO/IEC 17025and section 5.5.1.4 of ISO 15189: 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).

3. EGAC'S 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 17025and ISO 15189, 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 17025and ISO 15189 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 item 5.10.3.1 c and ISO 15189 item 5.5.3 m). 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.

4. 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 Note 2, item 5.4.6.2)
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 item 5.10.3.1 c and ISO 15189 item 5.5.3 m) 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, clause 5.4.6.2

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, metro

logically 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 (see 5.10)

ISO/IEC 17025, clause 5.4.6.3
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.]

ISO/IEC 17025, section 5.10.3.1(c)
[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.

Applicable ISO 15189 clauses on measurement uncertainty for medical labs:
ISO 15189clause 5.5.1.4:
The laboratory shall determine the uncertainty of results, where relevant and possible. Uncertainty components which are of importance shall be taken into account. Sources that contribute to uncertainty may include sampling, sample preparation, sample portion selection,

calibrators, reference materials, input quantities, equipment used, environmental conditions, condition of the sample and changes of operator.

ISO 15189 clause 5.5.3 (m)
[The report shall also include, but not be limited to, the following:]

Where applicable, information on detection limit and uncertainty of measurement should be provided upon request.