GUIDELINES

DANAK's policy concerning uncertainty of measurement in calibration and testing	No.:	RL 11
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1. Reference:

1. DS/EN 45001 "General criteria for the activity of testing laboratories," section 5.4.3, (is under revision and will be replaced by EN ISO 17025).

2. "Guide to the Expression of Uncertainty in Measurement, ISO, First Edition 1995" (reprinted).

3. Technical Regulation No.TF 8 – Determination of uncertainty of measurement (1998.05.20) – contained in EA-4/02, "Expression of the Uncertainty of Measurement in Calibration", December 1999.

4. "Guidance for the implementation of EAL-R2, Expression of the Uncertainty of Measurement in Calibration" by accreditation bodies.

5. "Quantifying Uncertainty in Analytical Measurement" - EURACHEM, First Edition 1995 (being updated).

6. The Expression of Uncertainty in Quantitative Testing", First Edition 1996, EAL-G23.

1. Delimitation and objective

These guidelines shall apply to DANAK in relation to accredited laboratories. The purpose is to describe DANAK's policy concerning rules relating to uncertainty of measurement in the field of calibration and testing. The rules should have such content that the objective becomes a harmonised interpretation of the requirements of EN 45001 in connection with DANAK's accreditation of calibration and testing laboratories and should be in accordance with the requirements for members of EA's MLA.

Standard EN 45001 lays down the general requirement that the uncertainty of measurement shall be stated in the calibration certificates. With regard to test reports (analytical reports) the uncertainty of measurement shall be indicated where relevant and where the reports contain quantitative results.

3. Definition – uncertainty of measurement

Uncertainty of measurement is a parameter, connected with the result of a measurement and characterising the distribution of values that can reasonably be ascribed to the size of measurement.

Uncertainty of measurement is characterised by an interval within which the so-called "true value" is expected to lie, and within which the result of a repeated measurement can be expected with determined probability. This interval can be increased by multiplying the calculated uncertainty of measurement with a so-called "cover factor" (security factor: k).

2. General policy concerning uncertainty of measurement

- It is DANAK´s policy that all accredited laboratories should indicate the uncertainty of measurement in all accredited calibration certificates and in accredited test reports where these contain quantitative results.

- With regard to those fields where approving bodies have prescribed implementation of testing in a specific way, with given equipment, calibrated in a specified way, under defined environmental conditions and with use of documented criteria for acceptance, DANAK does not require calculation of uncertainty.

- With regard to calibration laboratories, the indicated uncertainty of measurement shall comply with EA-4/02 (3) and current DANAK's Technical Regulations.

- Laboratories in the fields of general chemistry, clinical chemistry and microbiology shall formulate uncertainties of measurement for their methods divided into appropriate groups on the basis of the principles in the EURA-CHEM document (5) and possibly on the basis of other sector-specific documents.

  The results from the on-going analysis control, such as *Control cards*, can be used as elements in the formulated uncertainty budget.

  Laboratories for general testing shall work out the basis for uncertainties of measurement on the basis of the principles in GUM (2) and with possible support in sector-specific guidance documents. These guidance documents should separately indicate how the current uncertainty of measurement can be subjected to on-going control..

- All uncertainties of measurement shall be indicated as so-called expanded uncertainty of measurement by multiplication with the "cover factor" (security factor) normally k=2 corresponding to 95% confidence interval by an infinite number of degrees of freedom.

- The principles for indicating uncertainty of measurement in calibration certificates shall be introduced in the course of 1999 and laid down and fully implemented by the end of the year 2000.

  Before the end of the year 2000 the testing laboratories should also have and use the procedure for estimating uncertainty. For the areas where the testing procedure excludes a metrologically and statistically correct estimate of the uncertainty, the laboratory must identify all uncertainty components and give an acceptable estimate of these so that the reporting of results is not misleading with regard to the uncertainty.

1. Policy concerning uncertainty of measurement in calibration

DANAK will supervise that the accredited calibration laboratories:
- comply with the rules stated in references 1-2-3 and 4,
- have a policy and method for determining uncertainties of measurement.
- report uncertainties of measurement in accordance with TF 8,
- are able to document their stated uncertainties in accordance with TF 8,
- state uncertainties in accordance with, for instance, the laboratories' results from performance testing or comparative calibrations. (See also the section on performance testing and comparative calibrations).

6. Policy concerning uncertainty of measurement in testing

The level of detail in estimating uncertainty of testing depends on:
- the requirements of the testing method,
- the client's requirements, and
- the existence of possible narrow acceptance limits in the relevant specification or standard.

DANAK will supervise that the accredited testing laboratories:
- comply with the rules stated in references 1-2-5 and 6,
- have a policy and method for determining uncertainties of measurement,
- have a policy for reporting uncertainties of measurement,
- comply with the policy and methods concerning uncertainties of measurement,
- are able to document their stated uncertainties.

DANAK will:
- inform laboratories and authorities about initiatives and decisions concerning the established rules for uncertainties of measurement in test reports,
- consider the principles to be applied in sector-specific fields,
- compare the stated uncertainties of laboratories with, for instance, results from double determinations, reference materials, validation of method and quality control, comparisons of laboratories and performance tests if the stated "target value" is indicated with uncertainty and is traceable. (See also the section on performance testing and comparative calibrations),
- describe the general and sector-specific rules in DANAK's guidelines.

7. Specific testing fields

a) General

With regard to the field of testing in general, which is very broad, there are no detailed and ready to use directions as to how uncertainty of measurement should be calculated and treated, but it is expected that the principles stated in GUM (2) will be adapted to the extent possible.

It is expected that each specific testing field (for instance, according to sector) will develop methods for stating uncertainty of measurements in accordance with the above-mentioned basic principle. For this purpose EA has issued a general descriptive document EAL-G23 (6), which deals with stated uncertainties of measurement in connection with testing.

In a number of common testing fields, for instance, mechanical testing of building materials and components and testing of components, it may be necessary to introduce the indicated uncertainty of measurements in reports as to whether items 3.5 – 3.7 of EAL-G23 have been complied with. In such common testing fields, experience from comparative testing and professional cooperation in connection with the development of test methods may also be an important part of the basis for determining uncertainty of measurement.

b) Chemical analysis

Determination and statement of uncertainty of measurement in chemical analyses may be complicated by the many methods, possible variations and influence parameters applying to certain types of analyses.

EURACHEM, which is a European cooperation body for chemical analysis laboratories, has, with point of departure in the chemistry-specific problem complex for uncertainty of measurement budgets, developed an especially descriptive adjustment document for GUM (2).

This document – *Quantifying Uncertainty in Analytical Measurement* (5) – contains examples of current uncertainty components, quantitatively estimated, and a number of detailed examples of calculation in practice.

c) Microbiological testing

Determination and indication of uncertainty of measurement in microbiological testing is complicated by the absence of any field-specific documents that might form the basis for calculating uncertainties of measurement. To the extent possible, the same documents should therefore be used as those for chemical testing as well as approved experience in the individual testing fields.

d) Other testing fields

With regard to other testing fields the stated uncertainties of measurement are primarily based on the basic principles in GUM (2), but should be adjusted to the different sectors in an appropriate manner.

With regard to general testing activities there is, apart from GUM (2), nothing but the generally descriptive documents EAL-G23 (6) to support the calculated uncertainty budgets. The basic principles for stating uncertainty of measurement shall be formulated for each sector.

It is typical for many of the general testing fields that there are often a few uncertainty components which dominate the entire uncertainty budget, and the uncertainty of measurement must often be determined on the basis of comparative tests or must be subject to an estimate.

Generally, for all sectors, great importance is attached to the results of the laboratories' comparisons and performance testing in relation to the stated uncertainty budgets, and to the uncertainty of measurement of the accreditation being in compliance with the international guidelines for quantification and uncertainty of measurement (2, 6).

8. Indication of uncertainty of measurement in certificates and reports

Uncertainties of measurement must always be stated in the calibration certificates from an accredited calibration laboratory.

Uncertainties of measurement in test reports from accredited testing laboratories must be indicated when relevant.

Indication of the uncertainty of measurement should be made directly in the report or with reference to a separate document. If it is not relevant to indicate the uncertainty of measurement, it should be stated in the report that the ***"indication of the uncertainty of measurement for the testing is not relevant".***

In certain situations the client may wish the laboratory not to indicate the uncertainty of measurement in the test report. If this is the case, this must be expressed in writing to the accredited laboratory. Under all circumstances the laboratory must document the actual uncertainty of measurement documents at the conclusion of the testing.

If the uncertainty of measurement is not stated in the test report due to the client's wish, the report must state where documentation concerning uncertainty of measurement is to be found.

In connection with internal assignments (among departments, for instance) special rules may apply to indications of uncertainty of measurement. If so, this should appear from the internal procedures.

9. Comparative calibrations – Performance testing

9.1 General

It is important that the indicated uncertainties should be tested in practice. This can in certain cases be done by participation in relevant comparative calibration or performance testing programmes if the "target value" is traceable and indicated with some uncertainty.

The result of such comparisons may, if there is a similarity of matrix, make it possible to evaluate the contribution of certain components to the uncertainty of measurement.

For this reason, among others, it is therefore of great value to participate in these programmes.

9.2 Calibration

Accredited calibrations laboratories are required to participate in any national and international comparative calibrations that are arranged.

In the few cases where it is not practically possible to check the measuring capacity by means of comparative calibrations laboratories should, if possible, perform internal calibration of their reference standards just before it is sent to the external reference laboratory and subsequently send the internal calibration certificate together with the calibration certificate of the reference laboratory to DANAK for evaluation.

9.3 Testing

Performance testing ensures, among other things, that laboratories have an opportunity to check test results for systematic errors, but it does not ensure that all uncertainty components are evaluated. Special tests may be necessary, for instance, for evaluating stability, durability and matrix interference. Comparison with data from quality control and results from method validation is also important. In cases where it is not feasible for laboratories to participate in approved performance testing, even limited comparisons among a few laboratories may be of great importance in the search for sources of errors and unknown uncertainty components for the use of uncertainty budgets.

Appendices:

EAL-G23 The expression of uncertainty in quantitative testing. § 4. Summary of procedure for evaluating and reporting uncertainty

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