1. Application

This Accreditation Regulation concerns evaluation of uncertainty for quantitative chemical and microbiological testing and medical analyses.

Where legislative requirements have been laid down for specific testing areas concerning uncertainty of measurement that deviates from this Accreditation Regulation, these shall apply.

The objective is to obtain a harmonised interpretation of the requirements in existing versions of DS/EN ISO/IEC 17025 and DS/EN ISO15189, which is in accordance with documents from EA and ILAC. ILAC-G17 and EA 4/16 constitute the background for this present Accreditation Regulation.

2. Definitions

For definitions of metrological terms used in these accreditation regulations, see VIM and GUM mentioned in the references at the bottom of the document.

3. Evaluation of measurement uncertainty

3.1 General

The laboratory shall have and use procedures for estimating measurement uncertainty.

The uncertainty of measurements may be evaluated in different ways depending on i.a. the individual method and need in relation to the use of the measurement result. Evaluation of the measurement uncertainty may range from evaluation based on existing data from, for instance, method validation and quality control for setting up a mathematical model function and an accompanying calculation of uncertainty.

3.2 Validation of method

Values from repeated measurements of the type of sample concerned and from measurements on sample material of known or predetermined content (if it can be obtained) may constitute part of the basis for evaluating the uncertainty of measurement in validating a method. The estimate thus obtained for the measurement uncertainty will normally be based on relatively few data, but the data basis must be sufficient to contribute to a reliable estimate of the uncertainty. Other significant contributions, including the uncertainty of establishing the nominal value of the reference materials, must be included in the measurement uncertainty.

3.3 Internal quality control

By means of internal quality control, data can be collected from the analysis of control and reference materials that may be used for calculation of intermediary precision (variability within a laboratory). If the nominal value of the reference materials is known, and the material represents the type of sample concerned, the data can be used for evaluating the systematic measuring error. Also, here significant contributions, including the uncertainty of defining the nominal value of the reference materials, shall be included in the measurement uncertainty.

3.4 Comparative testing

The distribution of the participants' results in comparative testing can be used as an estimate for the uncertainty of measurements if the test material is representative of the laboratory's activities. All significant uncertainty components must be included in the overall estimate for the measurement uncertainty.

The uncertainty of measurements evaluated on the basis of comparative testing will typically be higher than estimated by method validation and internal quality control.

3.5 Identification of other significant contributions to the uncertainty of measurements.

The use of data from method validation, internal quality control and comparative testing is incorporated in an uncertainty budget in which the contributions from many sources of uncertainty are combined. All significant uncertainty components are included in the total estimate, including the uncertainty contribution from, for instance, the pre-processing of samples.

The uncertainty relating to determination of the systematic measuring error must be included, irrespective of whether or not corrections have been made for it. For many chemical and microbiological parameters the uncertainty in evaluating the nominal value leads to a significant contribution to the total uncertainty of measurement.

If an uncertainty contribution is insufficiently founded, supplementary information can be obtained from literature, existing data (certificates, equipment, specifications, etc.), or it may be necessary to carry out supplementary experiments.

For guidance in the use of data from method validation, internal quality control and comparative testing for evaluating measurement uncertainty, see i.a. Nordtest Report TR 537 and Eurolab Report No. 1.

3.6 Establishing an uncertainty budget on the basis of a model function

An uncertainty budget can be set up on the basis of a model function and detailed knowledge of all important sources of measurement uncertainty. Such an estimate of measurement uncertainty consists of the following steps:

- identification of all relevant sources of uncertainty in an uncertainty budget,
- quantification of sources of uncertainty,
- setting up of model function,
- calculation of the combined standard uncertainty,
- calculation of the expanded measurement uncertainty.

The size of contributions from any traceable calibrated equipment used is obtained from the calibration certificates for the equipment, and the contribution from operation of the equipment should be added. With regard to internal calibrations and with reference to DS/EN ISO/IEC 17025, paras. 7.6.2, the calibration uncertainty of the equipment shall be decided in the same manner as if it had been carried out externally by an accredited calibration laboratory, unless the calibration uncertainty of the equipment contributes only slightly to the total uncertainty of the test result. For determination of the uncertainty of the calibrations, see GUM, AB 11 and EA-4/02.

For guidance in establishing an uncertainty budget on the basis of the model functions see Guide to the expression of uncertainty in measurement (GUM) and Eurochem.

4. Reporting of uncertainty of measurements

In test reports the uncertainty of measurements shall be indicated as the expanded measurement uncertainty *U* corresponding to a confidence level of 95%. The expanded measurement uncertainty can normally be calculated by multiplying the evaluated combined standard uncertainty *u* with a confidence factor of *k = 2*. This presupposes a sufficient range of freedom degrees. The uncertainty of a measurement value must appear clearly in the report and it must be shown what the indicated measurement uncertainty represents.

Examples of indication of the results of four measurements are presented in the box below, where the expanded uncertainty of measurement *U* is indicated with the same unit as the measurement result and as a percentage of the measurement result:

Example 1

Test	**Chloride** ***X*** **±** ***U*** **(mg/L)**
P1	50 ± 5
P2	30 ± 3
P3	0,05 ± 0,02
P4	1,0 ± 0,1

U indicates the expanded measurement uncertainty (confidence factor *k* = 2)

Example 2

Test	**Chloride (mg/L)**	**Uncertainty of measurement** ***U*** **(mg/L)**
P1	50	5
P2	30	3
P3	0,05	0,02
P4	1,0	0,1

U indicates the expanded measurement uncertainty (confidence factor *k* = 2)

Example 3

Test	**Chloride (mg/L)**	**Uncertainty of measurement** ***U*** **in percentage of measured value** ***X***
P1	50	± 10 %
P2	30	± 10 %
P3	0,05	± 40 %
P4	1,0	± 10 %

U indicates the expanded measurement uncertainty (confidence factor *k* = 2)

Information about the uncertainty of measurements in reports shall always be stated when this information is relevant for the use of measurement results, when the information is required by the client or when the uncertainty has influence on the compliance with a specification limit (declaration of compliance). A separate agreement may be entered into with the client or the requisitioner to the effect that the uncertainty of measurement is

stated in another manner than in reports or reports in response, for instance in method lists or in analysis lists accessible to the client.

If the laboratory has carried out sampling or other handling of the sample than by analysis, and the uncertainty of measurement for the sampling or other relevant contribution has not been included in the indication of uncertainty, this shall appear from the report.

The Accreditation Regulation comes into force on 15 December 2020. Any differences between the Danish and the English version of this document are not intended, but in case of doubt with respect to the correctness the version in Danish should be consulted.

References and literature

1) DS/EN ISO/IEC 17025:2017. General requirements for the competence of testing and calibration laboratories

2) DS/EN ISO 15189: 2013. Medical laboratories - Requirements for quality and competence

3) EA 4/16:2003. EA guideline on the expression of uncertainty in quantitative testing

4) ILAC-G17:2002. Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025 – under revision

5) Nordtest report TR 537 ed. 3.1 2012. Handbook for calculation of measurement uncertainty in environmental laboratories

6) NMKL Nr.8, 4th ed. 2008: Measurement of uncertainty in quantitative microbiological examination of foods. Available in Norwegian and English

7) Eurolab Technical Report No. 1/2007. Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation

8) Eurochem Guide 3. ed. 202012. Quantifying uncertainty in analytical measurement

9) Accreditation Regulation AB 11. Evaluation of uncertainty of measurement in calibration

10) EA-4/02:2013: Expression of the Uncertainty of Measurement in Calibration

11) JCGM 100:2008, with minor corrections, Evaluation of measurement data - Guide to the expression of uncertainty in measurement (GUM)

12) JCGM 200:2012: International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

13) ISO/TS 21748:2004: Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation

14) ISO/TS 19036:2019: Microbiology of food and animal stuffs – Guidelines for the estimation of measurement uncertainty for quantitative determinations