1. Application

This Accreditation Regulation concerns evaluation of uncertainty for quantitative chemical and microbiological testing accredited after DS/EN ISO/IEC 17025:2017. This Accreditation Regulation also applies to qualitative testing, where quantitative measurements are included.

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

2. Definitions

For definitions of metrological terms used in these accreditation regulations, see JCGM 200:2012 *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM).

3. Evaluation of measurement uncertainty

3.1 General

The laboratory shall identify contributions to the uncertainty of measurements and evaluate the measurement uncertainty as required in DS/EN ISO/IEC 17025:2017 clause 7.6.1 og 7.6.3.

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. ILAC-G17:01/2021 *ILAC Guidelines for Measurement Uncertainty in Testing* includes guidelines and references to evaluation and reporting of measurement 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 Establishing of uncertainty budget based on methods evaluation, internal quality control and comparative testing

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.

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.

Above mentioned contribution can be combined in an uncertainty budget based on a model function. 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 *Handbook for calculation of measurement uncertainty in environmental laboratories*. Within microbiology evaluation of measurement uncertainty can be based on NMKL Nr.8, *Måleusikkerhet ved kvantitativ mikrobiologisk undersøkelse av næringsmidler* or ISO 19036:2019 *Microbiology of food and animal stuffs – Guidelines for the estimation of measurement uncertainty for quantitative determinations*.

Evaluation of measurement uncertainty can also be based on Eurolab Technical Report No. 1 *Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation* or EURACHEM / CITAC Guide CG 4 *Quantifying uncertainty in analytical measurement*.
All mentioned guides are based on JCGM 100:2008, *GUM 1995 with minor corrections, Evaluation of measurement data – Guide to the expression of uncertainty in measurement* (GUM).
Situations may occur at e.g. qualitative testing where the measurement uncertainty on the result cannot be expressed as an expanded uncertainty. In this case other methods of evaluation might be relevant e.g. probability of false positive or false negative. References appear in ILAC G-17.

3.6 Internal calibration

This accreditation regulation does not concern evaluation of measurement uncertainty in connection with the laboratories' internal calibrations of the measurement equipment used for testing. With regard to internal calibrations in accordance with DS/EN ISO/IEC 17025:2017, clause 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 on the calibrations see DANAKs accreditation regulation AB 11 *Measurement uncertainty in calibration*

3.7 Measurement uncertainty from sampling

According to DS/EN ISO/IEC 17025:2017 clause 7.6.1 all contributions including those from sampling shall be included in the evaluation of measurement uncertainty. There is an international understanding that DS/EN ISO/IEC 17025:2017 pkt. 7.6. 3 also applies to sampling. A thorough evaluation of the measurement uncertainty from sampling can be excluded. This can be the case in following situations:

- The authority has explicitly expressed that the uncertainty does not include contributions from sampling and transport.
- The method of sampling clarifies how the sampling shall be made and/or includes information on the influence of method of sampling to the analysis which are subsequently performed on the samples.

- When the evaluation of measurement uncertainty cannot be performed in praxis without performing activities characterised as research and where knowledge of the analysis to be performed subsequently on the samples is present.
- When the laboratory that performs the analysis has not made the sampling it shall according to DS/EN ISO/IEC 17025:2017 clause 7.8.2.2 appear in the report that the results are valid for the test as received, see 4.2, and evaluation of the measurement uncertainty from the sampling is not relevant.

4. Reporting of uncertainty of measurements

4.1 Requirements on reporting of measurement uncertainty

According to DS/EN ISO/IEC 17025:2017 clause 7.8.3.1c the measurement uncertainty for the result shall be stated in the testing report in following cases:

- It is relevant for the validity or the use of the testing results
- It is required in instructions from the customer, or
- Compliance with specifications is influenced by the measurement uncertainty

The laboratory shall be aware that the need to evaluate the validity or use of the testing results including the measurement uncertainty can appear from the laboratories customers, from their customer, legal authorities, certification bodies and others. Examples can be:

- Compliance with specification limit, where the customer shall consider whether the test item complies with given specifications or where there is risk of not complying with legal requirements.
- Product tests where declaration of conformity is made and where the risk of a products missing compliance with a specification is critical to the customer.
- Comparison of testing results where objective evaluation of compliance only is possible if the measurement uncertainty is taken into consideration.

4.2 Indication of measurement uncertainty

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 estimated standard uncertainty *u* with a confidence factor *k*. When there is a sufficient range of freedom degrees is k = 2. An explanatory note can be added with the following content:

The reported expanded uncertainty is indicated as the standard uncertainty of the measurement multiplied med the coverage factor k=[the given value of k] such that the probability of coverage corresponds to approximately 95 %.

The measurement uncertainty should be indicated by, at the most, two significant figures, and the measurement result rounded off to the smallest significant figure in the reported uncertainty. If the uncertainty of measurements is not stated, the result of the measurement must not be indicated by so many figures that it may be considered as an expression of an unrealistically small degree of uncertainty. This means that the laboratory must in all cases be able to make a reasonable estimate of the measurement uncertainty.

There may be areas where another probability of coverage is used conventionally or where the measurement uncertainty and reporting of this is indicated in the method of testing.

It shall appear whether the uncertainty of measurement includes contribution from the sampling and/or whether there are other contributions that has not been included . According to DS/EN ISO/IEC 17025:2017 pkt. 7.8.2.1 l) the laboratory shall clarify that the result only relates to the taken sample.

Special attention shall be focussed to the results relation to where the sample is taken from (sampling target). See EURACHEM/EUROLAB/CITAC/Nordtest/AMC Guide *Measurement uncertainty arising from sampling: A guide to methods and approaches* or Nordtest Technical Report 604 *Uncertainty from sampling - A Nordtest Handbook for Sampling Planners on Sampling Quality Assurance and Uncertainty Estimation*.

When e.g. samples are taken from groundwater the reservoir of groundwater is the ”sampling target”. If a testing result is expanded to “sampling target” this will only be valid as a statement or an interpretation cf. DS/EN ISO/IEC 17025:2017 clause 7.8.7 except where it can be justified that the results and the related uncertainty takes into account inhomogeneity and variation in “sampling target” through relevant processes for sampling. This is e.g. applicable for batch sampling of slam.

The Accreditation Regulation comes into force on 1 October 2021. 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.

DANAK, 16 September 2021

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) ILAC-G17:01/2021. Measurement Uncertainty in Testing
4) Nordtest report TR 537 ed. 3.1 2012. Handbook for calculation of measurement uncertainty in environmental laboratories
5) NMKL Nr.8, 4th ed. 2008: Measurement of uncertainty in quantitative microbiological examination of foods. Available in Norwegian and English
6) Eurolab Technical Report No. 1/2007. Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation
7) EURACHEM / CITAC Guide CG 4 3. ed. 2012. Quantifying uncertainty in analytical measurement
8) Accreditation Regulation AB 11. Evaluation of uncertainty of measurement in calibration
9) EA-4/02:2013: Expression of the Uncertainty of Measurement in Calibration
10) JCGM 100:2008, with minor corrections, Evaluation of measurement data - Guide to the expression of uncertainty in measurement (GUM)
11) JCGM 200:2012: International vocabulary of metrology – Basic and general concepts and associated terms (VIM)
12) ISO/TS 21748:2004: Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation
13) ISO 19036:2019: Microbiology of food and animal stuffs – Guidelines for the estimation of measurement uncertainty for quantitative determinations

14) EURACHEM/EUROLAB/CITAC/Nordtest/AMC Guide (2019) Measurement uncertainty arising from sampling: A guide to methods and approaches, Second Edition

15) Nordtest Technical Report 604 (2020) Uncertainty from sampling - A Nordtest Handbook for Sampling Planners on Sampling Quality Assurance and Uncertainty Estimation