1. Application

This accreditation regulation applies to DANAK's accreditation of calibration laboratories according to:

a. DS/EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories or

b. DS/EN ISO 15189 Medical laboratories - Requirements for quality and competence

2. Specification of the scope of accreditation

2.1 The scope of accreditation for a laboratory specifies the services comprised by the accreditation The scope emerges from the decision on accreditation and is *published* on DANAK's website.

2.2 The scope of accreditation is determined individually and is clearly specified by the following:

a. For testing the scope of accreditation is described by fields of testing and a list of methods.

b. For medical examination the scope of accreditation is described by diagnostic fields and a list of methods.

c. For calibration the scope of accreditation is described by fields of calibration and a measurement capability table.

In annex 1 the fields of testing, fields of diagnostic and fields of calibration used are listed.

2.3 For application of accreditation and for changes to the scope of accreditation the laboratory is required to type methods or measurement capabilities into the DANAK database. The database can be accessed through www.danak.dk under Extranet where instructions about how to use the database also can be found. If test and calibration activities including medical examination are performed at more sites it shall for each activity be specified in the list of methods or measurement capability table from which site the activity may be performed.

2.4 The laboratory shall inform DANAK when typing in of data has been finished whereupon the assessment of the activities, which the typing in concerns can be performed.

2.5 Accreditation to a flexible scope of accreditation is specified separately. For more information, see DANAK Accreditation regulation AB 10 – Accreditation of laboratories to flexible scope of accreditation.

3. Proficiency Testing and Interlaboratory Comparison

3.1 Interlaboratory Comparison is a significant instrument for demonstrating the technical competence of accredited laboratories, and an activity the accredited laboratories shall participate in for DANAK to maintain its recognition in multilateral agreements (EA MLA and ILAC MLA). The following definitions are used:

a. **Proficiency Testing (PT):** Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

b. **Interlaboratory Comparison (ILC):** Organization, performance and evaluation of measurements of tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

The definitions derive from DS EN ISO/IEC 17043 and are almost similar in the documents ILAC P9 and EA-4/18.

3.2 It is the responsibility of the individual laboratory to take the initiative for participation in the relevant PT offered or participate in ILC which adequately covers the scope of the accreditation.

3.3 In the instances in which an organizer of PT is not available, the laboratory shall in the extent possible themselves initiate participation in or arrangement of ILC with other laboratories. In the following, the term ILC is used for both officially offered proficiency testing and for interlaboratory comparisons, agreed between two or more laboratories.

3.4 The laboratory shall identify the areas where participation in ILC is not possible. For these areas the laboratory shall document credibility of measurement or examination in other means as specified in DS/EN ISO/IEC 17025:2017, section 7.7.1, or DS/EN ISO 15189:2022, clause 7.3.7.3.

3.5 Laboratories applying for accreditation shall have documentation for satisfactory results in ILC, in accordance with 3.2 – 3.4

3.6 Calibration laboratories which document comparativeness in measurements through bilateral comparative calibrations shall where possible ensure that the laboratory compared to has a better measurement capability than the laboratory itself.

3.7 The laboratories shall have procedures which ensures that the laboratory participates in ILC's and that ILC's are chosen in a sufficiently extend to cover the scope of the accreditation, see annex 2. The procedures of the laboratory shall also ensure evaluation and registration of results from ILC (see annex 3) and ensure that the laboratory reacts to discrepancies in results.

3.8 The laboratory shall elaborate plans for and maintain registrations of participation in ILC's. The plans shall be worked out in a way that makes it possible to evaluate whether the extent adequately and in accordance with identified risks covers the scope of the accreditation. The registrations should include both historical and current data to a degree that ensures a suitable level for future activities.

3.9 When participating in proficiency testing, the laboratory shall select competent proficiency testing providers and have appropriate evidence of the provider's competence. Accredited proficiency testing programs covered by EA's MLA and ILAC's Mutual Recognition Agreement (ILAC Arrangement) are considered to be provided by a competent provider. In other cases and/or when comparing with other laboratories, emphasis is placed on the following points, where relevant and possible:

- That reference values comply with requirements for metrology traceability, cf. section 4.
- That laboratories being compared to are accredited in the relevant area.
- That the comparison is required by authorities.
- That relevant requirements of DS/EN ISO/IEC 17043 are taken into account.

3.10 On request from DANAK, e.g. in instances of doubt on the validity of accredited services in specific areas, the laboratory is required to participate in ILC.

4. Metrological traceability

4.1 As documentation for metrological traceability to SI-units, laboratories can use certificates from accredited calibration performed by a laboratory accredited by an accreditation body included in the EA MLA and ILAC arrangement on mutual recognition within calibration. Laboratories can also use certificates from calibration performed by a national metrology institute included in the CIPM MRA for the service.

4.2 For quantities which have metrological traceability to SI units and where the laboratory does not document this as described in 4.1, the laboratory shall in other ways ensure documentation for metrological traceability to SI units of the external laboratory services as described in 4.6.

Metrological traceability established like this should only be applied when it is not possible to establish metrological traceability as described in 4.1 and cannot be expected to be economically advantageous.

4.3 Laboratories establishing traceability of results by internal calibration shall comply with the requirements in DANAKs accreditation regulation AB 11 *Uncertainty of measurement in calibration*.

4.4 Laboratories may as documentation for metrological traceability use reference materials from an accredited producer of reference material covered by the multilateral agreement of EA (EA MLA) and the ILAC agreement on mutual recognition (ILAC Arrangement) for reference materials. Laboratories may also use reference materials which appears in the KCDB of BIPM and are comprised by the MRA of CIPM or the database for Joint Committee for Traceability in Laboratory Medicine (JCTLM).

Reference materials and control materials on the medical area delivered from the producer and are included in a CE marked analysis complies with the requirements for metrological traceability trough the IVD regulation.

4.5 Where the laboratory is not documenting metrological traceability to reference materials as described in 4.4 the laboratory shall document the competence of the reference material producer and the suitability of the reference materials, see 4.6.

4.6 Documentation for technical competence and metrological traceability for external laboratories or producers of reference material can include but is not restricted to the following (numbers in parenthesis refer to clauses in ISO/IEC17025:2017):

a. Records of validity procedures for calibration and/or testing (7.2.2.4)
b. Procedures for estimation of uncertainty (7.6)
c. Documentation for traceability of measurements (6.5)
d. Documentation for assuring the quality of results (7.7)
e. Documentation for competence of staff (6.2)
f. Records for equipment that may influence the activities of the laboratory (6.4)
g. Documentation for accommodation and environmental conditions (6.3)
h. Audits of the external calibration laboratory or the producer of reference material (6.6 and 8.8)

4.7 Laboratories unable to establish traceability to SI-units can use traceability to e.g. certified reference materials, agreed methods and/or standards or reference materials based on consensus, cf. DS/EN ISO/IEC 170:2017, section 6.5.3. Documentation shall be available for comparability of such reference materials.

5. Reporting

5.1 Accredited reports and certificates shall contain results of own accredited activities.

5.2 The laboratory shall, in the accredited reports and certificates it releases, clearly identify results from sub-contractors, and the individual sub-contractor shall also be clearly identified.

5.3 The laboratory shall in accredited reports and certificates clearly mark results not covered by the scope of the accreditation for either the laboratory or an eventual sub-contractor.

6. References

Section 2.2: DS/EN ISO/IEC 17011 section 7.8.3

Section 2.3: DS/EN ISO/IEC 17011 section 7.8.1c) + d)

Section 2.4: DANAK

Section 2.5: DS/EN ISO/IEC 17011 pkt. 7.8.4

Section 3: ILAC P9

Section 4: ILAC P10

Section 5: ILAC P8

Appendix 2: EA 4/18 and ILAC P9

Appendix 3: ISO 13528

The accreditation regulation came into effect 12 November 2024. 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.

APPENDICES

Appendix 1: Overall description of scopes of accreditation.

Appendix 2: Definition of sub-areas and frequency for Proficiency Testing.

Appendix 3: Evaluation of results from Proficiency Testing and laboratory comparisons.

Annex 1

General description of accreditation scopes

Fields of Calibration

Kalibreringsområde (dansk)	**Field of Calibration (English)**
Acceleration og hastighed	Accelerometry, velocity and displacement
Akustik og ultralyd	Acoustics and ultrasonic
Kemisk	Chemical
Densitet og viskositet	Density and viscosity
Geometri	Dimensional
Elektricitet DC og LF	Electricity DC and LF
Elektricitet HF	Electricity HF
Flow	Flow
Kraft og moment	Force and torque
Hårdhed	Hardness
Fugt	Humidity
Ioniserende stråling	Ionising radiation
Magnetisme	Magnetism
Masse	Mass
Optik	Optical
Tryk og vakuum	Pressure and vacuum
Referencemateriale	Reference material
Temperatur	Temperature
Tid og frekvens	Time and frequency
Volumen	Volume
Andre	Other

Fields of Testing

Prøvningsområde (Danish)	**Field of Testing – (English)**
Akustisk prøvning	Acoustics
Biologisk og biokemisk prøvning	Biological and biochemical testing
Kemisk prøvning	Chemical testing
Klinisk prøvning	Clinical testing
Elektrisk og elektronisk prøvning	Electrical and electronical testing
Klimatisk prøvning	Environmental engineering testing
EMC prøvning	EMC testing
Brandteknisk prøvning	Fire testing
Forensisk prøvning	Forensic testing
Mekanisk og fysisk prøvning	Mechanical and Physical testing
Mikrobiologisk prøvning	Microbiological testing
Ikke destruktiv prøvning	Non-destructive testing
Ioniserende stråling og radiokemi	Ionising radiation and radiochemistry
Prøvetagning	Sampling
Sensorisk prøvning	Sensory testing
Anden prøvning	Other tests

Diagnostic fields

Diagnotisk område (Dansk)	**Field of Diagnostic (English)**
Biokemi	Biochemistry
Farmakologi	Pharmacology
Fysiologi og nuklearmedicin	Physiology and Nuclear Medicine
Genetik	Genetics
Immunologi	Immunology
Mikrobiologi	Microbiology
Patologi	Pathology
Speciallaboratorium	Special laboratory

Annex 2

Determination of sub-areas and frequency for participation in laboratory comparisons

. This Annex is based on a translation of Appendix C of ILAC P9:2024, which highlights the general principles of EA-4/18, but is not a direct copy of either Appendix C or EA-4/18.

Guidance document EA-4/18 (Guidance on the level and frequency of participation in performance reviews) aims to promote harmonisation between accreditation bodies on how the level and frequency of participation in performance testing (PT) is assessed in the accreditation process and to help laboratories determine their own level and frequency of participation.

A: General aspects

The following aspects should be taken into account regarding appropriate participation and plan for participation in PT. This means the laboratory's "level" and "frequency" of participation in PT in relation to the activities included in the accreditation area:

(1) The level and frequency of participation should be defined after a thorough analysis of its other measures to ensure the validity of results (in particular those capable of detecting, quantifying and tracking the evolution of bias of a given magnitude). The level of participation should be made dependent on the extent to which other measures have been taken. Other types of measures to ensure the validity of results include, but are not limited to, those listed in ISO/IEC 17025:2017, Section 7.7.1 and ISO 15189:2022, Section 7.3.7.3.

(2) The level of risk to the laboratory, the sector in which it operates or the method it uses may be determined, for example, by considering:

- Number and frequency of tests/calibrations/sampling;
- Replacement of technical personnel;
- The experience and knowledge of the technical personnel;
- Source of metrological traceability (e.g. availability of reference materials, national measurement standards, etc.);
- Known stability/instability of the test or measurement technique;
- The stability of the analyte and matrix and the impact of storage and transportation
- Significance and final use of testing, calibration and/or sampling data (e.g. forensics, food safety and medical laboratories represent areas requiring a high degree of safety);
- The level of risk of the biohazardous PT items used and the necessary contamination measures;
- The number of different calibration intervals;
- The complexity and robustness of the method;
- When declarations of conformity are required and changes are made to related specifications;
- Risks and opportunities associated with the laboratory activities, in particular those that will prevent or reduce undesirable influences and potential errors in the laboratory activities and achieve improvements;
- The extend of validation and/or verification.

(3) Different types of comparative tests (ILCs) that can be used include:

- ILC organized by a sufficient number of laboratories as a stand-alone or continuous activity;
- Organization of small comparisons between laboratories.

Note: Laboratories organising a comparison should apply the relevant requirements of ISO/IEC 17043:2023 and EA-4/21 INF if the results and evaluation of performance are to be used as a tool to monitor and demonstrate the validity of their results.

(4) There may be sectors where it may be difficult to participate in PT due to the characteristics of the testing or calibrations, the lack of PT schemes, the low number of existing laboratories in the sector, etc. For some areas, PT may only be feasible or economically feasible for parts of the test/calibration performed (e.g. EMC (electromagnetic compatibility) testing on simple objects for a limited number of quantities to be determined). In these areas, other approaches to quality assurance are essential.

(5) Any requirements for frequency and type of PT participation from other sources, e.g. legislation, clients, etc.

B: Level and frequency of participation

The first step for laboratories is to consider the scope of accreditation and the testing/calibration/sampling for which they are accredited.

Ideally, a laboratory will participate in a specific PT for each test or measurement technique it uses and for each characteristic (component, parameter) measured in each product. However, it is recognized that this is not always possible, both logistically and financially. Therefore, laboratories should identify groups of technical competence areas (defined by at least one test or measurement technique, property and product that are related). The performance achieved in the PT for a combination in a defined area can be directly correlated with the other combinations of test or measurement techniques, characteristics and products in the same technical area of competence.

As mentioned above, a technical competence may include more than one test or measurement technique, characteristic or product, as long as equivalence and comparability can be demonstrated. The first consideration for a laboratory when determining a technical area of competence is that, in general, it should not include different technical competences. Different technical competences can usually be identified by the need for different qualifications, training and the use of different equipment, knowledge or experience.

When determining a technical area of competence, it may be useful to consider a step-by-step approach by working your way up from the testing or measurement technique through product properties. This is because it is more likely that there will be more products and/or properties associated with one test or measurement technique in a given area than the other way around:

(i) With reference to the test or measurement technique:
It is possible, but not common, to include different testing or measurement techniques in the same technical area of competence;

(ii) With reference to the quantity to be measured, determined or identified:
Whether it may be possible to include more than one characteristic in the same technical area of competence;

(iii) With reference to products to be tested or calibrated:

Whether it may be possible to include different products in the same technical area of competence, provided that the dies, objects or materials included are of a similar nature.

Where a laboratory determines that more than one test or measurement technique, property or product is classified within the same technical field of competence, it should be assessed whether it can justify and demonstrate equivalence. This can usually be done by, for example:

- Method validation data or;
- Using the same test method

The establishment of technical areas of competence may be different for each individual laboratory. Therefore, the laboratory should consider whether it is able to justify the technical arguments that have led to the decision on the defined areas, the level and frequency of participation in PT.

Annex 3

Informative

Evaluation of results from laboratory comparison (ILC)

For participating in ILC criteria of acceptance are often available so that the individual laboratory can evaluate the result of its participation. This applies to both quantitative and qualitative measurements. Different criteria of acceptance can be used depending on the ILC in question.

For quantitative measurements are there in certain cases no calculation of how the individual laboratory's result is corresponding to the criteria of acceptance and the laboratory should then take initiative itself to such an evaluation. Likewise, with comparative testing it will also often be necessary for the laboratory itself to take initiative to evaluate the result.

This appendix mentions specific methods for calculation for evaluation of the criteria of acceptance for quantitative measurements. The appendix is meant as assistance to the laboratories.

Calculation of E_n values

For a comparative test where a reference laboratory is used the so-called E_n – score is calculated by

$$E_n = \frac{x_{lab} - x_{ref}}{\sqrt{U_{lab}{}^2 + U_{ref}{}^2}}$$

where x_{lab} is the value determined by the Laboratory with a corresponding expanded uncertainty U_{lab}, og x_{ref} is the measured (or assigned) value from the reference laboratory with the corresponding expanded uncertainty U_{ref}. See AB 11 "Measurement uncertainty" for more information on determination of the expanded uncertainty.

If $|E_n| \leq 1$ the value determined by the laboratory x_{lab} concur with the reference value x_{ref} with a coverage factor of more than 95%. The result of the comparative testing is thus found satisfactory.
If $|E_n| > 1$ the result is unsatisfactory.

Calculation of E_n – score is traditionally used for ILC and bilateral comparisons within calibration. More information on treatment of date can be found in ISO guide 43-1.

For participation in a comparative testing, where E_n – score is used for evaluation of results, it is essential whether traceability derives from an accredited laboratory, a primary laboratory or a national reference laboratory. For foreign providers the traceability should be secured according to current multilateral agreements (MLA).

The provider does not necessarily need to deliver the traceability for the ILC by itself.

Calculation of *z*-score

For a comparative testing, where a reference laboratory is not used the so-called z-score can be calculated by

$$z = \frac{x_{lab} - x_{ref}}{s}$$

where x_{lab} is the value determined by the Laboratory, x_{ref} is a calculated value, and s is an expression for deviation on results. The reference value can be found as a weighed mean of the measurements of the participating laboratories, where statistical outliers are regarded.

If $|z| \leq 2$ the value determined by the laboratory x_{lab} concur with the reference value x_{ref} with a coverage factor of more than 95%. The result of the comparative testing is thus found satisfactory.
For $2 < |z| < 3$ compliance is doubtful.
If $|z| \geq 3$ the compliance is found unsatisfactory.

Calculation of zeta-score

For a comparative testing, the so-called zeta-score is calculated by

$$zeta = \frac{x_{lab} - x_{ref}}{\sqrt{u_{lab}{}^2 + u_{ref}{}^2}}$$

where x_{lab} is the value determined by the laboratory, and x_{ref} is the reference value. u_{lab} is standard uncertainty on the determined value and u_{ref} is the standard uncertainty for the reference value. The reference value will often be determined by a certified reference material or by a weighed mean of the measurements of the participating laboratories, where statistical outliers are regarded.

If $|zeta| \leq 2$ the value determined by the laboratory x_{lab} concur with the reference value x_{ref} with a coverage factor of more than 95%. The result of the comparative testing is thus found satisfactory.

For $2 < |zeta| < 3$ compliance is doubtful.

If $|zeta| \geq 3$ the result is found unsatisfactory.