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 specialties 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, diagnostic specialties 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:

1. **Proficiency Testing (PT):** Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons
2. **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 15189:2013, section 5.6.

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 a policy which ensures that the laboratory participates in ILC's that covers the scope of the accreditation. The policy shall ensure that resources are devoted to the participation in ILC's.

3.8 The Laboratory shall have procedures which ensures that ILC's are chosen in a sufficiently extend, 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.

3.9 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 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.

3.10 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.

3.11 On request from DANAK, the laboratory is required to support the Multilateral Agreement (MLA) by participation in ILC's arranged or recommended by the European co-operation for Accreditation (EA) or the International Laboratory Accreditation Cooperation (ILAC). The participating laboratories shall bear the costs themselves.

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. Documentation for technical competence and metrological traceability to SI units for external laboratories can include but is not restricted to the following (numbers in parenthesis refer to clauses in ISO/IEC17025:2017):

a. Records of validity of calibration procedures (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 calibration results (7.7)
e. Documentation for competence of staff (6.2)
f. Documentation for accommodation and environmental conditions (6.3)
g. Audits of the external calibration laboratory (6.6 and 8.8)

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

4.3 Laboratories which establish traceability to results from internal calibration shall comply with the requirements for estimation of uncertainty in DANAK's accreditation regulation 11 (AB 11) Estimation of uncertainty in calibration.

4.4 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.

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 7.8.1d)
Section 2.4+2.7: DS/EN ISO IEC 17011 section 7.8.4

Section 2.5: DANAK
Section 2.6: DS/EN ISO/IEC 17011 section 7.8.4
Section 3: ILAC P9
Section 4: ILAC P10
Section 5: ILAC P8
Appendix 2: EA 4/18
Appendix 3: ISO 13528

The accreditation regulation came into effect 31 January 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.

APPENDICES

Appendix 1: 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 Specialties

Diagnotiske Specialer (Dansk)	**Diagnostic Specialties (English)**
Biokemi	Biochemistry
Mikrobiologi	Microbiology
Immunologi	Immunology
Patologi	Pathology
Billeddiagnostik	Medical imaging
Fysiologi og nuklearmedicin	Physiology and Nuclear Medicine
Genetik	Genetics
Farmakologi	Pharmacology
Prøvetagning	Sampling

Annex 2

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

In the Procedure and Plan for ILC it will for most Laboratories be necessary to sub classify the scope of accreditation. This is done to the effect, that a single ILC for each sub-area ensures representative coverage of the whole scope. Such a classification can take point in:

1. Measurement principle/testing technique used. This can e.g. be identified according to use of the same equipment, or that the root for the traceability is the same.
2. The property or the parameter measured. More familiar parameters, where the root for the traceability is the same can be included (e.g. different metals in water solutions, or currency, voltage and resistance in a calibration)
3. The objects or items measured upon. This includes measurements, where the same measurement principle/testing technique is used for different objects/items.

If the measurement principle/testing technique, property/parameter and object/item differ significantly, it will normally not be possible to regard the activities as being a part of the same part of the scope of accreditation.

For the *frequency* for participation in ILC the following factors will have influence:

1. Traceability to the SI-system through internal and external calibrations.
2. Traceability to a certified reference material.

If there is no traceability to the SI-system or to certified reference material the insurance for correctness of own measurements are in these cases very depended on the results from ILC. This should normally lead to an increased frequency for participation.

Independently of the used traceability and the frequency of participation chosen, prolonged intervals of participation should be related to satisfactory results in previous ILC. Contrary, unsatisfactory results could lead to increased or extraordinary participation to clarify the extent of the problem.

The above mentioned methods and considerations for sub classifying the scope of accreditation and to establish frequencies of participation in ILC is only meant as a help for the Laboratory. There could be other fully satisfactory ways to establish a Plan.

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 "Determination of 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.