1. Application

This accreditation regulation applies to DANAK's accreditation of laboratories for flexible scopes within testing or medical examination in accordance with:

1. DS/EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories or
2. DS/EN ISO 15189 Medical laboratories —Requirements for quality and competence

2. Flexible scope of accreditation

Having a flexible scope of accreditation means that the laboratory has the opportunity to make changes to the scope within a defined area, cf. 4.2 item 1, without DANAK assessing the change prior to this.

It is only possible to introduce new or changed methods **if the same test technique/measurement principle can be used for which the laboratory is already accredited.** The change can be permanent or apply to a single task. Flexible accreditation area can include one or more of the following types of flexibility:

2.1 Flexibility for test type/topic: Relates to the type of test/subject for which the method is used. In special cases this may be a group of test types/topics.

Using this degree of freedom, it is possible to expand with test types/topics that were not previously included in the scope of accreditation. This can be done for parameters and testing techniques for which the laboratory is already accredited and includes the necessary changes to the methodology. The method can be a self-developed method or a standardized method.

2.2 Flexibility to parameter:

Relates to the parameter being measured, e.g. tensile strength, hardness, chromium content, pH value, salmonella, albumin, etc.

Using this degree of freedom, it can be extended with parameters that were not previously included in the accreditation area. This can be done for sample types/items and testing techniques for which the laboratory is already accredited and includes the necessary changes to the methodology. The method can be a self-developed method or a standardized method.

2.3 Flexibility of the performance of the method: The documented characteristics of the method, for instance range of measurement, uncertainty of measurement and detection limit.
Using this degree of freedom can change the performance of the method. This can be done for parameters in types/items for testing and with testing techniques for which the laboratory is already accredited and includes the necessary changes in the method. The method can be a self-developed method or a standardized method.

2.4 Flexibility to the method: The procedure, including also the testing technique used for the test/examination. The method shall be a standardised method (e.g. ISO XYZ:20XX). A standardised method is developed by a regional, national or international standardisation body or other organisations, which methods are generally accepted within a specific technical area.

By using this degree of freedom technically equivalent or revised standardized methods may be used. This can be done for parameters in sample types/items and with test techniques/apparatus for which the laboratory is already accredited. This requires that the laboratory is already accredited for similar, standardized methods. The degree of freedom cannot be used for non-standardized methods.

3. Application for accreditation or changes to flexible scope of accreditation

The laboratory must apply for accreditation to or changes to flexible scope of accreditation, by completing the "Application Flexible Accreditation Area" found on danak.dk.

4. Requirements for laboratories with a flexible scope of accreditation

4.1 The competence and activity of the laboratory must be at a level that ensures a low risk of deviations in the flexible scope of accreditation. Emphasis is therefore placed on:

1. The laboratory's understanding of the requirements and procedures for implementing and managing a flexible accreditation area.
2. The laboratory's management system within the defined area must be robust, i.e. that validations, registrations (including any logbook), performance tests, deviations, internal audits and management evaluations meet relevant requirements.
3. The laboratory and their activities must be of an appropriate extend to maintain competence within the flexible accreditation area.
4. The laboratory must currently be able to present evidence to DANAK for the performance of activities under the defined flexible scope of accreditation. This means that an area included in the flexible scope of accreditation without any activities cannot be expected to be maintained.

In order to meet the above, it will only be possible in particularly justified cases to obtain a flexible accreditation area during the first accreditation period.

4.2 The laboratory procedures and documentation for managing the flexible scope of accreditation must as a minimum include:

1. Description of area, techniques and degrees of freedom cf. 3.1-3-4 that are included in flexible scope of accreditation also including indication of the authorised/responsible for each area. Changes herein are subject to the duty of information, cf. AB 1.
2. Procedure for validation and/or verification to be performed before a method within the flexible scope of accreditation can be used. Changes to the procedure are subject to the duty of information, cf. AB 1.
3. Cooperation with customers with special attention to inquired methods that are requested to be included in the flexible scope of accreditation.
4. In the specific case of an agreement on a service that has not yet been validated under the flexible accreditation area, and the conclusion of the validation/verification is that the service does not comply with requirements for accreditation this shall be handled as a non-compliance. This includes information to the customer about the consequences.

4.3 Employees authorized as responsible for flexible scope of accreditation shall be considered as key persons and are subject to DANAK's requirements concerning duty of information both at accession and resignation etc. Their competence will be assessed by DANAK e.g. by interviews and review of CV before accession.

The person authorised for the individual validation task must have documented experience of independent evaluation of methods within the specific technical area, and have a competence to (depending on the degree of flexibility):

1. evaluate the suitability of the method, including also its suitability in relation to the customer's needs

2. draw up a specific validation and/or verification plan
3. evaluate the uncertainty and evaluate the method's performance in relation to the requirements specified for the use of the method.

4.4 The laboratory shall undertake on-going registration of all changes within the flexible scope of accreditation (e.g. a form of logbook). The laboratory's registration shall as a minimum comprise:

1. What is comprised by the change
2. Which degree of freedom is used
3. the date from which the change applies which means is included in the accreditation
4. reference to the documentation of validation-/verification or other documentation for the change (may in the cases of simple changes be included in the logbook)
5. identification for the staff member responsible for the validation

4.**5** When the laboratory has introduced changes covered by the flexible scope of accreditation, the changes have to be entered into DANAK's database. The lead assessor is then informed so that the change can be published on DANAK's website.

The new method is considered accredited from the moment the laboratory has approved the validation that the change is based on

4.6 The internal audit and management review must include activities within the flexible scope of accreditation

5. References

Section 2: ISO/IEC 17011
Section 3: DANAK
Section 4: EA-2/15

This Accreditation regulation comes into force on 1 March 2025. 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.