Accreditation of laboratories for flexible scope

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. Terms

The following terms are used in connection to flexible scope of accreditation:

2.1 Test type: The test for which the method is used. In special cases this may be a group of products (or matrices). Typically the following terms are used in the respective technical areas:

- Chemical testing: Matrice
- Physical testing: Test object
- Medical examination: System

2.2 Parameter, property/analysis parameter, component: The parameter/property measured, for instance, tensile strength, hardness, chrome content, pH, salmonella, albumin, immunoglobulin G etc.

Respectively the following terms are used:

- Chemical testing: Parameter
- Physical testing: Property, test parameter
- Medical examination: Component

2.3 Method performance: The documented characteristics of the method, for instance range of measurement, uncertainty of measurement and detection limit.

2.4 Method: The procedure, including also the measuring technique used for the test/analysis. The method can be a standard or a non-standard method. A standard method is developed by a regional, national or international standardisation body or other organisations, which methods are generally accepted within a specific technical area. A non-standard method is a method developed in the laboratory or introduced by another laboratory.

3. Flexibility of the scope

A flexible scope of accreditation means that it is possible for the laboratory to make changes within the scope and the accredited service without DANAK assessing the change beforehand. Introducing new or changed methods is possible if the same testing technique as the laboratory already is accredited for can be used. The change can be permanent or used for one single task.

Flexible scope can include the following types of flexibility:

3.1 Flexibility concerning test type implies for changes in the testing area with regard to various matrices, test objects and systems provided this can be carried out using the same testing techniques on parameters, properties and component, for which the laboratory is already accredited.

3.2 Flexibility concerning parameters, properties or component implies a flexibility to change in the scope of testing regarding these provided this can be done by using testing techniques for matrices, test objects or systems for which the laboratory is already accredited.

3.3 Flexibility concerning performance of the method makes it possible to make changes to the performance of the method by measuring given parameters in given testing types provided this can be done using the same testing technique for which the laboratory is already accredited.

3.4 Flexibility concerning test method makes it possible to use technically equivalent or revised methods provided this can be done by using existing or equivalent apparatus or equivalent testing techniques or/and detection principles, when the laboratory has already been accredited for similar methods.

4. Application for accreditation to flexible scope

4.1 The application for flexible scope of accreditation must contain the following:

1. Which types of flexibility are desired to be included (3.1 – 3.4)
2. Description and definition of scope that is desired to be comprised including methods and techniques (5.1)
3. Procedures for management of the flexible scope of accreditation (5.2)
4. Documentation for the competence of the personnel authorized to perform the validation (5.3 – 5.4)
5. Examples of validation of methods within the applied scope

4.2 The extent of the flexible scope of accreditation shall be specified in connection with the description of the scope of accreditation, see accreditation regulation AB 3 – Accreditation of laboratories.

5. Requirements for laboratories with flexible scope of accreditation

5.1 In its management systems, the laboratory must have procedures and documentation that describes and defines the area and methods, included in the flexible scope of accreditation. Changes in these procedures and documentation are comprised by DANAK's requirements for information provided by the laboratory.

The laboratory must apply DANAK for expansions of the flexible scope of accreditation, in accordance with item 4.1.

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

1. Authorisation and responsibilities for the staff, covering all activities within the flexible scope of accreditation
2. Cooperation with customers with special attention to inquired methods not yet included in the scope of accreditation
3. The validation and/or verification to be performed before a method of testing within the flexible scope of accreditation can be used
4. The management of deviations in validations where it is concluded that a service does not meet accreditation requirement. This include information to the customer on the consequences

5.3 Laboratories with flexible scope of accreditation shall maintain registration of which staff members the management has authorised to be responsible for management of the flexible scope of accreditation and for validation and/or verification of the individual test methods within this scope. These staff members are 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 for instance through interviews and review of CV.

5.4 The person responsible for the individual validation task must have documented experience of independent development of methods within the specific technical area, and have a competence equal to that the person depending on the degree of flexibility can:

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. lay down the necessary uncertainty estimates and evaluate the method's performance in relation to the requirements specified for the use of the method

5.5 Dependant on the degree of flexibility, the laboratories shall draw up validation plans for each change of method implemented in the flexible scope of accreditation. Results from validations and if relevant, verification, shall be documented.

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

1. What is comprised by the change
2. the date from which the change applies
3. reference to the validation report or other documentation for the change (may in the cases of simple changes be included in the logbook)
4. identification for the staff member responsible for the validation

5.7 When the laboratory has introduced changes to its list of methods 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

5.8 The internal audit and management review must include processes and methods which have been changed within the flexible scope of accreditation

This Accreditation regulation comes into force on 29 September 2015. 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.