

GUIDELINE

Flexible scope of accreditation for testing laboratories

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1. Scope of accreditation

This guideline applies to all testing laboratories that have been accredited for testing and wish to have a flexible scope of accreditation. In cases where specific requirements are laid down by the authorities (in statutory orders, etc.) such requirements must, however, be complied with.

This guideline does not apply to laboratories that are accredited for calibration.

2. Objective

DANAK's guidelines express DANAK's interpretation of relevant sections in accreditation standards, etc. to ensure harmonisation of the terms imposed on the accredited laboratories.

The objective of this guideline is to describe the requirements that must be complied with by testing laboratories in order to become accredited for a flexible scope of accreditation. This form of accreditation has also been described in European co-operation for Accreditation's guideline EA-2/05 and in International Laboratory Accreditation Cooperation's guideline ILAC G18.

Flexible scope of accreditation means that the laboratory — within a defined scope of testing — has the right to issue accredited reports without having the specific test methods and tests assessed by DANAK beforehand.

The terms determined should as a minimum at all times be in accordance with this guideline.

3. Definitions

The Scope of accreditation is for any accredited testing laboratory described in a letter of acceptance, an accreditation document, and in the method list approved by DANAK and is described by the following elements.

Test object. The material or product or types of matrices for which the method is used. In special cases this may be a group of products (or matrices).

Test parameter (property/analysis parameter). The parameter/property which is measured or for which the content is determined, for instance, tensile strength, hardness chrome content, pH value, salmonella, etc.

Test method/method. The procedure, including also the measuring technique used at the test/analysis. The method may be a national, regional or international standard method, a method developed in the laboratory (in-house method) or a method introduced from another laboratory/enterprise.

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

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4. Possibilities for flexible scope of accreditation

Flexible scope of accreditation means that the testing laboratory is given the possibility of making changes within the scope of testing and within the terms and conditions for accreditation without DANAK being involved. The change may be permanent or apply to one single assignment. The flexibility may comprise the following forms of flexibility.

4.1 Flexibility concerning test object

This implies a flexibility that makes changes in the scope of testing possible with regard to various products (for instance change of matrices) within a product area, provided this can be done by using the same testing techniques for the test parameters (*properties/analysis parameters*), for which the laboratory has already been accredited.

4.2 Flexibility concerning test parameters

This means a flexibility to change in the scope of testing with regard to *test parameters (properties/analysis parameters)*, provided this can be done by using *testing techniques and test types* for which the laboratory has already been accredited.

4.3 Flexibility concerning method performance

This means a flexibility to make changes in the method (modifications) by measuring given objects and parameters and performance of the method provided this can be done using the same testing principle for which the laboratory has already been accredited.

4.4 Flexibility concerning test method

This implies a flexibility to include technically equivalent or revised standard methods on the method list provided this can be done by using existing apparatus when the laboratory has already been accredited for similar standard methods. The laboratory must by reviewing the methods be able to document similarities and differences in accordance with the laboratory's procedure.

Extension of a laboratory's accreditation for a flexible scope of accreditation may only take place on the basis of a method assessed and accredited by DANAK. Utilising flexibility under the above-mentioned points requires validation of the change by the laboratory in relation to each of the points that the change concerns. See also ref. 9.4 concerning validation in the chemical field

5. Requirements for laboratories with flexible scope of accreditations

The development of new or modified methods necessitates thorough technical understanding of the methods and techniques to be used.

In addition to the general requirements applying to accredited testing the laboratory must be prepared to accept the following:

5.1 The laboratory's application must specify what flexibility it is applying for (4.1, 4.2, 4.3 and 4.4).

5.2 Laboratories with flexible scope of accreditation must have documented procedures that describe the internal validation and verification to be performed before a test method can be used within the laboratory's flexible scope of accreditation.

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5.3 In its documentation the laboratory must state which members of staff have been authorised by the management to be responsible for validation and verification of the individual method to be changed. These staff members are considered as key persons and are subject to DANAK's requirements concerning duty of information in connection with termination of employment, etc. These persons must be competent staff authorised by the management to take overall responsibility for validation, change, development and implementation of new or revised methods.

There must always be one person who has overall responsibility for the individual validation task. The person responsible must have documented experience of independent development of methods within the specific technical area, and depending on the degree of flexibility this person's competence should correspond to the person being able to:

- assess the suitability of the method, including also its suitability in relation to the customer's needs;
- draw up a specific validation and verification plan;
- lay down the necessary uncertainty budgets and evaluate the measurement area.

5.4 Dependant on the degree of flexibility validation plans shall be drawn up for each change of method that is implemented within the flexible scope of accreditation. Results from validation and, if relevant, verification shall be documented in a report. The report must be signed by the person responsible for the validation.

5.5 The laboratory shall undertake ongoing registration of all changes of methods within the flexible scope of accreditation (a form of logbook).

The laboratory's registration should as a minimum comprise:

- what is comprised by the change;
- the date from which the change applies;
- reference to the validation report or other documentation for the change (may in the cases of minor changes be included in the logbook);
- name and occupation of the staff member responsible for the validation.

6. Assessment of laboratories concerning flexible scope of accreditation

It must be expected that DANAK's assessment requires extra time for the laboratories with flexible scope of accreditation. At all regular visits, and when it is considered necessary, DANAK will assess the laboratory's competence within the flexible scope of accreditation.

6.1 In connection with application for flexible scope of accreditation and subsequent regular visits, DANAK will assess whether the laboratory complies with the requirements in Section 5.

6.2 Competence possessed by the persons who the laboratory wishes to be responsible for the validation of methods carried out under the flexible scope of accreditation will be assessed by DANAK, i.a. by interview and review of CVs.

6.3 After having been granted accreditation for a flexible scope of accreditation, the laboratory's registrations (logbook) covering changes implemented in the scope of accreditations must be made available to DANAK according to an agreement.

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7. Coming into force

This Guideline shall replace RL 2 of 2004.01.06 and shall come into force on 19 March 2006.

DANAK, 6 March 2006

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Allan Munck, Quality Manager

8. REFERENCES

- 9.1 DS/EN ISO/IEC 17025: "Generelle krav til prøvnings- og kalibreringslaboratoriernes kompetence", 2. udgave, 10. juni 2005.
- 9.2 EA-2/05: "The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing", EA, European co-operation for Accreditation, August 2001 rev. 02.
- 9.3 ILAC-G18: 2002: "The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing", ILAC, International Laboratory Accreditation Cooperation.
- 9.4 DANAK's Retningslinie RL 1: "Metodevalidering i kemisk analytiske laboratorier. Kvantitative analysemetoder. 2003.08.18.

10. APPENDICES

None.