

## **Accreditation with flexible scope of testing laboratories, calibration laboratories and medical laboratories**

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### **Scope:**

This document defines the general conditions for accreditation with a flexible scope, provided that this is allowed according to the accreditation rules of the sector. They should ensure a field-covering harmonization of the requirements and approach in the context of accreditation with a flexible scope and apply to all testing laboratories, medical laboratories and with limitation to calibration laboratories<sup>1</sup> that are seeking for accreditation with a flexible scope.

**Date of confirmation by the Accreditation Advisory Board: 15.07.2015**

Substantive changes in comparison to the previous issue of this rule are marked with a line on the right side or highlighted with a **yellow** background.

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<sup>1</sup> For the limitations, see page 6-7.

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## 1 Scope

This document defines the general conditions for accreditation with a flexible scope, provided that this is allowed according to the accreditation rules of the sector. They should ensure a field-covering harmonization of the requirements and approach in the context of accreditation with a flexible scope and apply to all testing laboratories, medical laboratories and with limitation to calibration laboratories that are seeking for accreditation with a flexible scope.

## 2 Terms

<b>Scope of accreditation</b>	Certain activities of conformity assessments for which the accreditation was applied for or was granted (DIN EN ISO/IEC 17011:2005-02)
<b>Type of testing / type of examination</b>	Technique-related or application-related conformity assessment activities which are based on similar technique-methodical procedures, comparable principles of validation and training basis  In the following only the term “type of testing” is used for easier legibility
<b>Testing field / calibration field / examination field</b>	Field within which different testing methods / calibration- / examination procedures are carried out that is characterised by matrix/sample/test item/calibration item and measurand/testing parameter/analyte  In the following only the terms testing field and calibration field are used for easier legibility
<b>Testing methods / examination procedures</b>	Agreed technical procedure for the realisation of a test <sup>2</sup> or calibration on the basis of a measuring principle  In the following only the terms testing methods and calibration procedure are used for easier legibility

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<sup>2</sup> in the medical area the term examination is used for test

<b>Testing area / examination area</b>	<p>Scientific-technically area which is defined by the sector committees of DAkkS</p> <p>In the following only the term testing area is used for easier legibility.</p>
<b>Measurement principle</b>	<p>Phenomenon serving as a basis of a measurement. (International vocabulary of metrology — Basic and general concepts and associated terms (VIM), JCGM 200:2008)</p>
<b>Verification</b>	<p>Confirmation through the provision of objective evidence that specified requirements have been fulfilled</p> <p>(DIN EN ISO 9000 section 3.8.4.)</p>
<b>Validation</b>	<p>Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled</p> <p>(DIN EN ISO 9000 section 3.8.5.)</p> <p>A standard test method is taken to be validated</p>

### **3 Responsibilities**

The sector committees can define guidelines or specifications for describing a flexible scope of accreditation within their area of responsibility.

The assessors are responsible, in cooperation with the customer manager, to evaluate the possibility of an accreditation with flexible scope for a particular laboratory, taking into account the regulations set by the relevant sector committee for the respective testing area.

The accreditation committee decides while considering the accreditation rules of the relevant sector if an accreditation with flexible scope may be granted. It must be taken into account that in some areas for the purpose of notification of a conformity assessment body, the accreditation with flexible scope may not be appropriate.

## 4 Description

### 4.1 General

**Scope of Accreditation:** The scope of accreditation can be clearly defined with the characteristics as described in table 1.

**Table 1: Typical characteristics to describe the scope of accreditation**

Testing laboratories		Medical laboratories	
testing area <i>(e.g., veterinary medical examinations and mechanical tests)</i>		examination area <i>(e.g., clinical chemistry, hematology)</i>	
Testing field <sup>3</sup>	Type of testing <i>(e.g., gas chromatography, hardness testing, amplification procedure)</i>	Examination field <sup>4</sup>	Type of examination <i>(e.g., infrared spectrometry, atomic spectrometry)</i>
	matrix / sample / test item / test object <i>(e.g., soil, water, food, plastics and oils)</i>		examination material <i>(e.g. whole blood, serum, bodily fluids)</i>
	measuring quantity (measurand) / test parameter / analyte* <i>(z. B. Shore-hardness, Cadmium, pH-Value)</i>		analyte/examination parameter <i>(e.g., CO<sub>2</sub>, glucose, differential blood count)</i>
Specification of a standard method (if appropriate and applicable) <i>(e.g. ISO 14577-1:2003)</i>		Specification of a standard method (if appropriate and applicable)	
reference to in-house test method		reference to in-house examination procedure	

According to Clauses 5.4.3 and 5.4.4 of ISO/IEC 17025 accredited laboratories can be allowed to modify their own test methods (developed in the laboratory), or use updated versions of standard test methods for which they were accredited for, as well as to introduce similar standard or additional test methods, without having to inform the DAkkS beforehand. This apply provided that these modifications and updated versions or new test methods do not include any **other measurement principles** which are not covered by the original description of the testing- and calibration scope.

<sup>3</sup> A **testing field** is characterized by type of testing, matrix/sample/test-item/test object and measurand/test parameter/analyte

<sup>4</sup> An **examination field** is characterized by type of examination, examination material and analyte/examination parameter

The scope of accreditation can be described

- by a fixed list of all test methods;
- more general in form of testing fields (accreditation with flexible scope).

Applying accreditation with flexible scope, first of all the two following categories have to be distinguished, that can possibly be operated in combination:

**Category I: the free choice of standard methods or equivalent/similar methods within a defined testing field**

**Category II the modification, refinement and development of test methods within a defined testing field**

The accreditation with flexibility scope is granted within the limits defined based on the experience as demonstrated by a laboratory within the scope of accreditation (see section 4.3).

All testing methods, which are operated by the laboratory with reference to accreditation must be verified or validated, respectively. For the verification (category I) or validation (category II) process, the laboratory must provide appropriate documented procedures.

The inclusion of new testing fields is considered as an extension of accreditation and must be applied for at DAkkS.

The categories I und II can be applied by testing and medical laboratories. According to ILAC G18 „Guideline for the Formulation of Scopes of Accreditation for Laboratories“ calibration laboratories cannot apply for accreditation with flexible scope for the categories I und II.

In addition, accreditation with flexible scope is applicable in the following category:

**Category III Application of standard test methods/standard calibration procedures or equivalent methods with different issue dates**

Category III is applicable to testing-, calibration- and medical laboratories. With this category it is possible to confirm on the annex to the accreditation certificate the application of standardized or equivalent methods/calibration procedures with different issue dates. A new version of a standard/equivalent method can be used under the existing accreditation, if the standard/equivalent method has the similar scope in comparison with the previous standard/equivalent method and includes no new measuring principle, or only such new measuring principles, which are already included in other standards/equivalent methods within the accreditation scope. If this is not the case, an assessment by the DAkkS is necessary. Within the framework of category III, it is not necessary to indicate any testing-/calibration field on the annex to the accreditation certificate. Category III is

applicable to all usual descriptions of accredited standards or equivalent methods on the annex to the accreditation certificate. However, if category III is applicable only to specific parts of the accreditation scope, these have to be indicated accordingly.

The decision that specific technical method/regulation can be considered as equivalent to standards is up to DAkKS subsequent to consultation of the responsible sector committee.

Category II includes the competence to work according to categories I and III. Category I includes the competence to work according to category III. For testing fields where category II was granted, there will be no extra recognition for categories I and III. For testing fields where category I was granted, there will be no extra recognition for category III.

#### **4.2 Limits of accreditation with flexible Scope**

The flexibility can be applied based on the following degrees of freedom:

- *Flexibility regarding matrix / sample / test item / test object*  
The flexibility which allows changes with regard to matrix / sample / test item / test object (e.g., changes in the matrices) within a product area, e.g., food.  
It concerns, e.g., the atomic absorption spectroscopy, which is extended from cadmium determination in fruit and fruit products to the determination in cereals and bakery products. Another example is the mechanical testing of various components (e.g., as wheels and wheel suspensions) for automotive applications.
- *Flexibility regarding measurand / test parameter / analyte*  
The flexibility which allows changes with regard to the test parameters. An example is the extension of the cadmium determination in food products to other trace metals using atomic absorption spectroscopy.
- *Flexibility regarding of performance of the testing methods*  
The flexibility which allows changes in the performance of the testing methods for a given scope and test parameters. This includes, e.g. the change of the measuring range and the accessible measurement uncertainty.
- *Flexibility with respect to the testing method*  
The flexibility which allows the inclusion of methods which are equivalent to those which are already covered by the accreditation.

For the description of the accredited flexible scope it is important that the accreditation is not only set for a specific test method, but that the limits of the flexibility of the accreditation scope are clearly defined. The testing fields have to be clearly and unambiguously described according to the defined terms and these are to be substantiated with a representative number of testing methods.

### 4.3 Requirements for the laboratory

Accreditation with a flexible scope can only be granted upon application and based on proven competence in the specific area. To apply for a flexible accreditation scope, the laboratory should focus as far as possible on existing descriptions which are established and published by the sector committees of DAkkS. Requirements from sectoral accreditation rules, if applicable, are to be considered. If for a specific testing area, no description of the desired flexible scope of accreditation is defined by the sector committee, the laboratory can submit a proposal to DAkkS for the desired flexible scope in good time before the assessment.

If a laboratory develops new testing methods or modifies them, it requires a sound technical understanding of the testing methods and the techniques used. This competence can be acquired, for instance, by suitable training, participation in suitable research projects or developing projects, in projects for the development of test method or by means of gaining comprehensive experience in the respective testing area. This includes experience accumulated by participating in scientific or standardisation committees as well as activities in providing of expertise. Internal quality assurance procedures and practices (including validation) are to be mastered.

A university degree in engineering, science, a completed medical degree or an equivalent qualification is a requirement for senior technical staff. Especially for competence in validation, a relevant scientific qualification is expected. Several years of professional experience in the testing area or comparable scientific experience is required.

If a testing method in the framework of the accreditation with flexible scope is to be modified, further developed or another non standard testing method is introduced, it will be considered as accredited, only after its validation has been successfully completed (category II).

In the case of **category I, the validation is not required**, if standardised or equivalent testing methods are used. However, this is in general not applicable when the standard method is used beside its intended scope.

Using of standard or equivalent test methods is subject to the condition that expertise in application competence (**verification** by the laboratory) has been proved.

Rules and responsibilities for the development, implementation and validation of test methods within the organisation must be documented. Modifications and updates of testing methods or development activities, including all fundamental results arising from the validation and verification as well as other relevant data must be fully recorded and be approved for the final use in the testing or medical laboratory.

The responsible staff must evaluate the modified, revised or newly developed methods with appropriate measures of quality assurance regularly. Procedures and responsibilities associated with the development or revision of testing methods within the accreditation scope must be checked at regular intervals by the responsible management. The results of the internal or external quality control

measures have to be taken into account. Records about these evaluation activities must be made available to DAkKS.

If a site wishes to use new or modified testing methods that were developed and validated in another site, this can only be applied within the accreditation scope, when the site itself is accredited with a flexible scope of category I or II and has carried out a verification or it has received an approval by the DAkKS for a suitable extension of its scope of accreditation beforehand.

The laboratory must maintain an updated list of all testing methods, including the modified, revised or newly developed methods covered by the flexible scope of accreditation.

#### **4.4 Special requirements for assessment**

When an accreditation with flexible scope is applied for, the assessment focuses in addition to the general requirements, in particular on:

- the ability of the laboratory to develop new test methods, to modify and validate them, to verify selected standard or equivalent testing methods;
- the ability of the laboratory to technically implement standards **or equivalent testing methods/calibration procedures** with different issue dates;
- necessary qualifications of the staff, its management, as well as their experiences and/or training in the relevant technical areas;
- technical equipment;
- testing- and especially validation procedures;
- the management system, specifically with regard to validation and verification;
- records of validations and verifications performed.

Requirements of sectoral accreditation rules are to be considered, as applicable. The assessor shall interview staff authorised for the development and validation of testing methods, in order to evaluate their abilities. It is the responsibility of the assessor, if necessary, taking into account sectoral requirements of the sector committees, to randomly select characteristic testing methods to be subject to a more detailed examination.

Criteria for the selection of these methods are:

- the technical complexity of the tests;
- the potential consequences of errors in tests;
- the frequency of use of the test methods;
- the ratio of routine tests (standard procedure) to non-routine tests;
- the frequency of reviews or assessment of testing method in previous years.

The number of random checks should be large enough so that confidence in the ability of the laboratory to introduce new or modified testing methods can be established. During each surveillance assessment and reassessment recently modified methods, new methods introduced or methods developed by the laboratory must be reviewed at random.

If a laboratory applies for accreditation with flexible scope at several sites, the requirements at each site must be assessed.

The report of the assessor must include a clear recommendation for the accreditation with flexible scope, including which types of testing should be accredited, are limited or to be cancelled. It shall also indicate to which test items, test objects, examination materials, matrices relate to its respective type of testing. The recommendation is to be justified. In the recommendation it must clearly stated which category / categories are recommended for which flexible accreditation scopes.

#### **4.5 Description of accreditation with flexible Scope on the Accreditation Certificate**

For categories I and II, testing fields and selected test methods that are associated with the respective testing field are listed. For this purpose, the accreditation with flexible scope may be summarised in a table. In category III it is not necessary to define testing fields. Test methods listed in the annex to the accreditation certificate, can be indicated completely or to some extent to mark which part is belonging to category III.

In addition, the following sentence will be added to the first page of the annex to the accreditation certificate, indicating the actual conditions of the laboratory, respective statement 1) (for category I) and / or 2) (for Category II).

For testing laboratories:

**Within the given testing field marked with \*), the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following:**

- 1) the free choice of standard or equivalent testing methods.**
- 2) the modification, development and refinement of testing methods.**

**The listed testing methods are exemplary. The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.**

For medical laboratories:

**Within the given examination field marked with \*), the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following:**

- 1) **the free choice of standards or equivalent examination procedures.**
- 2) **the modification, development and refinement of examination procedures.**

**The listed examination procedures are exemplary. The medical laboratory maintains a current list of all examination procedures within the flexible scope of accreditation.**

The annex to the accreditation certificate must clearly state, for which sites of the laboratory the accreditation with flexible scope applies.

If necessary, for example upon customer request or due to requirements in the legally regulated field, the exemplary list of testing methods may be amended by specific test methods, if these were previously assessed on site at random and / or by means of document review.

For the description of category III on the first page of the annex to the certificate, one of the following sentences, as listed below (or combinations of different options) may be used:

For testing laboratories:

If the Category III applies to the entire scope of accreditation:

**The testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use standards or equivalent testing methods listed here with different issue dates.**

**The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.**

If the Category III applies to parts of the scope of accreditation:

**Within the scope of accreditation marked with \*), the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use standards or equivalent testing methods listed here with different issue dates.**

**The testing laboratory maintains a current list of all testing procedures within the flexible scope of accreditation.**

For calibration laboratories:

If the Category III applies to the entire scope of accreditation:

**The calibration laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use calibration standards or equivalent calibration procedures listed here with different issue dates.**

**The calibration laboratory maintains a current list of all calibration standards / equivalent calibration procedures within the flexible scope of accreditation.**

If the Category III applies to parts of the scope of accreditation:

**Within the scope of accreditation marked with \*), the calibration laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use calibration standards or equivalent calibration procedures listed here with different issue dates.**

**The calibration laboratory maintains a current list of all calibration standards / equivalent calibration procedures within the flexible scope of accreditation.**

For individual measurands/calibration items:

**Within the measurands/calibration items marked with with \*), the calibration laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use calibration standards or equivalent calibration procedures listed here with different issue dates.**

**The calibration laboratory maintains a current list of all calibration standards / equivalent calibration procedures within the flexible scope of accreditation.**

For medical laboratories:

If the Category III applies to the entire scope of accreditation:

**The medical laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use standards or equivalent examination procedures listed here with different issue dates.**

**The medical laboratory maintains a current list of all standards / equivalent examination procedures within the flexible scope of accreditation.**

If the Category III applies to parts of the scope of accreditation:

**Within the scope of accreditation marked with with \*), the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, to use standard examination procedures listed here with different issue dates.**

**The medical laboratory maintains a current list of all standards / equivalent examination procedures within the flexible scope of accreditation.**