

Principles for the assessment of flexible scope

Policy document A3/2022

28.1.2022

FINAS Finnish Accreditation Service

Helsinki 2022



Foreword

The original policy document for FINAS was drawn up by a working group appointed by the Advisory Committee for Accreditation Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A3/2022 replaces the previous version A3/2020. The guidelines take into account that FINAS Leaflet 10 is no longer published and the data is presented at the website.

The purpose of FINAS policy documents is to clarify the practical application of accreditation requirements. They have been drawn up taking into account the principles agreed within the international cooperation organisations of accreditation bodies (European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF)).

The requirements for accreditation activities are set out in Decision P1. Information on the policy documents and binding guidelines can be found on the FINAS website (www.finas.fi).

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1 Introduction

The purpose of this assessment principle is to harmonise practices in the field of accreditation of flexible scope. The guidelines highlight the prerequisites of the flexible scope area and the most important points of the assessment. The guidelines are meant for the assessors, applicants for accreditation and accredited operators.

Accreditation shall be carried out in accordance with the principles for defining the scope of accreditation as presented in the documents of the EA, ILAC and IAF (see Clause 6 References). The principles presented in this document for assessing the scope of accreditation conform to international principles and policies.

The scope of accreditation shows the activities for which the operator in question has requested accreditation and in which the operator has been deemed to be competent, following an assessment. As a rule, scopes of accreditation are fixed scopes described in detail. An accredited body may also have a flexible scope, where the scope is presented at a more general level. Predominantly, the flexible scope has been developed to meet the needs of operators whose activities change quickly and the properties or proficiency testing needs of the object to be tested, calibrated, inspected or certified cannot always be predicted in advance. In many cases, the needs, requirements and operating environment of the customers of the operators concerned require that changes can be quickly accredited. There is no significant difference between a fixed and flexible scope, and the fixed scope might also contain flexibility.

2 Fixed and flexible scope

2.1 Fixed scope

In the fixed scope, the activities encompassed by the operator's accreditation decision are described more precisely than in the flexible scope. On the proposal of the operator, the scope can be extended, modified and reduced. Extension and modifications require the operator to have commissioning procedures (validation/verification) in place to demonstrate that the operator is competent with respect to the extension or modification presented. The extension/modification is assessed and the scope is changed as a result of the assessment. After the amendment of the accreditation decision, the operator can refer to accreditation pertaining to the modifications. A fixed scope is the most

practical solution for most accredited operators and provides an informative picture of the accredited operator's competence to its customers.

In some cases, the test type of a fixed scope of a testing laboratory has some flexibility, for example, when the tested analytic is written in a general level, such as PAH compounds. Within the fixed scope, this is specified either by writing all specific compounds by name that are assessed and accredited by FINAS or by writing the number of compounds after analytics. When compounds are expressed by number, the laboratory shall maintain a precise list of the accredited compounds. The list shall be assessed as part of the laboratory's activities.

2.2 Flexible scope

The flexible scope allows the operator to make changes to the fixed area of their scope without prior assessment. When making changes, the operator must comply with the requirements laid down for the use of the flexible scope and maintain clear documentation on the use of the flexible scope. The changes made are assessed afterwards, in connection with assessment and surveillance visits. In addition to the flexible scope, an operator can have a fixed scope that supports the activities covered by the flexible scope.

Flexibility does not allow the adoption of completely new procedures in any field of accreditation (testing/calibration/inspection/certification/proficiency testing). Instead, any changes made in activities must be based on the existing activities. For completely new procedures, the normal procedures for the extension of the scope are followed and the operator must apply for an extension/modification to their scope.

In the flexible scope, the activities encompassed by the scope of accreditation are presented at a more general level than in the fixed scope. Activities within the flexible scope are recorded within the scope of accreditation of the laboratories in such a way as to distinguish them from the fixed scope. In the scope, the fixed scope can be found under a separate heading, and it shows at which area the flexibility is targeted (FLX* marking). Adaptability can concern all areas described in the scope (see examples in chapter 5).

3 Preconditions for a flexible scope

The operator shall analyse the need for flexible scope and identify and define the activities suited to the flexible scope. The operator must also have a need to introduce changes between assessment visits. The operator must comply with the principles presented in this document.

The flexible scope requires the operator to have planned activities and a well-functioning management system that also takes into account the flexible scope.

Basic conditions for the introduction of a flexible scope:

- demonstration that the operator has effective and daily deployment procedures that are effective and transparent (validation/verification procedures).
- comprehensive quality assurance procedures that are appropriate for the activities and take into account the factors of uncertainty. They are also monitored systematically for their efficiency. FINAS policy document A2 shall be taken into account in laboratory activities.
- a description of the principles of flexible scope and the activities that are encompassed by the flexible scope.
- an up-to-date list of activities which are part of the flexible scope corresponding to the fixed scope.

Requirements for management:

- commitment and assurance of sufficient resources.
- definition of the personnel's responsibilities, authorisations and maintenance of their professional skills, also with respect to the flexible scope.
- appropriate procedures for identifying risk factors in activities.
- expertly conducted audits that also pay attention to activities covered by the flexible scope.
- active monitoring of customers' needs/feedback and co-operation with customers

Requirements for those responsible of the flexible scope:

- competence to modify activities in response to customers' needs
- the ability to analyse the effects and risks of the new or modified activities (such as resource needs).
- good management of documentation. Documentation must be traceable, comprehensive and clearly show the operative changes.

4 Assessment of a flexible scope

When a management system is assessed, the focus is on the operating principles and procedures defined in the flexible scope. In the assessment of technical operations, the emphasis is on the methods or activities proposed for the

flexible scope. When assessing a flexible scope for the first time, the assessors check that the operator has the necessary prerequisites and well-functioning procedures for the flexible scope, as well as clear and comprehensive documentation. During the subsequent visits, how the operator has adhered to the principles of the flexible scope is assessed along with how it has applied the relevant procedures in its operations.

The decision to apply the flexible scope is always made on a case-by-case basis.

The assessment is based on a targeted risk assessment. One of the acknowledged risk factors is the use of flexible scope and its extent.

Prior to the assessment visit, the operator will be asked to provide a written list of activities under its flexible scope, as well as clarification on the use of the flexible scope and any changes made to it (documentation request). Any modifications made to the operations subject to the flexible scope and the related documentation are always checked during assessments.

If it is found that the operator has not complied with the principles of the flexible scope and/or does not have sufficient competence to maintain a flexible scope, the assessors will assess the significance of the situation. The situation or deviation might lead to the suspension or permanent cancellation of the flexible scope where necessary. The operator may continue under its flexible scope if its activities are compliant with the requirements.

The operator must also take into account the requirements of FINAS V1 with regard to the flexible scope. The operator must ensure that customers are not misled as to the extent of accreditation.

5 Allocation of flexibility

In **testing**, flexibility can apply to the material, product or testing method to be tested.

When the flexibility concerns material to be tested, the laboratory must prove the correctness of the test results by validation/verification using different types of matrixes (such as environmental samples, food, water).

Flexibility is suitable for testing methods in which one method can be used to determine several analysts/compounds (such as screening of narcotics and identifying new ones), in which case the subject of flexibility is the determined

test type/examined parameter in the scope area in question. Other flexibility targets related to the examined parameter could include: VOC, PAH and PCB compounds and elements.

A flexible scope may also be practical in situations where a selection can be made between alternative testing methods (such as pre-processing and analysis standards), but only so that the technic stays the same (for example, qPCR, ICP-MS). In these cases, the technic used in FINAS scopes is described generally and the more detailed list maintained by the customer determines the methods used in the flexible scope, such as standards, more in detail. However, it should be noted that the laboratory cannot introduce a completely new type of standard.

The flexibility of a **calibration laboratory** can be associated with the object of calibration, a quantity/group of quantities or the measurement range. For instance, the quantities to be calibrated or their derivatives can be defined so that, whenever necessary, the laboratory applies and optimises the methods and quantities described in the laboratory's fixed scope.

In **inspection activities**, a fixed scope of accreditation is normally sufficient to describe the scope of accreditation of an inspection body. A fixed scope allows some flexibility for method versions, for example.

Certification covers the certification of products, systems and persons; these three differ in character. In systems certification, the scope is described by branch, in product certification by product group, and in defining the tested feature, by the applicable method (standard). Certification of persons is based on certification programmes that define the criteria. A fixed scope of accreditation is normally sufficient to describe the scope of accreditation of different certification activities.

The flexibility of a **proficiency test providers** may be associated with the material, product or matrix and/or property to be tested and/or proficiency testing programme.

6 References

ILAC G18:04/2010 The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing (Under revision)

EA-2/15 M:2019 EA Requirements for the Accreditation of Flexible Scopes

EA-4/17 M:2008 EA Position Paper on the Description of Scopes of Accreditation of Medical Laboratories

SFS-EN ISO/IEC 17011:2017 Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies.

Changes from the previous version

Changes 28.1.2022

	Chapter		Change
	Foreword		FINAS Leaflet 10 is no longer published. The corresponding information can be found on the www.finas.fi website.
1	Introduction	1	Removed a reference to research from the introduction and described the current practice
2	Fixed and flexible scope	2	Moved text on scope from section 4.
3	Preconditions for a flexible scope	3	Changes in the structure of the text.
4	Assessment of a flexible scope	4	Text on scope has been moved to section 2.
5	Allocation of flexibility	5	The example was specified by adding that the introduction of an entirely new type of standard requires a separate extension to the scope.