

Principles for the Assessment of Flexible Scope

FINAS Finnish Accreditation Service

Helsinki 2020

Foreword

This FINAS original policy document is drawn up by a working group appointed by the Advisory Committee for Conformity Assessment Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A3/2020 replaces the previous version A3/2019. In the new version, presenting and assessing of fixed and flexible scope has been described more in details.

The purpose of the policy documents is to clarify the application of accreditation requirements in practice. The policy documents have been drawn up in accordance with principles agreed within the international co-operation organisations of accreditation bodies (European Co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF)).

FINAS accreditation criteria, policy documents and guidelines are presented in the valid FINAS Leaflet 10.

Further information www.finas.fi

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1 Introduction

The purpose of the FINAS policy document A3 is to harmonise the procedures used for accreditation of flexible scope. Preconditions for a flexible scope and relevant aspects of the assessment are presented in this document which is intended for the use of assessors, accredited bodies and applicants for accreditation.

Accredited scopes are defined according to the principles 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 body in question has requested accreditation and in which the body 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. In the main, the flexible scope has been developed to meet the needs of bodies that work in research and/or development, for situations where the properties of an object to be tested, calibrated, inspected or certified or proficiency testing needs cannot always be predicted in advance. Often these bodies have clients whose needs and requirements change quickly. The difference between a fixed and a flexible scope is not large, and a fixed scope might also contain flexibility.

2 Fixed and flexible scopes

Fixed scope

In the fixed scope, the activities encompassed by the accreditation decision are described precisely. If requested by the body, the scope can be extended, modified and reduced. Extension and modifications require validation/verification indicating that the body is competent with respect to the extension or modification presented. The extension/modification is assessed and granted to the body on the basis of the outcome of the assessment. After the amendment of the accreditation decision, the body can refer to accreditation pertaining to the modifications. A fixed scope is the most practical solution for most accredited bodies and gives an informative picture of the accredited body's competence to clients as well.

In some cases, in fixed scope there is some flexibility in test type, for example when analytics is written in a general level, for example PAH compounds. This

is specified either by writing all specific compounds that are assessed and accredited by FINAS or by writing number of compounds after analytics. When compounds are expressed by number, laboratory shall maintain precise list of accredited compounds. The list shall be assessed part of the assessment.

Flexible 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. Flexibility can refer to all elements described in the scope of accreditation (see examples from chapter 5). The scope of accreditation shows which elements of the scope flexibility refers to and it is customer's responsibility to maintain specified list of methods/activities included to the flexible scope.

The flexible scope allows the body to make changes in activities and methods included in the flexible scope of accreditation without prior assessment. When making changes, the body must comply with the requirements laid down for the use of the flexible scope. The body shall maintain a fully documented system for the use of flexible scope. The changes made are assessed afterwards, in connection with assessment and surveillance visits. In addition to the flexible scope, the body usually has 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). Any changes made in activities shall be based on the existing activities. For additions outside the bounds of the flexible scope the CAB need to apply extension following the normal route for an extension to scope.

3 Preconditions for a flexible scope

The body shall analyse the need for a flexible scope and shall identify and define the activities suited to the flexible scope. The body shall comply with the principles presented in this document. Decision to apply flexible scope will be considered case-by-case.

A precondition for the flexible scope is that the body has the following

- systematic activities and a well-functioning management system, where the flexible scope has also been considered
- a description of the principles of flexible scope and the activities that are encompassed by the flexible scope
- the management's commitment and assurance of sufficient resources
- definition of the personnel's responsibilities and authorisations, also with respect to the flexible scope

- human resources and other resources in line with the nature and extent of activities
- systematic procedures for ensuring the competence of the personnel and for the maintenance of expertise and professional skills, taking into account national and international requirements and developments in the field
- appropriate procedures for identifying risk factors in activities
- efficient and transparent validation/verification procedures for daily working
- competence to modify testing/calibration/inspection/certification/proficiency testing activities in response to clients' needs, while taking into account the appropriate validation/verification of the modifications made, the needs for quality assurance procedures stemming from the modifications and the impact of the modifications on the uncertainty of measurement or on factors causing uncertainty.
- the body has the ability to analyse the effects and risks of the new or modified activities as well as the need for resources.
- comprehensive and appropriate quality assurance procedures, which are monitored systematically for their efficiency. FINAS policy document A2 shall be taken into account in laboratory activities.
- traceable, comprehensive and clear documentation of activities and changes that have been done and good management of documents
- an up-to-date list of activities which are part of flexible scope corresponding to fixed scope
- expertly conducted audits that also pay attention to activities covered by the flexible scope
- active monitoring of clients' needs/feedback and co-operation with clients.
- real need to have flexible scope due to the constant changes in activity during the assessment visits.

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 body has the necessary prerequisites and well-functioning procedures for the flexible scope, as well as clear and comprehensive documentation. During the next visits, it is assessed how the body has adhered to the principles of the flexible scope and how it has applied the relevant procedures in its operations.

The assessment is made by risk basis according the body's activities. One of the acknowledged risk factors is the use of flexible scope and its extent.

The body shall maintain a list of activities and changes conducted under its flexible scope. This documentation is part of the material which is asked from the body before an assessment visit. Any modifications made to the operations subject to the flexible scope and the related documentation are always checked during assessments. If the body wants to keep the flexible scope, it must maintain the necessary prerequisites even when, in practice, it has had no need to apply the flexible scope in its operations.

If it is discovered that the body has not complied with the principles of the flexible scope and/or the body does not have sufficient competence for the maintenance of the flexible scope, the assessors evaluate the importance of the situation from the perspectives of both accreditation and customer service. The situation or non-compliance may lead to the suspension or, if necessary, permanent cancellation of the flexible scope. It may be possible for the body to continue operations so that the scope is fixed, provided that the requirements set for the fixed scope are met.

In the scope of accreditation of laboratories, the operations encompassed by the flexible scope are recorded so that they are distinguished from the fixed scope. If so wished by the body, the modifications adopted can also be transferred to the fixed scope and described in more detail there.

When referring to accreditation, the body must take into account the requirements laid down for reference to accreditation and must ensure that the modifications made in the flexible scope meet the requirements set for the use of the flexible scope. The body must ensure that clients are not misled with respect to the extent of accreditation.

5 Use of flexibility

In testing, flexibility may apply to the material or product to be tested or to the testing method. Then the material to be tested is flexible (e.g. environmental samples) the laboratory shall prove the correctness of the test results by validation/verification using different types of matrixes. Flexibility is suited to testing methods in which one method can be used to determine several analysts/compounds (e.g. screening of narcotics and identifying new compounds). In that case the flexibility applies to the test type/measurement parameter defined in the accredited scope. A flexible scope may also be practical in situations where a selection can be made between alternative testing methods (such as standards). Nevertheless the technic shall remain the same (like qPCR).

The flexibility of a calibration laboratory may 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, a fixed scope of accreditation is normally sufficient to describe the scope of accreditation of an inspection body. A fixed scope allows some flexibility.

Certification covers the certification of products, systems and persons; these three differ in character. In systems certification, the scope is described by branch, and in product certification by product group. Certification of persons is based on certification programmes. A fixed scope of accreditation is normally sufficient to describe the scope of accreditation of a certification body.

The flexibility of a proficiency testing provider may be associated with the material, product or matrix and/or property to be tested (parameter).

In the scopes flexibility is indicated in the header and also with FLX* marking for each of the aspects that are considered flexible.

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 EA M:2008 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 21.04.2020

Chapter	Change
Foreword	Updated
1 Introduction	1
2 Fixed and flexible scopes	2 Specified the description of the fixed scope and the responsibilities of a client using the flexible scope
3 Preconditions for a flexible scope	3
4 Assessment of a flexible scope	4 Flexibility is granted only if there is a need.
5 Use of flexibility	5 Specified the flexibility of the test method and marking of flexibility in the scopes.
6 References	6
Changes to the previous version	Updated