

Rules for Accredited Scopes

Requirement V2/2024

08.11.2024



Content

1	Introduction	3
2	Entry into force	3
3	Definitions	4
4	The scope of accreditation	4
4.1	Fixed scope	5
4.2	Flexible scope	5
5	Requirements for Flexible Scope	6
6	Assessment of Flexible Scope	7
7	Targeting of Flexibility	8
7.1	Methods, standards, requirements	8
7.2	Flexible scope for Testing	8
7.3	Flexible Scope for Calibration	9
7.4	Flexible Scope for Inspection	9
7.5	Flexible Scope for Certification	9
7.6	Flexible Scope for Proficiency testing providers	9
7.7	Flexible scope for Biobank	10
8	References	10
9	Changes from the previous version	11

1 Introduction

The national accreditation body FINAS Finnish Accreditation Service (hereafter referred to as FINAS) describes in this document the requirements for fixed and flexible scopes of accreditation. The procedures described in the requirement apply to assessors, applicants for accreditation, and accredited bodies.

The original document was the assessment principle A3, *Principles for Accreditation of Flexible Scopes*, which this requirement document replaces. The requirements of the mandatory guide EA-2/15 M *EA Requirements for the Accreditation of Flexible Scopes* have been considered in this document. The requirements for procedures for flexible scopes, set by the FINAS Finnish Accreditation Service, consider the principles agreed upon in international cooperation organizations of accreditation bodies (European co-operation for Accreditation (EA), International Laboratory Accreditation Cooperation (ILAC), and the International Accreditation Forum, Inc. (IAF)).

2 Entry into force

FINAS Finnish Accreditation Service confirms these rules based on the Act 920/2005 on the verification of the competence of conformity assessment services (testing, calibration, inspection, certification, proficiency testing, verification, and biobank operators) and its amendment 764/2014.

Director

Katriina Luoma

Senior Specialist

Annika Wickström

3 Definitions

EA (European co-operation for Accreditation)

A cooperation organization for European accreditation bodies across all accreditation areas.

ILAC (International Laboratory Accreditation Cooperation)

An international cooperation organization for accreditation bodies (with accreditation areas including laboratories, inspection bodies, proficiency testing providers, reference material producers, and biobanks).

IAF (International Accreditation Forum)

An international cooperation organization for accreditation bodies (with accreditation areas including certification bodies (system, product, personnel certification, and verification)).

Accreditation follows the principles for defining accredited scopes as presented in the documents of EA, ILAC, and IAF (see section 8 References). The assessment procedures for scopes of accreditation presented in this document are consistent with international principles and guidelines.

4 The scope of accreditation

The scope of accreditation refers to the activities proposed by the operator for accreditation, which have been assessed, and for which the operator has been deemed competent. Generally, scopes of accreditation are specifically described as so-called fixed scopes. An accredited operator may also have a flexible scope, in which the scope is presented at a more general level.

The flexible scope has been developed primarily to meet the needs of operators whose operations are rapidly changing. Often, the needs, requirements, and operating environments of these operators' customers require swift incorporation of changes within the scope of accreditation. If necessary, the activities within an operator's flexible scope can also be described under a fixed scope.

FINAS adheres to the requirements of ISO/IEC 17011 when defining scopes of accreditation. FINAS has defined subfields of operation (such as food testing) under the main fields of operation, according to which various activities are grouped. These subfields (e.g., food testing, chemistry, gravimetric methods) are uniform for operators in the same field.

An operator may refer to accreditation for the procedures (methods) covered by its scope of accreditation.

4.1 Fixed scope

In their application, the operator provides a description of the activity they wish to have included to the scope of accreditation. For most accredited operators, a fixed scope is suitable. A fixed scope offers a precise and unambiguous description of the accredited activities offered by the operator. The operations covered by the operator's accreditation decision are described in the fixed scope more precisely than in a flexible scope.

Changes can be made to the fixed scope upon the accredited operator's request. Extension or modifications of the accreditation scope requires implementation procedures (validation/verification) that demonstrate the operator's competence regarding the proposed extension or modification. The extension or modification is assessed, and the scope of accreditation is updated as a result of the assessment. After the amendment of the accreditation decision, the operator may refer to the accreditation regarding the modifications.

4.2 Flexible scope

A flexible scope allows an operator to make changes to a defined area within the scope of accreditation (e.g., testing) without prior assessment. Flexibility does not permit the introduction of entirely new procedures in any part of the accreditation. For entirely new procedures (such as methods), an extension must be applied for, as in a fixed scope.

A flexible scope is typically suited to activities where the accredited operator's customer needs are rapidly changing. In a flexible scope, the activity is described at a more general level than in a fixed scope, and thus the clear and precise description is the responsibility of the operator itself.

A flexible scope requires greater responsibility from the operator, and the operator must demonstrate that the flexible scope is suitable for its operations and that the flexible scope is being utilized. When making changes, the operator must adhere to the requirements set for the use of the flexible scope and maintain clear documentation regarding the use of the flexible scope. The changes made are assessed afterwards during assessments.

Activities included in the flexible scope are recorded in the scope of accreditation in a way that distinguishes them from activities within the fixed scope. The designation FLX* indicates the area to which the flexibility applies. The flexibility of different activities/sectors is discussed in section 7.

After the accreditation has been granted, the operator must be prepared to provide a detailed list of procedures (methods) under the flexible scope upon request. This requirement is noted in the scope alongside the flexible scope.

5 Requirements for Flexible Scope

The operator must apply to FINAS for a flexible scope. The application must clearly describe the parts of the scope to which flexibility is to be applied. There must be a demonstrated need for the flexible scope, which the operator must justify. The operator must comply with the requirements described in this document.

Before granting a flexible scope, FINAS ensures, through the evidence obtained during assessments, that the operator under assessment has the necessary maturity to operate in accordance with the requirements of a flexible scope.

Basic requirements for implementing a flexible scope

- A description of the principles of the flexible scope and the activities included within it.
- A description and demonstration that the operator has effective, operational, and transparent implementation procedures (validation/verification procedures).
- Comprehensive and appropriate quality assurance procedures that take into account factors causing uncertainty, with systematic monitoring of their effectiveness. The operations must consider FINAS's assessment principle A2 Principles for the assessment of the quality assurance and proficiency testing practices in laboratories.
- An up-to-date list of activities included in the flexible scope, providing information similar to that of a fixed scope.
- A traceable and comprehensive list that clearly shows the changes made to the activities (including reductions).
- A risk analysis covering the flexible scope.

Requirements for management

- Commitment and assurance of sufficient resources.

- Definition of staff responsibilities and authorities, as well as the maintenance of competence, including for the flexible scope.
- Effective procedures to identify risk factors in the operations.
- Assurance that internal audits take into account the activities covered by the flexible scope.

Requirements for persons responsible for the flexible scope

- Competence to adapt operations according to customer needs.
- Ability to analyze the effects and risks of new or modified activities (e.g., resource needs).
- Informing customers about what the accreditation covers and any limitations.
- Good documentation management.

6 Assessment of Flexible Scope

FINAS assesses the need for a flexible scope on a case-by-case basis. The assessment takes into account the operator's ability to demonstrate sufficient management of the flexible scope, the stability of the staff working within the flexible scope, the risks, and the requirements outlined in this document.

The assessment of the management system focuses on the principles and procedures for the flexible scope. The assessment of technical operations emphasizes the methods or activities proposed within the flexible scope and the management of changes, such as validations/verifications.

If, during the first assessment of the flexible scope, it is determined that the operator lacks the maturity and readiness to operate in accordance with the requirements, the flexible scope will not be granted.

During assessments, any changes made to activities under the flexible scope and the related documentation are always reviewed.

The operator must have:

- A detailed list of activities included in the flexible scope.
- Documentation of the use of the flexible scope and any changes made (reductions or expansions within the scope of flexibility).
- Implementation data for extensions (validation/verification data).

If it is found that an operator with a flexible scope has not complied with the requirements of the flexible scope or lacks sufficient expertise to maintain the flexible scope, the assessors will evaluate the significance of the situation. The situation or non-conformity may lead to the temporary or, if necessary, permanent revocation of the flexible scope. The operator may continue operations under a fixed scope if the operations comply with accreditation requirements. The operator must keep its customers informed about the impact of any non-conformity recorded in the flexible scope on their operations.

The assessment ensures that references to accreditation comply with the requirements outlined in the document FINAS V1 Rules for Referring to Accreditation.

7 Targeting of Flexibility

7.1 Methods, standards, requirements

Some method references, such as many standards, are updated frequently, or there may be a need to use older versions of a standard. In such cases, the specific identifier of the method/standard/requirement, such as the year, is omitted from the description of the flexible scope. The operator must have effective procedures in place to monitor updates to methods, standards, and requirements. Review, identification of changes, and implementation must be documented.

7.2 Flexible scope for Testing

In testing operations, flexibility can apply to different parts of the scope: the material/product being tested, or the component/parameter/characteristic being tested, or the test method/standard/technique.

When flexibility concerns the material/product being tested, the laboratory must demonstrate, through adequate validation/verification, the accuracy of the results with different types of materials/products (e.g., environmental samples, food, water).

Flexibility is suitable for test methods where a single method can be used to determine multiple analytes/compounds (e.g., screening for drugs and pharmaceutical substances and identifying new drug and pharmaceutical substances). In such cases, the focus of flexibility in the scope is on the component/parameter/characteristic defined in the scope. Other flexibility targets related to the component/parameter/characteristic being tested could include VOC, PAH, and PCB compounds, as well as elements.

In cases where multiple alternative test methods are available, such as analysis standards, a flexible scope may be useful, provided that the technique remains the same (for example, qPCR, ICP-MS). In these cases, the technique described in the FINAS scope is presented at a general level, and the operator maintains a more detailed list of the specific methods, such as standards, used under the flexible scope. However, it should be noted that the laboratory cannot implement entirely new types of techniques (standards).

7.3 Flexible Scope for Calibration

In calibration laboratories, flexibility can be applied to method versions (see section 7.1), provided that the new method version does not affect the Calibration and Measurement Capability (CMC). In other respects, a fixed scope is sufficient for describing the scope of accreditation for calibration laboratories.

A flexible scope does not apply in situations where a method change affects the CMC value. If the CMC value changes, the calibration laboratory must apply for a modification in the same way as with a fixed scope.

7.4 Flexible Scope for Inspection

In inspection operations, flexibility can be applied to the requirements used in inspections (e.g., standards, see section 7.1). In other respects, a fixed scope is sufficient for describing the scope of accreditation for inspection bodies.

7.5 Flexible Scope for Certification

In certification operations, flexibility can be applied to the requirements used in certification (e.g., standards, see section 7.1). Generally, a fixed scope is sufficient for describing the scope of accreditation for certification bodies.

7.6 Flexible Scope for Proficiency testing providers

For proficiency testing providers, flexibility may relate to the material, product, or matrix and/or the property being tested. Flexibility applies to changes where the proficiency testing provider can add, for example, new types of matrices or new analytes to existing rounds, without making significant changes to the

round itself.

Significant changes could include modifications in the preparation of proficiency test samples (new technique), changes in homogeneity/stability testing, changes in the determination method of the reference value, changes in statistical methods (e.g., from consensus value to reference material), and new types of rounds. These significant changes must be assessed before implementation, and flexibility does not apply to them.

7.7 Flexible scope for Biobank

In biobank operations, flexibility may relate to the method (see section 7.1) or the material.

8 References

ILAC G18:01/2024 Guideline for describing Scopes of Accreditation

EA-2/15 M:2023 EA requirements for the accreditation of flexible scopes

EA-4/17 M:2022 Description of scopes of accreditation for medical laboratories

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

9 Changes from the previous version

This is the first version of FINAS V2