

Swedac's policy on accreditation with flexible scope

Table of contents

1	Introduction.....	3
2	Description of the scope of accreditation	3
2.1	Fixed Scope	3
2.2	Flexible scope.....	3
3	Requirements for accredited bodies with accreditation with flexible scope	4
3.1	Detailed Method List.....	5
3.2	Record of Change	5
3.3	Application	5
4	Swedac's Assessment of Accredited Bodies with Accreditation with Flexible Scope	6
5	Definition of Accreditation with Flexible Scope and Decision on Accreditation	6
5.1	General.....	6
5.2	Testing laboratories including Medical Testing Laboratories	8
5.3	Calibration laboratories	8
5.3.1	Proficiency testing providers	8
5.4	Producers of reference material	9
5.5	Inspection body.....	9
5.6	Certification body for products.....	9
5.7	Certification body for person	10
5.8	Notified bodies according to Regulation (EU) No 305/2011 on construction products (CPR) 10	
5.9	References.....	10

1 Introduction

The purpose of this document is to describe Swedac's policy for the application of flexible scope for accredited bodies and assessors, to clarify the requirements, and to provide guidance to organizations wishing to apply for or already granted flexible scope.

Historically, the scope of the accredited body is based on the accreditation scope published by Swedac. The advantage with this is that it makes clear which activities are accredited, and that competence is re-evaluated each time the accreditation is extended. Some accredited bodies feel that their activities are constrained by only reporting what activities they have accredited instead of giving an account of what they have the competence to perform.

Accredited bodies with granted flexible scope can make changes within its scope without first having it assessed by Swedac.

Accreditation with flexible scope places more responsibility on the accredited body. The organization must demonstrate that it operates according to applicable requirements so that it fulfills its purpose and is carried out impartially, competently, and consistently. Moreover, the organization needs to demonstrate that flexible scope is included in the management system and management review, in internal audits, and relevant risk assessments.

2 Description of the scope of accreditation

2.1 Fixed Scope

For an accredited body, the decision contains a detailed description of the fixed scope of the accreditation, i.e. what the body has the competence to perform within its accreditation. The design and details contained in the description of the scope are adapted to each conformity assessment procedure and area.

2.2 Flexible scope

In decisions on accreditation with flexible scope, Swedac's description of the scope is more comprehensive. However, the accredited body itself must maintain a detailed list of accredited methods/activities, see the heading below.

Accreditation with flexible scope can be obtained when the body meets the necessary requirements. An accredited body that applies for accreditation with flexible scope must demonstrate that it has the competence and resources to meet the requirements.

Competence means that the accredited body is assessed to meet the requirements for compliance with the standard used for accreditation. Additionally, the body is expected to demonstrate that it has implemented a process that ensures the way of working is validated and suitable for the intended area under accreditation.

Changes in the flexible scope must never arise from the accredited body adding completely new areas for which Swedac has not assessed the competence, e.g. accreditation areas and, where applicable, technical areas. For guidance on what this entails for each type of control, see the section entitled [Definition of Accreditation with Flexible Scope and Decision on Accreditation](#). Accreditation may also not be extended to include new branches under flexible scope. If the accredited body already consists of several branches, an activity previously accredited within one branch can be introduced into another using flexible scope, provided it can be demonstrated that the competence for the activity, premises, and equipment is available at the relevant branches within the accredited body, and the requirements of the standards are met.

3 Requirements for accredited bodies with accreditation with flexible scope

There must be processes that ensure the accredited body:



- informs the client/stakeholder during the contract review about and when the assignment may be covered by the flexible accreditation, and any consequences such as costs.
- has sufficient resources, personnel, and equipment to perform the assignment under flexible scope.
- has documented routines for validation/verification that describe
 - how the requirements to be achieved are established,
 - how it develops and validates the process against the set requirements,
 - and verifies that the requirements have been met.
- has routines for training and authorizing personnel who perform specific activities, including established competence requirements for those who approve validation/verification respectively maintains transparent and correct information about what is covered by the accreditation.

- has documented approved personnel who make decisions to introduce/not introduce a new method/activity or change within the given accreditation with flexible scope.
- Participates in proficiency testing, interlaboratory comparisons, or other processes to ensure the reliability of results before a decision on accreditation is made.

Documentation for decisions on the modification or introduction of a new method/activity must be archived. This documentation should include a validation and verification plan, documentation of the validation and verification, and a plan for how the change is implemented in the activities.

3.1 Detailed Method List

The accredited body must always be able to provide a detailed list of the methods/activities included in the flexible scope, updated at the same pace as changes occur. The list is drawn up in accordance with the requirements of Swedac's regulations in force concerning accreditation. On [Swedac's website](#), there are suggestions for the recommended way to present a detailed method list.

The list must be made publicly available upon request and to Swedac before each assessment. The purpose of the list is to provide an up-to-date picture of the flexible scope.

3.2 Record of Change

The accredited body needs to maintain a record that reports the changes made during the four-year assessment cycle, and notify Swedac of this before each inspection. The record needs to specify the changes made since the previous inspection, which method/activity involved, a brief description of the changes made, as well as the date when the change was introduced and implemented and put into use, or removed within the flexible scope of the accreditation.

[Swedac's website](#) provides suggestions on the recommended way to report changes.

3.3 Application

The accredited body must apply in writing to Swedac for accreditation with flexible scope. Swedac normally conducts an assessment cycle before a decision on accreditation with flexible scope can be made.

To the application, the following should be attached:

- A statement of which methods are to be covered and which type of flexible scope the application concerns.
 - Documented process that describes the routine for validation/verification as above,
 - the responsibility for managing both the overall scope of flexible accreditation and the individual activities effectively and adapting as needed to achieve the goals.
- Examples of completed validation/verification
- Completed internal audit showing compliance with this document.

4 Swedac's Assessment of Accredited Bodies with Accreditation with Flexible Scope

During the assessment of the application for flexible scope, Swedac conducts a risk assessment taking into account the scope of the application, knowledge of the accredited body's stability and ability to manage the process for flexible scope, and the prescribing authorities' expectations.

During ordinary surveillance or renewed assessment, the flexible changes made are reviewed from a risk perspective based on the accredited body's stability and competence to work according to the requirements in the relevant standard and those placed on accredited bodies with flexible scope. The focus is to assess how the accredited body controls and implemented flexible changes with regard to validation/verification, traceability, quality controls, competence and training of personnel involved in the changed activity, availability of work instructions, legal requirements, directives, comparisons with other activities, and risk assessment.

If the accredited body have made reports under accreditation where the process for flexible scope does not meet the requirements in the referenced documents, or if deviations against the body's management system or routines are deemed serious, Swedac takes measures considered appropriate. This may involve revoking the accreditation with flexible scope.

5 Definition of Accreditation with Flexible Scope and Decision on Accreditation

5.1 General

A standard method usually refers to an established, generally accepted process or procedure used to perform a task in a consistent and effective manner. Standard methods are often developed through consensus within industries or organizations and aim to ensure quality, safety, and uniformity in performing tasks or managing situations. Examples of standard methods may be ISO standards or regulations developed by authorities or organizations.

A non-standardized method is a procedure that does not follow formally established standards. These methods can be adaptable and developed for specific needs where standards do not exist. They can vary between organizations, making results difficult to compare, but are useful for innovative solutions where standard methods are not sufficient. It is important that these methods are documented and validated thoroughly.

In Medical Testing Laboratories, tests are often determined by the specific analysis instrument used, in accordance with the manufacturer's instructions or protocol. A reference to the instrument, including the manufacturer's name and model or type, can therefore provide a unique identification of the method within the framework of the accreditation.

Principle of measurement is defined in ISO/IEC Guide 99:2004 as phenomenon serving as a basis of a measurement. The phenomenon can be of a physical, chemical, or biological nature.

The scope of accreditation is documented in the decision in force, i.e. the latest decision issued by Swedac (published on www.swedac.se). The level of detail in the decision to specify the scope of the accredited body is determined by the type of flexible scope granted.

The level of flexibility granted is shown in Swedac's decision on accreditation.

5.2 Testing laboratories including Medical Testing Laboratories

A testing laboratory may have accreditation with flexible scope according to one of the following:

Type 1

- Introduce new version of standard method and make editorial changes to non-standard method

Type 2

- Introduce new version of standard method and make editorial changes to non-standard method
- Introduce new version and modifications of standard and non-standard method. The procedure must be equivalent

Introduce new parameter/component/characteristics.

- Introduce new measurement range
- Introduce new material/new products/matrices
- Introduce new method equivalent to methods already in the accreditation decision

The changes introduced through accreditation with flexible scope shall not be based on measurement principles other than those referred to in the scope of accreditation

5.3 Calibration laboratories

A calibration laboratory may have accreditation with flexible scope according to one of the following types:

Type 1

- Introduce new version of standard method and make editorial changes to non-standard method

Type 2

- Introduce new version of standard method and make editorial changes to non-standard method
- Introduce new version and modifications of standard and non-standard method. The procedure must be equivalent.

The changes introduced through accreditation with flexible scope must not involve new measurement principles, changes in measurement range, CMC (best measurement capability), or new quantities other than those included in the accreditation decision for calibration laboratories.

5.3.1 Proficiency testing providers

Proficiency testing providers may have accreditation with flexible scope according to the following:

Type 1

- Introduce new parameter/characteristics in already accredited programme
- Introduce new type of test/test sample in already accredited programme

5.4 Producers of reference material

A producer of reference materials may have accreditation with flexible scope according to the following:

Type 1

- Introduce a new parameter/property into an already accredited reference material

5.5 Inspection body

Inspection bodies that have accreditation in areas regulated by law are not offered accreditation with flexible scope. In voluntary areas, an inspection body may have accreditation with flexible scope according to the following:

Type 1

- Introduce new version of external requirements specification
- Make editorial changes to its own requirements specification
-

5.6 Certification body for products

- Changes introduced through accreditation with flexible scope for product certification bodies must not involve altered requirements for the certification body and/or significant changes regarding the scope or frequency of conformity assessment, according to ISO/IEC 17067.

A certification body for products may have accreditation with flexible scope according to one of the following:

Type 1

- Introduce new version of requirements specification

Type 2

- Introduce new version of requirement specification
- Introduce new version of certification scheme*

Type 3 (only food and building products based on Swedish building regulations according to the regulations of Boverket - the Swedish National Board of Housing, Building and Planning; BBR and Planning and Building Act, PBL)

- Introduce new version of requirements specification

- Introduce new version of certification scheme*
- Introduce new product/process in existing cluster

*Refers only to an already accepted certification scheme (Certification scheme = an overarching term used to describe both the specification of requirements and the certification rule for the current product, service, process).

5.7 Certification body for person

A certification body for persons can have accreditation with flexible scope according to the following:

Type 1

- Introduce new version of requirements specification when it consists of an authority's regulation or standard.

A new version introduced through accreditation with flexible scope may not contain changes to the admission requirements or the examination procedure for personnel certification bodies.

5.8 Notified bodies according to Regulation (EU) No 305/2011 on construction products (CPR)

A notified body may have accreditation with flexible scope according to the following:

Type 1

- Introduce new version of technical specification
- Introduce additions to technical specification

For the notified body, a new version introduced through accreditation with flexible scope shall not introduce new systems for Assessment and Verification of Constancy of Performance (AVCP).

5.9 References

1. EA-2/15 M: 2023 EA Requirements for the Accreditation of Flexible Scopes
2. SS-EN ISO/IEC 17011:2018 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies (ISO / IEC 17011:2017)
3. ILAC P9:01/2024 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing
4. ILAC-G18:01/2024 Guideline for describing Scopes of Accreditation
5. ISO/IEC 17067:2013 Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes