

Policy

PL - 21

SNAS POLICY FOR ACCREDITATION OF FLEXIBLE SCOPE

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PURPOSE: This document determines SNAS Policy for Accreditation of Flexible Scope.

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1 INTRODUCTION

Fixed scope which precisely defines what concrete activities the conformity assessment body (CAB) is accredited for. CAB shall not refer to its accreditation status outside of these activities. In case of need for extension of accredited activities, CAB will request the accreditation body for so-called the extension of accreditation. After assessment and evaluation of fulfillment the relevant requirements the accreditation body will extend the field or scope of accreditation of CAB. This type of accreditation is suitable for CAB which has stable type of activities and need not adapt itself to the customer requirements often and quickly.

Contrary to the fixed scope the “flexible scope” enables CAB to take responsibility for control of its flexible accreditation scope. The scope of accreditation is not described in such a concrete way like in the case of fixed scope. It can be accommodated and extended after carrying out of documented steps (e.g. making changes and extensions to new activities within the allowed and defined flexibility) and fulfillment the relevant requirements defined by accreditation body and CAB without previous assessment by accreditation body.

2 SNAS POLICY FOR ACCREDITATION OF FLEXIBLE SCOPE

SNAS offers the accreditation of flexible scope in the field of accreditation of calibration, testing and medical laboratories. These types of laboratories shall fulfill the requirements of accreditation schemes and guidelines given in “SNAS policy for accreditation of laboratories” (PL-07), documents EA-2/15 „EA Requirements for the Accreditation of Flexible Scopes“ (MSA-07), MSA-L/01 „Field and scope of accreditation of laboratories” and MSA-04 “Procedure for the accreditation”.

According to implementation of the document EA-2/15, ILAC G18 and EA-4/17. SNAS enables laboratories to be accredited only with fix scope of accreditation or only with flexible scope of accreditation. There is also possibility to accredit partly fix and partly flexible scope of accreditation. Management of flexible scope of accreditation is the responsibility of laboratories and they don't need to ask SNAS for approval in advance.

The principle of flexibility laboratories can used e.g. within the materials, matrixes, environments, analytes and procedures for testing, clinical examination, calibration and it is described in MSA-L/01.

SNAS does not allow laboratories to use the principle of flexibility for:

1. In calibration laboratory:
 - the new principle,
 - the new field of accreditation defined by SNAS,
 - the new workplace,
 - the new place of activity,
 - the new field of accreditation covered by another accreditation scheme, (testing,

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clinical examination, inspection, certification).

- concerning CMC (uncertainty)
- concerning measurement range
- concerning the modification of the method other than the measuring range and the CMC

2. in testing laboratory:

- the new principle,
- the new field of accreditation defined by SNAS,
- the new workplace,
- the new place of activity,
- the new field of accreditation covered by another accreditation scheme, (calibration, clinical examination, inspection, certification).

3. In medical laboratory:

- the new principle,
- the new field of accreditation defined by SNAS,
- the new workplace,
- the new place of activity,
- the new field of accreditation covered by another accreditation scheme, (testing, calibration, inspection, certification).

The flexibility may cover the whole scope of accredited activities or the part of them only. SNAS following the decision on accreditation granting (first accreditation or re-accreditation) will issue the accreditation certificate which will include annex with description of flexible scope, too. Scope of accreditation is basis for the “List of accredited activities” (further “List” only), which also contains information regarding boundaries of flexibility. At the next assessment by SNAS, changes within a flexible scope can be included in the annex to the accreditation certificate. If SNAS finds that the CAB does not meet the requirements set out in this document, it may reconsider the scope, such as to reduce or even withdraw the flexibility.

Scope of accreditation, issued SNAS, is different from the List. The list of laboratories with a flexible scope shall provide updated transparent information on the application of the flexible scope of accreditation. The list has to be up-to-date and publicly accessible, unless there is a valid reason why not to do it (e.g. regulatory requirements). The scope of accreditation must include a reference to the List.

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The laboratory shall immediately inform SNAS in writing about changes carried out and keep the history of them during the period of validity of accreditation as a minimum.

The accredited laboratory flexible scope relates to the particular staff of laboratory who can modify and validate methods. These laboratory staff, competent to modify and validate methods, are listed in the valid scope of accreditation.

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SNAS considers the results of laboratory accredited activities (clinical examination, testing, calibration, measurement, etc.) as equal and on the same qualitative level regardless they were obtained under the fixed or flexible scope.

3 RELATED DOCUMENTS

ISO/IEC 17011	Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies
EA-2/15	EA Requirements for the Accreditation of Flexible Scopes
ILAC G18	Guideline for describing Scopes of Accreditation
EA-4/17	Description of scopes of accreditation of medical laboratories
PL-07	SNAS Policy on accreditation of laboratories
MSA-04	Procedures for Accreditation
MSA-07	EA Requirements for the accreditation of flexible scopes
MSA-L/01	Field and Scope of Accreditation of Laboratories

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