

LATAK-D.041

FLEXIBLE SCOPE OF ACCREDITATION

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Autorship and basic principles

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The text of the document can be translated to other languages. The text in Latvian language remains as official text.

Further information

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Purpose

The laboratories accredited in the field of testing, calibration and medical examinations (hereinafter – CAB), which have been granted a flexible scope of accreditation, are allowed to start using new methods without the procedure for expanding the scope, provided that they do not include new measurement principles, as well as to modify the methods elaborated by the CAB, and to introduce new versions of standards. By applying or maintaining a flexible scope of accreditation, CAB shall independently carry out the assessment of the method, commence activities, and issue results with reference to accreditation.

Such an approach enables the CAB to adapt its activities by providing a swift response to demand and supply, such as testing new products, using new testing equipment.

The document provides instructions for the CABs working in the field of testing, calibration, and medical examinations which have applied for or have already been granted accreditation in a flexible scope. The document incorporates certain requirements to ensure compliance with the requirements of standards LVS EN ISO/IEC 17025 and LVS EN ISO 15189, as well as to take into account the provisions of documents ILAC-G18, EA-2/15 and EA-4/17.

State Agency “Latvian National Accreditation Bureau” (hereinafter – LATAK) shall retain the right to decide how to define the scope and whether or not to grant a flexible scope to a particular CAB.

1. Scope of accreditation

1.1. The accredited activities of the CAB are described in the scope of accreditation. The fields of activities of the CAB must be defined in the scope of accreditation in such a way that it is possible to clearly and unambiguously determine and identify the range of activities covered by the CAB accreditation, being it also understandable for potential customers of the CAB and other interested parties.

1.2. The formulation and assessment of the scope of accreditation is a key element of the accreditation process. The task of the LATAK is to make sure that the CAB is competent, impartiality and consistent to offer services defined in the CAB’s scope of accreditation. LATAK carries out an assessment before every change in the scope of accreditation. During the accreditation cycle, CABs have an opportunity to expand the scope of accreditation at any time by applying for changes to LATAK, taking into account that this accreditation procedure is time-consuming and may impede timely execution of customer’s requirements.

1.3. Under the flexible scope of accreditation, based on the CAB competences assessed during the previous accreditation procedures, CABs are given the opportunity to independently update or, within the granted flexibility, to introduce new or modified methods and issue results with reference to accreditation.

2. General requirements

2.1. ANI with a flexible scope of accreditation can perform sampling, testing, calibration, medical examinations, primary sample collection and report results as accredited only within the accredited scope. Those new measurement principles that are outside the flexible scope of accreditation may not be included in the new or modified methods. In order to expand the scope with such methods, CAB must submit an application to LATAK related to the expansion of the scope, followed by certain process aimed at the expansion of the scope of accreditation.

2.2. Flexible scope of accreditation establishes an additional responsibility for the CAB related to the confirmation of its competence. The CAB having a flexible scope must confirm to LATAK that it has knowledge, experience and competences to perform activities within the framework of flexible scope, as well as that it is sufficiently provided with resources. The implementation of the flexible scope of activities must be individually performed by each CAB as may be needed, precisely defining the requirements for maintenance of the flexible scope and presenting this approach to LATAK, proving thereby that it is suitable for the intended use and the CAB can properly monitor it.

2.3. If a flexible scope of accreditation has been granted to the CAB, it is allowed to include additional activities in its accredited scope of activities and refer to the accreditation on the basis of the assessments made by the CAB itself. The possibility of introducing new, modified or elaborated methods into a flexible scope of activities does not include the introduction of new testing or calibration measurement principles which were not previously covered by the accreditation. A flexible scope of activities can be determined on the basis of different choices, e.g. flexibility may be referred to:

- a) object/ matrix/ sample;
- b) parameters/ components/ analytes;
- c) execution of a method (it allows changing the performance of the method for a sample of specific type and for a parameter);
- d) method (equivalent methods in the granted field of accreditation).

2.4. The CAB wishing to apply for a flexible scope of accreditation must demonstrate that its management system ensures monitoring of the relevant scope of activities and continuous conformity with all the requirements set in standard LVS EN ISO/IEC 17025 *or* LVS EN ISO 15189, proving that the activities performed by the CAB in order to monitor the flexible scope of accreditation are suitable for the relevant purpose, and that impartiality, personnel competences and consistent performance of activities are ensured. This approach must be included in the management system documentation and operational processes, such as audits, validation/verification procedures, competence of key personnel, maintenance of traceable records and reports. If ANI has multiple locations, the above applies to them as well.

2.5. Flexibility limits must be clearly defined upon formulation of the flexible scope of activities. The defined and flexible scope of activities may be described separately or

combined within single scope of accreditation (see Annex). In all cases, CAB must maintain and publish an updated list of methods on the CAB website, making it available to customers, LATAK and other interested parties.

2.6. In calibration, flexibility cannot be attributed to the range and uncertainty of calibration and measurement capability.

3. Requirements for maintaining the flexible scope of accreditation

3.1. Requirements related to the personnel qualification

3.1.1. Involved personnel must have documented job descriptions regarding the manage, maintenance and control of the flexible scope of accreditation.

3.1.2. The personnel that elaborates and modifies methods and has appropriate qualifications and the necessary understanding of the method and the technology applied in it must be able to consider the appropriateness of methods and reliability of the results obtained.

3.1.3. It is required to determine competence criteria for the personnel by specifying the qualification, experience and necessary knowledge, by requiring, for example, that the personnel must have:

- a) general knowledge of the scope of activities of CAB's customers and related risks, as well as knowledge of the use of the testing/ calibration results;
- b) knowledge of procedures, their applicability and related uncertainties;
- c) formal education and practical work experience in the relevant field;
- d) passed organised trainings with their effectiveness being assessed.

3.1.4. It is required to keep records on personnel's authorisations and competences.

3.2. Requirements for the implementation of new or modified methods in the accredited scope of activities

3.2.1. By maintaining the flexible scope of accreditation and implementing new methods or modifying existing ones, the CAB shall undertake full responsibility to ensure that all methods are validated or verified to the required extent to ensure their suitability for intended usage. The CAB must:

- a) elaborate and maintain procedures relating to the elaboration and confirmation of methods (including modifications of parameters and matrices) and to the additional checking of methods;
- b) authorise the competent personnel responsible for the elaboration and confirmation of new and modified methods;
- c) keep all records regarding the whole process – starting from the elaboration of a method, its validation/confirmation and verification. The information must be sufficient to make sure that the activities carried out upon implementation

of each new and/or modified method can be fully traced during internal and external audits;

- d) managing authorities of the CAB should be responsible for the proper maintenance of the accredited flexible scope.

3.2.2. ~~Managing authorities of the~~ CAB shall periodically review the procedures and authorisations related to the elaboration or revision of accredited methods, taking into account the results of internal and external quality control.

3.2.3. Validation shall not apply where standard methods or equivalent methods are selected in a given field. However, validation should be performed where in a standard method is used new testing/ calibration principle/ purpose.

3.2.4. A register of validation and verification of methods must be maintained and validation and verification protocols/ records must be kept. A revision of a method is not a basis for granting a new version, except in cases where it is necessary to demonstrate that the method still meets the requirements set by the client. In such cases, the reason for updating the method must be clearly reflected and LATAK must be informed accordingly when submitting documents prior to the assessment.

3.2.5. The list of methods in the accredited flexible scope, incorporating modified, recently introduced or improved methods, must be maintained and constantly kept updated.

3.3. Processing of documents/ protocols

3.3.1. The CAB must set up documented procedures for the elaboration of new methods or their modification (including parameters and matrices). LATAK shall assess the suitability of these procedures before granting accreditation in the flexible scope.

3.3.2. The CAB must constantly maintain and keep all records on the entirety of the activities relating to the methods in the flexible scope of accreditation. Records related to validation and verification of the activities performed and data obtained must be kept and submitted for review during the routine assessment by LATAK.

3.3.3. ANI must constantly maintain and update the list of methods for the flexible accreditation scope, in accordance with the document management procedures established by ANI (e.g., versioning, specified retention period for archived documents).

3.4. Management

3.4.1. The responsible personnel of the CAB must regularly review modified, updated or newly elaborated methods to ensure that they continue to meet the set requirements.

3.4.2. The process for implementing methods and maintaining the flexible scope of accreditation must be included in the internal audit programme and be reviewed in the management reviews.

3.4.3. Accordingly, demands, applications and contracts must be reviewed to determine customers' requirements and/or whether the required parameters are covered with the framework of the flexible scope of accreditation. If, at the customer's request, it is required to implement a new method or modify the existing one within the flexible scope, the CAB must assess whether the necessary technical resources are available to perform the order according to the deadline determined by the customer, and this information must be provided to the customer. If necessary, the customer must be informed about the procedure for implementing a new or modified method, the time and costs required for this purpose. The list of methods in the flexible scope of accreditation shall be updated only after all the relevant technical operations have been carried out and the new or modified method has been approved by the authorised personnel.

3.4.4. If, upon implementing the method or already working with an approved method, the CAB concludes that it is unable to deliver valid results, the CAB must analyse the relevant reasons and take appropriate corrective actions, including:

- a) the customer must be informed about the process of method implementation and reasons why the CAB cannot issue accredited results;
- b) procedures and methods must be reviewed to find out potential problems and to remedy possible non-conformities;
- c) the flexible scope is to be reviewed and its limits are to be redefined, informing LATAK accordingly thereof.

4. Application for accreditation in the flexible scope and procedures for assessing the CAB

4.1. Application for accreditation in the flexible scope shall be accepted from the CAB which has been accredited for at least one accreditation cycle, except for specific fields where it is not possible to draw up the accreditation scope in a defined manner.

4.2. By granting accreditation in a flexible scope, LATAK imposes additional high reliability requirements on the CAB. The CAB must ensure that the personnel has technical competence and confidence that the quality management system effectively controls the appropriate maintenance processes of the flexible scope of accreditation. Each application submitted by the CAB shall be considered on a case-by-case basis, taking into account previously demonstrated results and level of the operational risks of the CAB, in addition to the usual risks associated with accreditation processes (see EA-2/19 INF:2022), the following aspects:

- a) the CAB's understanding of the implementation and robustness of the management process of the flexible scope of activities;
- b) the performance and stability of the CAB management system;

- c) complexity and level of familiarity of the LATAK with the conformity assessment activities (with new and emerging activities the competency requirements may not yet be fully known);
- d) the degree of flexibility extended and granted by CAB;
- e) reputational risks for the CAB, LATAK and the market;
- f) stability of the CAB's technical personnel;
- g) requirements of the interested parties/ regulatory enactments;
- h) the planned frequency of use of the flexible scope of activities;
- i) location and geographical risks;
- j) historic knowledge of the CAB and its compliance to the relevant standards and activities;
- k) ability of the CAB to demonstrate that the way that it operates is valid, fit-for-purpose, and is undertaken impartially, competently and consistently.

4.3. For reassessment or scope expansion, CAB submits an application to LATAK for granting accreditation in the flexible scope, a correspondingly designed flexible accreditation scope project and a list of current methods. The current list of methods must also be submitted for regular monitoring. In the current list of methods, CAB indicates the minimum information included in the accreditation scope design form F.003 (published on the LATAK website).

4.4. When assessing the scope of flexible accreditation, LATAK shall assess the compliance of the CAB activities with the requirements of standards LVS EN ISO/IEC 17025 and LVS EN ISO 15189, the assessing process should include the examination of real examples, should take a risk-based approach described in point 4.2, including the following aspects:

- a) all additional/ modified activities and validation/ verification of the relevant methods;
- b) reviews of requests, competitions and contracts;
- c) the competence and powers of the personnel;
- d) assessment performed as to measurement uncertainty, traceability of equipment and measurements;
- e) monitoring of skill checks and reliability of results;
- f) reviews of procedures;
- g) internal audits performed and their results
- h) availability of regulatory and technical documents (technical regulations, standards, directives);
- i) performance and stability of the CAB's management system for the boundaries requested;

- j) the planned frequency of use of the flexible scope, i.e. release and publication of the list of flexible scope methods;
- k) risk assessment;
- l) proofs of the performance of the full process, including the actions and controls implemented by the ANI to manage the flexible scope for each requested border.

4.5. At the request of LATAK (e.g. before the routine monitoring visit, third party request, complaints), the CAB shall submit an updated list of methods in the flexible scope of accreditation, identifying the changes made compared to the list of methods previously submitted to LATAK.

4.6. Implementation and efficiency of the CAB quality management system as to controlling the flexible scope of accreditation shall be assessed as a part of the usual assessment cycle. According to certain time periods, there are performed monitoring and repeated assessment visits to assess the continuity of the quality management system. They shall include an assessment of laboratory protocols and this assessment shall be performed in a random manner with regard to decisions to make changes to the list of methods in the flexible scope of accreditation, including those made in relation to the usage of a new and/ or modified method that has taken place since previous monitoring or reassessment procedure by LATAK. Based on the information submitted by the CAB and the risk assessment, LATAK shall plan the routine or extraordinary monitoring process by carrying out an assessment of the practical activities for the newly implemented or modified methods in the flexible scope of accreditation. Number of days for these monitoring visits depends on selected system, technique of included field, number and complexity of included methods. In some cases, additional visit may be requested which is to be agreed during the course of routine visits.

4.7. Between regular visits, LATAK may choose to assess methods included within the flexible scope of accreditation, by requesting the CAB to submit protocols for assessment related to the validation/ verification/ reviewing of methods.

4.8. If it is found that the CAB's management system is not maintained and control is inefficient, thus resulting in implementation of inappropriate new and modified methods, LATAK shall take the necessary actions according to the extent of the nature, impact and frequency of the systemic non-compliance. LATAK actions may be as follows:

- a) suspension of the specific flexible field/ scope;
- b) withdraw CAB to operate in the flexible scope of accreditation;
- c) suspension of the entirety of the accredited scope.

5. Drawing up the flexible scope of accreditation

5.1. The flexible scope of accreditation shall be drawn up in a way similar to the general requirements set by LATAK for drawing up a scope of accreditation. The flexible scope shall be clearly identified in the accreditation certificate and in the annex to the certificate. In the

flexible scope, a reference to the list of methods applied by ANI, which is published on the ANI website, is indicated in the annex to the accreditation certificate.

5.2. The drawing-up of the flexible scope of accreditation depends on the type of the flexible scope, but it should always be agreed between the CAB and LATAK, following the instructions of ILAC G18, EA-2/15, EA-4/17.

References

1. LVS EN ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories (ISO 17025:2017)”
2. LVS EN ISO 15189:2023 “Medical laboratories — Requirements for quality and competence (ISO 15189:2022)”
3. ILAC-G18:01/2024 “Guideline for describing Scopes of Accreditation”
4. EA-2/15 M:2023 “EA Requirements for the Accreditation of Flexible Scopes”
5. EA-4/17 M:2022 “Description of scopes of accreditation for medical laboratories”

Register of changes made

Version	Content of changes	Date
03	The document has been recast.	16.06.2021
04	Updated, incl. bibliography, according to documents ILAC-G18:01/2024, EA-4/17 M:2022, LVS EN ISO 15189:202313 Added clause 2.6 that flexibility in calibration cannot be attributed to the range and uncertainty of calibration and measurement capability	25.03.2024
05	<p>The section “Purpose” has been supplemented – <i>State Agency “Latvian National Accreditation Bureau” (hereinafter – LATAK) shall retain the right to decide how to define the scope and whether or not to grant a flexible scope to a particular CAB</i></p> <p>Added clause 1.3 that CABs are given the opportunity to independently update or, within the granted flexibility, to introduce new <i>or modified</i> methods and issue results with reference to accreditation</p> <p>Added clause 2.1 – with sampling and primary sample collection</p> <p>Added clause 2.4 – <i>if ANI has multiple locations, the above applies to them as well</i></p> <p>Added clause 3.1.1 – involved personnel must have documented job descriptions regarding the <i>manage</i>, maintenance and control of the flexible scope of accreditation</p> <p>Added clause 3.1.3 a) – general knowledge of the scope of activities of CAB’s customers and related risks, as well as knowledge of the use of the testing/ <i>calibration</i> results</p> <p>Added clause 3.2.3 – however, validation should be performed where in a standard method is used new testing/ <i>calibration principle/ purpose</i></p> <p>Added clause 3.2.4 – <i>a revision of a method is not a basis for granting a new version, except in cases where it is necessary to demonstrate that the method still meets the requirements set by the client. In such cases, the reason for updating the method must be clearly reflected and LATAK must be informed accordingly when submitting documents prior to the assessment</i></p> <p>Added and updated clause 3.3.3. – <i>in accordance with the document management procedures established by ANI (e.g., versioning, specified retention period for archived documents)</i></p> <p>Added and updated clause 4.2 – each application submitted by the CAB shall be considered on a case-by-case basis, taking into account previously demonstrated results and level of the</p>	26.03.2025

	<p>operational risks of the CAB, <i>in addition to the usual risks associated with accreditation processes (see EA-2/19 INF:2022)</i>, the following aspects:</p> <p>a) the CAB's understanding of the implementation and <i>robustness of the management process</i> of the flexible scope of activities;</p> <p>c) <i>complexity and level of familiarity of the LATAK with the conformity assessment activities (with new and emerging activities the competency requirements may not yet be fully known)</i>;</p> <p>j) <i>historic knowledge of the CAB and its compliance to the relevant standards and activities</i>;</p> <p>k) <i>ability of the CAB to demonstrate that the way that it operates is valid, fit-for-purpose, and is undertaken impartially, competently and consistently</i></p> <p>Added clause 4.3 – <i>or scope expansion. In the current list of methods, CAB indicates the minimum information included in the accreditation scope design form F.003 (published on the LATAK website)</i></p> <p>Updated clause 4.4 – <i>the assessing process should include the examination of real examples, should take a risk-based approach described in point 4.2, including the following aspects:</i></p> <p>a) <i>all additional/ modified activities and validation/ verification of the relevant methods</i>;</p> <p>h) <i>availability of regulatory and technical documents (technical regulations, standards, directives)</i>;</p> <p>i) <i>performance and stability of the CAB's management system for the boundaries requested</i>;</p> <p>j) <i>the planned frequency of use of the flexible scope, i.e. release and publication of the list of flexible scope methods</i>;</p> <p>k) <i>risk assessment</i>;</p> <p>l) <i>proofs of the performance of the full process, including the actions and controls implemented by the ANI to manage the flexible scope for each requested border</i></p> <p>Added clause 5.1 – <i>in the flexible scope, a reference to the list of methods applied by ANI, which is published on the ANI website, is indicated in the annex to the accreditation certificate</i></p> <p>Updated the document EA-2/15 M:2023 in the list of references</p>	
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Examples of drawing up the flexible scope of accreditation

Example 1 – flexibility refers to the parameter to be determined (example, names of pesticides)

Object	Parameter	Testing principle	Method
Food products	Pesticides (CIPAC)	Gas chromatography	1. 2.

Example 2 – flexibility refers to the current version of standards

Environmental object	Parameter	Standard method
Soil, surface water	Total phosphorus	LVS EN ISO 6878

Example 3 – Flexibility refers to the parameter to be determined (example, medical scope)

Scope to be examined	Method, technology	Material to be examined
Clinical chemistry	Electrophoresis	Blood serum
Microbiology (bacteriology, mycology)	PCR	Blood serum