# LATAK-D.17043

## Accreditation scheme of proficiency testing providers

## Contents

## 1. Accreditation criteria

1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;
2. The Law “On Conformity Assessment”;
3. Cabinet Regulation No 754 of 19 December 2023 “Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies” (hereinafter – Regulation No 754);
4. Cabinet Regulation No 666 of 25 October 2022 “Price List for Paid Services of the State Agency "Latvian National Accreditation Bureau"”;
5. LVS EN ISO/ IEC 17043:2023 “Conformity assessment - General requirements for the competence of proficiency testing providers (ISO/IEC 17043:2023)”
6. LVS EN ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017)” (hereinafter – standard LVS EN ISO/IEC 17025:2017);
7. LVS EN ISO 15189:2023 “Medical laboratories - Requirements for quality and competence (ISO 15189:2022)” (hereinafter – standard LVS EN ISO 15189)
8. LATAK document LATAK-D.007 “LATAK policy for participation in proficiency testing programmes and interlaboratory comparisons” (hereinafter - document LATAK-D.007);
9. LATAK document LATAK-D.008 “Accreditation procedures” (hereinafter - document LATAK-D.008);
10. LATAK document LATAK-D.011 “Regulations on the use of the national accreditation mark and the reference to accreditation and EA MLA” (hereinafter - document LATAK-D.011);
11. LATAK document LATAK-D.034 “LATAK policy for metrological traceability of measurement results” (hereinafter – document LATAK-D.034);

Additional criteria for PT schemes (hereinafter – PT) infield of calibration:

12. Document EA-4/02 M “Evaluation of the Uncertainty of Measurement in Calibration”;
13. Document ILAC-P14 “ILAC Policy for Measurement Uncertainty in Calibration”.

## 2. Additional information and specific requirements

Conformity assessment bodies (hereinafter – CABs) within the accreditation scope of proficiency testing providers shall ensure continual compliance with the accreditation criteria.

### 2.1. Metrological traceability

1. The CAB shall ensure metrological traceability of measurement results for the assigned value of the proficiency testing (hereinafter – PT) item, in accordance with

document LATAK-D.034, published on the LATAK website www.latak.gov.lv. For testing and calibration activities, document ILAC-P10 "ILAC Policy on Metrological Traceability of Measurement Results" also applies (link https://ilac.org/publications-and-resources/ilac-policy-series/).

2. For information on activities involving reference materials/ measurement standards, see document EA-4/14 INF "Selection and use of reference materials" (link: https://european-accreditation.org/publications/ea-4-14-inf/).
3. Metrological traceability of the assigned value used in the PT scheme shall be ensured in accordance with the metrological traceability requirements specified in ISO/IEC 17025 and ISO 15189. For PT schemes in the field of calibration, assigned values with metrological traceability to the International System of Units (SI) shall be mandatory. For PT schemes in fields other than calibration, the applicability of metrological traceability and the associated uncertainty of the assigned value shall be evaluated, taking into account the objective (intended use) of the PT scheme.

## 2.2. Development, planning and provision of proficiency testing schemes

1. When developing PT schemes, the type of expected results, frequency, method of distribution, process, method for assigning values and/or performance evaluation criteria shall be taken into account.
2. The CAB shall document all activities related to the development and planning of the PT scheme and retain the relevant records.
3. The PT scheme plan shall be available for initial accreditation and when planning new fields, to demonstrate that the requirements of the standards are met. A document review shall be performed when changes are made to the PT scheme.
4. The CAB shall have technical knowledge and experience in the field of testing, calibration, sampling, including statistics; where necessary, such expertise may also be provided by an advisory or consultant group
5. The CAB shall define and ensure a mandatory level of competence and experience for its management and personnel; permanent staff or contracted personnel shall be competent and subject to oversight.
6. The CAB shall indicate which PT scheme activities are performed by external service providers.
7. Performance criteria for the methods and equipment used to confirm the homogeneity and stability of the PT item (property/characteristic) shall be maintained. The procedure for evaluating homogeneity and stability shall be consistent with appropriate statistical models.
8. For PT schemes involving transport of the PT item, including between PT participants, documented transport instructions shall be in place.
9. The properties/characteristics of PT items (e.g., matrices, measurands, concentrations, etc.) shall be as close as possible to the items or materials used in routine testing or calibration.
10. The CAB shall clearly define the statistical model used and the data analysis methods.

11. The CAB shall have a policy, procedure and knowledge for comparing results obtained by different methods in cases where participants use methods of their own choice.
12. The CAB shall provide an alternative approach in cases where the number of participants is not sufficient.
13. The CAB shall develop a policy for communicating assigned values.
14. The CAB shall establish procedures for cases where collusion or falsification of results is detected.
15. The CAB shall develop and implement a procedure for the selection, procurement/acquisition, collection, identification, preparation, processing, transport, storage and, where applicable, disposal of PT items. In addition, specific actions shall be defined for cases of lost, delayed or damaged PT items.

## 2.3. Evaluation and reporting of proficiency testing scheme results

1. External service providers shall not be used for the evaluation of PT performance and the approval of reports.
2. The results received from participants shall be analysed using appropriate methods, e.g., ISO 13528. Procedures shall be in place to verify the correctness of data entry, transmission, statistical analysis and reporting. Using an appropriate statistical approach, the influence of outlying data on summary statistics shall be reduced.
3. There shall be a documented arrangement for data integrity and IT systems management for the collection, processing and reporting of results, including a description of data flows, access control, change traceability, validation of data entry/processing, ensuring the confidentiality of participant data, data backup/restore and incident management.
4. The PT provider shall develop criteria and procedures to be applied for handling results that may be unsuitable for statistical evaluation, as well as for identifying and managing PT items that have been distributed and subsequently found to be unsuitable for performance evaluation.
5. Appropriate evaluation methods, consistent with the PT scheme and including justification of the evaluation, shall be used to evaluate the performance of PT participants.
6. The report shall be clear, accurate, objective and comprehensive, and shall include data from all participants, additionally indicating the performance of each participant. Before reporting the final results, preliminary results may be issued (in the form of an interim report). If the report does not include all intended information, the CAB shall provide a justified explanation in the report.
7. In cases with a small number of participants, when evaluating results the provider may use document EA-4/20 INF:2018 “Guidelines for the assessment of the suitability of small interlaboratory comparisons within the process of laboratory accreditation” (link: https://european-accreditation.org/wp-content/uploads/2018/10/ea-4-21-inf-rev00-march-18.pdf).

8. The PT provider shall have a documented procedure for handling complaints and appeals. The description of the complaints and appeals handling process shall be publicly available.

## 2.4. Evaluation of measurement uncertainty

1. The CAB shall evaluate the measurement uncertainty of the assigned value of the PT item, identifying all contributions to measurement uncertainty, including those arising from sampling.
2. The unit of uncertainty shall always be the same as that of the measurand, or it shall be expressed as a dimensionless relative value with respect to the measured value.
3. In addition, if a consensus value is used as the assigned value, the CAB shall have an evaluation of the uncertainty of the assigned value.
4. The following documents may be applied for the evaluation of measurement uncertainty:
   4.1. EA-4/02M "Evaluation of the Uncertainty of Measurement in Calibration" (link: https://european-accreditation.org/publications/ea-4-02-m/);
   4.2. ILAC-P14 "*ILAC* Policy for Measurement Uncertainty in Calibration" (link: https://ilac.org/publications-and-resources/ilac-policy-series/);
   4.3. ILAC-G17 "*ILAC* Guidelines for Measurement Uncertainty in Testing" (link: https://ilac.org/publications-and-resources/ilac-guidance-series/).

## 2.5. Proficiency testing/ participation in interlaboratory comparisons

1. If the CAB itself provides the determination of the assigned value, the CAB shall participate in external proficiency testing and/or interlaboratory comparisons. If the determination of the assigned value is provided by a subcontractor, the CAB shall ensure oversight to confirm that the reliability of the measurement results for the PT item's assigned value is demonstrated through participation in proficiency testing and/or interlaboratory comparisons.
2. For additional information, see the following documents:
   2.1 LATAK-D.007 "LATAK policy for participation in proficiency testing programmes and interlaboratory comparisons";
   2.2 EA-4/18 G "Guidance on the level and frequency of proficiency testing participation" (link: https://european-accreditation.org/publications/ea-4-18-inf/);
   2.3 EA-4/21 INF "Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation" (link: https://european-accreditation.org/publications/ea-4_21-inf/);
   2.4 ILAC-P9 "ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing" (link: https://ilac.org/publications-and-resources/ilac-policy-series/).

## 2.6. Risks

1. The CAB shall assess risks in order to evaluate critical aspects and timely identify nonconformities that may affect/ alter PT activities.
2. For risk assessment, the CAB shall select a risk assessment methodology, identify risks, assess the likelihood of occurrence of the identified risks, evaluate the detectability of potential risks, the consequences of risks, and plan and implement risk-mitigating measures. In risk assessment, the main criterion is the impact of the risk on PT activities in order to achieve the PT provider's objectives and tasks.

## 3. Formatting of the scope of accreditation

1. The scope of accreditation describes the CAB's accredited activities. In the scope of accreditation, the CAB's fields of activity shall be defined in such a way that the object, the range of activities, and the parameter/measurand covered by the CAB's accreditation can be determined accurately and unambiguously, and that it is understandable to the CAB's potential customers and other interested parties.
2. For the preparation of the scope of accreditation, the CAB shall submit a properly completed scope of accreditation application form F.003 (see Section 4 of this document "Documents to be submitted").
3. In the CAB's scope of accreditation, the PT scheme identification, the type of PT item, measuring instrument or material, and the characteristic(s) to be determined shall be indicated, for example:
   3.1 the scheme identification may be indicated as a number, a name, or another distinct identification;
   3.2 the PT item may be specified explicitly, or it may be described by indicating the relevant technical field or by dividing it into sub-fields that include the PT item/ matrix.
4. For additional information on scope formatting, see document ILAC-G18 "Guidelines for describing scopes of accreditation" (link: https://ilac.org/publications-and-resources/ilac-guidance-series/).

## 4. Documents to be submitted

1. When applying for accreditation, the CAB shall submit to LATAK the documents necessary to initiate the accreditation process, as specified in form **F.002.PP** "Documents to be submitted to the Bureau" (this and other forms are available on the LATAK website https://www.latak.gov.lv/lv/prasmes-parbauzu-organizetajiem), including the application form F.003 (Annex 1 to document LATAK-D.008) and the attached scope formatting form "Proficiency testing" (Annex 9 to the application), available on the LATAK website https://www.latak.gov.lv/lv/visparejie-dokumenti-ieskaitot-pieteikuma-formu.
2. After accreditation has been granted, for the implementation of surveillance activities, before the assessment visit the CAB shall submit the following documents:

2.1 **information on changes to the scope of accreditation**. If changes have been made to the scope of accreditation (reduction, extension, update of the PT scheme) or if the information included in application form F.003 needs to be updated, the CAB shall submit application form F.003 (Annex 1 to LATAK-D.008) and the attached scope formatting form "Proficiency testing" (Annex 9 to the application), clearly identifying the changes made compared to the existing scope of accreditation;

2.2 **LATAK form F.045** "Report on participation in external proficiency testing or interlaboratory comparisons";

2.3 **LATAK form F.046** "List of reference materials/ measurement standards/ calibrators";

2.4 **LATAK form F.059** "Personnel list (in the conformity assessment field)";

2.5 **LATAK form F.060** "Information on equipment and measuring instruments";

2.6 **LATAK form F.069** "List of subcontractors";

2.7 Metrological traceability schemes, where applicable;

2.8 other documents specified in LATAK form F.002.PP, if changes have been made.

3. Before the scope extension procedure, the CAB shall submit to LATAK the documents referred to in item 2 of this section, including the PT scheme description and the report.
4. At the end of the accreditation cycle (5 years), for the implementation of the reassessment process, the CAB shall submit, 4 months before the end of the accreditation cycle, application form F.003 (Annex 1 to LATAK-D.008) and the attached scope formatting form "Proficiency testing" (Annex 9 to the application), as well as the documents specified in form F.002.PP, if changes have been made.
5. Detailed information on the procedure for submission and review of documents is specified in document LATAK-D.008, available on the LATAK website https://www.latak.gov.lv/lv/visparejie-dokumenti-ieskaitot-pieteikuma-formu.
6. Before planned surveillance and reassessment visits, LATAK sends the CAB an information request letter.

## 5. Assessment procedure by LATAK

1. In accordance with paragraph 10 of Cabinet Regulation No 754, LATAK concludes an agreement and initiates the CAB assessment process after receiving all necessary documents. Detailed arrangements for the CAB assessment process are specified in document LATAK-D.008, available on the LATAK website www.latak.gov.lv.
2. During the accreditation assessment process (initial assessment), the CAB's compliance with all accreditation criteria is assessed, including the requirements of the standard. Within the assessment, a technical expert and/or technical assessor is involved for the assessment of each field included in the applied scope of accreditation.
3. For the assessment of statistical data processing and mathematical calculations, an expert in the field of statistics is involved.
4. In the initial assessment, the implementation of the PT scheme is evaluated in each field of the scope of accreditation applied for.

5. In the reassessment, the CAB's compliance with all accreditation criteria is assessed, including the requirements of the standard. All elements of the quality management system are evaluated. LATAK reviews the implementation of the assessment programme of CAB's for the previous accreditation cycle and establishes the programme for the next accreditation cycle, assessing during the reassessment the newly included PP schemes of CAB's, as well as, on a representative basis, selected schemes from the entire scope of activities applied for accreditation.
6. Following the assessment of CAB, an accreditation decision is taken in accordance with paragraph 19 of Cabinet Regulation No 754 and the procedure laid down in document LATAK-D.008. For the surveillance process of accredited CABs, in accordance with paragraph 12 of Cabinet Regulation No 754, a CAB assessment programme is developed for the entire accreditation cycle. The programme is developed based on the principle that, within one accreditation cycle, the assessment of PP schemes shall be ensured across all accredited fields of activity. Based on the risk assessment and experience gained from previous assessments, LATAK plans the assessment of PP schemes within one accreditation cycle.
7. For identified nonconformities, within the timeframe set by LATAK, the CAB performs root cause analysis and evaluates the extent of the nonconformity consequences. The CAB shall be able to identify and evaluate the spread/extent of the specific nonconformity and implement appropriate corrective actions.

# List of documents

1. LVS EN ISO/IEC 17043:2023 “Conformity assessment — General requirements for competence of proficiency testing providers (ISO/IEC 17043:2023)”
2. LVS EN ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017)”
3. LVS EN ISO 15189:2023 “Medical laboratories — Requirements for quality and competence (ISO 15189:2022)”
4. LVS ISO 13528:2022 “Statistical methods for use in proficiency testing by interlaboratory comparison (ISO 13528:2022)”
5. LVS EN ISO 80000-1:2023 “Quantities and units — Part 1: General (ISO 80000-1:2022)”
6. LATAK-D.007 “LATAK policy for participation in proficiency testing programmes and interlaboratory comparisons”
7. LATAK-D.008 “Accreditation procedures”
8. LATAK-D.011 “Regulations on the use of the national accreditation mark and the reference to accreditation and EA MLA”
9. LATAK-D.034 “LATAK policy for metrological traceability of measurement results”
10. EA-4/02 M: 2022 “Evaluation of the Uncertainty of Measurement in Calibration”
11. EA-4/09 G:2022 “Accreditation for sensory testing laboratories”
12. EA-4/14 INF:2003 “Selection and use of references materials”
13. EA-4/18 G:2021 “Guidance on the level and frequency of proficiency testing participation”
14. EA-4/21 INF:2018 “Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation”
15. ILAC-P9:02/2024 “ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing”
16. ILAC-P10:07/2020 “ILAC Policy on Metrological Traceability of Measurement Results”
17. ILAC-P14:09/2020 “ILAC Policy for Measurement Uncertainty in Calibration”
18. ILAC-G17:01/2021 “ILAC Guidelines for Measurement Uncertainty in Testing”
19. ILAC-G18:01/2024 “Guideline for describing Scopes of Accreditation”
20. ILAC-G24:2022 “Guidelines for the determination of calibration intervals of measuring instruments”

## Register of changes made

| Version | Content of changes | Date |
|---|---|---|
| 00 | New document | 12.05.2026 |
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