LATAK - D.17025-TK03/04.2022

Accreditation scheme for the assessment of conformity of testing and calibration laboratories

Content

I Accreditation criteria

- 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;
- Law "On Conformity Assessment";
- Cabinet Regulation No. 673 of 17 December 2019 “Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies” (hereinafter Regulations No. 673);
- Cabinet Regulation No. 114 of 27 February 2018 “Price List of Paid Services of the State Agency “Latvian National Accreditation Bureau”;
- LATAK-D.008 “Accreditation procedures”;
- LVS EN ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories (IOS/IEC 17025:2017)” (hereinafter – standard);
- LATAK-D.034 “LATAK Policy on the Metrological Traceability of Measurement Results”;
- LATAK-D.007 “LATAK Policy for participation in proficiency testing programs and interlaboratory comparisons”;
- LATAK-D.011 “Terms of use of national accreditation mark, reference to accreditation and EA MLA”.

Additionally for calibration laboratories:

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

Additionally for notified bodies:

- Cabinet Regulation No. 1376 of 3 December 2013 “Procedures for establishing Notification Committee, as well as the procedures by which the Notification Committee assesses and notifies to the European Commission of conformity assessment bodies performing conformity assessment in the regulated area”;
- EA-2/17 M:2020 EA Document on Accreditation for Notification Purposes.

II Additional information and specific requirements

Conformity assessment bodies in the field of testing and calibration (hereinafter – CAB) must ensure continued compliance with the requirements of the standard. In regulated areas, CAB must ensure continued compliance with the requirements of the specific regulatory framework of the standard and area.

1. Metrological traceability

The CAB must ensure the traceability of measurements in accordance with the document LATAK-D.034 "LATAK Policy on the Metrological Traceability of Measurement Results" which is available on the LATAK website www.latak.gov.lv. For further information see the document ILAC-P10 "ILAC Policy on Metrological Traceability of Measurement Results (link https://ilac.org/publications-and-resources/ilac-policy-series/).

For information on reference materials, see EA Information Document EA-4/14 INF "Selection and use of reference materials" (link: https://european-accreditation.org/publications/ea-4-14-inf/).

If the testing laboratory itself calibrates its own equipment (e.g. pipettes, dispensers, thermometers), the mandatory documents applicable for calibration must be taken into account. In such cases, LATAK shall involve calibration experts for the assessment.

2. Selection, verification and validation of methods

The CAB shall confirm the validation procedures where the following methods are used: non-standard methods, laboratory-elaborated methods, standard methods that are used outside the intended area of activities, and subsequently modified validated methods.

The CAB shall perform an independent verification before using recognised and confirmed testing and calibration methods, provided that methods have not been changed.

The CAB shall record all the activities related to the **initial** verification and validation, and the records must be duly maintained and be presented to LATAK on request upon the assessment.

3. Sampling

Sampling may be the only accredited activity of the CAB, provided that samples are used for further testing or calibration. It is required to evaluate the factors affecting uncertainty upon sampling.

4. Evaluation of measurement uncertainty

The CAB must evaluate the uncertainty of calibration and testing measurements. For detailed information for calibration CAB`s, see **ANNEX A** of this document known as **Evaluation of the Uncertainty of Measurement in Calibration**, as well as mandatory and guidance documents:

- EA-4/02 M "Evaluation of the Uncertainty of Measurement in Calibration" (link: https://european-accreditation.org/publications/ea-4-02-m/);

- ILAC-P14 “ILAC Policy for Measurement Uncertainty in Calibration” (link: https://ilac.org/publications-and-resources/ilac-policy-series/);
- ILAC G17 “ILAC Guidelines for Measurement Uncertainty in Testing” (link: https://ilac.org/publications-and-resources/ilac-guidance-series/).

5. Proficiency testing / interlaboratory comparisons

The CAB must develop a plan (recommended for a full accreditation cycle) and must ensure participation in proficiency testing or interlaboratory comparisons, taking into account the requirements set out in the document LATAK-D.007 “LATAK Policy for participation in proficiency testing programs and interlaboratory comparisons” which is available on the LATAK website www.latak.gov.lv. If interlaboratory comparison is unavailable or impossible, the CAB must develop other approaches and provide objective evidence to determine the acceptability of calibration and testing results.

For further details, see the following documents:

- ILAC P9 ILAC Policy for Participation in Proficiency Testing Activities (link: https://ilac.org/publications-and-resources/ilac-policy-series/)
- EA-4/18 INF Guidance on the level and frequency of proficiency testing participation (link: https://european-accreditation.org/publications/ea-4-18-inf/)
- 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/)

6. Reporting of results

The Latvian national accreditation mark must be used on the issued test reports and calibration certificates subject to the requirements set out in the document LATAK-D.011 which is available on the LATAK website www.latak.gov.lv, and also when identification of results obtained using non-accredited methods, and externally provided services take place.

If the CAB makes statements of conformity, see **ANNEX B** of this document known as **Statements of Conformity**, as well as guidance document ILAC G8 “Guidelines on Decision Rules and Statements of Conformity” (link: https://ilac.org/publications-and-resources/ilac-guidance-series/).

If the CAB gives opinions and interpretations, then, during the course of the assessment, LATAK shall take into account the informative document EA-4/23 INF “The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2017” (link: https://european-accreditation.org/publications/ea-4-23-inf/).

7. Guidance documents in the specific testing areas

The document EA 4/09 G "**Accreditation For Sensory Testing Laboratories"** (link: https://european-accreditation.org/publications/ea-4-09-g/) contains information on personnel, accommodation and environment, test methods and method validation, technical records, equipment, reference materials, sampling, sample handling, ensuring the reliability of results – internal and external control.

The document ILAC G19 **"Modules in a Forensic Science Process"** (link: https://ilac.org/publications-and-resources/ilac-guidance-series/) contains information on actions at the scene of crime, investigations and testing, interpretation of results, reporting of results.

The document EA-4/22 G "**EA Guidance on Accreditation of Pesticide Residues Analysis in Food and Feed**" (link: https://european-accreditation.org/publications/ea-4-22-g/) contains information on accreditation criteria for technical and management issues, flexible scope, and use of accreditation mark.

III. Status of the notified body

If the CAB is at the same time a notified body, LATAK's assessment group must assess its compliance with the regulated requirements of the specific area and requirements of the document EA-2/17 M (link: https://european-accreditation.org/publications/ea-2-17-m/).

IV Scope of accreditation

The accredited activities of the CAB are described in the scope of accreditation. The areas 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.

In order to prepare a scope of accreditation, the CAB must submit an application for drawing-up a scope of accreditation which is to be accurately filled-up, i.e. Annex 1 of the application document LATAK-D.008 in case of calibration, Annex 2 in case of testing (see Section V of this document "Documents to be submitted").

The accredited CABs may apply for a flexible scope of accreditation, which allows CABs to start testing using new/actualised methods without prior notification to LATAK, provided that the changes are not related to new measurement principles which are subject to the initial accreditation. The CABs accredited in the flexible scope of accreditation must maintain and post an up-to-date list of methods on the CABs website so that it is available to the client, LATAK and other interested parties. It is required to observe the requirements set out in the document LATAK-D.041 "Flexible scope of accreditation" which is available on the LATAK website www.latak.gov.lv. In calibration, the application of the flexible scope of accreditation

is more limited than in testing, as flexibility cannot be attributed to the performance of the method, equipment / calibration objects and methods, incl. calibration and measurement capability (CMC).

For more information, see the document EA-2/15 M "EA requirements for the accreditation of flexible scopes" (link: https://european-accreditation.org/publications/ea-2-15-m/) and ILAC-G18:12/2021 "Guideline for the Formulation of Scopes of Accreditation" (saite: https://ilac.org/publications-and-resources/ilac-guidance-series/).

The CAB may be eligible for accreditation only with regard to their own testing and calibration, and not for permanently outsourced testing and calibration.

V Documents to be submitted

When applying for accreditation, the CAB shall submit to LATAK the documents necessary for starting the accreditation process which are listed on the LATAK website www.latak.gov.lv. The form **F.002.TK** is applicable for testing and calibration laboratories.

In order to carry out the supervision process after the accreditation is obtained, the CAB shall, prior to supervision, submit the following documents:

- Written information about maintaining of the existing scope of accreditation or an application on changes of the scope of accreditation (expansion, narrowing, update of methods). Application form and an application attached thereto for drawing-up a scope of accreditation, i.e. Annex 1 of the document LATAK-D.008 in case of calibration / Annex 2 in case of testing.
- **List of current methods in the flexible scope** (for CABs that are granted a flexible scope of accreditation).
- The changes made, as compared with the existing scope of accreditation, must be clearly identified in the scope of accreditation and in the list of methods in the flexible area submitted to LATAK. Changes are identified similarly if updates are made as result of corrective actions.
- **F.045** REPORT on laboratory's participation in interlaboratory (external) comparison.
- **F.046** List of benchmarks and reference materials.
- **F.059** List of personnel.
- **F.060** Information on equipment and measuring instruments.
- **Traceability schemes in calibration** (calibration laboratories).
- **and other documents specified in F.002 in case of changes made.**

At the end of the accreditation cycle (5 years), the CAB, in order to carry out a reassessment process, shall submit an application form of the document LATAK-D.008 and an application attached thereto for drawing-up a scope of accreditation, i.e. Annex 1 of the application in case of calibration / Annex 2 of the application in case of testing, 4 months before the accreditation cycle.

For detailed procedure of submission and review of documents see LATAK document D.008 "Accreditation procedures" which is available on the LATAK website www.latak.gov.lv.

Prior to the scheduled supervision and reassessment visits, LATAK shall send a letter requesting information to the CAB.

VI Procedure of the assessment by LATAK

According to paragraph 9 and 12 of Regulations No. 673, LATAK shall enter into a contract and start the CAB accreditation process after receipt of all the necessary documents.

The assessment under the process for obtaining accreditation (initial assessment) applies to the CAB compliance with all the accreditation criteria, incl. standard requirements, or, in the regulated area, compliance with the specific regulatory framework of the standard and area in the CAB location/s in the entire accreditation scope to be assessed. A technical expert and/or technical assessor in each area applied for accreditation shall be involved in the assessment. During the course of the initial assessment, practical performance of testing and calibration methods shall be assessed in all the areas of the accreditation scope applied for the assessment, provided that all the principles of the methods used in testing/calibration are covered. For equivalent methods, it is possible to assess the technical aspects of the execution of the methods without assessing the practical performance.

After the assessment of the CAB, an accreditation decision shall be taken in accordance with the procedure laid down in Chapter 3 of Regulations No. 673 and in the LATAK document D.008 "Accreditation procedures".

In order to ensure the process for supervision of the accredited CABs, a CAB assessment programme for the whole cycle of accreditation shall be developed in accordance with paragraph 18 of Regulations No. 673. The programme shall be developed subject to the principle that the monitoring of practical activities of the CAB shall be ensured within one accreditation cycle in all the accredited scopes/areas of activities and in the important places of activities of the CAB. Based on the risk assessment and the experience gained from the previous assessment, LATAK shall, if possible – within one accreditation cycle, plan the assessment of the entirety of the CAB locations (including those where the main activity does not take place).

During the course of reassessment, CAB compliance with all the accreditation criteria shall be assessed, incl. compliance with standard requirements, or, in the regulated area, compliance with the specific regulatory framework of the standard and area. All the elements of the quality management system are subject to assessment. LATAK shall assess the implementation of the assessment programme of the previous

CAB accreditation cycle and develop a program for the next accreditation cycle by assessing, during the course of reassessment, the practical activities performed by the CAB for the newly introduced methods and by assessing, in the representative part, the methods chosen from the entire area of activities of the body applied for accreditation.

Information on the process of assessment, accreditation and supervision of conformity assessment bodies is specified in the **LATAK document "Accreditation procedures"** which is available on the LATAK website www.latak.gov.lv.

ANNEX A

Evaluation of the Uncertainty of Measurement in Calibration

Calibration and Measurement Capability (CMC) – achieved in laboratory **under normal conditions**, quoted in the scope of laboratory accreditation and available to the customer

Uncertainty of measurement shall be evaluated according to the document "Guide to the expression of uncertainty in measurement" (GUM) JCGM 100:2008, GUM 1995 (Available at https://www.bipm.org/en/publications/guides/

CMC must be quoted in the scope of accreditation and be assessed taking into account:

- measurand or reference material;
- calibration or measurement method/procedure, type of instrument to be calibrated/measured, or object to be calibrated;
- measurement range, additional parameters where applicable, e.g. frequency of applied voltage;
- measurement uncertainty.

The CMC shall be expressed as the smallest measurement uncertainty that can be achieved by a laboratory during a calibration or a measurement. Where the measurand covers a value, or a range of values, one or more of the following methods for expression of the measurement uncertainty shall be applied:

- a single value, which is valid throughout the measurement range;
- a measurement range – linear interpolation may be used to find the uncertainty at intermediate values;
- an explicit function of the measurand and/or a parameter;
- a matrix where the values of the uncertainty depend on the values of the measurand and additional parameters;
- a graphical form, providing there is sufficient resolution on each axis to obtain at least two significant digits for the uncertainty.

Open intervals (from..to.., less than) are incorrect in the expressions of CMCs. The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a coverage probability of approximately 95%. The unit of the uncertainty shall

always be the same as that of the measurand or in a term relative to the measurand, e.g., percent, μV / V.

The CMC quoted shall include the contribution from a best existing device to be calibrated.

The measurement result shall include the measured quantity value y and the associated expanded uncertainty U. In calibration certificates the measurement result should be reported as $y \pm U$. Measurement result and the relative expanded uncertainty $U / |y|$ may be used if appropriate. The coverage factor and the coverage probability shall be stated on the calibration certificate, adding to this an explanatory note, e.g. *"The reported expanded measurement uncertainty is stated as the standard measurement uncertainty multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %."*

The numerical value of the expanded uncertainty shall be given to, at most, two significant digits. Where the measurement result needs to be rounded, that rounding shall be applied when calculations have been completed.

Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer's device.

The calibration uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except that uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device. Therefore, reported uncertainties in calibration certificates tend to be larger than the uncertainty covered by the CMC. Contributions that cannot be attributed, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory anticipates that such contributions will have significant impact on the uncertainties, the customer should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.

ANNEX B
Statements of Conformity

The requirement included in the standard ISO/IEC 17025: 2017 relates to the way how measurement uncertainty is accounted for when defining the decision rule.

The decision rule describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

It is provided for in the procedure for the review of requests, tenders and contracts that: when the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the decision rule shall be clearly defined. Records shall be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

All the information agreed with the customer and necessary for the interpretation of the results shall be included in test reports and calibration certificates – measurement uncertainty affects conformity to a specification limit.

When statements of conformity are provided, the CAB shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed.

For detailed information, see the guidance document ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity describing three conformity assessment choices to be used and risks related to each choice which are to be discussed and agreed with the customer. The document describes a simple acceptance choice, as well as two possible choices based on guard band, which is the interval between a tolerance limit and a corresponding acceptance limit.

In order to avoid dependency on guard bands and narrowing of acceptance interval among laboratories, the regulator may develop other rules for the evaluation of results relating to statements of conformity.

If a statement of conformity is issued to a laboratory, the decision rule applied shall be clearly identified in this statement (unless it is inherent in the requested specification or standard). In this case, the CAB shall:

- understand the needs of customers relating to statements of conformity;
- communicate the information during the stage of preparation of contracts/requests;
- The application of the statements shall be taken into account and it is necessary to agree with the customer the decision rules to apply **based on the risk the customer will accept.**

List of documents

1. LVS EN ISO/IEC 17025:2017 Testēšanas un kalibrēšanas laboratoriju kompetences vispārīgās prasības (ISO 17025:2017).

2. LATAK-D.008-03/03.2022 Accreditation procedures

3. LATAK-D.011:2021 Terms of use of national accreditation mark, reference to accreditation and EA MLA

4.LATAK-D.034-07/07.2021 LATAK Policy on the Metrological Traceability of Measurement Results

5. LATAK-D.041-03/06.2021 Flexible scope of accreditation

6. LATAK-D.007-10/07.2021 LATAK Policy for participation in proficiency testing programs and interlaboratory comparisons

7. EA-2/17:2020 EA Document on Accreditation for Notification purposes

8. EA-4/14 INF:2003 Selection and use of references materials

9. EA-2/15 M:2019 EA Requirements for the Accreditation of Flexible Scopes

10. EA-4/02 M:2022 Evaluation of the Uncertainty of Measurement in Calibration

11. EA-4/18 (2021-11-15) INF Guidance on the level and frequency of proficiency testing participation

12. EA-4/21 INF (2019) Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

13. EA-4/23 INF (2019) The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2017

14. EA 4/09 G rev02 (February 2017) Accreditation for sensory testing laboratories

15. ILAC-P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results

16. ILAC G18:12/2021 Guideline for the Formulation of Scopes of Accreditation

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 G24:2007 Guidelines for the determination of calibration intervals of measuring instruments

20. ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities

21. ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity

22. ILAC G19:08/2014 Modules in a Forensic Science Process

23. EA-4/22 G (30.11.20218.) EA Guidance on Accreditation of Pesticide Residues Analysis in Food and Feed.

Register of changes made

Version	Content of changes	Date
01	New document	14.07.2021
02	Clause II, 5: A plan of participation in proficiency testing or interlaboratory comparisons is recommended for a full accreditation cycle.	26.01.2022.
	Clause II, 6: Text included “and externally provided services”, text excluded “and subject to the requirement that the mark should be used where 80% of the testing/calibration results have been obtained by accredited methods.”	
	Clause II, 7: Adding of the document EA-4/22 G EA “Guidance on Accreditation of Pesticide Residues Analysis in Food and Feed”.	
	Clause III: The only reference to EA-2/17:2020 EA “Document on Accreditation for Notification purposes” is remained.	
	Clause IV: Title of an application form is clarified.	
	Clause V: Title of an application form is clarified. Details on submission of written information about changes of the scope of accreditation, and their identification are clarified.	
	List of documents: Reference included EA-4/22 G (30.11.20218.), documents updated EA-4/02 M (2021-11-15) Evaluation of the Uncertainty of Measurement in Calibration, EA-4/18 INF (2021-11-15) Guidance on the level and frequency of proficiency testing participation.	
03	Paragraph 4 specifies the information on Annex A that applies to calibration laboratories.	14.04.2022.
	Chapter IV additionally refers to ILAC-G18: 12/2021 and explains the limitations of the scope of flexible accreditation for calibration. Includes information on maintaining and updating the updated list of methods.	
	Updated information on documents LATAK-D.008-03 / 03.2022, EA-4/02 M: 2022, ILAC-G18: 12/2021.	