# LATAK-D.17025-TK04/04.2024

## Accreditation scheme of testing and calibration laboratories

## Content

## 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 17025:2017 “General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017)” (hereinafter - standard LVS EN ISO/IEC 17025:2017);
6. LATAK document LATAK-D.007 “LATAK policy for participation in proficiency testing programs and interlaboratory comparisons” (hereinafter - document LATAK-D.007);
7. LATAK document LATAK-D.008 “Accreditation procedures” (hereinafter - document LATAK-D.008);
8. 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);
9. LATAK document LATAK-D.034 “LATAK policy for metrological traceability of measurement results” (hereinafter - document LATAK-D.034);
10. LATAK document LATAK-D.041 “Accreditation in the flexible scope” (hereinafter - document LATAK-D.041).

Additional criteria for calibration laboratories:

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

Additional criteria for notified bodies:

13. Cabinet Regulations No. 1376 of 3 December 2013 “Procedures for Establishing the Notification Commission, as well as Procedures by which the Commission Takes a Decision and Notifies the European Commission on the Conformity Assessment Bodies, which Carry Out the Conformity Assessment in the Regulated Sphere”;
14. Document EA-2/17 M “EA Document on Accreditation for Notification Purposes”.

## 2. Additional information and specific requirements

Conformity assessment bodies in the field of testing and calibration (hereinafter - CABs) shall ensure continuous compliance with accreditation criteria.

## 2.1. Metrological traceability

1. CABs shall ensure the traceability of measurements, in accordance with the document LATAK-D.034, which is published on the LATAK website www.latak.gov.lv. In addition to the field of testing and calibration, the document ILAC-P10 "ILAC Policy for the Metrological Traceability of Measurement Results" (link: https://ilac.org/publications-and-resources/ilac-policy-series/) is applicable.
2. Information on operations with reference materials/standards can be found in the document EA-4/14 INF "The Selection and Use of Reference Materials" (link: https://european-accreditation.org/publications/ea-4-14-inf/).
3. If testing laboratories maintain calibration of their own equipment/ measurement devices (e.g., pipettes, dispensers, thermometers, etc.), then CABs shall consider the mandatory documents applicable in the field of calibration. In such cases, LATAK can involve an expert in the field of calibration in the assessment process.

## 2.2. Selection, verification and validation of methods

1. The CAB shall choose the latest valid versions of methods, unless regulatory or another document allows the use of methods that are no longer valid. If internationally or nationally recognized methods are not available in any field, then CABs have the right to develop or modify one of internationally recognized methods. If one of the recognized methods does not specify the testing/calibration process in detail, then the CAB shall develop an additional instruction/procedure that ensures consistent application of testing/calibration, including preparation of objects, result processing, etc.
2. Verification of the method is applied if CABs choose internationally or nationally recognized standard methods to prove the correct performance of the method and confirm that the performance characteristics of the measurement system or regulated requirements have been met.
3. The CAB shall develop a validation procedure if using:
   3.1. non-standard methods,
   3.2. a method developed by the CAB,
   3.3. standard methods applied outside the intended scope of activity or otherwise modified.
4. The CAB shall document all activities related to the initial verification and validation, and all corresponding records shall be retained.
5. Records of verification shall include at least: full identification of the method, the personnel authorized to verify the method, approach of the verification applied, results, conclusions, and other information that proves the correct performance of the method.
6. Records of validation shall indicate the reference to the validation procedure, according to which the method version has been validated, specification of the requirements, determination of the performance characteristics of the method (e.g., various conditions, accuracy, measuring range, including min and max specification

limits, measurement process capability, uncertainty, limit of detection, repeatability, reproducibility, linearity, etc.), results obtained, a statement of the validity of the method and details of its for the intended use.

## 2.3. Sampling

1. Sampling may also be the only accredited activity of a CAB with conditions that obtained samples are used for subsequent testing or calibration.
2. Measurement uncertainty of sampling shall be evaluated. The CAB which performs sampling only shall provide all sampling related information (all significant contributions to measurement uncertainty) upon request from the testing or calibration laboratory.
3. The CAB shall retain records of sampling activities.
4. The CAB, which performs sampling and does not participate in interlaboratory comparison of sampling, shall ensure the reliability of the results, e.g., by conducting replicate testing of samples and/or comparison of results with a blind sample.

## 2.4. Evaluation of measurement uncertainty

The CAB shall evaluate measurement uncertainty of calibration and testing, identifying all contributions to measurement uncertainty, including those arising from sampling. Detailed information on the principles of uncertainty evaluation in the field of calibration can be found in **ANNEX A "Evaluation of measurement uncertainty in calibration"** of this document, in mandatory and guideline documents:

- EA-4/02 M "Evaluation of Measurement Uncertainty 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/).

## 2.5. Proficiency testing / participation in interlaboratory comparisons

1. According to the document LATAK-D.007, available on the LATAK website www.latak.gov.lv, the CAB shall develop **a schedule** for the entire accreditation cycle for all methods included in the scope of accreditation, and ensure participation in proficiency testing or interlaboratory comparison.
2. If an interlaboratory comparison is not available or impracticable, the CAB shall develop alternative approaches and provide objective evidence to determine the acceptability and reliability of calibration and testing results. If the CAB organizes interlaboratory comparison itself, then LATAK will evaluate the interlaboratory comparison program and reports according to the Annexes of the LATAK-D.007. If the CAB chooses organizers of interlaboratory comparisons who have not received accreditation according to the standard LVS EN ISO/IEC 17043:2023 "Conformity assessment. General requirements for proficiency testing providers (ISO/IEC

17043:2023)", then the CAB shall demonstrate to LATAK that it has evaluated organizers of interlaboratory comparisons.

3. For additional information, see documents:

- LVS EN ISO/IEC 17043:2023 "Conformity assessment. General requirements for proficiency testing providers (ISO/IEC 17043:2023)";
- LATAK-D.007 "LATAK Policy for Participation in Proficiency Testing Programs and Interlaboratory Comparison";
- EA-4/18 G "Guidelines for the Level and Frequency of Participation in Proficiency Testing" (link: https://european-accreditation.org/publications/ea-4-18-inf/);
- EA-4/21 INF "Guidelines for the Suitability Assessment of Small Interlaboratory Comparisons in the Laboratory Accreditation Process" (link: https://european-accreditation.org/publications/ea-4_21-inf/);
- ILAC-P9 "ILAC Policy for Participation in Proficiency Testing and/or Interlaboratory Comparisons other than Proficiency Testing" (link: https://ilac.org/publications-and-resources/ilac-policy-series/).

## 2.6. Risks

The CAB shall consider risks to evaluate critical aspects and promptly reveal non-conformities that could affect/ reduce the quality of results.

For risk assessment, the CAB selects a risk assessment methodology, identifies risks, evaluates the probability of occurrence of detected risks, assesses the possibilities of detecting potential risks, the consequences of risks, plans and implements activities for the reduction of risks. The main criterion in risk assessment is the impact of risks on the quality, accuracy, reliability, promptness, etc., of results.

## 2.7. Reporting of results

1. The Latvian National Accreditation mark shall be used in issued test reports and calibration certificates according to the requirements stated in the document LATAK-D.011, available on the LATAK website www.latak.gov.lv, with a clear distinction of non-accredited activities and those provided by external providers.
2. If the CAB makes conformity statements, refer to **ANNEX B "Statements of conformity"** of this document, as well as the guideline document ILAC G8 "Guidelines on Decision Rules and Statements of Conformity".
3. If the CAB expresses opinions and interpretations, during the assessment of the CAB, LATAK considers 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/).

## 2.8. Additional requirements in the field of testing

For additional information, see documents:

- EA-4/09 G **"Accreditation of Sensory Testing Laboratories"** (link: https://european-accreditation.org/publications/ea-4-09-g/) includes information on personnel, premises and environmental conditions, testing methods and validation of methods, technical records, equipment, reference materials, sampling, handling of samples, ensuring the validity of results – internal and external control;
- 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/) outlines accreditation criteria for the quality management system, technical actions, flexible scope, as well as procedures for using of the accreditation mark;
- ILAC-G19 **"Modules in the Forensic Science Process"** (link: https://ilac.org/publications-and-resources/ilac-guidance-series/) includes information on activities on the scene of crime, examination and testing, result interpretation, and reporting of results.

## 3. Status of a notified body

An institution which applies for notified body status in accordance with regulatory requirements indicates that in section 8 of the accreditation application. Additionally, in Annexe 1 and 2 of the application, it specifies the relevant applicable regulatory documents for conformity assessment, as well as the harmonized standards. The application for accreditation shall be arranged according to the information available in the NANDO database.

The list of harmonized standards is available at https://www.lvs.lv/page?slug=harmonized-standards.

Modules are provided in the Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

During the assessment, LATAK shall evaluate the compliance of the notified body with the specific area's regulatory documents and the requirements of the document EA-2/17 M "EA Document on Accreditation for Notification Purposes" (link: https://european-accreditation.org/publications/ea-2-17-m/).

## 4. Description of scopes of accreditation

1. The scope of accreditation shall define the CAB's accredited activity area in such a way that it is possible to precisely and explicitly identify the testing/calibration object, the range of activity, the parameters/quantities to be determined, and to be clearly to clients and other stakeholders of the CAB.
2. For the preparation of the scope the accreditation, the CAB shall submit a precisely filled application and its corresponding Annex (LATAK document LATAK-D.008 Annex 1 "Application" allows arranging the calibration field in Annex 1, and the testing field in Annex 2) (link: https://www.latak.gov.lv/en/general-documents-including-application-form).
3. In the accreditation application, the CAB shall indicate only those documents where specific requirements (criteria) are outlined and which completion is confirmed by the

CAB, and assessed by LATAK within the LATAK accreditation procedures, including regulatory documents that set specific criteria for performance of the method or values of permissible limits.

4. In Annex 1 and 2 of the application, the section "Source of information" refers to regulatory documents that set specific criteria for performance of the method or values of permissible limits.
5. For additional information, see the document ILAC-G18 "Guideline for describing Scopes of Accreditation" (link: https://ilac.org/publications-and-resources/ilac-guidance-series/).
6. If an institution reports a statement of conformity, the scope of accreditation shall include documents where conformity requirements/criteria are stated.
7. Describing the scope in the calibration field, open intervals (e.g., <; >; ≥; ≤) are not permissible, measurement ranges shall not be indicated with the phrase "up to", rounding of the uncertainty shall be given to, at most, two significant digits, and ppm and ppb units of measure are not permitted. For additional information, see the standard LVS EN ISO 80000-1 "Quantities and units. Part 1: General" and the document ILAC-P14 "ILAC Policy for Measurement Uncertainty in Calibration" (link: https://ilac.org/latest_ilac_news/revised-ilac-p14-published/). See **ANNEX A "Assessment of Measurement Uncertainty in Calibration"** of this document for examples of rounding.

## 5. Flexible scope

1. A flexible scope can only be awarded when the CAB has proven its competence and compliance with accreditation criteria for at least one accreditation cycle, on the condition that modifications are not related to new measuring principles covered by the initial accreditation. The CAB which has been awarded an accreditation in a flexible scope shall maintain and upload an updated list of methods on its website so that it is accessible to clients, LATAK, and stakeholders. Detailed information can be found in the document LATAK-D.041 "Accreditation in the Flexible Scope", available on the LATAK website www.latak.gov.lv.
2. In calibration field, flexibility cannot be awarded to performance of the method (e.g., range, uncertainty).
3. For additional information, see documents:
   - EA-2/15 M "EA Requirements for the Accreditation of Flexible Scopes" (link: https://european-accreditation.org/publications/ea-2-15-m/);
   - ILAC-G18 "Guideline for describing Scopes of Accreditation " (link: https://ilac.org/publications-and-resources/ilac-guidance-series/).
4. The CAB cannot apply for accreditation in a flexible scope for activities that are permanently outsourced.

## 6. Documents to be submitted

1. When applying for initial and repeat accreditation, the CAB shall submit to LATAK an application and the necessary documents for initiating the LATAK accreditation process, as specified in the LATAK form F.002.TK "List of documents", published on the LATAK website www.latak.gov.lv.
2. Before initiating the monitoring procedure, the CAB shall submit the following documents to the LATAK:
   2.1. a written application for changes in the accreditation scope (narrowing, expansion, updating of methods). In the case of changes, ANI submits a filled application;
   2.2. LATAK form F.045 "Overview of interlaboratory (external) comparison";
   2.3. LATAK form F.046 "List of Reference Materials/ Standards/ Calibrators";
   2.4. LATAK form F.059 "List of personnel (in the field of compliance assessment)";
   2.5. LATAK form F.060 "Information on equipment and measuring device";
   2.6. List of up-to-date methods in a flexible scope of accreditation (applicable to the CAB with a flexible accreditation scope), clearly identifying what changes have been made, as well as the document version and update date;
   2.7. traceability schemes (for calibration laboratories);
   2.8. other documents specified in the LATAK form F.002.TK if changes have been made.
3. Before the extension procedure of scope, ANI submits to LATAK the documents mentioned in section 2 of this chapter and additionally:
   3.1. a description of the method;
   3.2. a confirmation of method validation/verification;
   3.3. a confirmation of participation in inter-laboratory comparison;
   3.4. an assessment of uncertainty;
   3.5. a testing report/calibration certificate;
   3.6. any other information LATAK considers essential/necessary.
4. Before a planned repeated assessment visit, LATAK sends a letter to CAB requesting the necessary information.

## 7. Assessment procedure by LATAK

1. According to paragraph 7 and 10 of Regulations No. 754, LATAK shall enter into a contract and start the CAB accreditation process after receipt of all the necessary documents. A detailed CAB accreditation process is outlined in document LATAK-D.008, which is available on LATAK's website www.latak.gov.lv.
2. The initial accreditation process assesses the CAB's compliance with all accreditation criteria, including standard requirements and sector-specific regulatory regulations at all the CAB locations.
3. The initial accreditation shall assess the practical implementation of testing and calibration methods in all areas of the scope of accreditation applied for, provided that all principles of methods used in testing/calibration are covered. For equivalent

methods, a technical assessment of method implementation can be conducted without evaluating practical operation.

4. For identified non-conformities in the CAB, LATAK, within a specified period, conducts a cause analysis and assesses the spread of non-conformity consequences. The CAB must be able to identify and evaluate the spread of specific non-conformities, thereby applying corrective actions.
5. Following the CAB evaluation, the accreditation commission makes a decision in accordance with Cabinet Regulation No. 754 paragraph 19 and the procedure specified in document LATAK-D.008.
6. For the accredited the CAB supervision process, according to paragraph 12 of Regulation No. 754, the CAB evaluation program is developed for the entire accreditation cycle. The program is designed based on the principle that observation of CAB's practical operations must be ensured in all accredited activity spheres/areas and the CAB locations within one accreditation cycle. Based on risk assessment and experience gained from previous evaluations, LATAK plans the evaluation of all the CAB locations within one accreditation cycle.
7. In the reassessment process, the CAB's compliance with all accreditation criteria, including standard requirements and sector-specific regulatory regulations, is assessed. All elements of the quality management system are evaluated. LATAK assesses the execution of the CAB's previous accreditation cycle evaluation program and creates a program for the next accreditation cycle, reassessing the CAB's practical operations for newly included methods, as well as evaluating selected methods from the entire scope of activities declared for accreditation by the Institution.

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 on https://www.bipm.org/en/publications/guides/).

In evaluating CMC, the following should be taken into account:

1) measurand or reference material;
2) calibration or measurement method/procedure, type of instrument to be calibrated/measured, or object to be calibrated;
3) measurement range, additional parameters where applicable, e.g. frequency of applied voltage;
4) 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:

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

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 presented shall include the contribution of the calibration results of the best existing device.

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 ± 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 %*".

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.

The numerical value of the expanded uncertainty shall be expressed with no more than two significant digits. If rounding of the measurement result is necessary, this rounding is done after completing the calculations.

**Examples of rounding with two significant digits:**

661 ml → 660 ml
119 ml → 120 ml
1.59 A → 1.6 A
1.16 MΩ → 1.2 MΩ
1.85 W → 1.9 W
2.33 V → 2.3 V
2.14 MΩ → 2.1 MΩ
1.15 MΩ → 1.2 MΩ
0.579 g → 0.58 g
0.702 g → 0.70 g

## 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.

If a client requests a statement of conformity to a testing or calibration standard or specification (e.g. pass/fail, in-tolerance/out-of-tolerance), according to the standard ISO/IEC 17025:2017, 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 "*Guidelines on Decision Rules and Statements of Conformity*" (link: https://ilac.org/latest_ilac_news/revised-ilac-g8-published/) 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.

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:

1) understand the needs of customers relating to statements of conformity;
2) communicate the information during the stage of preparation of contracts/requests;
3) 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 “General requirements for the competence of testing and calibration laboratories (ISO 17025:2017)”
2. LVS EN ISO/IEC 17043:2023 “Conformity assessment. General requirements for proficiency testing providers (ISO/IEC 17043:2023)”
3. LVS EN ISO 80000-1:2023 “Quantities and units. Part 1: General (ISO 80000-1:2022)”
4. LATAK-D.007 “LATAK policy for participation in proficiency testing programmes and interlaboratory comparisons”
5. LATAK-D.008 “Accreditation Procedures”
6. LATAK-D.011 “Regulations on the Use of the National Accreditation Mark and the Reference to Accreditation and EA MLA”
7. LATAK-D.034 “LATAK Policy for the Metrological Traceability of Measurement Results”
8. LATAK-D.041 “Flexible scope of accreditation”
9. EA-2/15 M:2019 “EA Requirements for the Accreditation of Flexible Scopes”
10. EA-2/17 M:2020 “EA Document on Accreditation for Notification purposes”
11. EA-4/02 M: 2022 “Evaluation of the Uncertainty of Measurement in Calibration”
12. EA-4/09 G:2022 “Accreditation for sensory testing laboratories”
13. EA-4/14 INF:2003 “The selection and use of reference materials”
14. EA-4/18 G:2021 "Guidance on the level and frequency of proficiency testing participation”
15. EA-4/21 INF:2018 “Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation”
16. EA-4/22 G:2018 “EA Guidance on Accreditation of Pesticide Residues Analysis in Food and Feed”
17. EA-4/23 INF:2019 “The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2017”
18. ILAC-P9:02/2024 “ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing”
19. ILAC-P10:07/2020 “ILAC Policy on Metrological Traceability of Measurement Results”
20. ILAC-P14:09/2020 “ILAC Policy for Measurement Uncertainty in Calibration”
21. ILAC-G8:09/2019 “Guidelines on Decision Rules and Statements of Conformity”
22. ILAC-G17:01/2021 “ILAC Guidelines for Measurement Uncertainty in Testing”
23. ILAC-G18:01/2024 “Guideline for describing Scopes of Accreditation”
24. ILAC-G19:06/2022 “Modules in a Forensic Science Process”
25. ILAC-G24:2022 “Guidelines for the determination of calibration intervals of measuring instruments”

## 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. | |
| 04 | Chapter 1 "Accreditation Criteria" updated Cabinet of Ministers regulations and added a reference to LATAK-D.041 21.02.2024. | 09.04.2024 |
| | Chapter 2 "Additional information and specific requirements" excluded the regulated area. | |
| | Section 2.2 "Method selection, verification, and validation" has been supplemented with an additional explanatory part, minimum information to be included in verification protocols, information to be specified in validation protocols. | |
| | Section 2.3 "Sampling" has been supplemented with information to be provided to the CAB, which takes samples, ensuring the reliability of results. | |
| | Section 2.4 "Evaluation of measurement uncertainty" has been supplemented evaluation of measurement uncertainties, specifying that all contributions, including those arising from sampling, must be identified. | |

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| | Section 2.5 “Proficiency testing/participation in interlaboratory comparison” is supplemented with the procedure if the CAB itself organizes interlaboratory comparison, what to include in the program and reports, additional references to the standard LVS EN ISO/IEC 17043:2023 and LATAK-D.007 included | |
| | Section 2.6 “Risks” – developed new | |
| | Chapter 3 “Status of notified body” supplemented by a procedure for applying for accreditation when applying for status of notified body, given reference to the NANDO database and the list of harmonized standards, included additional reference to the DECISION No. 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL | |
| | Chapter 4 “Description scopes of accreditation” supplemented by the procedure for documents to be indicated in the application and formulating the calibration scope, included additional reference to the standard LVS EN ISO 80000-1 | |
| | Chapter 5 “Flexible scope” separated out specifically, supplemented with what cannot be applied to the flexible scope in calibration | |
| | Chapter 6 “Documents to be submitted” excluds *the requirement to submit written information on maintaining the accreditation scope*, updated LATAK form names, the list of current methods in the flexible scope must clearly identify changes made, indicate document versions and update dates, supplemented with documents for expanding the scope | |
| | Chapter 7 “Assessment procedure by LATAK” supplemented with item 4, which specifies that *for non-conformities found, the CAB, within a period set by LATAK, conducts a root cause analysis and evaluates the spread of the non-conformity effects. The CAB must be able to identify and assess the spread of specific non-conformities, as a result, apply corrective actions* | |
| | Annex A supplemented by rounding examples with two significant digits | |
| | Annex B excluded *to avoid dependence of laboratories on border bands and narrowing the acceptance interval, the Regulator may develop other rules for assessing the results of conformity notifications* | |
| | | |