

LATAK - D.17020-I/04/02.2024

Inspection institutions accreditation scheme

List of Contents

I Accreditation criteria	2
II Design of the accreditation scope	2
III Documents to be submitted	3
IV Assessment and accreditation procedure of the institution	4
V Tests to be used during the inspection process	4
VI Metrological traceability of measurement results	5
VII Inspection report (protocol, report, certificate).....	5
VIII Practical activity assessment policy	5
IX Status of notified body	6
Register of changes	6

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The document text may be translated into other languages. The text in Latvian shall be considered the main text.

Additional information

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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 of Ministers Regulations No. 754 “Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies” of 19 December 2023 (hereinafter - Rules No. 754);
- Cabinet of Ministers Regulations No. 666 “Pricelist of Paid Services of the State Agency “Latvian National Accreditation Bureau”” of 25 October 2022 (hereinafter - Rules No. 666);
- Cabinet of Ministers Regulations No. 1376 “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” of 3 December 2013;
- LVS EN ISO/IEC 17020:2012 “Conformity assessment. Requirements for various bodies that perform inspection (ISO/IEC 17020:2012)” (hereinafter – the Standard);
- ILAC-P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results;
- ILAC P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies;
- ILAC G27:07/2019 Guidance on measurements performed as part of an inspection process;
- LVS EN ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories (ISO 17025:2017)”;
- EA-2/17 M:2020 EA Document on Accreditation for Notification Purposes;
- LATAK-D.007 “Proficiency testing in the Latvian national accreditation system”
- LATAK-D.008 “Accreditation procedures”;
- LATAK-D.034 “LATAK policy for metrological traceability of measurement results”;
- LATAK-D.011 “Regulations for use of the national accreditation mark, reference to accreditation and EA MLA”.

II Design of the accreditation scope

On the website of the State Agency “Latvian National Accreditation Bureau” (hereinafter - LATAK) www.latak.gov.lv, an Application Form (F.003) is available, which contains information on the notified accreditation scope (Annex 3 to the Form).

The design of the accreditation scope contains information on:

- Column 1: Inspection object – product project, product (material or equipment), service, factory or process (the process covers inspection of personnel, equipment,

- technology and methodology) and the range of inspection capabilities of the inspected object, where necessary;
- Column 2: Inspection type – inspection of a new and/or already operated object and/or inspection type (technical inspection, inspection of annual report, testing, etc.);
 - Column 3: Regulatory documents, standards, method – regulatory enactments approved by the Cabinet of Ministers of the Republic of Latvia, regulatory documents of the European Union or other regulatory documents, standardised technical specifications, name of the method or procedure of the inspection body, and the date of approval of such a method or procedure;
 - Column 4: Locations – displayed if there are several locations. If the conformity assessment institution performs the inspection activities at the client's premises, then the 4th column of the table of the scope of accreditation shall not be included in the accreditation certificate.

Accreditation certificate and accreditation scopes of the accredited inspection bodies are published on the website of LATAK www.latak.gov.lv.

III Documents to be submitted

The Inspection institution (hereinafter - Institution) submits to LATAK documents necessary for **commencement of the accreditation process** (form F.002.I), which are indicated on the website of LATAK www.latak.gov.lv for Inspection Institutions, as well as completed forms:

- F.003 Application (incl. Annex 3);
- F.003.I Information on the inspection institution;
- F.060 Information about the calibration status of equipment;

After obtaining accreditation **for the purpose of surveillance process** the Institution shall before implementation of the surveillance process submit the following respectively completed forms and necessary documents:

- F.003 Application and Annex 3 (accreditation scope) attached to the form, if changes have been made to the accreditation scope, together with an application for narrowing or extension of the scope;
- F.020.I Information for surveillance of the inspection body;
- F.060 Information about the calibration status of equipment;
- Institution management report;
- relevant test (inspection) methodologies;
- changes made to the management system documentation (current management system manual or updated parts of it);
- list of documents of the Institution management system.

At the end of the accreditation cycle (five years), for the re-accreditation process, the Institution should fill out the form F.003 Application, including Appendix 3 of this form (scope of accreditation) 4 (four) months before the end of the accreditation cycle, and submit it to LATAK

Prior to implementation of the process of re-accreditation, the Institution shall, in addition to the documents mentioned above, submit documents necessary for implementation of the assessment process, which are the same as asked before a surveillance visit.

More detailed procedure of submission and examination of documents is specified in LATAK-D.008 document “Accreditation procedures”, which is available on the website of LATAK www.latak.gov.lv.

IV Assessment and accreditation procedure of the institution

When assessing the Institutions competence and ability to perform inspection in accordance with the requirements of the accreditation criteria, LATAK follows the general principles of evaluation and surveillance, which are defined in the document LATAK-D.008 "Accreditation Procedures".

According to Regulation No. 754 paragraph 10, LATAK concludes the contract and starts the evaluation process of the Institution after receiving all the necessary documents.

After receiving all the necessary documents and payment for the relevant evaluation procedure according to the contract, LATAK starts the evaluation process of the Institution. In framework of evaluation process, the Institution's compliance with the requirements of the Standard or, in the regulated sphere, compliance with the requirements of the Standard and the field-specific regulatory framework at the institution's location/s (on-site visit) is assessed.

In the assessment process, the compliance of the Institution's quality management system and practical operations with the requirements of the Standard is evaluated, in the regulated sphere, the compliance with the standard and field-specific regulatory framework.

After the assessment of the Institution, an accreditation decision is made in accordance with Regulation No. 754, point 19 and document LATAK-D.008 "Accreditation Procedures" for the procedure.

V Tests to be used during the inspection process

Certain inspection processes include testing activities that can be classified into one of two categories, functional and analytical. Functional testing (eg crane load testing) is a normal part of the Institution operations and is therefore covered by the Standard. Analytical testing (which must be performed in a laboratory under well-controlled environmental conditions and using more sophisticated equipment or test procedures) (eg electrical resistance tests of an electricity meter; pressure testing of pressure equipment valves) is a laboratory activity. Inspections that wish to perform such laboratory-type analytical tests, the results of which are evaluated and the compliance of the inspected object with applicable criteria is determined, should take into account and ensure the corresponding requirements of the standard LVS EN ISO/IEC 17025:2017. The institution must provide the applicable means for the conformity of the testing results: metrological traceability of the measurement results; method validation; monitoring the reliability of the results.

Institutions operating in the field of verification of measuring devices (for example, verification of scales, verification of water consumption meters, verification of pressure gauges) must develop a plan and ensure participation in proficiency tests or inter-laboratory comparison programs in order to ensure the reliability of the results, in accordance with the requirements specified in document LATAK-D.007.

If interlaboratory comparison is not available or possible, the Institution should develop other approaches and provide objective evidence to determine the acceptability and reliability of inspection results. If the Institution itself organizes the inter-laboratory comparison, then LATAK evaluates the inter-laboratory comparison program and reports according to the appendix of the document LATAK-D.007 "LATAK policy for participation in proficiency testing programs and inter-laboratory comparison". If the Institution chooses an inter-laboratory comparative program with organizers that have not received accreditation according to the standard LVS EN ISO/ IEC 17043:2023 " Conformity assessment - General requirements for

the competence of proficiency testing providers (ISO/IEC 17043:2023)", then the Institution must certify to LATAK that it has evaluated the organizer of the comparison of stapling laboratories.

VI Metrological traceability of measurement results

If measuring equipment is used during the inspection process, this equipment shall be calibrated as stipulated by the standard LVS EN ISO/IEC 17020:2012. In separate cases measuring equipment may also be verified, if by doing so appropriate uncertainty of measurements and decision-making on the inspected object can be ensured. The test results of the measuring equipment to be used must be traceable to national or international standards, if available. If such benchmarks are not available, the Institution must document the correlation or accuracy of the inspected object.

The policy regarding metrological traceability of measurement results, which shall be observed by conformity assessment bodies, is specified in the document LATAK-D.034 "LATAK policy for metrological traceability of measurement results" and ILAC-P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results.

VII Inspection report (protocol, report, certificate)

The results of the inspection process must be documented in an identifiable, traceable inspection report (report, certificate). If the inspection report does not indicate the inspection parameters and their results, such as measurements, then this information must be documented in a separate test report, which is identifiable and traceable to the relevant inspection report. If a subcontractor is engaged in the inspection process, then this subcontractor must be identifiable in the inspection report, unless the reference to the engaged subcontractor is provided for by the national regulatory act, for example, the Inspection report forms developed in the regulatory acts, where such a requirement for the engaged subcontractor is not provided for. The actions performed by the subcontractor must be clearly indicated in the test report, for example test results, the measuring devices used, their test calibration certificate numbers, a reference to the measurement traceability, the subcontractor's test report.

Certain applicable regulatory acts set requirements that the inspection protocol or report should indicate the measuring devices with which the test was performed, their identification, the calibration certificate number and the name of this calibration institution.

VIII Practical activity assessment policy

During the initial assessment process, the Institution shall be capable to demonstrate to LATAK assessment group the inspection activities performed by the Institution, which are applied for accreditation. For equivalent methods, it is possible to perform an assessment of the technical aspects of the execution of the methods without an assessment of the practical operation. In separate cases these activities may be demonstrated after grant of accreditation at the site of the first client of the Institution. LATAK shall elaborate the Institution practical activity demonstration plan (Form F.057), providing that during the accreditation cycle all accreditation areas at all indicated sites of activity of the Institution are assessed (Paragraph 12 of the Regulations No. 754). The elaborated plan may be respectively modified, based on the results of the performed monitoring and assessment of practical activity, and considering the identified risks and received information, for example, personnel turnover, legislative changes, complaints, development of the technical area.

After the practical activity demonstrated by the Institution, LATAK assessment group assesses the documented results (protocol, certificate, report) of the inspection process. The relevant documents must be submitted to the LATAK evaluation group for evaluation after the evaluation visit, with mutual agreement on the submission deadlines, and it is not possible to evaluate it during the evaluation of the practical activity.

When planning the initial assessment of the Institution, expansion of the scope of accreditation, applying a risk-based approach, a person is selected who will demonstrate the practical operation of the relevant applied accreditation scope to the LATAK evaluation group. Other authorized persons of the Institution are also interviewed during the initial assessment and accreditation scope expansion visit, making sure of their competence and ability to perform inspection activities.

Prior to the surveillance visit, Institution is requested to fill in LATAK form F.020I, which provides information on the number of staff of the Institution, or changes in the composition of the staff, information on the number of inspections performed by each staff member. When planning a surveillance visit of the Institution, the above information is evaluated and it is determined which person of the Institution will demonstrate the practical activity. During the assessment visit, when performing the vertical audit of the previously performed inspections, a representative number of inspection documents performed by other persons of the Institutions is selected. At the same time, during the assessment visit, interviews are conducted with other authorized persons of the Institution.

IX Status of notified body

If the Institution has applied for the status of notified body or already operates as a notified body, LATAK assessment group shall assess its conformity to the regulated requirements of the particular area and the document EA-2/17 M:2020.

Register of changes

Version	Content of changes	Date
01	New document	03.08.2021
02	Clause IX: The only reference to EA-2/17:2020 EA “Document on Accreditation for Notification purposes” is remained.	04.04.2022.
03	Section VIII Practical Performance Assessment Policy - supplemented information on the assessment of the competence of the staff of the Inspection Body during the assessment visit The list of documents has been deleted and the information contained therein has been transferred to Section I Accreditation Criteria	25.04.2022.
04	Reference is made to Regulations No. 754 and Regulations No. 666; clarified information about the documents to be submitted and the location of the institution to be indicated in the accreditation certificate; Sections V and VIII have been updated	29.0.2024.