

LATAK - D.17020-I/03/04.2022

Accreditation scheme for conformity assessment of inspection bodies

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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

Information on LATAK documents can be obtained at the office of LATAK. Reproduction of this document for resale is forbidden.

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. 673 “Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies” of 17 December 2019;
- Cabinet of Ministers Regulations No. 114 “Pricelist of Paid Services of the State Agency “Latvian National Accreditation Bureau”” of 27 February 2018;
- 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 P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies;
- 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.001) 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.

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 Body 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 Bodies, as well as completed forms:

- F.001 Application (incl. Annex 3);
- F.003.I Information on the inspection body;
- F.060 Information on the status of calibration of equipment/benchmarks;

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

- F.001 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 monitoring of the inspection body;
- F.060 Information on the status of calibration of equipment/benchmarks;
- summary of performed internal audits;
- management report for the reporting period;
- respective inspection methodologies;
- management system handbook;
- list of documents of the Inspection Body management system.

Upon expiration of the accreditation cycle (five years), **for implementation of repeated assessment process** the Inspection Body shall submit to LATAK a completed Form F.001 Application, incl. Annex 3 (accreditation scope) to this Form, 4 (four) months before the end of the accreditation cycle for commencement of the process of repeated assessment.

Prior to implementation of the process of repeated assessment, the Inspection Body 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 monitoring 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 LATAK assessment procedure

According to Paragraph 9 and 12 of the Cabinet of Ministers Regulations No. 673 “Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies” of 17 December 2019, LATAK shall conclude an agreement and commence the assessment process of the Inspection Body after receipt of all necessary documents.

During the initial assessment, conformity of the Inspection Body to requirements of the Standard is assessed, and in the regulated sphere – conformity to the specific requirements of the regulatory framework of the Standard and the respective area, performed at the location/s of the Inspection Body (onsite visit).

Within the framework of the accreditation cycle, conformity of the quality management system and practical operation of the Inspection Body to the requirements of the Standard is assessed, and in the regulated sphere – conformity to the specific regulatory framework of the standard and the area.

V Tests to be used during the inspection process

Certain inspection processes include testing activities, the results of which are assessed and conformity of the inspected object to the applicable criteria is determined. If test results are used within the framework of the inspection process, the Inspection Body shall verify that these activities have been performed in accordance with requirements of the standard LVS EN ISO/IEC 17025:2017.

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 used measuring equipment shall be traceable up to the national or international benchmarks, if such are available. If such benchmarks are not available, the Inspection Body shall certify documentarily the correlation and 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”.

VII Inspection overview (protocol, report, certificate)

The results of the inspection process shall be documented in an identifiable, traceable inspection overview (report, certificate). If inspection parameters and their results, for example, measurements, are not indicated in the inspection overview, this information shall be documented in a separate inspection protocol, which is identifiable and traceable by a respective inspection overview. If a subcontractor is involved in the inspection process, this subcontractor shall be identifiable in the verification overview, unless an indication to the attracted subcontractor is not provided for in the national regulatory enactment, for example, Inspection overview forms are developed according to regulatory enactments, where such a requirement concerning the attracted subcontractor is not provided. The activities performed by the subcontractor shall be clearly indicated in the inspection protocol, for example, inspection results, used measuring equipment, numbers of their inspection calibration certificates, reference to traceability of measurements, and the subcontractor's inspection protocol.

In separate applicable regulatory enactments requirements are specified that the inspection protocol or overview shall contain information on the measuring equipment used during the inspection process, their identification, number of the calibration certificate and the name of body of such calibration.

VIII Practical activity assessment policy

During the initial assessment process, the Inspection Body shall be capable to demonstrate to LATAK assessment group the inspection activities performed by the body, which are applied for accreditation. In separate cases these activities may be demonstrated after obtaining accreditation at the site of the first client of the Inspection Body. LATAK shall elaborate the Inspection Body practical activity demonstration plan (Form F.057), providing that during the accreditation cycle all accreditation areas at all indicated sites of activity of the Inspection Body are assessed (Paragraph 18 of the Regulations No. 673). 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 Inspection Body, LATAK assessment group assesses the documented results (protocol, certificate, overview, report) of the inspection process. The respective documents shall be submitted for assessment to LATAK assessment group after the assessment visit, mutually agreeing on the submission deadlines.

When planning the initial assessment of the Inspection Body, the person who will demonstrate to the LATAK assessment team the practical activity of the respective applied accreditation scope is selected for the extension of the scope of accreditation. The choice is made on the basis of a risk-based approach, with prior knowledge of the competence of the staff of the Inspection Body. During the initial assessment and extension of the accreditation visit, other persons authorized by the Inspection Body are also interviewed, ascertaining their competence and ability to carry out the inspection activities.

Prior to the surveillance visit, the Inspection Body is requested to fill in LATAK form F.020I, which provides information on the number of staff of the Inspection Body, 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 Inspection Body, the above information is evaluated and it is determined which person of the Inspection Body will demonstrate the practical activity. During the assessment visit, a representative number of inspection documents from other persons of the Inspection Bodies (20% of the number of staff) are selected for the vertical audit of previous inspections. At the same time, interviews with other persons authorized by the Inspection Body are conducted during the assessment visit.

IX Status of notified body

If the Inspection Body 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	25.04.2022.



	The list of documents has been deleted and the information contained therein has been transferred to Section I Accreditation Criteria	
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