

LATAK-D.17065-S1/05/11.2024

Product, process and service certification institutions accreditation scheme

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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 Regulation No. 754 “Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies” (hereinafter - Rules No. 754);
- Cabinet of Ministers Regulation No. 666 “Price list of paid services of the state agency "National Accreditation Bureau of Latvia”;
- 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 17065:2013 “Conformity assessment. Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012) (hereinafter – the standard);
- LVS EN ISO/IEC 17067:2013 “Conformity assessment. Basic principles of product certification and guidelines for product certification schemes (ISO/IEC 17067:2013)”;
- EA-2/17 M:2020 EA Document on Accreditation for Notification Purposes;
- EA-6/02 M: 2013 EA Guidelines on the Use of EN 45 011 and ISO/IEC 17021 for Certification According to EN ISO 3834;
- EA-3/12 M: 2020 EA Policy for the Accreditation of Organic Production Certification;
- EA-1/22 A-AB: 2020 EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members;
- IAF MD4:2023 “IAF mandatory document for the use of information and communication technology (ICT) for auditing/assessment purpose”;
- IAF MD 25:2023 Criteria for Evaluation of Conformity Assessment Schemes
- LATAK-D.008 “Accreditation procedures”;
- 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 6 to the Form).

The design of the accreditation scope contains information on:

- Column 1: Certified object;
- Column 2: Certification scheme, for example, system 1; 1+; 2+ according to requirements set in EU Regulation No. 305/2011; EU type examination, etc.;

- Column 3: Regulatory documents, standards, methods – regulatory enactments approved by the Cabinet of Ministers of the Republic of Latvia, regulatory documents of the European Union or other regulatory documents, standards, standardised technical specifications, name of the method or procedure of the product certification body, and the date of approval of such a method or procedure and the date of its approval.

The accreditation certificate of the accredited Product, process and service certification institutions (hereinafter - the Institution), including the scope of accreditation, is published on the LATAK website www.latak.gov.lv .

III Documents to be submitted

The product certification body submits to LATAK the documents necessary **for commencement of the accreditation process** (Form F.002.S1), which are indicated on the website of LATAK www.latak.gov.lv for Product Certification institutions, as well as a completed Forms -

- F.003 Application (incl. Annex 6);
- F.003.S1 Information on the product certification institution.

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 6 (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.S1 Information on the product certification institution;
- list of issued certificates;
- documented management report for the previous period;
- information on the areas of competence of auditors and technical experts according to certification schemes and technical areas;
- relevant certification schemes;
- changes made to the documentation of the management system (current management system manual or updated parts thereof);
- list of documents of the Institution's management system.

Before the demonstration of the practical operation of the certification, the Institution submits the relevant documentation to LATAK:

- customer information;
- audit/evaluation plan, sample selection plan, certificate (if available);
- offer or certification agreement;
- client documentation analysis report and/or previous re-/certification or surveillance audit report;
- CV and qualification evaluation of the Institution's auditors/experts in the technical areas/schemes of the client's activity;
- Institution's certification procedure;
- audit documentation (audit report, audit discrepancies) after the audit.

The documentation to be submitted may change depending on the specifics of the certification scheme.

At the end of the accreditation cycle (five years), for the implementation of the re-accreditation process, the Institution submits to LATAK a completed form - F.003 Application, including Appendix 6 of this form (scope of accreditation) 4 (four) months before the end of the accreditation cycle.

Before implementing the re-accreditation process, the Institution, in addition to the above-mentioned documents, submits the documents that are required before the surveillance visit. A more detailed procedure for submitting and examining documents is set out in LATAK-D.008 document "Accreditation procedures", which is available on the LATAK website at www.latak.gov.lv.

IV Institution assessment and accreditation procedure

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

According to Rules No. 754 for paragraph 10, LATAK concludes the contract and starts the assessment process of the Institution after receiving all the necessary documents. After receiving all necessary documents and payment for the relevant assessment procedure according to the contract, LATAK starts the evaluation process of the Institution. In the initial assessment, the compliance of the Institution with the requirements of the Standard is evaluated, in the regulated sphere, the compliance with the Standard and the specific regulatory requirements of the relevant field.

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

V Institution's surveillance procedure and decision-making

For the surveillance process of accredited Institutions, according to Rules No. 754 point 12, an assessment program of the certification institution is developed for the entire accreditation cycle (form F.057 – assessment of practical activity; form F.047 – assessment of the management system). As part of the accreditation cycle, LATAK assesses the Institution's compliance with the requirements of the Standard or the regulated sphere of the Standard and the field-specific regulatory framework in all spheres of accreditation.

Within the framework of the accreditation cycle, the compliance of the Institution's practical activities with the requirements of the Standard, in the regulated sphere, compliance with the Standard and the specific regulatory framework of the field is assessed. Surveillance assessments are carried out once every 12 (twelve) months. The periodicity of surveillance of accredited

certification institution can be extended up to 18 (eighteen) months, based on the performed risk assessment.

The procedure for making a decision on the results of the certification institution surveillance is defined in document LATAK-D.008 "Accreditation procedures", available at www.latak.gov.lv.

VI Practical activity assessment policy

As part of the initial assessment or scope expansion process, the Institution must be able to demonstrate to the LATAK assessment group its performed certification activities applied for accreditation. In some cases, they can be demonstrated after obtaining accreditation within a certain period at the Institution's first client (for example, in the regulated sphere, the notified sphere). The mentioned additional condition cannot exceed 18 (eighteen) months from the granting of the accreditation sphere. If the assessment of the Institution's practical operation is not provided to LATAK within the specified period, LATAK makes a decision to suspend the accreditation of the Institution in the relevant part of the sphere for up to 6 (six) months or until the demonstration of practical operation is provided. If the Institution is unable to provide a demonstration of its practical operation during these 6 (six) months, when the Institution's accreditation has been suspended in the relevant field, LATAK makes a decision to reduce the Institution's accreditation or withdraw the accreditation (in cases where the Institution has only 1 (one) area of accreditation).

LATAK develops the Institution's practical activity demonstration program (form F.057), providing that during its accreditation cycle, the Institution's competence and ability to perform relevant conformity assessment activities are assessed (practical activity assessment or replaced by other alternative methods, such as technical interviews with in area responsible employees, simulation of practical operation with technical tasks) (Paragraph 12 of Regulation No. 754). The developed program can be changed accordingly, based on the results of the performed assessment, as well as taking into account the identified risks and received information, for example, staff turnover, legislative changes, complaints, development of the technical field. When preparing the evaluation program of the Institution's practical activity (form F.057), the requirements of the relevant applicable regulatory acts must also be taken into account.

Regarding the field of certification of construction products, REGULATION (EU) No 305/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC is taken into account the information given in Annex IV of Table 1, as a result of which the evaluation of the practical operation (witness) or the use of alternative assessment methods (see above) is carried out according to the division of the mentioned table (assessment of the certification process of at least one construction product from each field code during the accreditation cycle).

The LATAK assessment team evaluates the documented results (protocol, certificate, report) of this demonstrated certification process (witness audit). The relevant documents must be submitted to the LATAK assessment group for evaluation after the assessment visit, mutually agreeing on the submission deadlines, if it is not possible to evaluate them during the practical demonstration.

VII Status of notified body

If the Product Certification Body has applied for the status of notified body or already operates as a notified body, LATAK assessment group shall assess its conformity to requirements of regulatory documents and the document EA-2/17 M:2020.

During the assessment, the notified body or the institution applying for the status of the notified body (hereinafter - notified body) is assessed in order to verify its compliance with the Directive or Regulation and standard requirements of the relevant field. Since the requirements for notified bodies set out in the Directives and Regulations derive from the Decision of the European Parliament and the Council no. 768/2008/EC, then during the assessment LATAK makes sure of the compliance of the notified body with the requirements of the decision that apply to notified body (R12.3.; R17; R20; R27; R28). If the standard requirements do not cover the requirements specified in the decision, LATAK assesses whether the requirements set forth in the decision are met by the notified body, and if the requirements are not met, LATAK refers to the requirements of the relevant Directive or Regulation in case of non-compliance. When assessing the notified body, LATAK also assess the subcontractors engaged by the notified bodies and verifies their compliance with point R20 of the decision and verifies whether the notified bodies has taken all necessary measures to fulfil the requirements of point R20.

Specific requirements regarding the European Parliament and Council Regulation (EU) No. 305/2011 are determined in document EA-2/17 M:2020

Register of changes

Version	Content of changes	Date
01	New document	03.08.2021
02	Clause VI: The only reference to EA-2/17:2020 EA “Document on Accreditation for Notification purposes” is remained.	04.04.2022.
03	Reference is made to Rules No. 754 and Rules No. 666; clarified the policy of practical activity evaluation and information about the documents to be submitted; separate Section V created; deleted section – Register of Documents	29.02.2024.
04	Reference to document IAF MD 4 included	08.05.2024.
05	Clarified Section VI on the assessment of practical performance or the application of other alternative methods and section VII Status of notified body to clarify assessment principles and requirements.	14.11.2024.