LATAK - D.15189-M03/08.2023
Accreditation scheme for conformity assessment of medical laboratories

Table of contents

I Accreditation criteria

1. Regulation (EC) No. 765/2008 setting out the requirements of accreditation and market surveillance relating to the marketing of products, and repealing Regulation (EEC) No 339/93;
2. Law "On Conformity Assessment";
3. Regulations of the Cabinet of Ministers of 17 December 2019 No. 673 “Regulations Regarding the Assessment, Accreditation and Supervision of Conformity Assessment Bodies”;
4. Regulations of the Cabinet of Ministers of 25 October 2022 No. 666 “Price list of paid services of the State Agency “Latvia National Accreditation Bureau”;
5. Regulations of the Cabinet of Ministers of 20 January 2009 No. 60 “Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units” (hereinafter – Regulations No. 60);
6. LATAK-D.008 “Accreditation Procedures”;
7. LVS EN ISO15189:2013 Medical laboratories. Requirements for quality and competence (hereinafter – the standard);
8. LATAK-D.034 “LATAK policy for metrological traceability of measurement results”;
9. LATAK-D.007 “LATAK policy for participation in proficiency testing programs and interlaboratory comparisons”;
10. LATAK-D.011 “Regulations on the use of the National Accreditation Mark, references to Accreditation and the EA MLA”.

II General information

Medical laboratory services include a variety of processes – patient preparation, patient identification, collection, transportation, storage, processing, assessment, maintenance and safe disposal of samples, as well as further validation, interpretation, reporting of results and consultations, meanwhile adhering to safety and ethical standards in the medical laboratory.

The services of a medical laboratory should meet the needs of patients and clinical staff, as well as other stakeholders.

The standard contains the elements necessary for medical laboratories to demonstrate the quality and competence of their services, as well as to consistently provide technically sound test results. The standard specifies requirements for personnel competence, equipment and reagent management, pre-analytical processes, assessment processes, quality assurance of results, post-assessment processes and communication of results.

According to the Regulations No. 60 subsection 110.1, a multi-profile hospital must have a medical laboratory accredited in accordance with the standard LVS EN ISO 15189:2013 and in accordance with paragraph 185, the medical institution must ensure the accreditation of the medical laboratory in accordance with the standard LVS EN ISO 15189:2013.

Medical laboratories perform examination of human material (e.g. microbiological, immunological, chemical, immunohaematological, haematological, cytological, etc.) and/or direct testing of the human body to provide information for the diagnosis, preventive treatment and/or monitoring of human diseases (or human health assessment). These tests also include the detection, measurement or other characterization of the presence or absence of various substances or micro-organisms.

The standard could be suitable and intended for use in other disciplines, such as clinical physiology, medical imaging, and medical physics.

Medical laboratories also provide advisory services covering all aspects of laboratory assessments, including the interpretation of results and advice on further appropriate investigations.

Premises where only samples are removed and/ or prepared for further examination in a medical laboratory must be included in the management system of the unit to be accredited.

III Additional information and specific requirements (according to ILAC G26:11 and other documents)

Conformity assessment bodies in the field of medical examinations (hereinafter referred to as CABs) must ensure continued compliance with the requirements of the standard.

1. Organization and management

Medical laboratories can be separate medical institutions or a part of larger organization, such as a hospital or clinic. Management and staff must be independent and free from any commercial, financial, or other pressure. Potential conflicts of interest should be avoided.

Various medical ethics and practice considerations should be evaluated, such as sending the results directly to the patient without the clinician's interpretation.

The CAB must ensure that procedures are incorporated into the management system and are effectively implemented to ensure the confidentiality and protection of patient information at all times.

2. Risk management

Continuous improvement and risk management are essential in a quality management system. Risk management is the identification, assessment and prioritization of risks, followed by the coordinated and economic use of resources to minimize, monitor and control the likelihood and or impact of failures or to maximize the realization of opportunities.

The CAB must certify the assessment of work processes and the impact of possible failures on the results of the assessment as they affect patient and staff safety and process efficiency, as well as confirm that processes have been assessed and

actions have been taken to reduce or eliminate identified risks, and document the decisions and actions taken.

3. Assessments in authorized laboratories

Medical laboratories with a limited range of available tests may use the services of other laboratories to provide the full range of tests requested for the samples taken. The standard sets out requirements for testing in other laboratories, as well as for the selection and evaluation of consultancy services.

External laboratory services are used for additional sample testing and confirmatory testing. External services can be outsourced (e.g. due to workload, temporary incapacity, temporary equipment outages, premises repairs, etc.) or on a permanent basis through long-term subcontracting.

Medical laboratories may only be accredited for examination methods performed by the laboratory itself, and not for examinations sent to other laboratories.

4. Staff

The CAB should set requirements for the staff and their qualifications involved in the provision of medical laboratory services, incl. specified in Medical Treatment Law, as well as the need for additional training in the quality management system to fully implement the standard requirements.

The CAB should be aware of the relationship between laboratory tests and the doctor's authority/responsibility in medical practice.

The opening hours of a medical laboratory can be 24 hours a day, seven days a week. The CAB should assess risks and ensure continuity of quality testing.

The assessment of staff competence, including professional assessment, must be specifically designed and fit for purpose.

5. Laboratory equipment, reagents and accessories

The CAB must have all the necessary resources to ensure that the included / includable methods in the scope of accreditation are complied with. If the purchase and control of equipment, reagents and raw materials is organized by another department or engineering staff, the CAB must ensure that the standard requirements are met, appropriate materials have been purchased and appropriate services are provided.

CABs must comply with legal requirements for the procurement and testing of equipment, reagents and materials.

The CAB are responsible for meeting manufacturers' requirements for performance, electrical safety testing and maintenance and for ensuring that the calibration services provided by the manufacturers are appropriate. Suitability for the intended use must be ensured.

Adverse events and incidents that could be attributed to specific equipment shall be investigated by the CAB and reported to the manufacturer and the supervisory authorities.

The CAB must ensure traceability of measurements in accordance with the document LATAK-D.034 "LATAK policy for metrological traceability of measurement results", which is available on the LATAK website https://www.latak.gov.lv/en/media/410/download?attachment . For more 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 CAB calibrates its own equipment (e.g. pipettes, dispensers), the mandatory calibration documents must be taken into account:

1. EA-4/02 M Evaluation of the Uncertainty of Measurement in Calibration (link: https://european-accreditation.org/publications/ea-4-02-m/);
2. ILAC-P14 ILAC Policy for Measurement Uncertainty in Calibration (link: https://ilac.org/publications-and-resources/ilac-policy-series/).

If the calibration is performed by the medical laboratory itself, LATAK involves calibration experts in the assessment.

6. Pre-assessment processes

If the CAB is directly responsible for sample collection, procedures for sample collection, storage after collection, packaging, transportation, acceptance must be developed. It must be ensured that the specified storage time of the sample, environmental conditions and safety have been observed, and an appropriate preservative has been used.

The CAB must ensure that sampling instructions are available to all staff involved in sampling in the laboratory.

In cases where samples are not taken by medical laboratory staff, the CAB is responsible for ensuring that the samples received can be used for further investigation, i.e. taken, stored, transported, etc. according to the requirements of the specific assessment.

Personnel involved in sampling must be trained, appropriately qualified and demonstrate their skills in sampling techniques. The CAB should review the requirements for competence monitoring.

When accrediting medical laboratories, LATAK also evaluates sampling sites. All typical sampling points or a representative number of sampling points are assessed during the initial accreditation process and within one accreditation cycle.

7. Assessment process

Before introducing manufacturer-validated investigation methods into routine use, the CAB performs their verification. The manufacturer's validated investigation methods must be performed without modification. The laboratory must ensure

compliance with the manufacturer's recommendations regarding the stability and expiration dates of reagents, calibrators, and control materials.

If non-standard methods, laboratory-developed methods, standard methods used outside the intended scope, and later modified validated methods are used, the CAB performs validation of the investigation procedures.

The CAB must record all activities related to the initial verification and validation, keep the records accordingly and present them to LATAK in the assessment upon request.

For uncertainties in the measurement results, the guidance document ILAC G17 "ILAC Guidelines for Measurement Uncertainty in Calibration" can be referred to (link: https://ilac.org/publications-and-resources/ilac-guidance-series/).

8. Quality assurance of assessment results

The CAB shall establish and maintain a quality control procedure to ensure that the quality criteria of the assessment results is achieved.

The CAB applies internal quality control (hereinafter - IQC) to all investigations in the field of accreditation.

The CAB develops an IQK program with the achievement of certain, regular quality criteria, the fulfillment of which gives the opportunity to evaluate the objectivity and traceability of the investigation results at all stages of operation and within the boundaries of clinical decision-making. The regularity of IQK CAB determined, not less often than determined or recommended by the manufacturer who has validated the investigation procedure.

If the manufacturer has not recommended or determined specific requirements regarding the testing of the control material, the CAB ensures the development and implementation of the IQK program.

The CAB develops a plan and ensures participation in proficiency tests or interlaboratory comparison (hereinafter - IC) programs.

The CAB IC plan for all investigations in the field of accreditation foresees the frequency of participation every year.

If the IC program is unavailable or impossible due to objective reasons, the CAB should develop an alternative approach (for example, investigation with reference material with traceability to international standards, investigation of evaluated material - tissue, cell culture, standard strains, bilateral testing - testing of one sample between accredited laboratories etc.), ensuring an objective evaluation of the results, determining the acceptability of the examination results.

The CAB maintains all records and evidence of participation in IC programs with evaluation of results and analysis of the causes of identified non-conformities.

For additional information see the following documents:

1. LATAK-D.007 "LATAK policy for participation in proficiency testing programs and interlaboratory comparisons" (link: https://www.latak.gov.lv/en/media/407/download?attachment);

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

9. Post-assessment processes

When developing a procedure for reporting investigation results, ANI takes into account the procedure for reporting results and the practice of clinical consultations, the procedure for using authorized laboratories and consultation services, as well as the procedure for ordering/receiving examination results and the impact of testing on the clinical management of patient care.

The CAB shood ensure that investigation results are reviewed by authorized personnel prior to release, against internal quality control and, where applicable, against available clinical information and previous investigation results.

If the report involves automated selection and reporting of investigation results, a procedure should be implemented.

The CAB should define the retention time for clinical samples depending on the nature of the sample, the investigation and any applicable requirements.

Safe disposal of biological samples and contaminated materials must be ensured in accordance with legal requirements and recommendations for waste management.

10. Reporting of results

ANI should have a procedure to ensure correct transfer of results. Reports should include information necessary for the interpretation of results.

Investigation reports should include comments on sample quality that may compromise the results of the investigation; on the suitability of samples for acceptance/rejection criteria; for critical results, if applicable.

The content of the investigation report must include the information required in clause 5.8.3 of the standard.

The Latvian National Accreditation Mark must be used on the issued test/assessment reports, observing the requirements specified in the document LATAK-D.011 “Regulations on the use of the National Accreditation Mark, references to Accreditation and the EA MLA”, which is available on the LATAK website https://www.latak.gov.lv/en/media/587/download?attachment, incl. identifying tests that are not accredited and provided by authorized laboratories.

11. Management of laboratory information

The CAB should have a documented procedure to ensure that the confidentiality of patient information is permanently maintained and data protection is ensured.

The CAB is responsible for the reliability and traceability of all information obtained, regardless of whether the information is maintained in electronic or paper form. Laboratory Information System (LIS) is a software that captures, processes, and stores information generated by medical laboratory processes. These systems often need to be integrated with equipment and other structures' information systems, such as hospital information systems. LIS is a configurable application developed to provide a wide range of workflow models.

IV Scope of accreditation

The accredited activities of CAB are described in the scope of accreditation. In the field of accreditation, the scope of CABs should be defined in such a way that it is possible to define precisely and unambiguously the scope of CABs 'accreditation, which is comprehensible to potential CABs' clients and other stakeholders.

In order to prepare the scope of accreditation, the CAB must submit an accurate form for the presentation of the scope of accreditation – Annex 4 Medical Examinations to the application form F.003 (see Section V of this document "Documents to be submitted"). The submitted scope of accreditation is assessed by LATAK, taking into account the EA-4/17 M EA position paper on the description of scopes of accreditation of medical laboratories (link: https://european-accreditation.org/publications/ea-4-17-m/).

Accredited CABs may apply for a flexible scope of accreditation, which allows CABs to start testing with new methods without prior notification to LATAK, provided that the changes are not related to new measurement principles covered by the original accreditation. CABs accredited in the flexible scope 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 stakeholders. The requirements specified in the document LATAK-D.041 "Flexible scope accreditation", which is available on the LATAK website https://www.latak.gov.lv/en/media/413/download?attachment , are observed. For more information, see EA 2/15 M "EA Requirements for accreditation of flexible scopes" (link: https://european-accreditation.org/publications/ea-2-15-m/) and EA-4/17.

V Documents to be submitted

When applying for accreditation, a CAB submits to LATAK the documents necessary for starting the accreditation process, which are indicated on the LATAK website https://www.latak.gov.lv/en/medical-laboratories (Documents to be submitted to the office form F.002.M), incl. The application form (LATAK-D.008 Appendix 1) and the accompanying accreditation scope form "Medical laboratory investigations"

(Appendix 4 of the Application), available on the LATAK website https://www.latak.gov.lv/en/general-documents-including-application Accreditation application form.

After obtaining accreditation for the implementation of the supervision process, the CAB shall submit the following documents prior to supervision:

1. information on maintaining or changing the scope of accreditation. If changes have been made (narrowing, expansion, updating of methods) or the information contained in the Application form needs to be updated, CAB submits the Application form (LATAK-D.008, Appendix 1) and the accompanying accreditation scope design form "Medical Laboratory Examinations" (Appendix 4), which is available on the LATAK website Accreditation application form https://www.latak.gov.lv/en/general-documents-including-application, clearly identifying the changes made compared to the existing accreditation scope.
2. list of current methods of the flexible cope (CABs, to which the relevant accreditation has been granted), clearly identifying the changes made compared to the list submitted in the previous assessment.
3. **form F.045** REPORT on laboratory participation in inter-laboratory (external) comparison (https://www.latak.gov.lv/en/medical-laboratories);
4. **form F.046** List of standards and reference materials (https://www.latak.gov.lv/en/medical-laboratories) ;
5. **form F.059** Staff list(https://www.latak.gov.lv/en/medical-laboratories)
6. **form F.060** Information on equipment and measuring instruments (https://www.latak.gov.lv/en/medical-laboratories);
7. **other documents indicated in form F.002** (https://www.latak.gov.lv/en/medical-laboratories)**, if changes have been made.**

At the end of the accreditation cycle (5 years), for the implementation of the re-assessment process, the CAB submits the Application form (LATAK-D.008, Appendix 1) and the accompanying accreditation scope design form "Medical Laboratory Examinations" (Appendix 4), which is available on the LATAK website Accreditation application form https://www.latak.gov.lv/en/general-documents-including-application, as well as the documents specified in form F.002 (https://www.latak.gov.lv/en/medical-laboratories Documents to be submitted to the office), if changes have been made.

Detailed procedure for submission and review of documents can be found in the LATAK document D.008 “Accreditation Procedures”, which is available on the LATAK website https://www.latak.gov.lv/en/media/218/download?attachment.

Prior to the planned monitoring and re-assessment visits, LATAK sends a letter requesting information to the CAB.

VI LATAK evaluation procedure

Pursuant to Clauses 9 and 12 of the Regulations No. 673, LATAK enters into an agreement and starts the CAB evaluation procedure after receiving all the necessary documents.

In the evaluation of the accreditation process (initial evaluation), the compliance of the CAB with all accreditation criteria is evaluated, incl. standard requirements at the CAB location/s throughout the scope of accreditation applied for. A technical expert and/or technical evaluation in each field applied for accreditation is involved in the evaluation. The initial evaluation shall assess the practical performance of the medical examination methods in all areas of the scope of accreditation applied for, provided that all the principles of the methods used in the medical examinations are covered. For equivalent methods, it is possible to evaluate the technical aspects of the implementation of the methods without evaluating the practical operation.

After the evaluation of the CAB, an accreditation decision is made in accordance with Chapter 3 of the Regulation No. 673 and the LATAK document D.008 "Accreditation Procedures".

For the monitoring process of accredited CABs, in accordance with Article 18 of the Regulation No. 673, a CAB evaluation program is developed for the entire accreditation cycle. The program is developed in accordance with the principle that within one accreditation cycle, the observation of the practical activities of the CAB must be ensured in all accredited areas of activity and important locations of the CAB, including sampling points. Based on the risk assessment and the experience gained from the previous evaluations, LATAK plans to evaluate all CAB locations (including those where the main activity is not performed) within the framework of one accreditation cycle, if possible.

During the re-evaluation, the compliance of the CAB with all accreditation criteria, incl. standard requirements is evaluated. All elements of the quality management system are assessed. LATAK assesses the implementation of the evaluation program of the previous accreditation cycle of the CAB and establishes the program for the next accreditation cycle, re-evaluates the practical activities performed by the CAB with newly included methods, as well as evaluates selected methods from the whole scope of the Institution applied for accreditation.

Information on the process of assessment, accreditation and supervision of conformity assessment bodies is specified in LATAK document D.008 "Accreditation Procedures", which is available on the LATAK website https://www.latak.gov.lv/en/media/218/download?attachment.

List of documents

1. LVS EN ISO 15189:2013 Medical laboratories. Requirements for quality and competence

2. D.008: 04/06.2022 Accreditation procedures

3. LATAK-D.011:15/10.2022 Regulations on the use of the National Accreditation Mark, references to Accreditation and the EA MLA.

4.LATAK-D.034-07/07.2021 LATAK policy for metrological traceability of measurement results;

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

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

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

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

9. EA-4/02 M:2013 Evaluation of the Uncertainty of Measurement in Calibration

10. EA-4/18 INF Guidance on the level and frequency of proficiency testing participation

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

12. EA-4/17:2022 M Description of scopes of accreditation for medical laboratories

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

14. ILAC G26:11/2018 Guidance for the Implementation of a Medical Accreditation Scheme

15. ILAC-P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration

16. ILAC G17:01/2021 ILAC Guidelines for Measurement Uncertainty in Testing

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

Register of amendments introduced

Version	Content of amendments	Date
01	New document	14.07.2021
02	Paragraph 10 is supplemented by the need to identify the results provided by authorized laboratories; the text "provided that 80% of the test results have been obtained by accredited methods" has been deleted "	31.03.2022.
	Chapter IV is supplemented with a requirement to maintain and update an up-to-date list of methods for CABs accredited in the flexible scope	
	The list of documents has been supplemented by EA-4/17:2022 M Description of scopes of accreditation for medical laboratories	
03	Updated information about LATAK's website and documents (Cabinet of Ministers regulations of 25 October 2022 No. 666, D.008:04/06.2022, LATAK-D.011:15/10.2022, as well as Section I contains Regulations No 60.	11.08.2023.
	In Chapter II, information on handling the sample and Regulation No. 60, subsection 110.1 has been added.	
	Point 1 has been supplemented with the provision of impartiality of personnel and protection of patient data.	
	Editorial corrections have been made in Point 2.	
	Point 4 "Personnel" has been supplemented with information on the Medical Treatment Law.	
	Point 5 has been supplemented with electrical safety checks and maintenance of equipment.	
	Point 6 provides detailed information on sampling and further action.	
	Point 7 editorially specifies information on validation and verification of methods, as well as compliance with manufacturers' recommendations.	
	Point 8 specifies the requirements for ensuring the reliability of the results (internal and external quality control).	
	In point 9, information on the issuance of investigation reports and the storage of clinical samples has been added.	
	Information on the transfer of investigation results and the information to be included in the reports has been added to point 10.	
	Point 11 contains information on the confidentiality of patient information and data protection.	
	In Chapter V, technical corrections were made and information on the procedure for submitting documents for monitoring was clarified.	