LATAK-D.15189:2023

Accreditation scheme for conformity assessment of medical laboratories

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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 19 December 2023 No 754 "Rules for evaluation, accreditation and surveillance of conformity assessment institutions" (hereinafter – Regulations No 754);
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 document LATAK-D.008 “Accreditation Procedures” (hereinafter – document LATAK-D.008);
7. LVS EN ISO15189:2023 “Medical laboratories. Requirements for quality and competence (ISO 15189:2022)” (hereinafter – the standard);
8. LATAK document LATAK-D.034 “LATAK policy for metrological traceability of measurement results” (hereinafter – document LATAK-D.034);
9. LATAK document LATAK-D.007 “LATAK policy for participation in proficiency testing programs and interlaboratory comparisons” (hereinafter – document LATAK-D.007);
10. LATAK-D.011 “Regulations on the use of the National Accreditation Mark, references to Accreditation and the EA MLA” (hereinafter – document LATAK-D.011);
11. LATAK document LATAK-D.041 “Accreditation in flexible scope” (hereinafter – document LATAK-D.041).

II General information

1. The operation of medical laboratories makes a significant contribution to the health care process and plays an important role in patient care.
2. Medical laboratory operations include activities and processes related to patient preparation, identification, primary sample collection, transport, handling, storage and safe disposal, as well as subsequent confirmation, interpretation, reporting and counseling of results, respecting safety and ethics in medical laboratory work.
3. Medical laboratories ensure appropriate selection of examinations, urgent or "cito" testing, notification of results, including reporting of critical results, as well as interpretation of results and provision of consultations.
4. Medical laboratories activities are carried out in accordance with ethical rules and guidelines, which define the responsibility of health care providers towards the patient.
5. Medical laboratory services must meet the needs of patients and clinical staff as well as other stakeholders.

6. The goal of the medical laboratory is to ensure the satisfaction of the laboratory's customers and the well-being of patients, promoting trust in the quality of medical laboratory services, competence, ensuring the comparability of patient examination results, and cooperation between other health care providers.
7. The standard contains the elements necessary for medical laboratories to demonstrate the quality and competence of their services, as well as to consistently provide reliable test results. The standard defines requirements for personnel competence, equipment and reagent management, pre-analytical processes, investigation processes, quality assurance of results, post-investigation processes and reporting of results.
8. According to Regulation No 60 of subsection 110.1, the multi-profile hospital has a medical laboratory accredited in accordance with the standard and in accordance with Paragraph 185 of this regulation, the medical institution must ensure the accreditation of the medical laboratory in accordance with the standard.
9. Medical laboratories perform biological, microbiological, immunological, hematological, cytological and other examinations of human-derived material to provide information for diagnosis, treatment, prophylaxis, health assessment, as well as provide advisory services, interpretation of results and recommendations for further investigation.
10. The standard could also be suitable and intended for use in other disciplines, such as clinical physiology, diagnostic imaging, respiratory therapy, blood banking and transfusion services, and medical physics. Premises that only remove and/or prepare samples for further examinations in a medical laboratory must be included in the management system of the accredited unit.

III Additional information and specific requirements

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

1. Structure and management

1.1. 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.

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

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

2. Laboratory activities

2.1. CAB must document compliance with the standard only for those activities it performs itself and does not outsource.

2.2. If the CAB conducts its activities in more than one location, the activities that meet this standard must be identified and documented at each of its locations.

2.3. The CAB should provide advice and professional judgment on the interpretation of investigation results.
2.4. CAB activities complying with the standard are shown in LATAK accreditation scope, which ANI submits to LATAK, and which reflects ANI's activities at each location, including activities at primary sample collection site.

3. Risk management

3.1. The laboratory manager is responsible for applying risk management to all aspects of laboratory operations to systematically identify and prevent risks to patient care and harm to patients.
3.2. The CAB must establish, implement and maintain processes to identify risks associated with harm to patients and develop operational risks to prevent and/or reduce them.
3.3. The CAB must confirm the that the risk assessment has been carried out in relation to the validation of the results to prevent diagnostic and treatment errors due to incorrect results, 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.

4. Assessments in authorized laboratories

4.1. The CAB must communicate its requirements to the authorized laboratories, such as the management of critical results, the delivery time of test results, and other requirements important to the laboratory.
4.2. The CAB 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.
4.3. 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.
4.4. The CAB may only be accredited for examination methods performed by the laboratory itself, and not for examinations sent to other laboratories.

5. Staff

5.1. The CAB should have enough competent employees who perform their activities in accordance with the laboratory's quality management system.
5.2. The CAB should determine the competence, education, qualification requirements of employees, incl. prescribed by Medical Treatment Law, as well as the need for additional training (for example, work with the laboratory information system (hereinafter – LIS)). The CAB should ensure personnel competence management and determine its periodicity based on risk assessment.
5.3. Personnel should be authorized to perform specific functions, including operations with method selection, development, verification and validation, review of results and operation with LIS.

6. Laboratory equipment, reagents and accessories

6.1. 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 management of equipment, reagents and consumables organized by another department or engineering staff, the CAB must ensure that the standard requirements are met.

6.2. The CAB must verify the equipment prior to commissioning to ensure that it can achieve measurement accuracy and/or measurement uncertainty for valid results.

6.3. Preventive maintenance must be performed on the equipment in accordance with the manufacturer's instructions and must be maintained in a safe working condition.

6.4. The CAB must ensure that measurement results are traceable to the International System of Units (SI).

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

6.6. 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.

6.7. The CAB should provide processes for inventory management that include performance testing of each reagent or new set of reagents prior to use.

6.8. Reagents, consumables and equipment should be used in accordance with the manufacturer's instructions and specifications. If they are used outside the manufacturer's instructions for use, validation from CAB should be carried out to the extent necessary to ensure the validity of the results relevant to clinical decision-making.

6.9. 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.

6.10. The CAB must ensure traceability of measurements in accordance with the document LATAK-D.034, which is available on the LATAK website https://www.latak.gov.lv/lv/medicinas-laboratorijam.

6.11. 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/).

6.12. If the CAB calibrates its own equipment (e.g. pipettes, dispensers, etc.), the mandatory calibration documents must be taken into account:

6.12.1. EA-4/02 M “Evaluation of the Uncertainty of Measurement in Calibration” (link: https://european-accreditation.org/publications/ea-4-02-m/);

6.12.2. ILAC-P14 “ILAC Policy for Measurement Uncertainty in Calibration” (link: https://ilac.org/publications-and-resources/ilac-policy-series/).

6.13. If the calibration is performed by the CAB itself, LATAK involves calibration experts in the assessment.

7. Pre-assessment processes

7.1. The CAB should have procedures for all pre-investigation activities and make them available to relevant personnel. The information and instructions must be sufficient to ensure that the integrity of the sample is not compromised.

7.2. Information about primary sampling and actions with them must be available to the persons responsible for sampling.

7.3. The CAB should identify potential patient care risks in pre-investigation processes.

7.4. If the CAB is directly responsible for primary 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.

7.5. 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.

7.6. When accrediting medical laboratories, LATAK also assesses sample collection sites included in the field of laboratory scope (Standard point 5.3.1). All typical sampling points or a representative number of sampling points are assessed during the initial accreditation process and within one accreditation cycle.

8. Assessment process

8.1. The requirements of the standard are designed with an emphasis on ensuring the validity of examination results and clinical decision-making.

8.2. The CAB should identify potential patient care risks in investigative processes.

8.3. Before implementing manufacturer-validated investigative methods into routine use, the CAB shall verify that they can properly perform the investigative methods prior to their use, ensuring that the performance specified by the manufacturer or method is achieved. The CAB should ensure that the extent of verification of investigative methods is sufficient to ensure the validity of results relevant to clinical decision-making.

8.4. The CAB must conduct a review of the updated methods and reagent versions of the developer/manufacturer, assess the significance of the changes, and decide on re-verification to the required extent.

8.5. The CAB should select and use investigative methods validated for the intended use. To ensure **the clinical accuracy** of examinations for patient investigation, preference is given to in vitro diagnostic medical devices (hereinafter - IVD) - methods that are considered standard methods and only with the CE mark.

8.6. When using IVD methods developed, validated and manufactured in accordance with a recognized risk management standard such as ISO 14971, the CAB should follow all manufacturer's instructions and instructions, including for reagents, calibrators, control material expiration dates, stability, calibration performance and control material frequency of testing. If the CAB does not follow the manufacturer's recommendations, the CAB should perform validation to an extent sufficient to ensure the validity of the results related to clinical decision-making.

8.7. 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 to the extent to ensure the validity of results relevant to clinical decision-making.

8.8. The CAB must record all activities related to the verification and validation, incl. results of a review of updated methods and reagent versions, keep the records accordingly and present them to LATAK in the assessment upon request.

8.9. 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/).

8.10. The laboratory should establish and periodically review biological reference intervals and clinical decision limits, indicating their rationale and/or source of information.

9. Ensuring the validity of investigation results

9.1. The CAB establish and maintains a procedure for control the validity of the results to ensure that the quality criteria of the investigation results is achieved.

9.2. The CAB should provide internal quality control (hereinafter – IQC) to continuously monitor and ensure the validity of results according to clinical decision-making.

9.3. The CAB should also use third-party IQC material as a supplement or alternative to manufacturer-supplied control material.

9.4. The CAB applies IQC to all investigations in the field of accreditation.

9.5. The CAB develops an IQC program to regularly verify the achievement of quality criteria, the fulfillment of which gives the opportunity to evaluate of the investigation results. The regularity of IQC CAB determined, not less often than determined or recommended by the manufacturer who has validated the investigation procedure.

9.6. If the manufacturer has not recommended or determined specific requirements regarding the testing of the control material, the CAB provide IQC to continuously monitor the validity of the results.

9.7. The CAB should ensure the implementation of investigation results by participating in external quality assessment (hereinafter - EQA) programs that meet the requirements of standard ISO/IEC 17043.

9.8. Only in cases where the EQA program is not available or not suitable, the CAB may apply alternative methods for ensuring the execution of the investigation method, confirming the validity of the chosen alternative.

9.9. The CAB develops a plan and ensures participation in EQA programs.

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

9.11. If the EQA 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.

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

9.13. If different equipment is used in the examination and/or examinations are performed in different places, the comparability of the results should be determined in all clinically relevant intervals and the client should be informed about clinically significant differences in the results.

9.14. For additional information see the following:

9.14.1. LATAK document LATAK-D.007 (link: https://www.latak.gov.lv/lv/medicinas-laboratorijam);

9.14.2. ILAC P9 ILAC "Policy for Participation in Proficiency Testing Activities" (link: https://ilac.org/publications-and-resources/ilac-policy-series/);

9.14.3. EA-4/18 INF "Guidance on the level and frequency of proficiency testing participation" (link: https://european-accreditation.org/publications/ea-4-18-inf/);

9.14.4. 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/).

10. Post-assessment processes

10.1. The CAB should identify potential patient care risks in post-investigation processes.

10.2. 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.

10.3. A procedure should be developed if the CAB has implemented a system for automatic selection and reporting of results.

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

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

11. Reporting of results

11.1. The reports should include all available information necessary for the interpretation of the results, as well as an indication of any critical results.

11.2. The Latvian National Accreditation Mark must be used on the issued reports, observing the requirements specified in the document LATAK-D.011, 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.

12. Date and information management

12.1. The CAB must have access to the data and information necessary to carry out its activities.

12.2. The CAB is fully responsible for information systems.

12.3. Information systems must be validated by the supplier and their functionality must be tested by the CAB before use. Any system changes, software changes must be validated before implementation.

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

12.5. 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

1. 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.
2. In order to prepare the scope of accreditation, the CAB must submit an accurately completed form "Medical laboratory examinations" (Appendix 4 of 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 document EA-4/17 M "Description of scopes of accreditation for medical laboratories" (hereinafter – EA-4/17 M) on the description of scopes of accreditation of medical laboratories (link: https://european-accreditation.org/publications/ea-4-17-m/) and the guidelines document ILAC G18 for the design of accreditation scopes (link: https://ilac.org/publications-and-resources/ilac-guidance-series/).
3. 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 constantly must maintain and post an up-to-date list of methods under the flexible scope on the CABs website so that it is available to the client, LATAK and other stakeholders. The list of methods under the flexible scope must also be updated if the developer of the method has updated the method, and the CAB has evaluated the changes (see point 8 of this document). The list of methods under the flexible scope must reflect the method **or** equipment and its developer's method current code/ version number (according to available information), date (usually a method description attached to a reagent or reagent kit). For information on receiving and maintaining the flexible scope, see document LATAK-D.041, which is available on the LATAK website https://www.latak.gov.lv/en/medical-laboratories, 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.
4. Additional requirements for describing the scope of accreditation:

4.1. if the CAB is granted flexibility regarding parameters and/or measurable indicators, then a group of parameters (analytes) and/or measurable indicators must be specified in the flexible scope of accreditation, such as hormones, vitamins, enzymes, etc. Flexibility is manifested by including new parameters and/or measurable indicators in the defined group;

4.2. if CAB is accredited for the collection of primary samples - then specific sample collection locations and the activity performed at each location must be specified in the scope of accreditation;

4.3. if CAB is not granted flexibility regarding the examination method, the scope of accreditation must reflect the method **or** equipment and its developer's method current code/ version number (according to available information), date (usually a method description attached to a reagent or reagent kit). The results of the investigation can be presented as accredited in the reports, if LATAK has carried out an evaluation of the updated methods.

V Documents to be submitted

1. When applying for accreditation, a CAB submits to LATAK the documents necessary for starting the accreditation process, which are specified in form F.002.M "Documents to be submitted to the office" (this and other forms are available on the LATAK website https://www.latak.gov.lv/en/medical-laboratories). The pplication form F.003 (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.
2. After obtaining accreditation for the implementation of the supervision process, the CAB shall submit the following documents prior to supervision:
   2.1. 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), clearly identifying the changes made compared to the existing accreditation scope;
   2.2. 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;
   2.3. **LATAK form F.045** "OVERVIEW of participation in proficiency testing (external) or interlaboratory comparison";
   2.4. **LATAK form F.046** "List of reference materials/ standards/ calibrators";
   2.5. **LATAK form F.059** "LIST of personnel (in the field of compliance assessment)";
   2.6. **LATK form F.060** "Information on equipment and measuring instruments";
   2.7. **other documents indicated in form F.002, if changes have been made**.
3. At the end of the accreditation cycle (5 years), for the implementation of the re-assessment process, the CAB submits the Application form F.003 (LATAK-D.008, Appendix 1) and the accompanying accreditation scope design form "Medical Laboratory

Examinations" (Appendix 4), as well as the documents specified in form F.002 (Documents to be submitted to the office), if changes have been made.

4. Detailed procedure for submission and review of documents can be found in the document LATAK document D.008, which is available on the LATAK website https://www.latak.gov.lv/en/general-documents-including-application.
5. Prior to the planned monitoring and re-assessment visits, LATAK sends a letter requesting information to the CAB.

VI LATAK evaluation procedure

1. Pursuant to Article 10 of the Regulations No 754, LATAK enters into an agreement and starts the CAB evaluation procedure after receiving all the necessary documents. Experts in the field of information technology will be engaged once in the accreditation cycle to evaluate the compliance of data and information management with standard requirements.
2. 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.
3. After the evaluation of the CAB, an accreditation decision is made in accordance with Article 19 of the Regulation No 754 and the document LATAK D.008.
4. For the surveillance of the accredited CABs, in accordance with Article 12 of the Regulation No 754, 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. Based on the risk assessment and the experience gained from the previous evaluations, LATAK plans to evaluate all CAB locations within the framework of one accreditation cycle, as well as a representative number of sampling points.
5. 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.
6. Information on the process of assessment, accreditation and supervision of conformity assessment bodies is specified in document LATAK document D.008, which is available on the LATAK website https://www.latak.gov.lv/en/general-documents-including-application.

List of documents

1. LVS EN ISO 15189:2023 “Medical laboratories. Requirements for quality and competence (EN ISO 15189:2022)”
2. LATAK-D.008 “Accreditation procedures”
3. LATAK-D.011 “Regulations on the use of the National Accreditation Mark, references to Accreditation and the EA MLA”
4. LATAK-D.034 “LATAK policy for metrological traceability of measurement results”
5. LATAK-D.041 “Flexible scope accreditation”
6. LATAK-D.007 “LATAK policy for participation in proficiency testing programs and interlaboratory comparisons”
7. EA-2/15 M:2023 “EA Requirements for the Accreditation of Flexible Scopes”
8. EA-4/02 M:2022 “Evaluation of the Uncertainty of Measurement in Calibration”
9. EA-4/14 INF:2003 “Selection and use of references materials”
10. EA-4/17:M 2022 “Description of scopes of accreditation for medical laboratories”
11. EA-4/18 INF:2021 “Guidance on the level and frequency of proficiency testing participation”
12. EA-4/21 INF:2019 “Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation”
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 P9:01/2024 “ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing”
18. ILAC G18:01/2024 “Guideline for describing Scopes of Accreditation”

Register of amendments introduced

Version	Content of amendments	Date
01	New document	08.03.2024
02	Point 2 specifies information about the coverage of CAB's activities in the field of accreditation in all its locations, incl. at primary sample collection points	21.10.2024
	Point 8 has been supplemented with information on reviews, verification, and nots of updated methods by the developer	
	Chapter IV specified information on the permanent maintenance of the list of current methods of the flexible accreditation scope, presentation of the current versions of the developer's method in the list of methods, as well as additional requirements for the design of the accreditation scope (added 3 points)	
	The document has been updated in accordance with the specified documents EA-4/02 M:2022 and EA-4/21 INF:2019	
03	Chapter IV Point 3 has been specified – the list of methods under the flexible scope must reflect the method or equipment and its developer's method current code/ version number (according to available information), date (usually a method description attached to a reagent or reagent kit)	04.06.2025
	Chapter IV Point 3 has been specified – if CAB is not granted flexibility regarding the examination method, the scope of accreditation must reflect the method **or** equipment and its developer's method current code/ version number (according to available information), date (usually a method description attached to a reagent or reagent kit).	