

Valsts aģentūra "Latvijas Nacionālais akreditācijas birojs"

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# **Accreditation procedures**

# LATAK-D.008-04/06.2022.

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#### 1. GENERAL TERMS AND CONDITIONS

1. These Terms and Conditions stipulate the procedure and criteria for assessment, accreditation and monitoring of conformity assessment bodies (hereinafter – the Bodies), and are binding upon the national accreditation body - State Agency "Latvian National Accreditation Bureau" (hereinafter – LATAK), its accredited Bodies and Bodies that are willing to acquire LATAK accreditation.

2. LATAK assesses, accredits and monitors the Bodies, which operate in areas specified in <u>the Cabinet of Ministers Regulations No. 754</u> "Regulations Regarding the Assessment, Accreditation, and Monitoring of Conformity Assessment Bodies" of 19 December 2023.

3. LATAK performs the activities mentioned in Paragraph 2 of these Terms and Conditions in accordance with the requirements specified in regulatory enactments of the Republic of Latvia and the European Union, national, European and international standards, as well as mutual recognition agreements with international accreditation organizations (European Accreditation Cooperation, International Accreditation Forum, International Laboratories Accreditation Cooperation) and binding documents issued on their basis, as well as <u>LATAK</u> Inviolability, Objectivity and Confidentiality Compliance, Conflict of Interest Prevention and Anti-Corruption Policy. If a conflict between the national applicable regulations and standard ISO / IEC 17011 is determined, the standard ISO/IEC 17011 shall be applied.

4. The objective of accreditation is to obtain a reliable and independent certification by a third party at a national level that the specific Body is capable to demonstrate its competence and ability to carry out specific conformity assessment measures.

5. LATAK develops specific accreditation-related assessment process and accredited Bodies monitoring methodologies and procedures, including specific accreditation schemes, which are published by LATAK on its website <u>www.latak.gov.lv</u>.

6. The binding documents of the European Accreditation Cooperation, the International Accreditation Forum and the International Laboratories Accreditation Cooperation are available on the website of the European Accreditation Cooperation <u>https://european-accreditation.org/</u>, on the website of the International Accreditation Forum <u>https://www.iaf.nu/</u> and on the website of the International Accreditation Cooperation <u>https://ilac.org/</u>.

7. The original language of these Terms and Conditions is Latvian. In case of any discrepancy between the original text of these Terms and Conditions in Latvian and the translation in a foreign language, the Latvian wording shall prevail. These Terms and Conditions may be republished after receiving written approval from LATAK.

8. LATAK publishes the current version of these Terms and Regulations on the website www.latak.gov.lv.

## 2. TERMINOLOGY USED IN THE TERMS AND CONDITIONS, AND ACCREDITATION CRITERIA

9. The terminology included in the Law "On Conformity Assessment" and the standard LVS EN ISO/IEC 17000 "Conformity Assessment. Dictionary and General Principles", as well as the standard LVS EN ISO/IEC 17011 "Conformity Assessment. Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies" is used in these Terms and Conditions, as far as a different use of a term is expressly determined in these Terms and Conditions.

10. Accreditation criterion is conformity of the Body to requirements specified in regulatory enactments, national, European and international standards, as well as mutual

recognition agreements with international accreditation organizations (European Accreditation Cooperation, International Accreditation Forum, International Laboratories Accreditation Cooperation) and binding documents issued on their basis (documents developed by the European Accreditation Cooperation, documents of international accreditation organizations approved by the European Accreditation Cooperation, mandatory documents of the International Accreditation Accreditation Cooperation, and the International Laboratories Accreditation Cooperation).

11. Accreditation scheme is a set of conditions and procedures binding upon the Bodies for acquiring the accreditation, which can be specified in a regulatory enactment, national, European or international standard, or binding documents issued by international accreditation organizations (the European Accreditation Cooperation, the International Accreditation Forum, the International Laboratories Accreditation Cooperation).

12. Accreditation scope is specific conformity assessment activities related to accreditation.

13. Flexible accreditation scope is an accreditation scope, which allows the Bodies to make changes to methods and other parameters, observing the competence and ability of the Body to perform specific activities approved by LATAK.

## **3.** COMMENCEMENT OF THE ACCREDITATION PROCESS

#### 3.1 Accreditation process

14. Types of accreditation procedures:

14.1. **initial assessment** – first assessment after conclusion of the accreditation agreement, which is aimed at verifying the competence and ability of the Body to perform specific conformity assessment activities in accordance with the accreditation criteria;

14.2. **repeated assessment** – assessment carried out at the end of each accreditation cycle, which is implemented within the framework of one accreditation agreement and is aimed at verifying continuous conformity of the management system of the Body to the accreditation criteria, as well as efficiency of the Body and continuous suitability to the accreditation scope;

14.3. **extension of accreditation scope** – assessment aimed at verifying the competence and ability of the Body to perform specific conformity assessment activities in accordance with the accreditation criteria within the additionally applied accreditation scope;

14.4. **monitoring procedure** – a set of activities carried out by LATAK during effective accreditation, the objective of which is to verify that the management system of the Body accredited by LATAK is maintained and retains its compliance with the criteria criteria, incl. the Body is competent to perform specific conformity assessment activities in accordance with the accreditation scope.

#### 3.2 Submission and examination of the accreditation application

15. The initial assessment, repeated assessment and scope extension procedures are commenced pursuant to an application of the Body (hereinafter – the Accreditation Application).

16. The Body shall indicate in the Accreditation Application the information mentioned in Annex 1 "Accreditation Application" to these Terms and Conditions and shall attach all documents necessary for assessment in accordance with the requirements set in the accreditation scheme of the specific field. At the same time, the Body shall indicate in the Accreditation Application, which information shall be considered commercial secret and cannot be disclosed to third parties.

17. If the Accreditation Application does not contain the entire information and documents necessary for assessment, LATAK shall request the Body to submit the missing information and documents within a specific term.

18. If the Body fails to submit the information requested by LATAK within the specified term, LATAK shall not commence the assessment procedure of the Body, notifying the Body in writing.

19. If the Body submits the Accreditation Application in a field, in which LATAK has not accredited any Body, LATAK shall inform the Body in writing about the necessity to acquire a new accreditation field, indicating a term, in which the accreditation process of the Body can be commenced.

20. If the Accreditation Application and attached documents are submitted to LATAK in printed format, the Body shall ensure their submission also in an electronic data carrier.

21. The accreditation field indicated in the Accreditation Application, which is subject to the mandatory assessment of conformity of products, processes or services specified in regulatory enactments, shall conform to the terminology used in the respective regulatory enactment and have a reference to the respective regulatory enactment.

22. The Body is entitled to technically specify the accreditation field until the assessment visit, except the cases, when it is necessary to make changes in substance, for example, include a new field, when the Body shall submit a new Accreditation Application.

23. If the Body wants to narrow, suspend or cancel the accreditation scope, it shall submit an application, indicating precisely the substance of changes.

# 3.3 Contract on the accreditation process of the Body and an agreement on costs of the accreditation process

24. If the preliminary accreditation application is accompanied by all documents necessary for assessment and commencement of assessment is possible, LATAK and the Body shall conclude an agreement on the accreditation process of the Body (hereinafter – the Accreditation Agreement).

25. Prior to commencement of each accreditation procedure specified in Subparagraph 3.1 of these Terms and Conditions, except the cases mentioned in Paragraphs 53.1 and 53.5, according to the Accreditation Agreement concluded between LATAK and the Body, a written agreement on the costs of the accreditation process shall be concluded.

26. After receiving the payment specified in the agreement on the costs of the accreditation process, LATAK shall commence the assessment procedure of the Body. In the instance specified in Subparagraphs 53.1 and 53.5. of these Terms and Conditions, the assessment procedure may be implemented before receiving the payment for the accreditation process.

#### 4. ASSESSMENT PROCESS OF THE BODY

# 4.1 Preconditions for commencement of the assessment, and the assessment group

27. The Body is assessed by an assessment group set up by LATAK, which is composed of LATAK leading assessors, technical experts or technical assessors with appropriate competence in the respective field, provided that participation in the assessment process of the Body does not cause a conflict of interest, incl. if a member of the assessment group:

27.1. has not consulted the Body, which may influence the accreditation process and assessment objectivity;

27.2. the spouse or relative (father, mother, grandmother, grandfather, child (also adopted), grandchild, brother, sister, stepbrother, stepsister) of the member of the assessment group is not a participant, shareholder, member, member of the supervisory, control or executive body of the Body;

27.3. has not been in employment legal relations with the assessed Body within the last two years prior to the planned date of assessment;

27.4. is not personally or financially interested in the outcome of the accreditation process, and there are no other circumstances that raise reasonable doubts about impartiality of the member of the assessment group.

28. Not later than 7 (seven) working days before the planned Body assessment visit, LATAK shall send electronically to the Body an assessment plan and inform the Body on the composition of the assessment group. The Body may apply for rejection of the composition of the assessment group, submitting to LATAK a reasoned application, indicating the basis for rejection of each rejected member of the assessment group. LATAK shall assess the information provided by the Body and, if necessary, approve a different composition of the assessment group and agree on another date of the assessment visit.

#### 4.2 Assessment of the Body

29. The assessment group shall carry out assessment of the Body in accordance with the procedure specified in the assessment plan. The assessment visit involves the opening meeting, assessment of compliance with the Body competence and accreditation criteria, the closing meeting and onsite or remote monitoring of activities within the Body accreditation scope and subject to the conformity assessment (hereinafter – monitoring of practical activity).

30. The assessment visit and the monitoring of practical operation may be carried out remotely, using information technologies, if the Body timely submits all documents related to the assessment and a possibility to carry out remote assessment at the same level as if the assessment visit and monitoring of practical activity would be carried out onsite at the place of operation of the Institution with assistance of information technologies, is ensured, and if LATAK considers that by implementing these activities remotely objective assessment of conformity of the Body to the accreditation criteria is possible. The audiovisual channel of safe and reliable communication to be used during remote assessment shall be determined by the Body, taking into consideration the requirements for information security specified in the Body, and technological capabilities of LATAK.

31. The agenda sequence indicated in the assessment plan may be changed, without changing the assessment plan it its substance, if it is mutually coordinated during the opening meeting with the management of the Body and members of the assessment group.

32. Assessment of the Body competence includes assessment of documents and notes of the Body, assessment of the personnel competence, monitoring of practical activity of the Body, as well as assessment of sufficiency of required resources. The leading assessor of the assessment group shall determine the operation to be demonstrated and the person who shall demonstrate it. As a result of competence assessment, LATAK obtains evidence of conformity of the Body to the accreditation criteria.

33. During the initial assessment:

33.1. The practical activity of the Body is assessed according to the requirements stated in the accreditation scheme;

33.2. The conformity of the Body is assessed at locations of the Body and places, where conformity assessment activities are carried out;

34. The Body is obliged to ensure a possibility for LATAK assessment group to participate in the conformity assessment process, monitoring the practical activity of the Body, also at the location of the client of the Body.

35. If a certification, inspection and verification Body is unable to attract a client before accreditation and therefore is unable to ensure demonstration of the practical activity, LATAK may carry out competence assessment based on the submitted documents (also performing simulation of situations of practical activity). In the case stated in this Paragraph, practical activity shall be assessed at the moment, when the Body carries out the first conformity assessment procedure after acquiring accreditation.

36. The assessment visit shall be concluded with the closing meeting, where the assessment group gives to the Body an oral report and explanation on the assessment results and issues a written report on the detected non-conformities, where, among other things, requests the Body to submit analysis of causes of such non-conformities within a specified term, describe the analysis of prevalence of non-conformities, planned corrective measures and corrections, as well as evidence of implemented corrective measures/corrections for elimination of detected non-conformities.

37. If issuing of written report on the detected non-conformities is impossible during the closing meeting, the leading assessor of the assessment group shall prepare and send it to the Body not later than 5 (five) working days after the closing meeting.

#### 4.3 Classification of findings and elimination terms

38. **Observation** – insignificant non-conformity, which does not significantly affect fulfilment of the accreditation criteria.

39. **Non-conformity** is a finding related to inability of the Body to ensure fulfilment of the accreditation criteria, including:

39.1. Documents of the Body do not comply with the accreditation criteria;

39.2. Personnel of the Body does not observes requirements of the documents of the Body;

39.3. Insufficient justification of the documents developed by the Body is detected for the Body to fulfil the accreditation criteria and implement the conformity assessment procedure;

39.4. The Body fails to comply with the accreditation scheme developed by LATAK or requirements of the accreditation agreement;

39.5. The management system of the Body does not contain the information required for efficient fulfilment of the accreditation criteria;

39.6. Several observations are detected for one standard requirement.

40. **Substantial non-conformity** – non-conformity related to inefficient process control or non-conformity of the result to the specified accreditation criteria, including non-conformities that have any of the features indicated below, for example:

40.1. Competent personnel or technical provision is not available to the Body;

40.2. The Body has issued results outside the accreditation scope with a reference to the accreditation;

40.3. The conformity assessment results issued by the Body are inadequate.

41. Terms for elimination of findings:

41.1. In case of preliminary assessment, the overall term for submission of evidence of implemented corrective measures shall not exceed 6 (six) months from the date of receiving the report on non-conformities; in other cases the term shall be set depending on the gradation of findings.

41.2. **Observation** – shall be prevented until the next assessment visit and the efficiency of the implementation of corrective measures is assessed during that visit.

41.3. **Non-conformity** – the term for elimination of non-conformities and submission of evidence of implemented corrective measures is 1 (one) month from the date of receiving the report on detected non-conformities.

41.4. **Substantial non-conformity** - the term for elimination of non-conformities and submission of evidence of implemented corrective measures is 7 (one) months from the date of receiving the report on detected non-conformities.

# 4.4 Submission of evidence of implemented corrective measures, and assessment of this evidence

42. Within the time limits specified in the Paragraph 41 of the Regulation (for observations within one month) the Body shall provide LATAK with an analysis of the causes, analysis of extend, description of corrections and/ or planned corrective measures for non-conformities and/ or observations identified during the assessment, as well as within the time limits specified in the Paragraph 41 of the Regulation the Institution shall provide LATAK with objective evidences of the corrections and corrective measures taken for non-conformities and/ or observations identified during the assessment.

43. Within 15 (fifteen) working days after receiving of the information referred to in the Paragraph 42 of the Regulation, the assessment group shall assess the sufficiency of the cause analysis, extend analysis and the performed corrections/ corrective measures implemented by the Body and its compliance with the accreditation criteria. The Body has right to submit clarifications regarding the information and confirmations specified in the Paragraph 42 of the Regulations within one term after the assessment of the corrective actions evaluated by the assessment group. The term for elimination of a substantial non-conformities shall not be extended.

44. If the evidence of the implemented corrective measures and corrections is not received within the term and the extent specified in the Paragraph 42 of the Regulation or the evidence is insufficient to confirm the elimination of non-conformities, LATAK shall decide on not granting, suspension or cancellation of certification in the entire accreditation scope or any part thereof, observing the provisions of these Terms and Conditions and regulatory enactments.

45. To verify efficiency of corrective measures implemented by the Body for elimination of non-conformities and obtaining relevant evidence according the Paragraph 42 of the Regulation, LATAK is entitled to carry out an additional Body assessment visit or monitoring of practical activity.

46. The additional Body assessment visit according the Paragraph 45 of the Regulation shall be carried out after LATAK and the Body have concluded an agreement on costs of the additional assessment visit and the Body has settled a payment for the said additional assessment.

47. If an additional visit according the Paragraph 45 of the Regulation is not required, but it is necessary to carry out monitoring of performance of corrective measures specified in the Paragraph 42 of the Regulation, implementation of these measures may be verified during the next visit.

#### 4.5 Accreditation cycle and monitoring

48. The accreditation cycle is a period of 5 (five) years from the moment of granting initial or repeated accreditation.

49. After granting the accreditation, LATAK shall develop the Body assessment programme for the entire accreditation cycle. LATAK shall perform monitoring of the Body in accordance with the said assessment programme, thus ensuring continuous monitoring of the Body.

50. The following aspects shall be taken into consideration in development of the Body assessment programme:

50.1. The information obtained by LATAK on the management system and activities of the Body, as well as the performance of the Body;

50.2. Each field/area of the activity shall be assessed at least once within one accreditation cycle, taking into account the experience gained during the previous assessments, risks related to the activity of the Body, locations of the operation and personnel, as well as requirements specified in the accreditation scheme;

50.3. During the accreditation cycle, LATAK shall plan assessment of all locations of the Body as far as possible (also locations where the main activity is not carried out), based on the risk assessment;

50.4. When selecting the manner of monitoring of the practical activity of the Body, LATAK shall observe the principle that monitoring of the practical activity of the Body shall be ensured in all accredited fields of activity at essential locations of activity of the Body within one accreditation cycle. Special requirements are specified in descriptions of the respective accreditation schemes.

51. Monitoring visits shall be carried out according to the assessment programme and plan at least once a year, and shall include monitoring of the Body at its locations and monitoring of the practical activity of the Body.

52. Monitoring visits shall be organised, taking into consideration the following principles:

52.1. Conformity of the Body and its management system to the accreditation criteria shall be assessed;

52.2. The assessment of the management system of the Body shall be planned in a way that all elements of the management system are assessed at least once during the accreditation cycle;

52.3. In addition to the aforesaid, efficiency of the implemented corrective measures on the findings detected during the previous assessment shall be assessed.

53. LATAK is entitled to carry out monitoring of the Body, including paying a visit outside the assessment programme and plan in the following cases:

53.1. LATAK holds a written complaint or information, which raises doubts about the competence of the Body to carry out conformity assessment activities. In this case, a visit shall not be previously coordinated with the Body and LATAK, according to the necessity, may invite a representative of the market surveillance authority to participate in the visit;

53.2. The Body has made a request to make changes to its accreditation scope, incl. with a purpose to restore the accreditation status of the Body in cases when it has been suspended;

53.3. The Body has notified of changes to its activity, which may affect its conformity to the accreditation criteria, and if it is impossible to assess such impact on the accreditation status

without visiting the Body, i.e., an analysis of documents does not provide sufficient evidence that the Body complies with the accreditation criteria;

53.4. The Institution has informed LATAK on changes to the methods or procedures included in its accreditation scope;

53.5. If it is necessary to visit the Body to verify its conformity to the specified accreditation criteria.

54. The monitoring activities may include requests of information, documents and notes of the Body, assessment of updating of documents of the Body, visits, monitoring of the practical activity of the Body, assessment of the technical provision and introduced management system, as well as other activities that allow LATAK to assess conformity of the Body to the accreditation criteria properly.

55. LATAK is entitled not to visit the Body at its locations of activity, if changes to the accreditation scope do not affect the ability of the Body to perform conformity assessment activities.

#### 4.6 Repeated assessment

56. Requirements of Subparagraph 4.1 of these Terms and Conditions shall apply to repeated assessment.

57. If the Body wants to retain its accreditation, it is obliged to submit for repeated assessment the required documents in accordance with the conditions of Subparagraph 3.2 of these Terms and Conditions at least 4 (four) months before expiration of the accreditation term. LATAK shall send to the Body a reminder of the accreditation term not later than 4 (four) months before expiration of the accreditation term.

58. Repeated assessment includes all activities of the preliminary assessment for certification of the competence of the Body and corresponds to the following principles:

58.1. The experience gained during the previous assessment is taken into consideration;

58.2. Conformity of the Body to all accreditation criteria is assessed;

58.3. Performance of the assessment programme of the Body and the practical activity of the Body is assessed in the representative part of the entire field of activity of the Body applied for accreditation;

58.4. The management system of the Body is assessed.

#### 4.7 Extension of the accreditation scope

59. The process of extension of the accreditation scope includes all activities of the initial assessment, and the procedure of initial assessment specified in these Terms and Conditions is applied.

60. To extend the accreditation scope, the Body shall submit the accreditation application and documents mentioned in Subparagraph 3.2 of these Terms and Conditions.

61. LATAK shall prepare an accreditation scope extension plan and determine appropriate assessment methods, considering the risks of activities related to scope extension or locations of activity of the Body. If the Body applies for extension of the scope of conformity assessment activities that are similar to already accredited activities and identical requirements concerning the required technical provision and competence shall be set for the additionally applied scope, LATAK may assess the competence and ability of the Body to conduct specific conformity assessment activities, assessing the certificates and documents submitted by the Body.

62. If extension of the accreditation scope corresponds to the period of monitoring visit, LATAK may carry out the process of extension of the applied accreditation scope concurrently with the monitoring visit, notifying the Body.

#### 4.8 Assessment of the Body that applies for the status of notified Body

63. The Body that applies for acquiring the status of notified Body (hereinafter – the Notified Body) according to requirements of regulatory enactments, in addition to the provisions of Paragraph 16 of these Terms and Conditions, shall indicate in the accreditation application the conformity assessment modules and products that the Body notifies itself as being competent in, as well as the respective applicable regulatory enactments.

64. Specific requirements for the Notified Body are specified in the European Accreditation Cooperation document EA-2/17 M "EA Document on Accreditation for Notification purposes".

65. The accreditation process and decision-making procedure specified in these Terms and Conditions shall apply to the accreditation process of the Notified Body, observing the provisions of this Chapter and paying particular attention to the ability of the Body to meet the requirements set in the applicable regulatory enactments.

## 5. ACCREDITATION DECISIONS

66. An accreditation commission shall be established by LATAK for accreditation decision-making. The accreditation commission shall adopt a decision for each separate accreditation process. The accreditation commission shall be comprised of the Chairperson of the commission, who is competent in the assessed field, and at least one LATAK leading assessor, who has not participated in the assessment process of the respective Body.

67. The accreditation commission may attract for participation in the accreditation commission the technical experts and technical assessors of the Body, on the assessment results of which the decision is made, as well as independent experts who participate in the commission work with advisory rights. Before participation in the meeting of the accreditation commission, the attracted technical assessors and technical experts shall sign a confirmation that they will not disclose to third parties the information obtained during the decision-making process.

68. LATAK may ask participants of the meeting of the accreditation commission to present an identity document, also asking the representative of the Body to present a document certifying the authorization. If a participant of the accreditation meeting is unable to present a personal identity document at a request of LATAK or a person, who wants to exercise representation of the Body, is unable to present documents certifying the authorization, LATAK is entitled to deny participation of this person in the meeting of the accreditation commission.

69. Meetings of the accreditation commission are closed. The meeting of the accreditation commission shall be attended without voting rights by the leading assessor of the assessment group of the respective accreditation process, who shall report about the plan of the assessment visit, the information obtained during the visit, the assessment results, the process of elimination of non-conformities, and fulfilment of the accreditation criteria and requirements stated in the accreditation scheme.

70. If the information submitted by the leading assessor of the assessment group is insufficient for taking the accreditation decision, the accreditation commission may request any required additional information from the Body. In the case stated in this Paragraph, the meeting

of the accreditation commission shall be suspended, making a respective mark in the minutes of the meeting, and shall be resumed not later than 5 (five) working days after receiving the requested information.

71. Based on the assessment results, the accreditation commission may take the following decisions:

71.1. **To grant accreditation** – if the Body has met the requirements of regulatory enactments/accreditation, thus complying with the accreditation criteria;

71.2. To refuse granting accreditation – if the Body has not met the requirements of regulatory enactments/accreditation, thus not complying with the accreditation criteria. A decision shall be made for the entire scope of activity applied for accreditation. The accreditation process shall be terminated also in the case, if LATAK holds verifiable evidence on fraudulent activities carried out by the Body, provision of false information or concealing of information related to the accreditation status;

71.3. **To retain accreditation -** if it is established as a result of the monitoring process or upon assessment of the Body after expiration of the accreditation period that the Body meets all requirements of regulatory enactments/accreditation, thus complying with the accreditation criteria;

71.4. To extend the accreditation scope - if it is established as a result of the assessment that the Body has met requirements of regulatory enactments/accreditation in the additionally applied scope, thus complying with the accreditation criteria;

71.5. To narrow the accreditation scope - if the Body has requested it or has not met requirements of regulatory enactments/accreditation in any part of the accreditation scope, thus not complying with the accreditation criteria in the respective part, incl. if the accreditation has been previously suspended and the Body has not eliminated the detected non-conformities within the specified term;

71.6. To suspend accreditation for the entire or any part of the accreditation scope – if the accredited Body has made a written request for such suspension or it has been detected during the assessment that the accredited Body has not met the accreditation criteria, but the non-conformities are not significant enough to cancel the accreditation. The accreditation suspension period shall not exceed 6 (six) months;

71.7. To cancel accreditation – if the accredited Body has requested it in writing or it has been detected during the assessment that the accredited Body has not met the accreditation criteria, incl., for example, has not eliminated non-conformities detected by LATAK within the specified term, has carried out fraudulent activities, provided false (misleading) information or concealed information related to the accreditation status.

72. If the accreditation commission should prima facie make the decision mentioned in Subparagraph 71.7 of these Terms and Conditions according to the non-conformities detected during the assessment, LATAK shall inform the Body about it before the meeting of the accreditation commission, calling the Body to provide the accreditation commission with additional information and explanations in a timely manner. In case of substantial non-conformities, the accreditation commission may adopt the decision mentioned in Subparagraph 71.7 of these Terms and Conditions, without prior notice to the Body.

73. If the accreditation of the Body is cancelled in the entire accreditation scope or narrowed in any part thereof, the Body shall discontinue using references to its accreditation in the entire scope or the respective part thereof. The certification Body (product, system and person) shall revoke the issued effective certificates with a reference to the accreditation (accreditation mark) and shall submit to LATAK respective documents certifying fulfilment of

the aforesaid requirements within 5 (five) working days, unless a different procedure is stipulated by the applicable regulatory enactments.

74. LATAK shall submit the accreditation decision mentioned in Paragraph 71 of these Terms and Conditions to the Body electronically within 7 (seven) working days after making the accreditation decision.

75. LATAK shall prepare an accreditation certificate and its annex within 10 (ten) working days after adopting the decision mentioned in Subparagraphs 71.1, 71.4 and 71.5 of these Terms and Conditions.

76. If the Body has not submitted the documents required for its assessment or does not observe the requirements stated in the accreditation scheme during the process of initial accreditation, thus preventing LATAK to carry out assessment of the Body and making a decision on the accreditation status of the Body, LATAK shall decide **on termination of the accreditation process**.

#### 6. INFORMATION REQUIREMENTS

#### 6.1 Confidentiality

77. Members of the assessment group shall not disclose to third parties any information that has come into their possession or has been generated about the Body during the accreditation procedures, and shall take care that the information obtained or generated concerning the Body during performance of duties is not directly or indirectly accessible to third parties without written consent of the Body, except the instances specified in regulatory enactments.

#### 6.2 Accreditation certificate and reference to the accreditation

78. The Body shall use a reference to the accreditation and to the accreditation mark observing the conditions for use of the accreditation mark for accredited Bodies, developed by LATAK, as well as the Cabinet of Ministers Regulations that stipulate conditions for assessment, accreditation and monitoring of Bodies.

79. An electronically prepared accreditation certificate is sent to the e-address or e-mail address of the Body.

80. Upon a request of the Body, the accreditation certificate may be prepared in paper format. An accreditation certificate prepared in paper format and its annex can be received by the Body at the office of LATAK.

81. An accreditation certificate prepared in paper format shall be issued to the authorised representative of the Body in person, who shall confirm the fact of receipt with personal signature. LATAK is entitled to ask the authorised representative mentioned in this Paragraph to present an authorization and an identity document.

82. Accreditation certificates are issued in A4 format (Annex 2), accompanied by its annex(-es), which is (are) an integral part of the accreditation certificate. A specific accredited scope of activity of the Body is defined in the accreditation certificate and its annex.

83. The Body is entitled to receive the accreditation certificate and its annex in a foreign language, coordinating it in writing with LATAK in advance and making a payment in accordance with the pricelist of paid services of LATAK specified in regulatory enactments.

84. If the Body is accredited in the field of testing and calibration, two separate certificates and their annexes are issued to the Body (for the testing scope and the calibration scope respectively).

85. If the name, address or the accredited scope of activity of the legal entity or the Body changes, LATAK shall issue a new accreditation certificate and its annex.

86. The Body is obliged:

86.1. To ensure that the accreditation certificate, its annex or the reference to accreditation is not used in a misleading way;

86.2. To ensure that, when using the reference to accreditation in informative materials, mass media, various documents and other types of publications, accreditation is not referred to the non-accredited scope of activity and the provisions and procedure specified in the conditions of use of the accreditation mark for accredited Bodies, developed by LATAK, are observed;

86.3. To discontinue using of documents or informative materials, or otherwise used reference to its accreditation, if the accreditation of the Body has been suspended or cancelled with a decision adopted by LATAK.

## 7. COMPLAINTS AND APPEALS

#### 7.1 Procedure of submission of complaints and appeals

87. LATAK shall accept, examine and reply to an application pursuant to the procedure specified in regulatory enactments.

88. Upon receiving an application with a complaint regarding the activity of LATAK or the accredited Body, and which shall be replied to in its substance (hereinafter – **the complaint**), the Director of LATAK shall assess the content of the complaint and delegate the task of examining the complaint and preparing a reply to the responsible officer of LATAK or shall issue an order to set up a commission for examination of the complaint.

89. Decision adopted by the accreditation commission may be appealed pursuant to the procedure specified in the Administrative Procedure Law, submitting a respective application to LATAK (hereinafter – **the appeal**).

90. The appeal shall be examined by an appeal commission set up by the Director of LATAK.

91. Decisions of the appeal commission may be appealed in the court pursuant to the procedure specified in the Administrative Procedure Law.

92. Written applications shall be submitted at the office of LATAK or sent by mail. Electronic applications shall be sent to the e-address or e-mail address of LATAK: <u>pasts@latak.gov.lv</u>.

### 7.2 Procedure of examination of complaints and appeals

93. Upon receiving a complaint or appeal, LATAK shall assess conformity of its design to requirements of regulatory enactments and these Terms and Conditions, and assess the jurisdiction of the matter.

94. If the complaint or appeal is not signed, submitted without observing requirements stated in the Official Language Law, or is not accompanied by documents certifying the authorization, the complaint or appeal shall be left without examination and LATAK shall inform the submitter about such non-conformities, specifying a term for elimination of these deficiencies. If deficiencies are not eliminated within the term specified by LATAK, the complaint or appeal shall be recognised as not submitted.

95. If the complaint or appeal is drafted according to requirements of regulatory enactments and examination of the complaint or appeal falls under the competence of LATAK, it shall be examined not later than within 1 (one) months after the date of its receipt. If it is impossible to observe the 1 (one) month term due to objective reasons, the submitter shall be notified about it.

96. The process of examination of the complaint or appeal shall not be participated by an employee, officer of LATAK or attracted expert, about impartiality of whom reasonable doubts may arise regarding the particular complaint or appeal.

97. If the circumstances indicated in the complaint have informative nature and the complaint does not require a reply in its substance or active action from LATAK, LATAK shall take note of the respective complaint and use it in the work of LATAK according to the content of the complaint.

98. Members of the assessment group of the Body shall not be included in the composition of the appeal commission. If necessary, with a purpose to ensure objective and competent examination of the appeal, LATAK is entitled to attract an independent expert to give an opinion on the circumstances mentioned in the appeal. In addition to the aforesaid, LATAK is entitled to attract also representatives of the Latvian National Accreditation Council or competent state Bodies in the respective fields for the work of the appeal commission. The requirements stated in Paragraphs 27 and 67 of these Terms and Conditions shall apply to the said attracted persons.

99. LATAK shall inform members of the appeal commission and the attracted persons about the time and place of the meeting of the appeal commission.

100. The appeal commission shall examine a complaint in accordance with the regulation of the appeal commission.

101. Meetings of the appeal commission consist of open and closed part. LATAK shall invite the submitter of the appeal for the open part of the meeting of the appeal commission. The open part of the meeting of the appeal commission shall be attended by members of the appeal commission, the attracted persons and the submitter of the appeal or its authorised person. During the open part of the meeting of the appeal commission, the circumstances indicated in the appeal and the applied request shall be assessed, opinions and arguments of the involved persons shall be clarified, and other activities required for objective decision-making in the case shall be implemented. During the closed part of the meeting of the appeal.

102. Before participation in the meeting of the appeal commission, LATAK shall verify the powers of the appeal submitter or its representative to represent the Body. Legal entities shall execute the representation rights with a written power of attorney or certify with documents, from which the rights of the official to represent the legal entity without special authorization arise. Natural persons shall execute the representation with a notarially certified power of attorney.

103. If a person, who wants to exercise representation of the appeal submitter, is unable to submit documents certifying the authorization and/or present an identity document, LATAK is entitled to deny participation of this person in the meeting of the appeal commission.

104. Non-participation of the appeal submitter in the meeting of the appeal commission shall not serve as an obstacle for examination of the appeal.

105. Minutes of the meeting of the appeal commission are taken, and LATAK sends electronically prepared minutes of the meeting to the participants of the appeal meeting within 7 (seven) working days from the date of the meeting. If any member of the appeal commission has an opposite position to the overall opinion of the commission, a respective note shall be made in the minutes of the meeting of the commission. The appeal commission shall operate, including make decisions, in accordance with the regulation of the appeal commission.

106. LATAK shall draft the decision of the appeal commission on the validity of the appeal and send it to the appeal submitter within 7 (seven) working days from the date of adoption of the decision of the appeal commission.

#### 8. TRANSITIONAL PROVISIONS

107. These Terms and Conditions shall be applicable from 1 September 2021.

108. These Terms and Conditions replace the following documents of LATAK:

108.1. LATAK - D.008-14/06.2015 "Accreditation Procedures"

108.2. LATAK-D.009-08/07.2013 "Monitoring and Repeated Assessment of the Accredited Bodies";

108.3. LATAK - D.014-08/06.2014 "Procedure of Examination of Complaints, Proposals and Appeals";

108.4. LATAK - D.016-09/07.2013 "Accreditation Decisions";

108.5. LATAK - D.021-06/12.2013 "Conditions of Use of Accreditation Certificates Issued by the Latvian National Accreditation Bureau";

108.6. LATAK-D.030-14/06.2015 "LATAK Accreditation Criteria and the List of Applicable Documents";

108.7. LATAK - D.032-04/09.2013 "Rights and Obligations of Accredited Conformity Assessment Bodies";

108.8. LATAK - D.045-02/06.2015 "Accreditation of Conformity Assessment Bodies for Notification Purposes".

109. Annex 2 referred in the Paragraph 82 of the Regulations shall be introduced gradually until 31 July 2023.

Annexes:

Annex 1. Accreditation Application

Annex 2. Sample of the Accreditation Certificate

#### 9. **Register of Changes**

| Version | Content of changes   | Date        |
|---------|--|-------------|
| 01      | Initial approval of the document                           | 18.05.2021. |
| 02      | Editorial corrections made                                 | 30.08.2021. |
|         | Paragraph 107 is supplemented with information on the date |             |
|         | of application of the Regulation                           |             |

| 03 | Subparagraph 41.2. is expressed in a different wording,      | 14.03.2022. |
|----|--|-------------|
|    | specifying the information regarding the elimination of the  |             |
|    | observations founded in the assessment                       |             |
|    | Chapter 4.4. has been updated, specifying information on the |             |
|    | prevention of the findings of the assessment and the         |             |
|    | submission of the corrective action plan                     |             |