Republic of Latvia

Cabinet

Regulation No. 673

Adopted 17 December 2019

**Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies**

*Issued pursuant to*

*Section 13, Paragraph one of the law On Conformity Assessment and Section 39, Paragraph four of the Environmental Protection Law*

**1. General Provisions**

1. The Regulation prescribes:

1.1. the fields in which the national accreditation body *valsts aģentūra “Latvijas Nacionālais akreditācijas birojs”* [State agency Latvian National Accreditation Bureau] (hereinafter – the Agency) shall assess, accredit, and supervise conformity assessment bodies;

1.2. the procedures by which the Agency shall organise the assessment, accreditation, and supervision of conformity assessment bodies, including the accreditation of environmental verifiers and their activity;

1.3. the composition, competence of the accreditation commission and the procedures for taking decisions;

1.4. the information to be included in the list of accredited conformity assessment bodies;

1.5. a sample of accreditation mark;

1.6. the procedures for establishing and maintaining the register of environmental verifiers.

2. The Agency shall assess, accredit, and supervise conformity assessment bodies (hereinafter – the bodies) which are operating in the following fields:

2.1. inspection;

2.2. certification of management systems;

2.3. certification of persons;

2.4. testing and calibration;

2.5. medical laboratory investigations;

2.6. certification of products;

2.7. environmental verification;

2.8. organising of skill tests;

2.9. validation and verification.

3. The Agency shall assess, accredit, and supervise the bodies operating in the fields referred to in Paragraph 2 of this Regulation:

3.1. in a regulated area – in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (hereinafter – Regulation No 765/2008) and the laws and regulations regarding conformity assessment;

3.2. in a non-regulated area – in accordance with Regulation No 765/2008.

**2. Procedures by which the Agency shall Organise Assessment, Accreditation, and Supervision of Conformity Assessment Bodies**

**2.1. General Procedures for the Assessment, Accreditation, and Supervision Process**

4. The Agency shall organise the assessment process and the supervision of accredited bodies in accordance with the methodology and procedures developed in accordance with the requirements laid down in Regulation No 765/2008 and published on the website of the Agency.

5. The bodies shall, within the scope of assessment, accreditation, and supervision, submit documents to the Agency which certify the conformity of the body with the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment in a regulated area or the conformity with the requirements laid down in Regulation No 765/2008 – in a non-regulated area.

6. Assessment of the bodies shall be performed by an assessment group established by the Agency and the composition of which includes lead assessors, technical experts, or technical assessors of the Agency with corresponding competence in the relevant field if participation in the assessment process of the body does not cause a conflict of interests.

7. The Agency shall attract technical experts and technical assessors in the assessment, accreditation, and supervision process of the body. Technical experts and technical assessors shall:

7.1. examine the documents submitted by the bodies;

7.2. assess the conformity of the body with the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment in a regulated area;

7.3. assess the conformity of the body with the requirements laid down in Regulation No 765/2008 in a non-regulated area;

7.4. prepare and submit an evaluation of the conformity of the body with the requirements of this Regulation;

7.5. in case of examining complaints, upon request of the Agency, submit information to the Agency on the body assessed.

8. The Agency shall post and maintain the list of accredited bodies and the register of environmental verifiers on its website. The following information shall be indicated in the register:

8.1. the accreditation number of the body;

8.2. the name, legal address, and address of the actual place of activity of the body;

8.3. the actual scope of accreditation of the body;

8.4. the term of accreditation;

8.5. the term of suspending the accreditation.

**2.2. Procedures for the Submission of an Accreditation Application**

9. In order to receive accreditation or to make changes in the accredited area, the body shall submit to the Agency a submission and all the documents necessary for assessment which are referred to in Paragraph 5 of this Regulation.

10. If the body has not submitted all the documents referred to in Paragraph 5 of this Regulation, the Agency shall request that the missing information is submitted, indicating the time period for the submission of documents.

11. Upon submitting the submission referred to in Paragraph 9 of this Regulation and the documents appended thereto to the Agency in paper form, the body shall also submit them on an electronic medium.

12. After receipt of all the documents referred to in Paragraph 9 of this Regulation, the Agency shall, in relation to the initial accreditation, enter into a contract with the body on accreditation process.

13. The Agency shall not commence the assessment process of the bodies if any of the following circumstances exists:

13.1. the body has not submitted the information referred to in Paragraph 10 of this Regulation within the time period stipulated by the Agency;

13.2. the body has not settled the payment for the relevant assessment procedure.

**2.3. Procedures for the Assessment of the Bodies**

14. The Agency shall inform the relevant body of the assessment plan and the composition of the assessment group referred to in Paragraph 6 of this Regulation. The body may, within three working days, raise an objection against technical experts or technical assessors by submitting a justified submission to the Agency, indicating the reasons for rejecting each rejected expert or technical assessor. The Agency shall evaluate the information provided by the body and, if necessary, approve other experts or technical assessors.

15. The assessment group referred to in Paragraph 6 of this Regulation shall perform the assessment of the body in accordance with the assessment plan referred to in Paragraph 14 of this Regulation.

16. The Agency shall perform the assessment of the body outside the assessment plan referred to in Paragraph 14 of this Regulation in the following cases:

16.1. it has information at its disposal on non-conformities in the activity of an accredited body. In such case a visit to the body need not be coordinated in advance and the Agency may invite a representative of a market surveillance institution, if necessary;

16.2. the body has expressed a request to make changes in its scope of accreditation;

16.3. the body has informed of changes in its activity which may affect its conformity with the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment in a regulated area or the conformity with the requirements laid down in Regulation No 765/2008 – in a non-regulated area, and if such impact on the status of accreditation cannot be assessed without a visit to the body;

16.4. the body has informed the Agency of changes in the methods or procedures included in its scope of accreditation;

16.5. if it is necessary to visit the body to ascertain its conformity with the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment in a regulated area or the conformity with the requirements laid down in Regulation No 765/2008 – in a non-regulated area.

17. The assessment group referred to in Paragraph 6 of this Regulation shall evaluate the submission of the body and the documents appended thereto, visit the body at the sites of activity thereof, assess the practical activity performed by the body, prepare an assessment report, and report to the accreditation commission on the conformity of the body with the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment in a regulated area or the conformity with the requirements laid down in Regulation No 765/2008 in a non-regulated area. The Agency has the right not to visit the body at its sites of activity if changes in the scope of accreditation do not affect the ability of the body to perform conformity assessment activities.

**2.4. Procedures for the Supervision of the Activity of Accredited Bodies**

18. Upon accrediting the body, the Agency shall prepare an accreditation certificate and an annex thereto and develop an assessment programme for the whole cycle of accreditation. Within the scope of the accreditation cycle in a regulated area the Agency shall assess the conformity of the body with the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment or in a non-regulated area – the conformity with the requirements laid down in Regulation No 765/2008 in all sites of activity and in the whole scope of accreditation.

19. In case of changes in the scope of accreditation, sites of activity, staff, or other changes in the body which may affect the conformity of the body with the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment in a regulated area or the conformity with the requirements laid down in Regulation No 765/2008 – in a non-regulated area, the Agency shall make the necessary changes in the assessment programme referred to in Paragraph 18 of this Regulation.

20. The Agency shall supervise the operation of accredited bodies by performing the planned supervision activities in accordance with Paragraphs 14, 15, and 17 of this Regulation and the assessment programme referred to in Paragraph 18 of this Regulation not less than once a year.

21. The body shall, upon request of the Agency within the time period stipulated thereby, submit all the documents necessary for supervision and referred to in Paragraph 5 of this Regulation, ensuring a possibility to perform assessment at the sites of activity of the body and to observe the practical activity performed by the body in person.

22. If an accredited certification body discontinues the provision of accredited services, it shall inform in writing all the persons or merchants to which it has issued a certificate and, if possible, hand over the certification files to such accredited certification body in which the certified person or merchant has decided to re-register.

23. The new accredited certification body shall issue a corresponding certificate to the certified person or merchant, indicating the start and end term of the operation of the certificate indicated in the certificate previously issued to the certified person or merchant as the term of validity of the certificate.

24. The certificate of the certification body which has discontinued the provision of accredited services shall be valid until the day when the certified person or merchant receives the certificate issued by the new accredited certification body, however, not longer than three months from the day when information has been received from the certification body that it discontinues the provision of accredited services.

25. The procedures referred to in Paragraphs 22-24 of this Regulation shall not be applicable to such accredited certification bodies for which the requirements in relation to the handing over of the files of certified persons have been laid down in the laws and regulations governing the relevant sectors.

**3. Composition, Competence of the Accreditation Commission and the Procedures for Taking Decisions**

26. The composition of the accreditation commission shall include the chairperson of the commission having competence in the field to be assessed and the lead assessor of the Agency which has not participated in the assessment process of the relevant body.

27. The accreditation commission may, in the process of taking a decision on accreditation, invite the body regarding the assessment results of which the decision is being taken, the technical experts and technical assessors involved in the assessment process, and also independent experts which participate in the work of the commission in an advisory capacity.

28. The accreditation commission shall:

28.1. examine the assessment documents of the body;

28.2. become acquainted with the report of the lead assessor on the course of assessment of the body;

28.3. evaluate the justification of the recommendation of the lead assessor.

29. On the basis of the assessment results, the Agency shall:

29.1. grant or continue accreditation in a regulated area if the body conforms to the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment or in a non-regulated area if the body conforms to the requirements laid down in Regulation No 765/2008;

29.2. refuse to grant accreditation in a regulated area if the body does not conform to the requirements laid down in Regulation No 765/2008 and the laws and regulations regarding conformity assessment or in a non-regulated area if the body does not conform to the requirements laid down in Regulation No 765/2008;

29.3. reduce the scope of accreditation if the body has expressed such a request.

30. If the body has not submitted the documents referred to in Paragraph 5 of this Regulation in the assessment process or it does not conform to the accreditation provisions and for this reason the accreditation commission is not able to perform its assessment and take the decision on accreditation of the body, the accreditation commission shall take the decision on the termination of the accreditation process. The accreditation process is terminated also if the Agency has at its disposal evidence that can be checked on fraudulent activities performed by the body, provision of false information or hiding of information which is related to the status of accreditation.

31. The Agency shall, after entering into effect of the decision, publish information on its website in accordance with Paragraph 8 of this Regulation.

32. The sample accreditation mark used by the bodies is specified in Annex to this Regulation.

**4. Closing Provisions**

33. The requirement referred to in Paragraph 32 of this Regulation in relation to the use of an accreditation mark shall come into force on 1 June 2020. Until 31 May 2020 in relation to the use of the accreditation mark, the requirements referred to in Cabinet Regulation No. 1059 of 16 December 2008, Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies, shall be applied.

34. The bodies which have been accredited in accordance with Cabinet Regulation No. 1059 of 16 December 2008, Regulations Regarding the Assessment, Accreditation, and Supervision of Conformity Assessment Bodies, conform to the requirements of this Regulation.

35. The Regulation shall come into force on 1 January 2020.

Prime Minister A. K. Kariņš

Acting for the Minister for Economics, Minister for the Interior S. Ģirģens

**Annex**

Cabinet Regulation No. 673

17 December 2019

**Accreditation Mark**



**EN ISO/IEC XXXXX**

**W-YYY**

1. The accreditation mark shall consist of the accreditation logo, the number of the standard, and the number of the body.

2. Accreditation logo:

2.1. dimensions (recommended for a sheet of A4 format) – height 10 mm, width 15 mm;

2.2. one of the following colours:

2.2.1. black;

2.2.2. a combination of dark blue and light blue colours:

2.2.2.1. letter T and stars – in Pantone 5415C colour range;

2.2.2.2. the remaining part of logo – in Pantone 654C colour range.

3. The number of the standard according to which the body has been accredited.

4. The accreditation number of the body shall consist of:

4.1. W – a respective designation of the conformity assessment body:

4.1.1. T – for a testing laboratory;

4.1.2. K – for a calibration laboratory;

4.1.3. S1 – for a product certification body;

4.1.4. S2 – for a management system certification body;

4.1.5. S3 – for a certification body for persons;

4.1.6. I – for an inspection body;

4.1.7. LV-V – for an environmental verifier;

4.1.8. M – for a medical laboratory;

4.1.9. GHG – for a validation and verification body;

4.1.10. PTP – proficiency testing providers;

4.2. YYY – the registration number of the accreditation of the body.

Acting for the Minister for Economics, Minister for the Interior S. Ģirģens