

## **Cabinet of Ministers Republic of Latvia**

December 16, 2008

Regulations No. 1059

### **Regulation for assessment, accreditation and surveillance of conformity assessment bodies**

Issued pursuant to Section 13. paragraph one of the Law on Conformity Assessment and Section 5<sup>2</sup>, paragraph four of the Law on Environmental Protection

#### **I General**

1. The regulation determines:

1.1. the actions of national accreditation system which includes assessment, accreditation and surveillance of testing and calibration laboratories, as well as certification bodies for quality systems, personnel and products, inspection bodies and environmental verifiers (hereinafter – conformity assessment body);

1.2. the order to establish and maintain the list of accredited conformity assessment bodies.

2. State agency for Metrology and Accreditation (hereinafter – agency) have its organisational unit – Latvian National accreditation bureau (hereinafter – bureau), who in the framework of legislation of European Community at national level acts as a National accreditation institution.

3. To fulfil the requirements of this regulation the Bureau publishes in the homepage of the agency the list of applicable documents of European and international accreditation organisations (hereinafter – applicable documents).

#### **II. The operation of the National accreditation system**

4. The Bureau performs assessment, accreditation and surveillance of testing and calibration laboratories, certification and inspection bodies and environmental verifiers in compliance with standard LVS EN 17011:2004 “Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies” and applicable documents.

5. The Bureau performs assessment, accreditation and surveillance in non-mandatory area:

5.1. for Inspection bodies according to standard LVS EN ISO/IEC 17020:2005 " General criteria for the operation of various types of bodies performing inspection " and applicable documents;

5.2. for management system certification institutions according to standard LVS EN ISO/IEC 17021:2007 "Conformity assessment - Requirements for bodies providing audit and certification of management systems" and applicable documents;

5.3. for certification institutions of persons according to standard LVS EN ISO/IEC 17024:2005 " Conformity assessment - General Requirements for Bodies operating Certification of Persons " and applicable documents;

5.4. for testing and calibration laboratories according to standard LVS EN ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories" and applicable documents;

5.5. for testing laboratories in field of medicine according to standard LVS EN ISO 15189:2008 "Medical laboratories - Particular requirements for quality and competence" or standard LVS EN ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories" and applicable documents;

5.6. for product certification institutions according to standard LVS EN 45011:2004 "General requirements for bodies operating product certification systems" and applicable documents;

5.7. environmental verifiers according to regulation of Regulation (EC) No 761/2001 of the European Parliament and of the Council of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) , and applicable documents.

6. The Bureau performs assessment, accreditation and surveillance in mandatory area according to criteria defined in article 5 of this regulation and defined criteria of legislative documents on conformity assessment as well as applicable documents.

### **III. Accreditation procedure**

7. Agency according to application of accreditation from conformity assessment body, signs a contract with conformity assessment body. Contractual relations include procedure of accreditation, and duties of the involved parties according to requirements defined in article II of this regulation.

8. The Bureau performs assessment separately for each kind of conformity assessment body according to requirements defined in the article 5 and 6 of this regulation taking into account the following sequence:

8.1. the conformity assessment body delivers to the Bureau all the necessary information requested for the assessment;

## 8.2. the Bureau:

8.2.1. appoints the assessors and experts, who are competent in the corresponding field of assessment;

8.2.2. analyses the documents in the declared scope and evaluates the conformity assessment body including proficiency tests at different sites of activities;

8.2.3 writes the assessment report to conformity assessment body after the assessment;

8.3. the conformity assessment body performs measures to eliminate the nonconformities defined in the assessment report.

9. Based on the results of the assessment the Bureau takes one of the following decisions:

9.1. to grant the accreditation, if the conformity assessment body fulfils the requirements defined in the article 5 or 6 of this regulation. The accreditation term is four year for first accreditation period and 5 years for subsequent periods;

9.2. to not grant the accreditation, if the conformity assessment body don't fulfils the requirements defined in the article 5 or 6 of this regulation;

9.3. to retain the accreditation, if the conformity assessment body fulfils the requirements defined in the article 5 or 6 of this regulation;

9.4. to suspend the accreditation, if the nonconformities, discovered during the assessment of the conformity assessment body, are not so essential to withdraw the accreditation in all scope of the accreditation or in part;

9.5. to withdraw the accreditation, if the conformity assessment body don't fulfils the requirements defined in the article 5 or 6 of this regulation or the nonconformities are not eliminated in the terms defined in the article 8.2.3 mentioned review;

9.6. to enlarge the scope of the accreditation, if the conformity assessment body fulfils the requirements defined in the article 5 or 6 of this regulation in the supplementary scope of the accreditation;

9.7. to reduce the scope of the accreditation, if if the conformity assessment body don't fulfils the requirements defined in the article 5 or 6 of this regulation in the part of the scope of the accreditation.

10. The decision to withdraw, suspend or to reduce the scope of the accreditation can be taken, if there is appropriate application from conformity assessment body on that.

11. The decision to suspend or withdraw the accreditation can be taken by the agency also, if the conformity assessment body don't fulfils the terms of the agreement defined in the article 7 of this regulation.

12. During one month time after the decisions mentioned in articles 9.1., 9.6. and 9.7. are taken the Bureau lay out the accreditation certificate and their appendix.

13. Bureau:

13.1. develops the conformity assessment body assessment plan for repeated evaluation and other activities needed to supervise that accredited conformity assessment body fulfils the accreditation requirements;

13.2. determines the interval between the assessment visits, that don't exceed the two year period;

13.3. plans the surveillance visits by taking into account the other supervision activities;

13.4. can realize extraordinary assessments, if there are complaints on activities of conformity assessment body or information on changes in their activities or considering other surveillance activities;

13.5. save the assessment reviews and safeguards their confidentiality.

14. The testing and calibration laboratories participates in the proficiency testing and other interlaboratory comparison programmes.

15. The accredited conformity assessment body uses the accreditation mark (appendix) on their conformity assessment results.

16. The accreditation mark can't be used to mislead. The usage can't be in contradiction to requirements mentioned in article 12. of this regulation.

17. The Bureau once in month informs the Environmental management state bureau on accredited environmental verifiers and indicate the information mentioned in article 18 of this regulation.

#### **IV. The development and maintenance of the list of accredited conformity assessment bodies**

18. The Bureau develops and maintains the list of accredited conformity assessment bodies. The list contains following information:

18.1. the accreditation number of the conformity assessment body;

18.2. the name, legal and actual address of the conformity assessment body;

18.3. the accreditation scope of the conformity assessment body;

18.4. the period of validity of the accreditation certificate;

18.5. the period of suspension of the accreditation in cases mentioned in article 9.4 of this regulation.

19. The Bureau keeps up to date the information in the list of the accredited conformity assessment bodies. The list is available on the homepage of the Agency.

## V. Final questions

20. The regulation of Cabinet of Ministers No. 96 from February 11, 2008 “Regulation on accreditation and supervision of conformity assessment bodies” is condemned (Latvijas Vēstnesis (*The Herald of Latvia*) 2008, No. 26).

21. The regulation comes into force on January 1, 2009.

Prime Minister

I. Godmanis

Minister of Economics

K. Gerhards

Appendix

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## Accreditation mark



1. Accreditation logo:

1.1. dimensions (preferable for A4 page) - height 10 mm, width 15 mm;

1.2. one of the following colours:

1.2.1. black;

1.2.2. composition of dark blue and light blue colours:

1.2.2.1. T letter and stars - *Pantone 5415C* colour;

1.2.2.2. the rest of the logo - *Pantone 654C* colour.

2. The number of the conformity assessment institution consists of:

2.1. X – the marking of type of the conformity assessment institution:

2.1.1. T – Testing laboratory;

2.1.2. K – Calibration laboratory;

2.1.3. S1 – Product certification body;

2.1.4. S2 – Management system certification institution;

2.1.5. S3 – Personnel certification body;

2.1.6. I – Inspection institution;

2.1.7. LV-V – Environmental verifiers;

2.1.8. M – Medical laboratory;

2.2. YYYY – The number of the conformity assessment institution.

Minister economy *K.Gerhards*