

**Act No. 505/2009 Coll.** on Accreditation of Bodies Responsible for Conformity Assessment and on Amendment of Certain Acts (in wording of No. 307/2013 Coll.)

**Dated:** 27 October 2009

**Valid from:** 8 December 2009

**In Effect from:** 1 January 2014

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**The ACT**

Of 27 October 2009

**On Accreditation of Bodies Responsible for Conformity Assessment and on Amendment of Certain Acts**

The National Council of the Slovak Republic has adopted the following Act:

**Article No. 1**

**§ 1**

**Subject and Scope of the Act**

This Act governs

- a) the proceedings regarding Accreditation of the Bodies responsible for Conformity Assessment and provision of accreditation services,
- b) rights and responsibilities of accredited bodies,
- c) the status, scope of authority, bodies, management and financing of the Slovak National Accreditation Service,
- d) scope of authority of the Slovak Office of Standards, Metrology and Testing (hereinafter "the Office") in the area of the conformity assessment bodies accreditation,
- e) violation and other administrative offences.

**§ 2**

**Basic Terms**

For the purposes of this Act the terms herein shall be interpreted as follows

- a) The accreditation service shall mean a single act or a set of acts of an accreditation body<sup>1)</sup> executed in the process of granting the accreditation,<sup>2)</sup> withdrawal of the accreditation, modification of accreditation, suspension of accreditation, extension of accreditation, restriction of accreditation, re-accreditation, surveillance, preliminary assessment or provision of professional information,
- b) Accreditation requirement shall mean a set of standards and documents determining the conditions of proceeding of the Conformity Assessment Body,<sup>3)</sup>
- c) Accredited body shall mean a Conformity Assessment Body that has been granted the accreditation on the basis of the proof of fulfillment of the accreditation requirements,
- d) Certificate on accreditation shall mean a document or a set of documents issued by the accreditation body, certifying granting of the accreditation for the specific area and scope,
- e) Surveillance shall mean a set of activities for monitoring current fulfilment of accreditation requirements by accredited bodies with the exception of the re-accreditation proceedings performed by the accreditation body within the timeframe of the accreditation validity,
- f) Re-accreditation shall mean a proceeding within which the accreditation body verifies the competence of the accredited body as regards further performing the activities stipulated by the Decision on granting the accreditation.

**§ 3**

**Accreditation granting**

- (1) Request regarding granting the accreditation shall be submitted by the Conformity Assessment Body (hereinafter "the Applicant"),
- (2) Request regarding granting the accreditation shall include
  - a) The designation and residence of accreditation body,
  - b)
    1. The name and surname, residence address of the establishment and (if applicable) the identification number of Applicant, in case the Applicant is a natural person, or
    2. The designation or commercial name, residence address or location of organization unit, and, (if applicable) the identification number of the Applicant, in case the Applicant is a legal entity,
  - c) The date and signature of the Applicant,
  - d) The specification of the area and the scope for which the request for granting the accreditation is submitted,
  - e) The name and surname of the person responsible for accuracy of the results within the activities of Applicant,
  - f) The information regarding education, expert knowledge, trainings and experience of the professional staff of Applicant.
- (3) Request for accreditation granting shall be supplemented with
  - a) The list of technical equipment necessary for the performing the accredited activities,
  - b) The documentation files describing the quality management system,
  - c) Other documents that may be of relevance for assessing whether the Applicant fulfills the accreditation requirements.
- (4) Should the certification body find out that the Request for granting the accreditation is lacking any necessary essentials, it shall address the Applicant within 30 days after the delivery with a requirement for rectifying the inadequacies within the stipulated period not shorter than 15 days, and the proceedings related to the granting of accreditation shall be suspended. In case of serious reasons involved, the accreditation body is entitled to prolong the above mentioned period based on the Applicant's request.
- (5) In case that the certification body finds out any discrepancies in terms of the fulfillment of the accreditation requirements, it shall address the Applicant to rectify such discrepancies within the stipulated period, and the proceedings related to the granting of accreditation shall be suspended. In case of serious reasons involved, the accreditation body is entitled to prolong the above mentioned period based on the Applicant's request.
- (6) When requested, the Applicant shall be obliged to provide the Accreditation body with any documents deemed necessary for assessment of fulfillment of the accreditation requirements; and he shall do so within the stipulated period not shorter than 15 days. The certification body is entitled to prolong this period based on the Applicant's request. The accreditation body shall also suspend the proceedings related to accreditation granting until the documents are submitted.
- (7) The accreditation body shall stop the proceedings related the accreditation granting, when the Applicant
  - a) Fails to rectify the inadequacies related to his request within the period stipulated in accordance with Paragraph 4,
  - b) Fails to rectify the inadequacies related to the fulfillment of accreditation requirements within the period stipulated accordance with Paragraph 5,
  - c) Fails to submit the required documents to the accreditation body within the period stipulated in accordance with Paragraph 6.

#### § 4

##### **Decision background**

- (1) The background for the decision related to accreditation granting shall be provided by the recommendation of the evaluation committee consisting of the employees of the accreditation body, or other experts in the specific area for which the fulfillment of the required conditions for accreditation granting is being assessed. The status, scope and principles of the evaluation committee activities shall be established by the statute and rules of procedure shall be issued by the Director.
- (2) The recommendation of the evaluation committee is based on the results submitted by the assessment group consisting of the employees of the accreditation body or other experts who are not members of the evaluation committee in relation to the same issue. The rules of procedure of the assessment group shall be issued by the Director.
- (3) In case the accredited body communicates changes according to § 6, subpar. 2 letter f) respective points 1, 2, 3 or 5, the background for the decisions may be the results of the changes assessment (provided) by the accreditation body, based on the documents submitted by the accredited body; the accreditation body shall proceed in the same way in case of learning about these changes otherwise.

#### § 5

##### **The Decision**

- (1) In case the accreditation body ascertains that the request contains the essentials as stipulated by §3, subparagraphs 2 and

3, and the Applicant fulfills the requirements defined by this Act along with the accreditation requirements, the accreditation body shall issue a decision on granting the accreditation.

(2) The Decision on granting the accreditation shall include the following:

- a) The designation and residence of accreditation body,
- b) The name and surname, residence address of the establishment and (if applicable) the identification number of Applicant, in case the Applicant is a natural person or the designation or commercial name, location of residence, and (if applicable) the identification number of the Applicant, in case the Applicant is a legal entity,
- c) The specification of the area and the scope for which the accreditation granted,
- d) The location where one or more of the accredited activities are to be performed,
- e) The statement ascertaining the conformity of the activities of accredited body with a standard or a normative document and, with a reference to the standard or normative document used in the process of evaluating the request,
- f) The validity period of accreditation,
- g) The number and date of the issuance of the Decision relating to granting the accreditation,
- h) The imprint of the seal of the accreditation body authority, and the signature of the person authorized to act on behalf of the accreditation body with the details of the person's name, surname and office held.

(3) The area and scope for which the accreditation has been granted can be included in the Annex to the Decision on Granting the Accreditation; in such a case the Annex shall be considered the integral part of the concluded Decision Granting the Accreditation.

(4) The Certification body is obliged to pass the decision regarding granting accreditation no later than six months after the beginning of the accreditation granting proceeding.

(5) Along with the Decision relating to granting the accreditation, the accreditation body shall simultaneously issue the Certificate of Accreditation that shall include all essentials in accordance with the specifications given by Subparagraph 2, letters (a), (b), (d)-(h), including short description of the area for which the Accreditation has been granted, number of the Accreditation Certificate, and the date of the issuance of the Accreditation Certificate.

(6) The Accreditation Certificate is public record document.

## § 6

### **The Rights and Obligations of an Accredited Body**

(1) The Accredited Body has the right to

- a. Make use of the references to the granted accreditation.
- b. Make use of the accreditation symbol of the Slovak National Accreditation Service; its template of which is found in the Annex,
- c. Obtain an assigned number of a registered member of the Slovak National Accreditation Service,
- d. Express his opinions in relation to the objectiveness and impartiality of the members of the assessment group,
- e. Receive free of charge information on the documents of the Slovak National Accreditation Service and international organizations associating accreditation bodies,
- f. Participate in activities organized by The Slovak National Accreditation Service.

(2) The Accredited Body is obliged to

- a) Comply with the requirements stipulated by this Act, and accreditation requirements in accordance with the Decision on Accreditation Granting,
- b) Provide for co-operation as regards verification of the fulfillment of the requirements set forth by this Act along with other accreditation requirements, in particular as regards rendering all necessary documents, information and explanations,
- c) Allow entry to the premises for persons authorized by the accreditation body, enable for them access to the technical equipment, and allow them to have an insight to the documentation files,
- d) Exercise the rights issuing from the accreditation granted, exclusively within the area and scope for which the accreditation has been granted,
- e) Observe the principles of impartiality, independence, reliability and fairness,
- f) Inform the Accreditation Body about any changes regarding granted accreditation without any delay; in particular those that relate to the following:
  1. The legal form or commercial activity,
  2. The organization, management and expertise of employees,
  3. The basic policy,
  4. The area and scope of accreditation,
  5. Other issues that might have impact on the capability of the Accredited Body to comply with the accreditation requirements.

- g) Allow the Accreditation Body to perform the surveillance,
- h) Fulfill other requirements determined by the Accreditation Body.

## § 7

### **Withdrawing of Accreditation, Suspension of Accreditation, Extension of Accreditation, Restriction of Accreditation, Modification of Accreditation, Reaccreditation and Expiration of Accreditation**

- (1) The Accreditation Body shall make the decision upon a request of the Accredited Body regarding withdrawing of accreditation or suspension of accreditation. The request regarding withdrawing the accreditation, or the request for suspending the accreditation shall include the subject matter of the request and other essentials as stipulated by §3, Subparagraph 2, Letters a) to c).
- (2) The Accreditation Body shall restrict the scope of granted accreditation on a request submitted by the Accredited Body. Request for restriction of the scope of granted accreditation shall include the subject matter of the request and other essentials as stipulated by §3, Subparagraph 2, Letters a) to c), as well as the specifications related to area and extend by which the accreditation is to be restricted. The Accreditation Body shall issue new Decision on Granting the Accreditation which at the same time terminates the original Decision on Granting the Accreditation.
- (3) Based on a request submitted by the Accredited Body, the Accreditation Body shall extend the granted accreditation, in case it ascertains that the Accredited Body person complies both with the necessary requirements defined by this Act, and accreditation requirements. The request for the extension of the accreditation shall include the subject matter of the request along with the essentials stipulated by §3, Subparagraph 2, Letters a) to c), as well as determination of the area and the scope, by which the accreditation is to be extended. The Accreditation Body shall issue new Decision on granting the Accreditation which at the same time terminated the original Decision on Granting the Accreditation.
- (4) Based on a request for reaccreditation submitted by the Accredited Body no later than six months prior to the expiration of the accreditation, the Accreditation Body shall decide about granting the accreditation, provided it is ascertained that the Accredited Body complies with the requirements defined by this Act, and accreditation requirements, and provided there are presumptions for their fulfilment in future term. The request for reaccreditation shall include the subject matter of the request with the essentials stipulated by §3, Subparagraph 2, Letters a) to c). In case that the Accredited Body requests reaccreditation for the scope differing from originally granted accreditation, the request shall also include the specifications related to the area for which the reaccreditation is to be granted. The Accreditation Body shall issue a new Decision on granting the Accreditation which, at the same time terminates the original Decision on Granting the Accreditation. The Accreditation Body shall issue its decision within six months since the beginning of the proceedings regarding the reaccreditation. In case the Accredited Body submits the request for reaccreditation in term shorter than six months towards the date of accreditation expiration, the request will be rejected by Accreditation Body decision.
- (5) In case the Accredited Body notifies changes as stipulated by §6, Subparagraph 2, Letter f) points 1 – 3 and 5, or in case the Certification Body learns about said changes on the basis of its own investigation, it shall issue the Decision on Granting the Accreditation in which such changes shall be taken into account, when being ascertained that the Accredited Body complies with the requirements stipulated by this Act, as well as accreditation requirements.
- (6) The Certification Authority shall suspend the accreditation without a proposal (being submitted), when:
  - a) The Accredited Body within their activities temporarily fails to fulfil the requirements stipulated by this Act or other accreditation requirements,
  - b) The Accredited Body, in spite of written notice, within the period no longer than two months, fails to rectify minor inadequacies related to fulfilment of the accreditation requirements, or the measures taken are insufficient for thorough rectifying of existing inadequacies for fulfilment of accreditation requirements,
  - c) The quality management system of the Accredited Body temporarily fails to secure for the required level of check/control,
  - d) The Accredited Body in consequence of changes stipulated by §6, Subparagraph 2, Letter f), Points 1 – 3 and 5, fails to fulfil duly the accreditation requirements,
  - e) The Accredited Body breaches their duty as stipulated by §6, Subparagraph 2, Letters b) and c).
- (7) The Accreditation Body shall withdraw an accreditation without a proposal (being submitted), when:
  - a) The Accredited Body within their activities fails to fulfil the requirements stipulated by this Act or other accreditation requirements,
  - b) The quality management system of the Accredited Body permanently fails to secure for the required level of check/control,
  - c) The Accredited Body in consequence of changes stipulated by §6, Subparagraph 2, Letter f), Points 1 – 3 and 5, fails to fulfil duly the accreditation requirements,
  - d) The Accredited Body repeatedly breaches their duty as stipulated by §6, Subparagraph 2, Letters b) and c),
  - e) The Accredited person breaches their duty as stipulated by §6, Subparagraph 2, Letter f).
- (8) The Accreditation Body shall restrict previously granted accreditation without a proposal (being submitted) in case when the reasons in Subparagraph 7 concern only specific part of granted accreditation. The Accreditation Body shall issue a new Decision on Granting the Accreditation that at the same time withdraws the original Decision on Granting the Accreditation.
- (9) Accreditation expires when:

- a) The validity period of accreditation expires,
  - b) The activities of the Accredited Body have been suspended for a period of six following calendar months, and the and no valid decision on withdrawing the suspension was issued,
  - c) The Accredited Body is put into liquidation,
  - d) The property of the Accredited Body is subject to bankruptcy,
  - e) The Accredited Body dies, is declared dead, or ceases to exist without specifying a legal successor.
- (10) Accreditation may be suspended for six months at most.
- (11) The Accreditation Body shall issue a decision regarding withdrawing the suspension of accreditation upon request submitted by the Accredited Body in case it is ascertained that the Accredited Body fulfils the requirements stipulated by this Act and the accreditation requirements. The request for withdrawing the suspension of accreditation shall contain the subject matter of the request and the essentials as stipulated by §3, Subparagraph 2, Letters a) to c).
- (12) For the proceedings regarding the withdrawal of accreditation, suspension of accreditation, withdrawal of suspension of an accreditation, modification of accreditation, extension of accreditation, restriction of accreditation, and the reaccreditation proceeding, § 3 to 5 shall apply accordingly.

## § 8

### The Appeal

- (1) The Director shall decide on appeal on the basis of the proposal of the Appeal Committee.
- (2) The members of the Appeal Committee shall be appointed by the Director. The member of the Appeal Committee cannot be a person that was a member of the Assessment Committee for the same issue, or was a member of the Assessment Group, as well as a person that might be deemed dubious in terms of impartiality, with regard to his relation to the subject matter, the participants of the proceedings, or their deputies.

## § 9

### The Status and scope of activities of the Slovak National Accreditation Service

- (1) Slovak National Accreditation Service has been established as a public institution.
- (2) Slovak National Accreditation Service is a legal entity with its residence in Bratislava.
- (3) Slovak National Accreditation Service is an accreditation body pursuant a specific regulation.<sup>4)</sup>
- (4) Slovak National Accreditation Service is entitled to use the abbreviated designation „SNAS“.
- (5) Slovak National Accreditation Service uses a seal when performing its activities; its template is shown in the Annex, and contains:
  - a) The designation „Slovak National Accreditation Service“,
  - b) The abbreviated designation „SNAS“,
  - c) The State Emblem of the Slovak Republic.<sup>5)</sup>
- (6) When performing its activities, the Slovak National Accreditation Service uses a logo; its graphic representation is shown in the Annex.
- (7) Slovak National Accreditation Service
  - a) Provides accreditation services,
  - b) Makes decisions related to granting the accreditation, withdrawal of accreditation, modification of accreditation, suspension of accreditation, withdrawal of suspension of accreditation, extension of accreditation, restriction of accreditation, and on reaccreditation,
  - c) performs surveillance upon fulfilment of the requirements stipulated by this Act, and other accreditation requirements by the Accredited Body,
  - d) Determines the criteria as regards selecting, appointing, training and monitoring of the members of the Assessment Group and of the Assessment Committee, and other experts,
  - e) Determines the amounts of payments as regards provided accreditation services and the calculation methods, and publishes relevant information on its web-site,
  - f) Provides information and expert opinions related to the area of accreditation of the bodies responsible for conformity assessment, when requested,
  - g) Arranges courses, trainings and learning events for the members of the Assessment Group and the Assessment Committee in the area of accreditation of bodies responsible for conformity assessment, as well as inspectors in the area of compliance with the Good Laboratory Practice principles in accordance with specific regulations<sup>6)</sup>
  - h) Provides for the organization of meetings of the Slovak Accreditation Council/Committee,
  - i) Provides for exchange of experience among the Accredited Bodies,
  - j) Performs surveys within the Accredited Bodies related to the activities of the Accreditation Body,
  - k) Performs inspections and verifications of the testing facilities as regards compliance with the Good Laboratory Practice principles in accordance with specific regulations<sup>6)</sup>
  - l) On the website acquaints the public with the templates of requests, and provides information regarding issued decisions on granting accreditation, decisions on suspending accreditation, and decisions on withdrawing accreditation,

- respectively.
- m) Represents the Slovak Republic in international organizations associating accreditation bodies in the area of accreditation of the bodies responsible for conformity assessment,
  - n) Fulfil the requirements as stipulated by specific regulation.<sup>7)</sup>
  - o) Performs the activities as stipulated by specific regulation.<sup>7a)</sup>

## § 10

### **The Authorities of the Slovak National Accreditation Service**

The authorities of the Slovak National Accreditation Service are:

- a) The Director,
- b) The Board of Supervisors

### **The Director**

## § 11

- (1) The Director is a statutory body of the Slovak National Accreditation Service, managing its activities and authorized to act on its behalf.
- (2) The Director
  - a) Is making the budget as regards expenses and earnings of the Slovak National Accreditation Service and submits it to the Board of Supervisors for approval,
  - b) Is responsible for fulfilment of specific tasks of the Slovak National Accreditation Service as set forth by § 9 f and other specific regulations<sup>8)</sup>,
  - c) Is submitting to the Office the plans regarding development of the Slovak National Accreditation Service,
  - d) Following the Board of Supervisors discussion, on a yearly basis and no later than the 30 April he approves the Annual Report on the activities of the Slovak National Accreditation Service and the principles regarding determination of the payments for services provided by the Slovak National Accreditation Service. He is submitting the Annual Report on activities of the Slovak National Accreditation Service related to previous calendar year to the President of the Office for information purposes no later than 30 days following its approval,
  - e) No later than 30 April he submits for approval to the Board of Supervisors the annual statement on economic/financial management. The annual statement on economic management is also submitted to the Office for information purposes on a yearly basis, no later than 30 days following its approval by the Board of Supervisors,
  - f) for approval he submits to the Board of Supervisors the official statement of finances agreed by an auditor, as well as the exceptional statement of finances; the official statement of finances shall be deposited into public section of the registry of statements of finances<sup>8a)</sup> no later than 30 days following its approval by the Board of Supervisors, provided the case that such statement of finances was not already deposited into the registry of statements of finances,
  - g) for approval he submits to the Board of Supervisors proposals related to transfers of property related to real estate, movable estate or other property rights in case that the cost of acquisition of such a property or right is higher than the price stipulated by the means of a specific regulation<sup>9)</sup> as well as drafts concerning leasehold for a period exceeding one year,
  - h) determines the policy and objectives in terms of quality in relation to the activities of the Slovak National Accreditation Service,
  - i) issues the rules of organization, working regulations, methodical directives and other internal regulations of the Slovak National Accreditation Service,
  - j) executes measures imposed by the Board of Supervisors on the basis of control findings,
  - k) for approval he submits to the Board of Supervisors proposal related to economic profit distribution,
  - l) for approval he submits to the Board of Supervisors proposals regarding the usage of the resources in the reserve fund in accordance with §22, Subparagraph 2, or proposals regarding the usage of the investment and development fund in accordance with §23, Subparagraph 2,
  - m) makes decisions regarding other matters provided that these are not entrusted in accordance with §14, Subparagraph 2, to the Board of Supervisors scope of powers.

## § 12

- (1) The Director is appointed by the President of the Slovak Office of Standards, Metrology and Testing (hereinafter "the President of the Office") based on the selection proceedings results, no later than 60 days following the publication.
- (2) In case of absence the Director shall specify in writing a representative from the employees of the Slovak National Accreditation Service. The Director's representative performs the tasks of the Director even in the case of termination of execution of the Director's office, until new Director is appointed.
- (3) The Director's term of office is 5 years; starting on the day of his appointment to office. The same natural person may be appointed a Director only for two consecutive terms of office.
- (4) The citizen of the Slovak republic may be appointed Director provided that he(he/she)

- a) Fulfils the prerequisites related to executing the work in the public interest as stipulated by specific regulation,<sup>10)</sup>
- b) Has completed second degree college education,
- c) Completed at least 5-years of working experience in the area of management and in the area of accreditation of authorities responsible for conformity assessment.

(5)The Director's function shall be incompatible with a function in a different body of public authority, entrepreneurial activities in the sphere of accreditation of authorities responsible for conformity assessment, or membership in any management, controlling or monitoring authority of a legal entity performing entrepreneurial activities in the sphere of accreditation of authorities responsible for conformity assessment or any other economic or earnings activity. The Director's function is also incompatible with the execution of a function of a member of the Board of Supervisors, or activities of other Authority responsible for Conformity Assessment or of Accredited Body, or with membership in any other managing, controlling or monitoring authority, or an Authority responsible for Conformity Assessment or of Accredited Body and with capital participation or voting rights in an Authority responsible for Conformity Assessment or an Accredited Body. This restriction shall also apply to the persons in close relationship to the Director<sup>11)</sup>.

(6)In case the Director at the time of his appointment to this function performs a function or activity which is incompatible with the function of the Director, he shall be obliged to terminate the above mentioned function or activities without unnecessary delay.

(7)Within 30 days following his appointment, the Director shall be obliged to submit a written notice to the President of the Office stating that he fulfils the criteria with regard to the incompatibility to perform his function, as stipulated within the meaning of Subparagraph 5.

(8)The Director's monthly salary is a double sum of the average monthly salary in the national economy of the Slovak Republic as calculated by the Statistic Bureau of the Slovak Republic for the previous calendar year. An adjustment of the Director's salary may be performed once in a year, with the effect from the 1 April of the calendar year. Based on a proposal of Board of Advisors, the President of the Office is entitled to approve an additional reward for the Director – provided that such reward does not exceed a six fold of the salary mentioned in the first sentence. When approving such reward, the fulfilment of the goals of the Slovak National Accreditation Service shall be taken into consideration as well as the financial management of the Slovak National Accreditation Service.

(9) The labour law relations management of the Director shall be subject to a specific regulation<sup>12)</sup> unless otherwise specified by this Act.

(10) The performance of the Director's function is terminated

- a) When the term of office expires in accordance with the Subparagraph 3,
- b) When the calendar month elapses after a written notice regarding the Director's resignation is delivered to the President of the Office provided that such notice does not include a later date of resignation,
- c) On the day of suspension from office issued by the President of the Office,
- d) In case of death of the Director, or when he is declared dead.

(11)The President of the Office shall recall the Director from his office in cases that:

- a) The Director started performing a function or activity incompatible with the function of the Director, or if he fails to fulfill his duties as stipulated by Subparagraphs 6 and 7,
- b) The Director ceased to fulfill his qualification for the execution of his function in accordance with the provisions set forth by Subparagraph 4, Letter a),
- c) The Director does not perform his function for period longer than 6 successive calendar months,
- d) The Director fails to fulfil the obligations stipulated by §11 Subparafraph 2, Leter f) and g),
- e) The Director breaks the obligations stipulated by §17.

## § 13

### **Selection proceeding**

(1)The selection proceeding for the function of the Director shall be announced by the Office in print and on its official website with includine following data:

- a) The designation and residence of the Slovak National Accreditation Service.
- b) Necessary qualifications for the performance of the Director's function,
- c) List of required documents,
- d) The date and place where the request regarding participation in the selection proceedings is submitted.

(2)The Selection proceeding stipulated by Subparagraph 1 is announced by the Office no later than 90 days before the date of Director's term of office expiration. In case the execution of the Director's function is terminated prior to the termination of his office term, the Office shall announce the selection proceeding in accordance with Subparafraph 1 within 30 days from the termination of the Director's terms of office.

(3)The selection proceeding shall be subject to a specific regulation<sup>12)</sup>,unless otherwise specified by this Act.

## The Board of Supervisors

### § 14

- (1) The Board of Supervisors is the supervisory and auditing body of the Slovak National Accreditation Service.
- (2) The Board of Supervisors
  - a) Audits the management of the Slovak National Accreditation Service, disposal of property and use of the financial resources in accordance with this Act,
  - b) Decides upon Director's proposal about economic profit distribution
  - c) Audits the data in the accountancy books and other documentation,
  - d) Approves the expenses and revenues budget of the Slovak National Accreditation Service,
  - e) Approves the regular statement of finances verified by an auditor and the exceptional statement of finances,
  - f) Approves the annual report on management of the Slovak National Accreditation Service,
  - g) Discusses the annual report on management of the Slovak National Accreditation Service and the principles for determining the amounts of payments as regards services the Slovak National Accreditation Service,
  - h) Approves the selection of an auditor responsible for verification of the statement of finances,
  - i) Submits to the Director the proposals for measures imposed on the basis of inspection findings,
  - j) on Director's proposal makes decisions concerning the use of resources of the Investment and Development fund, or the use of financial means from the Reserve Fund,
  - k) Approves the Director's proposals related to transfers of property related to real estate, movable estate or other property rights in cases when the cost of acquisition of such an asset or right is higher than the price determined according a specific regulation<sup>9)</sup>, and also approves proposals regarding leasehold for a period longer than one year,
  - l) Approves the rule of procedure of the Board of Supervisors,
  - m) Elects and suspends the Chairman of the Board of Supervisors, and the Vice-Chairman of the Board of Supervisors from its members.

### § 15

- (1) The Board of Supervisors consists of five members.
- (2) One member of the Board of Supervisors is a representative of the Ministry of the Economy of the Slovak Republic, one member is a representative of the Office, one member is a representative of the Slovak National Accreditation Service and the two members of the Board of Supervisors are representatives of the Slovak Accreditation Council.
- (3) The the President of the Office appoints and suspends the members of the Board of Supervisors based on the recommendation of an Authority that these members represent. The President of the Office informs the Slovak National Accreditation Service about respective appointments and suspensions of the members of the The Board of Supervisor by written notice.
- (4) In case that authority which is entitled to have a representative in the Board of Supervisors does not propose in writing to the President of the Office a suitable candidate to be appointed as a member of the Board of Supervisors who would take the available seat at the board within 30 days following a written notice by the the President of the Office, the President is entitled to appoint these members himself.
- (5) The Term of office of the Board of Supervisors member shall be five years; starting on the day of the appointment to function. The same natural person may be appointed a member of the Advisory Committee for no more than two consecutive terms.
- (6) Any natural person with legal capacity may be appointed a member of the Board of Supervisors provided that the candidate is morally irreproachable and has graduated in university education of second degree. A morally irreproachable individual is a natural person who has not been lawfully sentenced for having committed a intended/willful criminal offence or a negligence criminal offence, and provided that the court has not passed a decision regarding a imprisonment suspension of sentence; such impeccability shall be verified by the means of an extract from the criminal records that may not be older than three months.
- (7) The function of a member Board of Supervisors is incompatible with the function of the Director or the Deputy Director, with the activities of the Body responsible for Conformity Assessment, or of the Accredited Body, with the membership in managment, audit or supervellance office of the body responsible for Conformity Assessment or of Accredited Body, with capital participation or voting rights in the Conformity Assessment



Body, or in an Accredited Body, or with labour relation or similar employment relation to the Body responsible for Conformity Assessment or to an Accredited Body; these restrictions also apply to persons close<sup>11)</sup> to the member of the Board of Supervisors.

- (8) In case that a member of the Board of Supervisors performs a function or activity incompatible with the function of a member of the Board of Supervisors at the time of the appointment to this function, he shall be obliged to terminate such function or activity without any delay.
- (9) Within 30 days following the appointment to the function the member of the Board of Supervisors shall be obliged to provide the President of the Office with a written notice regarding his fulfilment of the conditions of compatibility in accordance with the provisions stipulated by Subparagraph 7.
- (10) The execution of the function of a member of the Board of Supervisors is terminated
  - a) When the term of office terminates in accordance with the provisions set forth by Subparagraph 5,
  - b) On the day of delivery of written notice regarding the member's resignation to President of the Office, provided the notice does not state a later date of resignation,
  - c) On the day of suspension issued by the President of the Office,
  - d) In case of death of the member, or when he is declared dead.
- (11) The member of the Board of Supervisors may be suspended by the President of the Office when
  - a) The member started to perform function or activity incompatible with the function of the member of the Board of Supervisors,
  - b) The member fails to fulfil the requirements for performing the function in accordance with the provisions set by Subparagraph 6,
  - c) The member fails to fulfil obligation set forth by Subparagraph 9,
  - d) Upon proposal of the subject that the member represents,
  - e) The member does not perform his function for more than 6 consecutive calendar months,
  - f) The member has not participated in three successive meetings of the Board of Supervisors, and has not submitted reasonable apology,
  - g) The member breaks obligations stipulated by Paragraph 17.
- (12) Execution of the office of the member of the Board of Supervisors shall be considered another act in general interest. The employer shall release an employee for time necessary along with salary compensation in the amount of the employee's average income.
- (13) In connection with performance of the function the member of the Board of Supervisors is entitled to justifiable traveling costs compensation, as stipulated by specific regulation<sup>13)</sup>.
- (14) When performing the function, the member of the Board of Supervisors shall not be represented by any other person.

## § 16

- (1) When performing their function, the members of the Board of Supervisors are entitled to audit all documents related to economic management of the Slovak National Accreditation Service, related to the management of property of the Slovak National Accreditation Service, utilization of financial means, in accordance with this Act, and enquire on necessary explanations provided by the Director and by the employees of the Slovak National Accreditation Service. Based on a request submitted by the Board of Supervisors, the Director shall elaborate necessary documentation requested by the Board of Supervisors for performance of their activities.
- (2) In case that the Board of Supervisors reasonable and probable cause on breach of any generally binding legal provisions within the activities of the Slovak National Accreditation Service, it shall inform the Director and authorities in accordance with specific regulations<sup>14)</sup>
- (3) The member of the Board of Supervisors shall perform the function with due professional care, impartially (without prejudice) and he shall refrain from proceedings where he might prefer personal interest to public interest.
- (4) In case of necessity, the meetings of the Board of Supervisors shall be summoned and chaired/administered by its Chairman or vice Chairman; these meetings shall be held at least once in a six months period. The Chairman of the Board of Supervisors shall be obliged to summon a meeting of the Board of Supervisors upon written proposal submitted by a member of the Board of Supervisors or by the Director.
- (5) The meetings of the Board of Supervisors shall be held as closed sessions. With the approval of the Board of Supervisors, the Director or other natural persons may participate in the meetings of the Board of Supervisors. If the Board of Supervisors demands so, the Director is obliged to participate in its meetings.

- (6) The Board of Supervisors is considered a quorate meeting provided there is an absolute majority of all its members. A resolution may be adopted in case there has been an approval of the absolute majority of all its members.

## **§ 17**

- (1) The Director or member of the The Board of Supervisors shall not
  - a) Conclude or mediate any business in connection with the activities of the Slovak National Accreditation Service on their own behalf or account.
  - b) Perform a function in a political party or movement, represent such subjects or act in their favour,
  - c) Provide an Accredited Body with any direct or mediated consulting or professional service, or any assistance in return or for a reward od other counter-value.
- (2) The Director or member of the The Board of Supervisors is obliged to observe the confidentiality regarding information and facts that they might learn in course of performing their functions; this shall also apply after the termination of their office terms.

## **§ 18**

### **The Slovak Accreditation Board**

- (1) Slovak Accreditation Board is considered a consultative body of the Director,
- (2) Slovak Accreditation Board is comprised of 21 members who are appointed and dismissed by the President,
- (3) The structure, tasks, organizational provisions and meeting modalities of Slovak Accreditation Board shall be governed by a statute and rule of procedures that shall be issued by the Office,
- (4) Approved by the Director and Vice director of the Office which performs activities as stipulated within the meaning of specific regulation.<sup>15)</sup>
- (5) The function of a member of the Slovak Accreditation Board shall be a honorary position)

## **§ 19**

### **Re-compensation of Accreditation Services**

- (1) Slovak National Accreditation Service performs its activities for recompensation in accordance with a specific regulation.<sup>16)</sup>.
- (2) The amounts of payments for provided accreditation services shall include the costs incurred by the accreditation body in connection with execution of respective accreditation services acts, and is calculated by the publicly accessible method.
- (3) The Applicant or Accredited Body is obliged to settle the payment for provision of accreditation services in due manner and time.
- (4) The payment for provision of accreditation services shall be settled in accordance with the terms defined by the Accreditation Body. In case that Applicant or Accredited Berson fail to settle the payment for provided accreditation services in accordance with provisions stipulated by the Accreditation Body, they shall be obliged to pay due interest on late payment to the Accreditation Body<sup>17)</sup>.

## **§ 20**

### **Financing of the Slovak National Accreditation Service**

- (1) The financial resources of the Slovak National Accreditation Service are held on the accounts of the State Exchequer (Štátna pokladnica).
- (2) The Slovak National Accreditation Service is obliged to use the financial resources in accordance with this Act.
- (3) The incomes of the Slovak National Accreditation Service are, in particular:
  - a) payments for accreditation services provided by the Slovak National Accreditation Service,
  - b) other revenues received in accordance with generally binding public statutes.

- (4) The income of the Slovak National Accreditation Service may also be a subsidy from the national budget for providing accreditation in novel areas or other non-self financing activities as defined by specific regulation.<sup>8)</sup>
- (5) The expenditure of the Slovak National Accreditation Service are, in particular:
  - a) Expenses for wages and extra remunerations of employees of the Slovak National Accreditation Service,
  - b) Expenses for materials, energy and services related to activities of the Slovak National Accreditation Service.
  - c) Travelling expenses of the Board of Supervisors as stipulated by specific regulation,<sup>12)</sup>
  - d) Contributions related to membership in international and regional organizations associating Accreditation Bodies.

## § 21

### **Management of property of the Slovak National Accreditation Service**

- (1) Specific regulation shall apply for the management of the Slovak National Accreditation Service's property.<sup>16)</sup>
- (2) The Slovak National Accreditation Service is obliged to utilize its property for accomplishing the obligations as stipulated by this Act, to maintain the property's proper condition, make use of legal means for its protection, and mind that the property is not damaged, lost or misused.
- (3) The Slovak National Accreditation Service manages its own financial resources in accordance with the budget for costs and revenues within respective calendar year.
- (4) The Slovak National Accreditation Service is not authorized to provide credits or loans, conclude contracts on silent partnership, accept or receive bills of exchange, enter credit, loan or other relationships as a warrantor. Furthermore, it shall not rent immovable property for indefinite period, and guarantee its liabilities by the means of right of lien.
- (5) On its website the Slovak National Accreditation Service shall publish the annual report on its activities approved by the Director after hearing at the Board of Supervisors, and the annual economic report approved by the Board of Supervisors.

## § 22

### **The Reserve Fund**

- (1) The Slovak National Accreditation Service creates/formates its Reserve Fund from the positive balance declared in the official statement of finances approved by the Board of Supervisors and verified by an auditor for the year in which such positive balance is reached in the amount of at least 3 % from such positive balance from operations declared in the official statement of finances up to the amount reaching at least the amount of the average total annual costs for the preceding three years.
- (2) The Reserve fund shall be used for
  - a) Compensation for losses resulting from the activities of Slovak National Accreditation Service,
  - b) Compensation of common needs that are not secured by the budget of Slovak National Accreditation Service including labor costs,
  - c) Compensation of other non-planned costs.

## § 23

### **The Investment and Development Fund**

- (1) The Slovak National Accreditation Service creates/formates the Investment and Development Fund from the positive balance declared in the official statement of finances approved by Board of Supervisors and verified by an auditor lowered by the deposit to the Reserve fund for the year in which such positive balance is reached; Investment and Development Fund shall be established for the first time in the year in which such positive balance is reached.
- (2) The Investment and Development Fund shall be used for
  - a) Procurement of both corporeal and incorporeal property,
  - b) Recruitment and development of human resources,
  - c) Innovation and development of working methods and procedures,
  - d) Other activities focused on investment and development of Slovak National Accreditation Service.

## § 24

### **The Execution of Monitoring**

- (1) The Office performs monitoring regarding compliance with this Act, and monitors on regular basis fulfillment of the obligations of Accreditation Body as stipulated by this Act and other specific regulations<sup>7)</sup>.
- (2) For the purposes of monitoring, the Certification Body is obliged to allow the persons authorized by President of the Office to enter the premises. On demand it shall submit the complete documentation, records, documents in writing and other supporting materials related to its activities, and to grant them access to its information system, and provide information and co-operation within necessary extent.
- (3) The persons authorized by President of the Office for performing the monitoring are entitled to ask the Accreditation Body employees for co-operation and information related to providing accreditation services. The persons authorized by President of the Office for performing the monitoring are obliged to observe confidentiality as regards any facts acquainted during the monitoring. The confidentiality also shall apply after termination of their state employment relationship, labor and employment relationship, or similar relationship with the Office. Confidentiality obligation, implied on the persons authorized by President of the Office for execution of monitoring, does not apply towards the President of the Office.
- (4) During performance of monitoring, the Office shall not interfere with the activities of assessment and decision-making of the accreditation body as regards accreditation of the conformity assessment bodies.

## § 25

### The Infringement

- (1) The infringement action is committed by those who
  - a) Unlawfully represent or act as Accreditation Body or Accredited Body,
  - b) Fail to inform the Accreditation Body about any changes regarding the granted accreditation as stipulated by § 6, Subparagraph 2, Letter f,
  - c) Breach the obligation stipulated as stipulated by §17 or §24, Subparagraph 3,

## § 26

### Other Administrative Offences

- (1) The Office shall impose a fine
  - a) Up to the sum of 100 000 Euro on a legal entity or natural person, entrepreneur who unlawfully acts as Accreditation Body or Accredited Body,
  - b) Up to the sum of 1 000 Euros on a legal entity or natural person, entrepreneur who fails to inform Accreditation Authority about changes regarding granted accreditation as stipulated by §6, Subparagraph 2, Letter f.
- (2) The proceedings regarding imposing of a fine may be commenced within one year from the day when the Office was acknowledged about the breach of duty; no later than within three years from the day such breach was committed.
- (3) When imposing a fine, the Office shall, in particular, take into consideration seriousness, manner, duration and consequences of the unlawful act.
- (4) Office shall impose the fine in the amount which does not exceed the double sum of the upper limit of such fine imposed by the means of a lawful decision in occurrence of repeated breach of duty, as stipulated by Subparagraph 1, within three years from the effective date of the decision regarding imposing the fine.
- (5) The yield of fines shall be considered the income to the State Budget,

## § 27

### The Common Provision

The Proceedings according to this Act shall be subject to general regulation on administrative proceedings<sup>20)</sup> unless otherwise specified by this Act.

## § 28

### The Temporary Provisions

- (1) The property owned by the Slovak Republic that was to 31 December 2009 administered by the Slovak National Accreditation Service, state contributory organization, shall be assigned to the ownership of the Slovak National Accreditation Service, public law institution, by 1 January 2010.

- (2) The Reserve fund of the Slovak National Accreditation Service, state contributory organization, shall be considered the Reserve Fund of the Slovak National Accreditation Service, public law institution, by 1 January 2010,
- (3) With effect from 1 January 2010, the Director of the Slovak National Accreditation Service, state contributory organization appointed before 1 January 2010 shall be considered the Director of the Slovak National Accreditation Service, public law institution. His term of office shall terminate after five years since his appointment to the office. Within 30 days since the effective date of this Act, the Director shall submit the President of the Office documentation regarding fulfillment of the conditions as stipulated by §12, Subparagraphs 5 and 7, respectively. Failure to comply with this obligation shall be considered justifiable reason for suspension as stipulated by §12, Subparagraph 11, Letter a).
- (4) The Ministry of the Economy of the Slovak Republic, the Slovak Accreditation Board and the Slovak National Accreditation Service shall submit the President of the Office a proposal of candidates who are to be appointed the members of Board of Supervisors, no later than 40 days from the effective date of this Act. The President of the Office shall appoint the members of the Board of Supervisors no later than 60 days from the effective date of this Act.
- (5) The Accreditation Certificates issued by the Slovak National Accreditation Service prior to the 1 January 2010 shall remain valid until their validity expires; however, no later till 31 December 2014.
- (6) The Accreditation Proceedings that were commenced but were not legally completed till the 1 January 2010, shall be accomplished in accordance with § 22 - 29 of Act No. 264/1999 Coll. on Technical Requirements for Products and on Conformity Assessment and on Change and Amendment of Some Acts in the wording effective till the 31 December 2009.
- (7) In case that after 1 January 2010 a reason regarding modification of the Accreditation Certificate granted in accordance with the previous provisions <sup>21)</sup> arises, the Slovak National Accreditation Service shall issue a decision regarding granting the accreditation, suspension of accreditation, or withdrawing of accreditation in accordance with provisions of this Act, and, simultaneously, the decision in question cancels the original Accreditation Certificate.
- (8) Rights and duties issuing from labour relations with the employees of the Slovak National Accreditation Service, state contributory organization, shall be assigned to the Slovak National Accreditation Service, public law institution, and this shall commence on the day of its establishment <sup>22)</sup>
- (9) Rights and duties of the Slovak National Accreditation Service, state contributory organization, issuing from its contractual-legal obligations and other legal relations shall be assigned to the Slovak National Accreditation Service, public law institution; and this shall commence on the day of its establishment.

## § 29

### **The Temporary Provisions effective from 1 January 2014**

The proceedings related to granting the accreditation, withdrawing the accreditation, suspension of accreditation, withdrawing suspension of accreditation, modification of accreditation, extension of accreditation, restriction of accreditation, and re-accreditation that are commenced till 31 December will be completed under the current regulations.

## **Article No. II**

The Act No. 264 of 7 September 1999 on Technical Requirements for Products and on Conformity Assessment and on Change and Amendment of some Acts in the Wording of Act No. 436/2001 Coll. and Act No.254/2003 Coll. Is amended as follows:

1. §22 - 29 shall be omitted.
2. In § 32, Subparagraph 3 shall be omitted.

The standing Subparagraphs 4 to 8 shall be designated as Subparagraphs 3 to 7.

3. In §32, Subparagraph 3, the words „1 to 3" shall be modified to „1 to 2".

## **Article No. III**

Act No. 575/2001 Coll. regarding the organization of the government's activities and organization of central state administration in the wording of Act No. 143/2002 Coll., Act No. 411/2002 Coll., Act No. 465/2002 Coll., Act No. 139/2003 Coll., Act No. 453/2003 Coll., Act No. 523/2003 Coll., Act No. 215/2004 Z. z., Act No. 351/2004 Coll., Act No. 405/2004 Coll., Act No. 585/2004 Coll., Act No. 654/2004 Coll., Act No. 78/2005 Coll., Act No. 172/2005 Coll., Act No. 474/2005 Coll., Act No. 231/2006 Coll., Act No. 678/2006 Coll., Act No. 103/2007 Coll., Act No. 218/2007 Coll.; Act No. 456/2007 Coll., Act No. 568/2007 Coll., Act No. 617/2007 Coll., Act No.

165/2008 Coll., Act No. 408/2008 Coll., Act No. 583/2008 Coll., Act No. 408/2008 Coll., Act No. 583/2008 Coll., Act No. 70/2009 Coll., Act No. 165/2009 Coll., Act No. 400/2009 Coll. and Act No. 403/2009 Coll. shall be amended as follows:

- 1) In § 30, Subparagraph 1: the word „and" between the words „quality" and “assessment of conformity” shall be supplemented by a comma, and the following words shall be added in the end „and Accreditation of Bodies for Conformity Assessment“.
- 2) In § 30, Subparagraph 2: the word „and" between the words „quality" and “assessment of conformity” shall be supplemented by a comma, and the following words shall be added in the end: „and Accreditation of Bodies for Conformity Assessment“.

#### **Article No. IV**

This Act shall become effective as of January, 1, 2014

**Ivan Gašparovič, in own hand**

**Pavol Paška, in own hand**

**Róbert Fico, in own hand**

- 1) Article No 2, paragraph 11 of the Directive of the European Parliament and Council (EC) No. 765/2008 of July 9, 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93 (Official journal of the EU L 218, 13. 8. 2008).
- 2) Article No.2, paragraph 10 of the Directive (EC) No. 765/2008.
- 3) Article No.2, paragraph 13 of the Directive (EC) No. 765/2008.
- 4) Article No. 4 of the Directive (EC) No. 765/2008.
- 5) § 3, Subparagraph 1, Letter g) of Act of the National Council of the Slovak Republic Act No. 63/1993 Coll. on state symbols of the Slovak Republic governing their use in the wording of the National Council of the Slovak Republic Act No. 273/1996 Coll.
- 6) Act No. 163/2001 Coll. on chemical substances and chemical preparations in the wording of later regulations, directive of the Slovak Republic Government No. 298/2007 Coll., laying down particulars concerning activity of test facilities, workload of their staff and particulars concerning activities and workload of the inspectors performing inspections and checks regarding conformity with the rules of appropriate laboratory practice.
- 7) Articles No. 3 to 12 of the Directive (EC) No. 765/2008.  
7a) §20 of Act No. 137/2010 Coll. on Air as amended by Act. No 318/2012 Coll., § 3 of the Act. No. 351/2012 Coll. on environmental inspection and registration of organizations within the European Union Scheme for Eco-Management and audit, and on amendments of certain Acts, and § 24 of the Act. No. 414/2012 Coll. on Trading the Emissions Quotas, and on amendments of certain Acts
- 8) E. g.: Directive (EC) No. 765/2008, Directive Of the European Parliament and Commission (EC) No. 764/2008 of July 9, 2008 governing procedures regarding implementation of certain domestic technical standards for products in accordance with legal regulations launched on the markets of a different member state and which supersedes and nullifies Decision No. 3052/95/EC (Official journal of the EU L 218, 13.8. 2008).  
8a) §23 of the Act No. 431/2002 Coll. on Accounting as amended by Act No. 547/2011 Coll.
- 9) §22 of Act No. 595/2003 Coll. on Income Tax in the wording of later regulations.
- 10) §3 of Act No. 552/2003 Coll. on performance of works in the public interest in the wording of later regulations.
- 11) §116 of the Civil Code.
- 12) Act No. 552/2003 Coll. in the wording of later regulations.  
12a) Act No. 176/2004 Coll. on the management of the property of public institutions, and on amending the Act of the National Council of the Slovak Republic No. 259/1993 Coll. On the Slovak Chamber of Forestry as amended by the Act No. 464/2002 Coll. as amended
- 13) Act No. 283/2002 Coll. on travelling expenses in the wording of later regulations.
- 14) For example Code of Criminal Procedure, Act of the National Council of the Slovak Republic No. 39/1993 Coll. on the Supreme Auditing Body of the Slovak republic in the wording of later regulations, Act No. 150/2001 Coll. on Tax Authorities which modifies and amends Act No. 440/2000 Coll. on Administration of Financial Control in the wording of later regulations.
- 15) Article No. 4, Paragraph 11 of the Directive (EC) No. 765/2008.
- 16) Article No. 4, Paragraph 7 of the Directive (EC) No. 765/2008.
- 17) §517, Paragraph 2 of the Civil Code.
- 18) Act No. 176/2004 Coll. on the Management of Property for Statutory undertakers and on Modification of Act of the National Council of the Slovak Republic No. 259/1993 Coll. on Slovak Forestry Chamber in the wording of Act No. 464/2002 Coll. in the wording of Act No. 581/2004 Coll.
- 19) Act of the Slovak National Council No. 372/1990 Coll. on infringement in the wording of later regulations
- 20) Act No. 71/1967 Coll. on Administration Proceedings (Administration regulation) in the wording of later regulations.
- 21) Act No. 264/1999 Coll. No. 264/1999 Coll. on technical requirements for products and Assessment of Conformity and on Modification and Amendment of Certain Acts in the wording of later regulations.
- 22) §28 of the Labour Code.