

# REGULATION

## ON MANNER OF DESIGNATION AND AUTHORIZATION OF CONFORMITY ASSESSMENT BODIES

*(“Official Gazette of RS”, No.98/2009)*

### I INTRODUCTION

#### Article 1

This Regulation sets out the manner of designation and authorization of conformity assessment bodies, determining of fulfilment of prescribed requirements for designation and/or authorization of conformity assessment bodies, notification of conformity assessment bodies, as well as withdrawal of approval for performing conformity assessment.

### II MANNER OF DESIGNATION AND NOTIFICATION OF CONFORMITY ASSESSMENT BODIES, AND WITHDRAWAL OF APPROVAL FOR PERFORMING CONFORMITY ASSESSMENT

#### Article 2

Designation of a conformity assessment body for performing conformity assessment of products with requirements from particular technical regulation shall be performed upon request for designation, which is submitted by the conformity assessment body (hereinafter referred to as: Applicant).

The request referred to in Paragraph 1 of this Article shall be submitted to the Ministry responsible for drafting and adoption of the relevant technical regulation upon which the designation is requested (hereinafter referred to as: competent Ministry).

The Applicant shall bear the costs of the designation procedure including performance-related costs of the Designating Commission (hereinafter referred to as: Commission).

#### Article 3

The Request referred to in Article 2 of this Regulation shall contain:

- 1) Business title, or name and address, legal status, organizational structure and main business activity of the Applicant;
- 2) Title of technical regulation upon which designation is requested and number of Official Gazette of the Republic of Serbia where that technical regulation was published;
- 3) Scope of conformity assessment activities, type, group, or name of product which is the subject of conformity assessment and other information for more accurate identification of product, with reference to corresponding provisions of the technical regulation;
- 4) Information on technical competence of personnel and other persons involved in conformity assessment activities (hereinafter referred to as: personnel);

- 5) Information on technical capacities, including equipment and location where conformity assessment activities will be conducted;
- 6) Information on other activities performed by the Applicant, including the activities which may influence on independency and impartiality of the Applicant, the director or management board and personnel in relation to persons connected with the product which is the subject of conformity assessment;
- 7) Information on the manner the Applicant regulated proceedings and decision making on complaints regarding its performance and decisions referring to conformity assessment activities, and manner of keeping professional secret;
- 8) Title of certificate proving the qualification of the Applicant for conformity assessment (e.g. accreditation certificate);
- 9) Information on concluded agreement on damage liability insurance;
- 10) Other information significant for designation procedure.

The request referred to in Paragraph 1 of this Article shall be enclosed with evidentiary documents confirming references made in the request, as well as the proof of administrative fee paid in accordance with the law.

#### **Article 4**

Fulfilment of the request for designation in accordance with the technical regulation referred to in Article 3 (1), point 2 of this Regulation shall be confirmed by the Commission competent for one or more technical regulations, appointed by the relevant Minister.

The Commission shall comprise of minimum three members: at least one of which shall be a representative of the competent Ministry, a representative of the Accreditation Board of Serbia who has not been involved in the accreditation procedure and a representative of the Institute for Standardization of Serbia.

Members of the Commission referred to in Paragraph 2 of this Article may have deputies.

Where appropriate, other experts, outside the competent Ministry, may take part in the activities of the Commission for the area governed by the corresponding Serbian technical regulation.

A representative of the competent Ministry shall manage the activities of the Commission.

#### **Article 5**

While reviewing the submitted request and enclosed evidentiary documents, the Commission may, with the aim of establishing facts or vital circumstances, conduct checks of fulfilment of requirements set out in the technical regulation.

## **Article 6**

When Applicant proves its competence for performing conformity assessment in regards to particular technical regulation with accreditation certificate, the Commission evaluates the scope of activities for conformity assessment which is subject of the request for designation, in regards to the scope of activities for which the Applicant has already been accredited.

If the scope of activities for conformity assessment, which is the subject of the designation request, is fully covered by the scope of activities contained in accreditation certificate referred to in Paragraph 1 of this Article, it shall be considered that the Applicant has demonstrated fulfilment of designation requirements prescribed in the technical regulation.

If the scope of activities for conformity assessment, which is the subject of the designation request, is not fully covered by the scope of activities contained in the accreditation certificate, the Applicant shall be asked to submit additional documentation proving competence for the scope of activities that is not covered by the accreditation certificate.

If Applicant does not have accreditation certificate to prove its competence for performing conformity assessment, that competence can be proven by some other appropriate documentation.

Documentation referred to in Paragraph 3 and 4 of this Article, which is not connected with accreditation procedure, cannot be older than 6 months as from the day of drawing up or issuing such documentation.

## **Article 7**

The Commission shall, on the basis of the submitted request for designation, enclosed evidentiary documents, and verified facts, establish if the Applicant fulfils the requirements for designation as prescribed in the particular technical regulation, and shall draft a report on that.

If the Commission establishes that the Applicant fulfils the requirements for designation, it shall submit a proposal for designation to the competent Minister, or propose rejection of the submitted request, if it is established that the Applicant does not fulfil requirements for designation.

The proposal referred to in Paragraph 2 of this Article must be properly justified.

On the basis of the proposal referred to in Paragraph 3 of this Article, the competent Minister shall issue a decision on designation or decision on rejection of the request.

## **Article 8**

The Decision on designation referred to in Article 7 of this Regulation shall contain, in particular;

- 1) Business name, or title and address of notified conformity assessment body (hereinafter referred to as: Notified Body)
- 2) Title of technical regulation referring to the issued decision and number of the Official Gazette where that regulation was published;

3) Type, or name of product and other information for the purpose of more accurate identification of product which the Decision refers to;

4) Scope of designation, or detailed description of activities for which competence has been established that the Notified Body is qualified;

5) Identity and name of the person authorized for signing conformity documents.

### **Article 9**

The competent Ministry shall submit the Decision on Designation as referred to in Article 8 of this Regulation to the Ministry responsible for maintaining the Registry of notified, or authorized conformity assessment bodies (hereinafter referred to as: Registry), for entering into the Registry, in accordance with the act governing technical requirements for products and conformity assessment and the regulation adopted on the basis of said act.

The Ministry responsible for maintaining the Registry, on the basis of written proposal of the competent Ministry, shall register the Notified Body to the European Commission, in accordance with ratified international agreements where the Republic of Serbia is one of signatories.

### **Article 10**

The Notified Body is obliged to comply with requirements for notification as set out in the technical regulation regarding its qualification as established by the Ruling on Notification, and to provide, at the request of the competent Ministry, within a deadline which shall not be shorter than three days from receipt of said request, information concerning activities for which it is notified, and in particular, to document all conformity assessment procedures for which it is notified.

Verification of compliance with requirements stipulated in Paragraph 1 of this Article shall be carried out by the competent Ministry, after issuing of the Ruling on Notification.

In cases when the Notified Body its qualification for conducting conformity assessment, established by the Ruling on Notification, is not fully covered by accreditation certificate, verification of compliance with requirements stipulated in Paragraph 1 of this Article shall be carried out by the Accreditation Board of Serbia, in accordance with the act, and inform the competent Ministry about inspection results.

### **Article 11**

If verification of the Notified Body as per Article 10 (3) and (4) of this Regulation establishes any non-compliance of requirements for notification or other failings in the implementation of obligations, the competent Minister shall issue a ruling on withdrawal of notification for conducting conformity assessment.

The Ruling under Paragraph 1 of this Article shall include the order to the Notified Body to, within the period not exceeding three working days from receipt of such Ruling, transfer documents relating to the conformity assessment procedure to other notified body, at the discretion of the manufacturer or his representative or importer (hereinafter referred to as: Party).

The competent Ministry shall submit the ruling on withdrawal of notification for conducting conformity assessment to the Ministry responsible for maintaining the Registry, in order to remove the Notified Body from the Registry, in accordance with particular regulation.

## **Article 12**

When the Notified Body informs the competent Ministry that it is no longer competent to conduct conformity assessment activities as per Ruling on Notification, it shall duly inform the Party at the request of which those activities were being conducted, for collection of conformity assessment documentation, or for transfer of said documentation to another notified body at the discretion of said party.

## **Article 13**

If the collection or transfer of conformity assessment documentation as per Articles 11 and 12 of this Regulation could not have been conducted due to the Party at the request of which conformity assessment was being conducted is no longer present and has been removed from the Economic Operator Registry, the Notified Body to which the Ruling on Notification withdrew the conformity assessment certificate shall transfer said documentation to the competent Ministry.

Documentation under Paragraph 1 of this Article shall be kept in accordance with regulations regulating archive documents, not later than expiry of deadline determined by the said technical regulation.

# **III PROCEDURE FOR AUTHORIZATION OF CONFORMITY ASSESSMENT BODIES FOR CONDUCTING TECHNICAL ASSESSMENTS**

## **Article 14**

Provisions of Articles 4 to 13 of this Regulation shall duly apply to authorization of conformity assessment bodies for conducting technical assessment.

## **Article 15**

Where technical regulation sets out that conformity assessment shall be conducted by a government institution (hereinafter: competent body), and technical assessment on behalf of such body is conducted by an authorized conformity assessment body (hereinafter: authorized body), said body may conduct technical assessment if it complies with requirements stipulated by the technical regulation.

The procedure of authorization of body for conducting technical assessment shall be initiated on the basis of a public invitation for application, announced by the competent Ministry.

The public invitation under Paragraph 2 of this Article shall be published in the Official Gazette of the Republic of Serbia and at least one daily newspapers distributed throughout the territory of the Republic of Serbia.

The public invitation contains in particular information on:

- 1) Title of competent body on behalf of which technical assessment shall be conducted;
- 2) Required number and type of body for technical assessment;

- 3) Title of technical regulation which pertains to the public invitation and number of Official Gazette of the Republic of Serbia where said regulation was published;
- 4) Scope of authorization and type of product for which technical assessment shall be conducted;
- 5) Technical regulation requirements which the technical assessment body shall comply with;
- 6) Application deadline.

Application deadline as per public invitation shall not be less than 15 days following the publication of such public invitation in the Official Gazette of the Republic of Serbia.

### **Article 16**

The public invitation is conducted by the Authorizing Commission which is appointed by the relevant Minister for one or more technical regulations.

The Commission under paragraph 1 of this Article shall verify the compliance of requirements authorisation with the technical regulation referred to in Article 15 (4), Point 3 of this Regulation.

## **IV TRANSITIONAL AND FINAL PROVISIONS**

### **Article 17**

Accredited, or authorized bodies for conformity assessment of product with technical regulation requirements which have been stipulated before this Regulation came into force, shall conduct conformity assessment activities until being notified in accordance with technical regulations which will establish requirements which notified bodies shall comply with.

Conformity assessment bodies as per Paragraph 1 of this Article may, within three months from date of coming into force of technical regulations which establish requirements which notified bodies shall comply with, and not later than three months from commencement of their application, submit to the competent Ministry an application for notification in accordance with this Regulation.

Conformity assessment bodies under Paragraph 1 of this Article, which do not submit application for notification within prescribed period, or conformity assessment bodies for which the competent Ministry, upon submitted application, establishes non-compliance with requirements of technical regulation under Paragraph 2 of this Article, shall not conduct conformity assessment activities as notified bodies in terms of the act governing technical regulations for products and conformity assessment and this Regulation.

### **Article 18**

When this Regulation enters into force, provisions of the Regulation on method of authorization of conformity assessment bodies, registry of notified conformity assessment bodies, records on conformity documents, conformance marks and conformity assessment bodies, and conditions for application of technical regulations of other states shall cease to have effect, in that part which establishes the procedure for notification of conformity assessment bodies and establishing conditions which conformity assessment bodies shall comply with.

## **Article 19**

This Regulation shall enter into force on the eighth day following its publication in the "Official Gazette of the Republic of Serbia", and shall apply as from 1 March 2010 with the exception of provision of Article 9 (2) of this Regulation which shall apply from the date of coming into force of the international Agreement on Conformity Assessment and Acceptance of Industrial Products with the EU, for that part of the product to which this Agreement applies.

The provision of Article 9 (2) of this Regulation, regarding the part of products to which the Agreement referred to in Paragraph 1 of this Article does not apply, shall enter into force as from the day of accession of the Republic of Serbia to the European Union.