



**INSTITUTE OF ACCREDITATION OF
THE REPUBLIC OF MACEDONIA**

Regulation on Accreditation Procedure



Based on the Article 14, paragraph 1, indent 1 of the Statute of the Law on Accreditation (Official Gazette of the Republic of Macedonia” No.120/09 and 53/2011) and Article 13, paragraph 2 of the Statute of the Institute for Accreditation of the Republic of Macedonia, the Council of the Accreditation Institute of the Republic of Macedonia at the meeting held on 29.01.2014 has adopted the following:

REGULATION ON ACREDITATION PROCEDURE

1. General provisions

Article 1

This Rulebook shall regulate the general rules of accreditation procedures of the Accreditation Institute of the Republic of Macedonia (hereinafter: IARM).

Article 2

As regards to Articles 1 and 4 of the Accreditation Law (“Official Gazette of Republic of Macedonia” No. 120/09), IARM shall perform works and tasks in the role of national accreditation body in the Republic of Macedonia.

This Regulation shall regulate the following:

- Activities that precede to the decision for initiating the accreditation procedure;
- Mutual rights and responsibilities between the IARM and conformity assessment bodies, in the process of accreditation procedure implementation;
- The language used in the procedures;
- Activities that precede to the assessment;
- The assessment;
- The accreditation decision;
- Retaining the accreditation
- Suspending and withdrawal of accreditation and
- Expanding the scope of accreditation.

2. Activities that precede the decision for initiating the accreditation procedure, making decisions and contracting

Article 3

Upon client’s request, IARM shall provide general information about accreditation, the criteria and accreditation procedure.

The information of paragraph 1 of this Article can be obtained by telephone, electron mail (e-mail), written request or by personal contact.

Upon client’s request, IARM shall submit informative materials related to accreditation available at the IARM web site: www.iarm.gov.mk

Article 4

IARM and client can meet prior to fulfilling the accreditation application form.

Article 5

The following shall be discussed at the meeting between the IARM and client:

- The client shall describe his/her status and the activities under the scope of required accreditation;
- IARM shall present the adequate standard and accreditation procedure
- IARM shall provide interpretation as to the special accreditation requirements

On the basis of meeting discussions and information received by the beneficiary of service, IARM shall assess if the activities of the client can be subject to accreditation.

Article 6

The client shall submit a signed application form, personally, by mail, by fax or by electronic mail (e-mail). The application form shall be precise and clearly defined.

Article 7

IARM shall examine the client's application form and shall ask for additional information or documentation so as to assess if the system, organization level or technical recourses of the beneficiary of services are sufficient to initiate the accreditation procedure as described below. If the client within 6 months did not provide the requested information and documents application for accreditation is considered to be invalid.

Article 8

The IARM can start the accreditation procedure if the following conditions are fulfilled:
The client shall:

- not compromise the confidentiality, objectivity and impartiality within its activities regarding granted or granting of accreditation;
- Have established and documented system according the appropriate standard;
- Have at least one internal audit and one management review .

The IARM shall:

- Have established accreditation scheme for the appropriate technical field;
- Have secured appropriate assessors for accreditation procedure enforcement.

Article 9

The IARM Director shall decide as to the start/not to start of the accreditation procedure, if met / unmet requirements of Article 8 of this Regulation.

If the decision is a negative one, the IARM shall submit to the client an explanation notice and an invoice of performed services of the IARM in line with R10 Regulation on reimbursement fee for IARM service costs.

Article 10

The client may appeal the adopted decision within 8 days following the receipt of the explanation note.

Article 11

When IARM decides to start the accreditation procedure the contract between IARM and client shall be signed.

The accreditation procedure chart is enclosed in attachment 1 of this Regulation.

3. Mutual rights and responsibilities

Article 12

The contract of Article 11 of this Regulation shall regulate the mutual rights and obligations of the IARM and the client. By signing of the Accreditation Contract, IARM and client shall commit to all provisions thereof.

The client shall fulfill the following requirements:

- Ensure a required level of co-operation with the IARM thus enabling enforcement of the accreditation procedure
- Payment of the accreditation fees in accordance with the Regulation on reimbursement fee for IARM service costs (R10) within designated time line;
- Enable access of IARM to all information, documents and reports needed to assess the fulfillment of the accreditation requirements under the accreditation procedure;
- Secure access of IARM to any information enabling assessment of the level of competence, confidentiality, impartiality and independence of client;
- Upon request by the IARM, to allow IARM supervision visits at any time;
- Adjustment of its operations and establishment of an organizational structure according to the confirmed IARM requirements within designated time line;
- Set limits to rights to accreditation only for the scope for which accreditation has been granted;
- Disable improper reference to accreditation pursuant to Regulation on requirements for reference to accreditation and the use of the accreditation mark (R 05);
- Continuous fulfillment of the accreditation requirements within the scope for which accreditation has been granted; and
- Regular and timely reporting to IARM on all relevant changes related to the legal and economic status, ownership, organizational structure, key management team, working policy, recourses, premises, equipment and all other relevant information influencing accreditation activities.

Article 13

The IARM shall guarantee confidentiality of information obtained by the client.

The IARM shall keep all information of paragraph 1 of this Article confidential regarding the client and well as client's beneficiaries of service, except for the information relating to the accreditation certificate and the scope of granted accreditation.

Article 14

If, in the course of implementation of accreditation procedure or maintaining of accreditation, changes occur in the standards or documents laying down the requirements and procedure for obtaining and maintaining accreditation, IARM shall notify the client of the

changes and how they affect the rights and responsibilities thereof and shall designate an appropriate time line for necessary corrections to be made by the client.

4. **Language used in the Accreditation process**

Article 15

The Macedonian language shall be the official language.

In cases when in the course of the accreditation procedure, IARM engages assessors and experts from abroad the communication shall be performed in the English language. If part of the documentation for the client shall require English language translation for the purposes of assessors and experts present from abroad, the client shall provide the translation of such documents.

IARM shall bear all fees and expenses for translation of its documentation necessary for implementation of the accreditation procedure.

Article 16

5. **Scope of accreditation**

The conformity assessment body submit application for accreditation with a scope for which it consider that is competent. This scope of accreditation is reconciled during the starting faze, preliminary visit and at least determined during the on-site visit on the base of results of assessment.

6. **Activities preceding the assessment (preliminary visit)**

Article 17

Upon the request of the client, IARM shall perform a preliminary visit.

For the purpose of the preliminary visit, IARM shall appoint an assessment team that can comprise of the following: lead assessor and if necessary, assessors and/or experts from the appropriate field.

IARM inform the client about the planned date of a preliminary visit, the composition of the assessment team and the program for the preliminary visit, at least 15 (fifteen) days in advance.

The client can submit written remarks as to the nomination of any of the assessment team members, elaborating the nomination in a written form, within eight days of receipt of the notification.

The Director of the IARM shall decide as regards to remark 4 of this Article.

The decision of the Director shall be final. The preliminary visit shall be carried out within one month of the decision to start the procedure for accreditation by the IARM. In cases of the client not requesting a preliminary visit, the initial assessment shall be performed by the IARM two months of the date when decision to start the procedure for accreditation is made.

Article 18

The client shall receive the report of the preliminary visit containing an opinion about the possibility of prolonging the accreditation procedure.

The report of paragraph 1 of this Article shall list the nonconformities by the conformity assessment body (nonconformities and remarks) that are to be eliminated by the client in a time line no longer than six (6) months.

Upon received evidence about eliminated nonconformities, the IARM shall propose a schedule for initial assessment.

7. Assessment (initial assessment)

Article 19

The IARM shall nominate an assessment team for the enforcement of the assessment that can be composed of the following: lead assessor, assessors and experts from the adequate field.

IARM shall arrange and inform the client of the date of the assessment, the composition of the assessment team and the initial assessment program, at least 15 days in advance.

The client can submit written remarks as to the nomination of any of the assessment team members, elaborating the nomination in a written form, within eight days of receipt of the notification

The Director of the IARM shall decide as regards to the remark 3 of this paragraph.

The Director's decision is final.

Article 20

The IARM can engage external experts and assessors for the purposes of enforcement of the accreditation procedure.

IARM shall guarantee confidentiality, independence, impartiality and professionalism of experts and assessors.

IARM can engage assessors registered by other national accreditation bodies.

Article 21

At the start of preparations for the assessment IARM shall request the client to report potential changes addressing its status or documentation occurred or inserted after the preliminary visit and submitted documentation. If IARM deems necessary, the client shall submit documents and other materials confirming the occurred changes.

Article 22

The assessment team shall conduct the assessment procedure at the client's premises following an agreed assessment program.

The assessors shall record the nonconformities and remarks (deviations from the requirements of accreditation or deviations from other procedures specified by the client) in the course of the assessment.

Article 23

In order to assess client's competency in the field of required accreditation, IARM shall assess the client's head office and premises of conducted conformity assessment procedures, which are the subject of accreditation, in accordance with the required accreditation scope.

The assessment shall include all or key activities by which IARM shall confirm that the client fulfills the accreditation requirements for all areas of accreditation scope for which accreditation has been granted, and in all or key places/premises of implementation of the procedures therein.

Article 24

The assessment team shall present the registered and identified nonconformities and remarks at the closing meeting with client. The lead assessors shall prepare a report.

The representative of the client shall confirm the identified nonconformities by the means of his/her signature and shall propose corrective actions and timeline for enforcement.

Upon implementation of the assessment procedure, the client within 30 days shall receive a report of the conducted assessment with recommendations of further activities.

Within the designated timeline, not longer than 3 months, the client shall submit to the IARM a report of undertaken corrective actions and enclose documentation confirming the aforementioned.

The assessment team shall prepare a report on verification of undertaken corrective actions and if needed shall conduct a follow – up assessment.

If the established nonconformities indicated in the report of paragraph 2 of this article are not eliminated within the time period of no longer than 3 months, the accreditation procedure shall be terminated.

8. Decision on Accreditation

Article 25

On the basis of the assessment report, the recommendations of the assessors and experts of the assessment team and the recommendation of the Accreditation Commission, IARM shall adopt a decision on granting or rejecting accreditation. The scope of accreditation shall be defined in accordance with required scope and the assessment team’s report.

Article 26

The decision of granting an accreditation shall be passed following the confirmation by the documents of the accreditation procedure of the absence of nonconformities or that identified nonconformities have been eliminated in an appropriate mode and designated timeline.

Article 27

When during accreditation procedure all the correction possibilities have been exhausted or upon follow – up assessment nonconformities are still present in the client’s system, or nonconformities have not been eliminated within designated timeline and mode, IARM shall not grant accreditation and the rejection shall be conveyed in a written form to the client.

The client shall have the right to appeal the decision for rejection of accreditation of the IARM within 15 days of the day of receipt of the decision. The appeal shall be reviewed and resolved pursuant to the Regulation on establishment and operation of the Appeals Committee– R 08.

The client have the right to resubmit new application for accreditation within a time period of no less than 6 months from the date of the decision for rejection of accreditation.

Article 28

In instances when the IARM shall decide on granting accreditation, the client shall be issued an accreditation certificate with an annex specifying the scope of accreditation to the client.

The IRM shall enlist the client in the accreditation bodies register.

The day of issuing of the Accreditation Certificate shall be considered as the date of accreditation.

Along the granting of the accreditation certificate the client shall acquire the right to refer to accreditation and use the IARM’s mark together with its registration number.

The service beneficiary (client) shall use the IARM’s mark in accordance with the “Regulation on conditions for reference to accreditation and the use of the accreditation mark” – R 05.

Article 29

The register of accredited bodies is available to the public (at the IARM's web site).

The Register shall include the name and the address of the accredited body, its registration number and brief and detailed description of the scope of accreditation.

Article 30

The granted accreditation certificate has a validity of 4 (four) years. After performing of at least 3 (three) regular surveillance visits, the IARM shall perform a reassessment. Prior to expiry date of the certificate, a reaccreditation, reassessment procedure shall be conducted.

9. Maintenance of Accreditation

Article 31

In order to maintain the granted accreditation, the client shall continuously fulfill the accreditation requirements.

9.1. Surveillance visit

Article 32

Upon granting of accreditation, the IARM shall perform the first regular surveillance visit within 6-12 months. Afterwards, following the one year rule, shall perform regular surveillance visits but in such way that the period between two successive surveillance visits is no longer than 18 months.

During the surveillance visits representative samples of the accredited scope shall be assessed. IARM can perform an extraordinary visit if client's key changes or suspicious information are identified.

The expenses for surveillance shall be specified every year.

Article 33

The surveillance and reassessment should follow the same procedure as in the initial assessment.

9.2. Decision on maintenance of accreditation

Article 34

The IARM shall decide on further maintenance of accreditation following a lack of nonconformities from the surveillance visit.

If there are nonconformities whose influence is not significant so as to question the granted accreditation and when the client commits to elimination of nonconformities identified in the surveillance visit within designated timeline by the IARM no longer than 2 months, the IARM shall decide on continuance of accreditation after their resolving.

10. Suspension and withdrawal of accreditation.

10.1 Suspension of accreditation

Article 35

If the client has not acted as stipulated in paragraph 2 of Article 34, the IARM shall suspend the granted accreditation.

If nonconformities have been identified during the assessments, which significantly influence the results of the accredited activities in a way so as to question the competency of the accredited body to operate under the accredited scope or a part thereof, the IARM can immediately suspend the granted accreditation for a part or full accreditation scope.

The suspension of paragraph 1 of this Article shall mean temporary withdrawal of accreditation for a part or full scope.

Upon elimination of the identified nonconformities, the client shall submit to the IARM evidence for elimination of nonconformities. The suspension shall last until all nonconformities have been eliminated, however not longer than 6 months.

10.2 Withdrawal of accreditation

Article 36

Withdrawal of accreditation shall refer to a procedure of withdrawal of accreditation for a part or full scope of accreditation.

If the client does not eliminate nonconformities within timelines of paragraph 4 of Article 35, the IARM shall adopt a decision for accreditation withdrawal.

If during assessments, nonconformities are identified which significantly influence the results of the accredited activities in a way so as to question the competency of the accredited body to operate under the accredited scope or a part thereof, the IARM can immediately withdraw the granted accreditation for a part or full accreditation scope

Article 37

Upon withdrawal of accreditation, the client can resubmit an application for accreditation within a time period of no less than 6 months from the date of the of the decision for the withdrawal of accreditation.

Article 38

The accreditation can also be completely or partially withdrawn at the client's request.

Article 39

The IARM shall publish the suspended or withdrawn accreditations on its web site.

11. Extending the Scope of Accreditation

Article 40

The client may request an extension of the scope of accreditation at any by submitting an accreditation application.

The assessment of the extension of the accreditation scope shall be performed in the same manner as the initial assessment.

The assessment of the requested extension of the accreditation scope can be performed at the same time as the following supervisory visit.

In cases of adoption of a decision for extension of the accreditation scope, a new annex of the accreditation certificate shall be added.

12. Transitional and Final Provisions



Article 41

With the entry into force of this Regulation, the Accreditation procedure Rulebook adopted on the 10.12.2013 shall cease to apply.

Article 42

This Regulation shall enter into force on the day of its adoption.

Date: 29.01.2014

Chairman of the Council
M-r Borce Razmoski



Attachment 1
Accreditation Procedure chart

| number of the activity | Activities of the SERVICE BENEFICIARY (CLIENT) | Shared activities | Activities of IARM | Stage |
|-------------------------------|---|--|---|---------------------------------|
| 1. | Interest in Accreditation | | | Pre application contacts |
| 2. | | | Information; invitation for meeting | |
| 3. | | Meeting between the IARM and client | | |
| 4. | Application | | | Application |
| 5. | | | Examination of application and submitted documentation | |
| 6. | | | Making decision on initiation or rejection of accreditation procedure | |
| 7. | | | Appointment of coordinator | |
| 8. | | Contract | | |
| 12 | | Preliminary visit on the basis of the request in Application | | |



| | | | | |
|-----|----------------------|------------|---|-------------------|
| 13. | | | Report on preliminary visit | |
| 14. | | | Preparation for assessment | Assessment |
| 15. | | Assessment | | |
| 16. | Report on assessment | | | |
| 17. | | | corrective actions and their verification | |
| 18. | | | Decision on accreditation | Decision |
| 18. | | | Issuance of accreditation certificate or report/notice of rejection/refusal | |