



**INSTITUTE FOR ACCREDITATION OF
THE REPUBLIC OF NORTH MACEDONIA**

Regulation on the Accreditation Procedure



Pursuant to Article 14, Paragraph 1, Indent 1 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 Institute for Accreditation of the Republic of North Macedonia at its meeting held on November 13, 2020, adopted the following:

REGULATION ON THE ACCREDITATION PROCEDURE

1. General provisions

Article 1

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

Article 2

In view of Articles 1 and 4 of the Law on Accreditation (“Official Gazette of the Republic of Macedonia” No. 120/09), IARNM shall perform works and tasks as the national accreditation body in the Republic of North Macedonia.

This Regulation shall regulate the following:

- Activities that precede the decision for initiating the accreditation procedure;
- The mutual rights and obligations between IARNM and the conformity assessment bodies, in the process of implementing the accreditation procedure;
- The language used in the procedure;
- Activities that precede the assessment;
- The assessment;
- The accreditation decision;
- Maintaining the accreditation;
- Suspension and withdrawal of the accreditation; and
- Expanding the scope of accreditation.

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

Article 3

At the request of the Client, IARNM shall provide general information about the accreditation, the criteria and the accreditation procedure.

The information referred to in paragraph 1 of this Article can be obtained by telephone, electronic mail (e-mail), following a written request or via personal contact.

At the request of the Client, IARNM shall submit the informative materials related to the accreditation, which are available at IARNM web site: www.iarm.gov.mk

Article 4

IARNM and the Client can meet prior to filling in the accreditation application form.

Article 5

The following shall be discussed at the meeting between IARNM and the Client:

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

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

Article 6

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

Article 7

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

Article 8

IARNM can start the accreditation procedure if the following conditions are fulfilled:
The Client:

- does not compromise the confidentiality, objectivity and impartiality regarding granted or granting of accreditation with its activities;
- has an established and documented system according to the appropriate standard;
- has carried out at least one internal audit and one management review.

IARNM:

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

Article 9

IARNM Director shall decide as to the start/non-start of the accreditation procedure, if the requirements of Article 8 of this Regulation are fulfilled/ not fulfilled.

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

Article 10

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

Article 11

When IARNM decides to start the accreditation procedure the contract between IARNM and Client shall be signed.

The accreditation procedure chart is enclosed in attachment 1 to 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 IARNM and the Client. By signing of the Accreditation Contract, IARNM and the Client shall be obliged to all provisions thereof.

The Client shall be obliged to fulfill the following requirements:

- Ensure the required level of co-operation with IARNM thus enabling enforcement of the accreditation procedure;
- Payment of the accreditation procedure fees in accordance with the Regulation on reimbursement fee for IARNM service costs (R10) within the designated deadline;
- Enable access of IARNM to all information, documents and reports needed to assess the fulfillment of the accreditation requirements under the accreditation procedure;
- Secure access to IARNM to any information enabling assessment of the level of competence, confidentiality, impartiality and independence of the Client;
- Upon request by IARNM, to allow IARNM supervision visits at any time;
- Adjustment of its operations and establishment of an organizational structure according to the confirmed IARNM requirements within the designated deadline;
- Set limits to the rights to accreditation only for the scope for which the accreditation has been granted;
- Disable improper reference to the accreditation pursuant to the Regulation on requirements for reference to the 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 IARNM 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 that affect the accreditation activities.

Article 13

IARNM shall guarantee confidentiality of information obtained by the Client.

IARNM shall keep all information referred to in paragraph 1 of this Article confidential regarding the Client as well as the 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 the accreditation procedure or maintaining the accreditation, changes occur in the standards or documents laying down the requirements and the procedure for obtaining and maintaining the accreditation, IARNM shall notify the Client of the changes and how they affect the rights and responsibilities thereof and shall designate an appropriate deadline for the 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, IARNM engages assessors and experts from abroad, the communication shall be performed in English.

If part of the documentation for the Client requires English translation for the purposes of assessors and experts from abroad, the Client shall provide the translation of such documents.

IARNM 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 shall submit an application for accreditation with a scope for which it considers itself to be competent. This scope of accreditation shall be aligned during the initial phase, at the preliminary visit and finally determined after the on-site visit on the bases of the results of the assessment.

6. Activities preceding the assessment (preliminary visit)

Article 17

Upon the request of the Client, IARNM shall perform a preliminary visit.

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

IARNM shall inform the Client about the projected date of the 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 receiving the notification.

The Director of IARNM shall decide as regards to the remark referred to in Paragraph 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 IARNM. In cases when the Client does not require a preliminary visit, the initial assessment shall be performed by IARNM two months of the date when a 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 referred to in 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 within a deadline no longer than six (6) months.

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

7. Assessment (initial assessment)

Article 19

IARNM shall nominate an assessment team to carry out the assessment that can be composed of a lead assessor, assessors and experts from the adequate field.

IARNM shall arrange and inform the Client of the assessment date, 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 receiving the notification

The Director of IARNM shall decide as regards to the remark referred to in Paragraph 3 of this Article.

The Director's decision shall be final.

Article 20

IARNM can engage external experts and assessors for the purposes of carrying out the accreditation procedure.

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

IARNM can engage assessors registered by other national accreditation bodies.

Article 21

At the start of preparations for the assessment, IARNM shall request the Client to report potential changes addressing its status or documentation that might have occurred after the preliminary visit and the submitted documentation. If IARNM deems necessary, the Client shall submit documents and other materials confirming that such changes have truly occurred.

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 for accreditation or deviations from other procedures specified by the Client) in the course of the assessment.

Article 23

In order to assess the Client's competency in the field of the required accreditation, IARNM shall assess the Client's head office and premises where the conformity assessment procedures take place, which are the subject to accreditation, in accordance with the required accreditation scope.

The assessment shall include all or key activities by which IARNM shall confirm that the Client fulfills the accreditation requirements for all areas of the 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 the Client. The lead assessor 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 measures and timeline for enforcement.

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

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

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

If the established nonconformities indicated in the report referred to in 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, IARNM shall adopt a decision on granting or rejecting the accreditation. The scope of accreditation shall be defined in accordance with the required scope and the assessment team’s final report.

Article 26

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

Article 27

When during the accreditation procedure all the correction possibilities have been exhausted or following the follow – up assessment nonconformities are still present in the Client’s system, or the nonconformities are not been eliminated within the designated timeline and in a proper manner, IARNM 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 that rejects the accreditation of IARNM within 15 days of the day of receiving 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 shall have the right to resubmit a new application for accreditation within a time period of no less than 6 months from the date of the decision for rejecting the accreditation.

Article 28

In instances when IARNM decides to grant an accreditation, the Client shall be issued an accreditation certificate with an annex specifying the scope of accreditation to the Client.

IARNM 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 with the granting of the Accreditation Certificate the Client shall acquire the right to refer to accreditation and use the IARNM’s mark together with its registration number.

The service beneficiary (Client) shall use the IARNM’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 shall be available to the public (at the IARNM's web site).

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

Article 30

The granted Accreditation Certificate shall be valid for 4 (four) years.

9. Reaccreditation/reassessment

Article 31

After performing at least 3 (three) regular surveillance visits, IARNM shall perform a reassessment. Prior to the expiry date of the Certificate, a reaccreditation, reassessment procedure shall be conducted.

The reaccreditation should be carried out 3 (three) months before the expiry of the Accreditation Certificate, so as not to exceed the deadline for implementation of any corrective measures, identified during the reaccreditation.

In order to carry out the reaccreditation procedure, the conformity assessment body (CAB) shall be obliged to submit an application for accreditation.

The recommended period for submitting an Application for accreditation is 4 (four) months before the expiry date of the Accreditation Certificate from the previous cycle.

IARNM shall nominate an assessment team for the reassessment. The IARNM's policy is that the engagement of one assessor for one body, whenever possible, shall last for one accreditation cycle (starting from the pre-assessment/ assessment until the completion of the third surveillance). The maximum period for which the team member can assess the same body is 2 (two) accreditation cycles.

10. Maintaining the Accreditation

Article 32

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

10.1. Surveillance visit

Article 33

Upon granting of accreditation, IARNM shall perform the first regular surveillance visit within 6-12 months. Afterwards, following the one year rule, it shall perform regular surveillance visits but in such a 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. IARNM can perform an extraordinary visit if there are key changes at the Client's or when suspicious information in relation to the proper performance of certain activities at the Client's have been identified.

The expenses for the surveillance visits shall be specified every year.

Article 34

The surveillance and the reassessment shall follow the same procedure as that of the initial assessment.

10.2. Decision on maintaining the accreditation

Article 35

IARNM shall decide on further maintaining of the 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 undertakes to eliminate the nonconformities identified in the surveillance visit within the designated timeline by IARNM, which cannot be longer than 2 months, IARNM shall decide to continue the accreditation after the elimination of nonconformities.

11. Suspension and withdrawal of accreditation, and expiration of the validity of the Accreditation Certificate

11.1 Suspension of accreditation

Article 36

If the Client has not acted as stipulated in Paragraph 2 of Article 35, IARNM 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 that questions the competency of the accredited body to operate under the accredited scope or a part thereof, IARNM can immediately suspend the granted accreditation for a part of or the full accreditation scope.

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

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

11.2 Withdrawal of accreditation

Article 37

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

If the Client does not eliminate the nonconformities within the deadlines referred to in Paragraph 4 of Article 35, IARNM 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 that questions the competency of the accredited body to operate under the accredited scope or a part thereof, IARNM can immediately withdraw the granted accreditation for a part of or the full accreditation scope



Article 38

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 decision for withdrawing the accreditation.

Article 39

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

11.3 Expiration of the Accreditation Certificate

Article 40

If the CAB does not submit an Application for accreditation before the expiration date of the Accreditation Certificate, or the Application for accreditation is submitted in the period before the Certificate expires, but the time is insufficient for carrying out the reassessment procedure, the CAB shall lose the status of an accredited body.

To restore the status of an accredited body, CAB shall be obliged to submit a new application for accreditation and conduct an initial assessment.

Article 41

IARNM shall publish the suspended, withdrawn and expired accreditations on its web site.

12. Extending the scope of accreditation

Article 42

The Client may request an extension of the scope of accreditation by submitting an accreditation application.

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

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

13. Transitional and final provisions

Article 43

With the entry into force of this Regulation, the Regulation on the Accreditation Procedure adopted on 05.06.2017 shall cease to apply.

Article 44

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

Date: November 13, 2020

Authorized signatory
Vice-President of the Council of IARNM
Tatjana Tasevska m.p.



Attachment 1

Accreditation Procedure chart

number of the activity	Activities of the SERVICE BENEFICIARY (CLIENT)	Shared activities	Activities of IARNM	Stage
1.	Interest in Accreditation			Pre application contacts
2.			Information; invitation for a meeting	
3.		Meeting between IARNM and the Client		
4.	Application			Application
5.			Examination of application and submitted documentation	
6.			Adopting a decision on initiation or rejection of the accreditation procedure	
7.		Contract		
8.		Preliminary visit on the basis of the request in the Application		
9.			Report on the preliminary visit	
10.			Preparation for assessment	Assessment



11.		Assessment		
12.			Report on the assessment	
13.	Corrective measures/Plan and evidence			
14.			Report on verification of the corrective measures	
15.			Decision on accreditation	Decision
16.			Issuance of an Accreditation Certificate or a report on rejection	