INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF NORTH MACEDONIA

Regulation on the Accreditation Procedure

Regulation: R 03

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 the 21st of September 2026, 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 North Macedonia (hereinafter: IARNM).

Article 2

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, withdrawal of the accreditation and expiration of the validity of the Accreditation Certificate;
- Extension or changes to 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 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 evaluate if the activities of the Client can be subject to accreditation.

Article 6

The Client shall submit a signed accreditation application form in person, by mail 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 available 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.

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;
- has competent personnel to make decisions regarding the reported scope of accreditation and regarding the accreditation scheme;
- has no evidence of fraudulent behavior or providing false information by the conformity assessment body

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 against the decision within 8 days following the receipt of the explanation note.

Article 11

For the implementation of the accreditation procedure, IARNM shall nominate an assessment team to carry out the assessment that is composed of a lead assessor, technical assessors and experts from the adequate field.

For the implementation of the accreditation procedure, IARNM can engage external experts and assessors. IARNM can engage assessors registered by other national accreditation bodies, who are selected and included according to the procedure for selection, training and assessment of evaluators PR 03-04.

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

Article 12

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 remark must be submitted in printed or electronic form and supported by an appropriate explanation. The Director of IARNM shall decide as regards the merits of the remark, in consultation with the assessment coordinator and the professional collegium.
The Director's decision shall be final.

Article 13

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 14

The contract of Article 13 of this Regulation shall regulate the mutual rights and obligations of IARNM and the Client. By signing 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 surveillance 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 for referring to accreditation only for the scope for which the accreditation has been granted;
- Disable improper reference to the accreditation pursuant to the Regulation on the use of the logo and the accreditation mark, referencing of accreditation, and referencing of the

status of IARNM as a signatory to the EA MLA, ILAC MRA, and IAF MLA agreements (R 05);

- Continuous fulfillment of the accreditation requirements within the scope for which accreditation has been granted;
- 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, resources, premises, equipment and all other relevant information that affect the accreditation activities;
- Regular visiting of the IARNM website to ensure timely awareness of changes related to IARNM regulations and procedures, as well as other accreditation requirements.

The client has the obligation to follow and fulfill the requirements of the regulations and procedures of IARNM and the legal and by-laws requirements related to the procedure for accreditation or to performing its activity, especially if obtaining the accreditation is a prerequisite for obtaining authorization or approval by other competent authorities.

The client shall not violate the credibility of IARNM with his activities.

Article 15

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 16

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 17

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 or another language agreed upon by IARNM, the assessor/expert and the client.

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.

5. Scope of accreditation

Article18

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 agreed during the initial phase, at the preliminary visit and finally determined after the on-site visit on the basis of the results of the assessment.

6. Activities preceding the assessment (review of documentation and preliminary visit)

Article 19

The client is required to submit documentation. According to Assessment Procedure PR 05-01, the lead assessor and members of the assessment team must confirm that the documentation has been received and reviewed and provides a good basis for starting the accreditation procedure (initial, extension). In cases where the applicant's documentation has significant deviations from the accreditation requirements, the evaluation team submits a Report on the reviewed documentation and the preliminary visit.

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

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 preliminary visit, as a general rule, shall be carried out within one month of the submission of the accreditation documentation by the client, or within a period agreed between the client and IARNM.

Article 20

The Client shall receive information that the documentation provides a good basis for conducting the initial evaluation or the report of review of the documentation and the preliminary visit containing an opinion about the possibility of continuing the accreditation procedure.

The report referred to in Paragraph 1 of this Article shall list the nonconformities by the conformity assessment body (references pointing to nonconformities) that are to be eliminated by the Client within a deadline no longer than six (6) months.

Upon receiving evidence and written notification about eliminated nonconformities, IARNM shall propose a schedule for initial assessment.

IARNM agrees and notifies the client of the date and program for the initial assessment, at least 15 days in advance.

7. Assessment (initial assessment)

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 (deviations from the requirements for accreditation) 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 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 at the closing meeting with the Client. The lead assessor along with the assessors shall prepare assessment team summary report.

The representative of the Client shall confirm the identified nonconformities by the means of his/her signature and according to the evaluation procedure of IARNM PR 05-01 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 if possible.

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

The assessment team shall prepare a report on verification of the undertaken corrective measures which may also include an additional visit to the client, if needed.

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 (or 6 months, if a decision was made to extend the deadline for removing the non-conformity, according to PR 05-06), 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 for the identified nonconformities appropriate corrective actions have been taken and within the designated timeline, in accordance with paragraph 6, Article 24 of this Regulation

Article 27

In case 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 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 6 months from the date of the decision for rejecting the request for accreditation.

Article 28

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

IARNM shall enlist the Client in the accreditation bodies register.

The date 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) is obliged to 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, the accreditation 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 procedure shall be conducted.

The reaccreditation shall be carried out 4 (four) months before the expiry of the Accreditation Certificate, so as not to exceed the deadline for implementation of any corrective measures for the nonconformities, 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, six (6) months before the expiry of the Accreditation Certificate from the previous cycle. In cases when, on the request of the CAB, the reassessment cannot be carried out four months before the expiry of the Accreditation Certificate, the provisions of Article 41, paragraph 3 of this Regulation shall apply.

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 preliminary assessment / assessment until the completion of

the third surveillance). In exceptional cases (as example, limited number of assessors/ experts in given accreditation field, frequent changes in CAB personnel, health issues, pandemic, etc.), the assessors or experts can be included in additional accreditation cycle. In this case, a mandatory risk analysis of its engagement on more than one accreditation cycle is carried out and is subject to mandatory monitoring during the assessment.

10. Maintaining 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 the 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 has been identified.

The expenses for the surveillance visits shall be specified separately for each surveillance assessment.

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 maintaining the accreditation following a lack of nonconformities from the surveillance visit.

If nonconformities are identified, the Client shall take corrective actions to eliminate them within the timeframe specified by IARNM, in accordance with PR 05-06. Following the elimination of the nonconformities within the specified timeframe, IARNM shall decide on maintaining the accreditation.

11. Warnings

Article 36

Regardless of the fulfillment of the requirements for accreditation, in case of violation of other obligations from the contract and Art. 14 of this Rulebook, IARNM can issue a warning, whereby the user is obliged to adjust his work within a certain period.

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

12.1 Suspension of accreditation

Article 37

If the Client has not acted as stipulated in Paragraph 2 of Article 35, IARNM shall suspend the granted accreditation.

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.

12.2 Withdrawal of accreditation

Article 38

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 3 of Article 37, IARNM shall adopt a decision for accreditation withdrawal.

In cases unrelated to assessment activities, where there is evidence that the accredited body does not meet the requirements of the standard and there is a high likelihood that the results and decisions of the accredited body are incorrect, thereby causing IARNM to lose confidence in the accredited body's continued operation, IARNM may immediately withdraw the accreditation, in accordance with the provisions of PR 10-01.

Article 39

Upon withdrawal of accreditation, the Client can resubmit an application for accreditation after the expiration of 6 months from the date of the decision for withdrawing the accreditation.

Article 40

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

12.3 Expiration of the Accreditation Certificate

Article 41

The Accreditation Certificate expires on the date determined as its final validity deadline, upon which the body loses its status as an accredited body and shall no longer be entitled to use the accreditation symbol.

A CAB that has lost its status as an accredited body due to the expiry of its Accreditation Certificate shall have the right to submit a new Application for Accreditation to initiate a new accreditation procedure.

Where a CAB has submitted an Application for Accreditation (re-accreditation), but, at its request, the assessment has been carried out less than four months before the expiry of the Accreditation Certificate, and the timeframe for submitting corrective actions for the identified nonconformities and their verification is shorter than three (3) months, IARNM may decide to

extend the deadline for eliminating the nonconformities for a period not exceeding three (3) months from the date of the re-accreditation assessment. In this case, where the re-accreditation procedure has been initiated, during the period between the expiry date of the Accreditation Certificate and the new date on which the re-accreditation decision is made, the accreditation shall not be valid, the CAB shall not be permitted to use the accreditation symbol, and the accreditation status of the CAB on the IARNM website shall be marked as "temporarily expired".

Article 42

IARNM shall publish the suspended, withdrawn and expired accreditations in the register which is publicly available on its official web site.

13. Extending or changes to the scope of accreditation

Article 43

The Client may request an extension or changes to the scope of accreditation by submitting an accreditation application, according to Procedure in case of changes in accredited bodies, PR 05-05.

The Director of IARNM makes a decision to accept / not accept the requested extension of the scope of accreditation if the CAB fulfilled/ not fulfilled the requirements from Article 8 of this Regulation. The assessment of the requested extension or change of the accreditation scope can be performed at the same time with the following surveillance visit, by conducting a new assessment or by reviewing documentation if the nature of the requested extension or change in scope permits the same.

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

14. Transitional and final provisions

Article 44

With the entry into force of this Regulation, the Regulation on the Accreditation Procedure adopted on 22.09.2025 shall cease to apply.

Article 45

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

Date: September 21, 2026

Authorized signatory
President of the Council of IARNM
Biljana Stoilovska

Annex 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 the available information and documentation	
6.			Adopting a decision on starting/non-starting of the accreditation procedure	
7.		Contract		
8.	Delivery of documentation	Preliminary visit on the basis of the request in the Application	Review of documentation	
9.			Notification of documentation/ Report of review of documentation	

			and 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	