INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF NORTH MACEDONIA

Procedure for extension and reducing the scope of activities of IARNM

PR 04-02

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1. PURPOSE

The purpose of this procedure, issued by the Director of the Institute for Accreditation of the Republic of North Macedonia (hereinafter IARNM) pursuant to Article 23 of the Statute of IARNM, is to describe the activities of IARNM in cases of accreditation development in a new field and in case of shortening the range of activities in a specific field.
NOTE: The term "field" in this procedure shall refer to an accreditation scheme /conformity assessment, area, sector.

2. PROCEDURE FOR EXTENTION OF THE ACTIVITIES OF IARNM

Implementation of new accreditation schemes

At the request of the interested parties and/or state bodies for development of new fields of accreditation, IARNM shall:

1. collect application information for new accreditation fields;
2. make an analysis of the current competence, convenience for extension, resources for the new field;
3. decide on the application of the new accreditation field;
4. plan the activities for application of the new accreditation field;
5. apply the planned activities.

Applications for extension of accreditation in completely new fields and in accordance with the applicable accreditation schemes

When there is an application for extension in completely new fields of accreditation according to the accreditation schemes applied, IARNM shall:

1. review the relevant application and analyze whether the requirements are established;
2. analyze which accreditation standard can be used;
3. analyze whether the accreditation process can be organized in accordance with the requirements of the standard MKC EN ISO IEC 17011;
4. present the results of the analysis of the Expert Collegium;
5. if necessary (e.g. in the case of a new scheme) the results of the analysis shall be presented to the Council;
6. in case of completely new schemes, if the owner of the conformity assessment scheme is a legal entity in RN Macedonia, if it accepts and verifies the scheme, inform EA (according to the requirements in EA - 1/22)
7. if the owner of the conformity assessment scheme is not a legal entity on the territory of RN Macedonia, require information whether it has identified an accreditation body that has already evaluated the conformity assessment scheme accepted by EA;
8. make a plan of activities for implementation;
9. implement the planned activities.

2.1 Information sources for extension of the activities

a) Legislation containing requirements for conformity assessment;
b) Intention expressed by an accredited conformity assessment body to extend its activities;
c) Intention expressed by a non-accredited conformity assessment body seeking accreditation;
d) The results of the analysis of the current ability of IARNM to provide the required accreditation services.

2.2 Analysis of the current resources of IARNM

The process of defining qualifications, experience and training of staff is listed in point 5.1 of PR 03-04 Selection, training and evaluation of assessors.
The Director, in coordination with the Head of Department/Unit shall appoint persons responsible for analysis and collection of information and analysis of the current resources of IARNM, as well as training and recruitment of new assessors for development in new areas of accreditation, in accordance with point 5.1 of PR 03-04.. The appointed persons shall enter this information in the register of activities (Annex 1).

2.3 Decision of IARNM for extension of the activities

a) The results of the analysis of the current resources of IARNM when an accreditation standard is used for a brand new accreditation application shall be discussed at the meetings of the IARNM Collegium. The Director/Council shall decide on the extension of the field;
b) If the new field is not included in Rulebook P04, the Director of IARNM at the meetings of the IARNM Council shall present the analysis for extending the scope of IARNM activities to new fields. The Council shall decide on the extension of the scope. If the decision is positive, the Council shall adopt a new amended Regulation R 04 - Regulation on general competence requirements for conformity assessment bodies.
c) The appointed persons shall use the results of the analysis to make a detailed plan for the extension of the activities.

2.4 Preparation of a detailed plan for extension of the activities

a) The appointed persons shall prepare a detailed plan for extension of the activities of IARNM (Annex 2).
b) The plan shall include the activities for the extension (documents for the clients to be prepared or supplemented, policies, criteria, IARNM procedures and other documents, training of assessors if necessary, establishment of a Technical Committee), responsible persons and time required for implementation.
c) The plan shall be approved by the Director of IARNM.

2.5 Staff training

a) The Director shall appoint a person(s) to implement the plan. The person(s) appointed for implementation can prepare to work in the new field through self-study, various trainings or using experiences from other accreditation bodies with experience in the relevant field.
b) The appointed persons shall determine whether there is a need for technical assessors and if there is, they shall select those from the list of assessors, publish information on the

IARNM website with a request for hiring assessors/experts in the relevant field or request assessors/experts from other accreditation bodies who have experience in the relevant field.
c) The selection of new assessors shall be made by the Personnel Assessment Committee in accordance with the procedure PR 03-04 - Selection, training and evaluation of assessors.
d) Further training of leading and technical assessors shall be performed in accordance with the procedure PR 03-04 - Selection, training and evaluation of assessors.

2.6 Implementation of the activities

The implementation of the activities shall be controlled by the appointed person(s) for implementation of the plan. Records shall be kept of the applied activities (Annex 3).
If the extension of the accreditation activities refers to a conformity assessment scheme established by a legal entity identified as the owner of the conformity assessment scheme and it is contractually used by the CAB, IARNM shall undertakes to fully apply the EA-1/22 A-AB document.
If a certain conformity assessment scheme is verified and recognized by a national accreditation body, a member of EA, IARNM shall not be obliged to perform an assessment in accordance with the given conformity assessment scheme.

3. PROCEDURE FOR REDUCING THE ACTIVITIES OF IARNM

Before abolishing a specific field (accreditation scheme/conformity assessment scheme, area, and sector), in part or in full, the following shall be taken into account:

a) the standpoints of the interested parties;
b) contractual obligations;
c) transitional arrangements;
d) external communication regarding the abolition;
e) the information shall be published on the IARNM website.

The Director, in coordination with the Head of Department/Unit, shall appoint a person responsible to prepare an action plan to reduce the scope of activities of IARNM.
The implementation of the activities shall be controlled by the appointed person(s) for implementation of the plan. Records shall be kept of the applied activities (Annex 3).

4. Normative documents

MKC EN ISO/IEC 17011 - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
EA-1/22 A-AB EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members

5. Other documents

PR 03-04 - Selection, training and evaluation of assessors
PR 11-01 - Regulation on the establishment and operation of Technical Committees
PR 11-02 - Regulation on the establishment and operation of Sectoral Committees

6. Annexes

Annex 1. Register of activities in new fields

No.	New fields of activities envisaged	Indication of a normative document	Name (type) of CAB and subsequent activities	Comments

Annex 2. Detailed plan for extension of the activities

No.	Description of the activity	Responsible personnel	Implementation date
1	Analysis of the requirements of standard XXX, mandatory documents and instructions Discussion with IARNM staff	Person(s) appointed by the Director	
2	Defining competency criteria	Person(s) appointed by the Director/ Working group	
3	Analysis of the current competence of IARNM (internal and external assessors)	Person(s) appointed by the Director in cooperation with the Personnel Assessment Committee	
4	IARNM staff training for leading assessor through: - independent study - IARNM employees - external sources	Person(s) appointed by the Director	
5	Review of existing internal documents and preparation of new system documents such as policies, criteria, procedures and/or amendments to the existing ones	Person appointed by the Director	
6	Presentation of the new documents for the clients on the IARNM website	Head of Department/Unit	
7	Preparation of new forms for assessment records in accordance with the requirements of the XXX standard	Person(s) appointed by the Director in cooperation with the Personnel Assessment Committee	
8	Preparation of materials for training of technical assessors	Person(s) appointed by the Director	
9	Selection of potential candidates for leading/technical assessors in the new field	Person(s) appointed by the Director	
10	Training for leading/technical assessors	IARNM employees	

		External sources	
11	Establishing a new Technical/Sectoral Committee or invite new members to an existing Technical Committee (and/or Sectoral Committee), if necessary	Director	
12	Preparation of materials for the meeting of the technical committee	Head of Unit	
13	Meeting of the technical/sectoral committee	Technical/Sectoral Committee	
14	Preparation of new guidelines or supplementation of existing IARNM clients and assessors on the recommendation of the Technical/ Sectoral Committee, if necessary	Technical/Sectoral Committee	
15	Assessment of CAB in a new field - through a team: - IARNM assessment team - IARNM assessment team with the involvement of experienced assessors from other accreditation bodies, - mutual assessment with a competent accreditation body in the respective field	IARNM Mutual assessment	
16	Information to the IARNM Council on the applied new field	IARNM Director	
17	Other		

Date
Prepared by: Head of Department/Unit
Name and surname
Signature

Date
Approved by: Director
Name and surname
Signature

Annex 3. Register of applied activities

No.	**Description of the activity (identification of a document or record to confirm the implemented activity)**	**Application date**	**Signature of the responsible person**	**Notes**