



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

**Procedure in case of changes
in accredited bodies**

PR 05-05

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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 IARNM Statute, is to describe the activities of IARNM in the case of changes in the work of accredited bodies.

According to the acts of IARNM, the accredited bodies shall be obliged to immediately inform IARNM of all important changes related to their: legal and economic status; ownership or organization; management or key people; the main operating policy, the main resources; the premises; the equipment; the scope of accredited activities or other elements that may affect the fulfillment of accreditation requirements. This procedure sets out the activities to be undertaken by IARNM in such cases and the activities through which IARNM monitors changes in accredited bodies.

2. CHANGES IN THE OPERATIVE STATUS

IARNM shall apply this procedure in cases where accredited bodies have:

- change of the legal and organizational status of the accredited body;
- change in management, i.e. change of persons in the management team;
- change of the location and the premises where the accredited activities are performed;
- change of key technical staff, equipment used, etc.;
- change of the authorized signatories.

If the accredited body or the legal entity to which the accredited body belongs changes the owner, the accreditation can be transferred to the new owner provided that:

- the new owner accepted and confirmed the quality policy;
- the key staff remains the same;
- it has the same procedures;
- it uses the same premises and equipment.

When transferring accreditation, supervision and re-accreditation plans do not change.

3. CHANGES IN THE ACCREDITATION SCOPE

IARNM shall consider the request of the accredited body to change its accreditation scope for any reason (for example, technical, personal), as a special type of change, as follows:

1. Changes in the accreditation scope shall include:
 - changes in certain points of the accredited range such as: replacement of a method in order to ensure better results, change of the method reference (due to a new edition of the standard method, new rulebook, technical specification, etc., new version of the instruments or the working procedure), within the fixed range of laboratories,
 - change in the (national) legislation that does not significantly change the final outcome of the activities taken by CAB,

The change of the scope may or may not change the principle of operation, which depends on the course of preparation and assessment within the accreditation procedure.

2. Extending the accreditation scope means adding additional activity to the accredited scope such as:
- introduction of new areas of calibration, testing, certification, inspection;
 - introduction of new methods for conformity assessment;
 - introduction of additional parameters, products and measuring range for testing (for testing laboratories and medical laboratories);
 - introduction of a new object for calibration, measuring range and CMC (for calibration laboratories);
 - introduction of additional codes, systems and products (for certification bodies);
 - introduction of a new area of inspection for a product, process, installation (for inspection bodies).

Extending the accreditation scope of an accredited body may lead to redefining the composition of the assessment team or the time required to carry out the supervision.

Reducing the accreditation scope means eliminating certain activities from the accreditation scope.

4. CLASSIFICATION OF CHANGES

IARNM classifies the changes as follows:

- planned changes;
- unplanned changes;
- changes for which IARNM has not been notified by the accredited bodies.

5. DEALING WITH CHANGES

According to the accreditation procedure, the accredited body must immediately inform IARNM about any planned and unplanned changes that influence the accredited activities.

5.1 Planned changes

When accredited bodies inform IARNM they are planning to introduce changes related to their employment status, the coordinator shall consult the assessment team and, if necessary, request the necessary data from the accredited body, which will enable making an assessment about whether the changes influence the fulfillment of accreditation requirements.

If changes do not influence the fulfillment of the accreditation requirements, the activities shall continue.

If the changes influence the fulfillment of the accreditation requirements, the assessment team shall require the accredited body to submit an action plan. The action plan must confirm that all necessary conditions for the implementation of the activities within the accredited scope are provided.

Following the received information, when there're grounds for suspicion that the planned changes do not ensure continuous fulfillment of the accreditation requirements, IARNM shall undertake extraordinary supervision in accordance with the accreditation procedure. If

necessary, IARNM may take a suspension measure during the period of adjustment to the changes.

5.2 Changes in the accreditation scope

When the accredited body plans to change the accreditation scope, it shall send a notification (request) to IARNM in view of the planned change accompanied by an Accreditation Application. Prior to the submission of the notification (request), the accredited CAB must perform an internal inspection (as part of the regular internal inspection or extraordinary internal inspection) and a management review of the notified (requested) change (within the regular annual or extraordinary meeting) in order to review the readiness for the notified (requested) change.

In this case, IARNM shall act in accordance with item 5.1 of this Procedure.

5.3 Extending the accreditation scope

When the accredited body plans to extend the accreditation scope, it shall send an application for extension of the scope in the relevant Accreditation Application [OB 05-02 (2018), OB 05-03-1, OB 05-04-1, OB-05-06, OB-05-22-1 (2018), OB-05-22-2-1]. Only the required extension shall be stated in defining the scope in the Accreditation Application, or the required extension (in red) shall be clearly distinguished from the existing range. The same shall apply to the locations, the persons involved in the activities of the requested extension, as well as the equipment, the documents related to the requested extension, etc.

Prior to submitting the Accreditation Application, the accredited CAB must perform an internal review (as part of the regular internal review or extraordinary internal review) and a management review of the requested extension (as part of the regular annual or extraordinary meeting) in order to re-examine the readiness for the requested extension.

According to the provisions of the accreditation procedure, if the application for accreditation extension is in a period longer than three months before the term of supervision, then the procedure for extending the accreditation scope may or may not be performed simultaneously with the supervision visit (simultaneously does not mean always at the same time).

IARNM shall consider the possibility for the assessment of the requested extension of the accreditation scope to be performed during the next supervision visit and in case the application for extension is sent in a period shorter than three months before the deadline set for the supervision visit. In that case, IARNM shall check whether it can select an assessment team that can fully cover the existing and extended accreditation scope, i.e. it shall check whether the selected team can cover the extension of the scope during the supervision visit. If this is not possible, another team shall be proposed and if necessary, it shall perform the assessment in different time.

When considering all these possibilities, IARNM shall strive to meet the needs of the client, but without compromising the rules of accreditation and assessment, the principles of non-discriminatory treatment of clients and the composition of the assessment team.

Changes in the already accredited range shall be reported to IARNM in the same way as during the extension and can be assessed by the assessment team during the supervision visit. IARNM shall have the right to decide whether to treat these changes as an extension of the accreditation

scope. The assessment of small changes in the accreditation scope is usually performed during the supervision visit.

5.4 Reducing the accreditation scope

When the accredited body wants to reduce its accreditation scope, IARNM shall prepare a new annex to the accreditation certificate with a reduced accreditation scope.

5.5 Unplanned changes

When the accredited body notifies IARNM of unplanned changes (for example, breakdown of key equipment, dismissal of key personnel, change of location specified in the Annex to the Accreditation Certificate, etc.), the coordinator, in cooperation with the assessment team, shall ask the accredited body for a plan of activities for adaptation to the new conditions and a deadline within which the accreditation requirements will be fully met again. During that period, the accredited body must suspend the accredited activities directly related to the specified equipment, personnel or location. Pursuant to OB 05-26 Accreditation Agreement, CAB shall be obliged to inform IARNM about such changes. If the implementation of the plan of activities for adaptation to the new conditions is accepted by the coordinator and the assessment team, the verification of its implementation shall be done through a review of documentation or on-site assessment.

5.6 Monitoring changes for which IARNM has no notification from accredited bodies

IARNM can be informed about the changes of the accredited bodies in the following way:

- a) through notification by the clients of the accredited body,
- b) through an assessment visit (supervisory or re-assessment visit),
- c) through complaints regarding the operation of the accredited body (from their clients or the competitors),
- d) through other information obtained about the operation of the accredited body, which is not of an appeal nature (for example, public messages, media).

If the accredited bodies do not inform IARNM about the changes, IARNM may interpret this as a critical non-compliance and may terminate the Accreditation Agreement.

Any changes for which IARNM becomes informed through complaints shall be treated in line with the procedure for resolving complaints, as complaints about the work of accredited bodies.

Any changes not detected by IARNM [see 5.6a), c) and d)] shall be properly checked by IARNM first to verify if those changes affect accredited activities. The IARNM inspection may include an extraordinary supervision visit.

When the accredited body undergoes permanent changes not reported to IARNM, this can be considered as a serious breach of the obligations of the Accreditation Agreement and may lead to withdrawal of accreditation.