



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

Assessment Methodology

PR 05-02



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1. PURPOSE

The purpose of this procedure, adopted by the Director of IARNM, pursuant to Article 23 of the IARNM Statute, is to define the tasks and responsibilities of each member of the assessment team, the assessment scope and techniques for different types of conformity assessment bodies.

2. GENERAL

The purpose of the assessment is to determine whether a conformity assessment body meets all the accreditation requirements.

In order to conduct the assessments, IARNM shall appoint an assessment team consisting of a leading assessor, and when necessary, technical assessors and/or experts from the respective field (definitions for assessors and experts are given in item 3 of the Procedure for selection, training and evaluation of assessors PR 03-04). To perform the assessment competently, the team, as a whole, must possess the necessary technical knowledge to cover the full scope of accreditation, knowledge in the application of accreditation standards, good communication skills and ability to work in a team.

Assessors should be well acquainted with and apply IARNM rules and procedures, as well as the guidelines of European and international accreditation organizations, to interpret the requirements in certain standards (see Rulebook “Competence requirement for accredited bodies” - R 04), or their application for different areas [Documents are available at IARNM website (www.iarm.gov.mk) as well as the websites of EA, ILAC, and IAF (www.european-accreditation.org, www.ilac.org and www.iaf.nu)]

Prior to each assessment visit, the leading assessor and, if necessary, the team members, shall review the documentation for the body under assessment. When planning the assessment visit, the team shall also take into account the critical points identified during documentation review.

The assessment visit program shall be prepared by the leading assessor in cooperation with the other team members.

If any observations during the on-site assessment require a change in the assessment visit program and, if possible, the leading assessor shall immediately offer an option to adjust it. Deviations from the defined assessment visit program is a matter of agreement between the members of the assessment team and the body under assessment.

Each assessor shall document the course and the most important findings from the assessment in accordance with the Assessment Procedure PR 05-01.

3. TASKS AND RESPONSIBILITIES

The leading assessor shall

- be responsible for the assessment as a whole, including planning and reporting;
- assist in selecting team members, if needed;

- conduct an assessment of the appropriate quality system of the conformity assessment body and its functionality;
- develop a risk analysis, for each assessment separately, in cooperation with the members of the assessment team;
- develop a four-year assessment plan, in cooperation with the members of the assessment team (technical assessors and experts);
- develop an assessment program for each assessment, in cooperation with the members of the assessment team (technical assessors and experts), so that the resources are used effectively in the course of the assessment;
- represent the team before the management of CAB;
- lead the introductory meeting, the assessment team meetings and the final meeting;
- lead and coordinate the assessment team;
- solve problems during the assessment, if any;
- lead the team towards drawing conclusions from the assessment;
- make assessment decisions;
- evaluate the overall CAB management system with the help of assessors/experts;
- identify inconsistencies, formulation and gradation of the same;
- prepare a short assessment report, in cooperation with the members of the assessment team (technical assessors and experts);
- approve, verify and evaluate the effectiveness of the proposed corrective measures by CAB, in cooperation with the members of the assessment team (technical assessors and experts);
- prepare a summary/final assessment report, in a way that will enable IARNM and the assessed CAB to make a decision and take appropriate action;
- give a recommendation for decision making.

The technical assessor shall

- conduct assessment of the technical competence in specific areas of testing, calibration, inspection and certification;
- conduct an assessment of part of the body quality system for conformity assessment;
- provide technical expertise;
- actively participate in the assessment;
- identify inconsistencies, formulate and grade the same;
- participate in the preparation of the short assessment report;
- approve and assess the effectiveness of the proposed corrective measures by CAB, in cooperation with the members of the assessment team (leading assessor and experts);
- prepare an assessment report;
- participate in the preparation of the summary/final assessment report;
- give a recommendation for decision making.

The expert shall

- provide technical expertise (give expert opinion on specific areas of testing, calibration, inspection or certification to the leading or technical assessor during the accreditation procedure);
- actively participation in the assessment;
- help identify inconsistencies;
- participate in the preparation of the short assessment report;
- participate in the approval and assessment of the effectiveness of the proposed corrective measures by CAB, in cooperation with the members of the assessment team (leading assessor and technical assessors);
- prepare an assessment report;
- give a recommendation for decision making.

Assessors shall be obliged to make an objective assessment of the fulfillment of the accreditation requirements for the body under assessment. They shall perform their work independently, impartially and professionally, in accordance with the requirements of good professional practice. The members of the assessment team must not give advice, which in any way can have an impact on the body under assessment and may compromise the accreditation procedure.

When assessing in the accreditation procedure, the assessors shall respect the principles of confidentiality, the rules for protection of the intellectual property, both in relation to the body under assessment and its suppliers.

The assessment shall be conducted in accordance with the principles of correctness, tactfulness, and mutual trust between the assessors and the body under assessment.

4. ASSESSMENT TECHNIQUES AND SCOPE

General assessment guidelines:

The assessor shall check the accreditation scope to ensure it is presented clearly and unambiguously and that it corresponds to the competence and activities of the body under assessment.

Assessment techniques:

1. **Document verification:** means verification of system documents, records, organizational chart, plans (reviewed before or during the visit);
2. **Checking files:** such as personal data of employees, ownership data, records, which are normally reviewed during the assessment (not submitted in advance);
3. **Interview:** as a tool for obtaining additional explanations and information; to assess the professional competence of the staff and the knowledge of the quality system in terms of the activities they perform;
4. **Checking resources:** premises, equipment, materials and staff;
5. **Witnessing the activities performed within the accreditation scope:** monitoring the regular activities performed by the body under assessment;

6. **Assesment of results:** assessment of the correctness of the results produced by the body under assesment (for example, the results of participation in PT schemes and interlaboratory comparisons).
7. **Horizontal assessment:** control of a single requirement of the standard in all parts of the organization (detailed examination of individual elements of the standard, to determine whether the management system meets the requirements of the standard).
8. **Vertical assessment:** control of all requirements of the standard in one part of the organization (examining the implementation of the quality management system, assessing several elements of the standard at the same time and assessing the course of the whole system - traceability).
9. **Remote Assessment:** is the assessment of a physical location or a virtual location of the conformity assessment body using electronic means.
Remote assessment shall be applied when the location is virtual, i.e. when the conformity assessment body performs processes online, such as in a cloud environment.
Remote assessment shall also be used for assessing physical locations when on-site assessment is technically impossible, i.e. witnessing the activities performed by the conformity assessment body is technically impossible.

The assessor shall perceive the factual situation for fulfillment (or non-fulfillment) of the requirements, and he/she can seek additional information in order to make a professional assessment.

The assessor's observations shall be clear, unambiguous and concretely worded (especially non-conformities). To cofirm this, the proposed corrective measures by the body under assessment shall match (expected from the assessor) the perceived inconsistencies.

Assessment scope:

During the first and re-assessment (every fourth year) the fulfillment of all accreditation requirements shall be checked.

During the regular supervisory assessments, a representative part of the accreditation requirements shall be assessed. During each regular supervisory assessment, the effectiveness of the applied corrective measures for non-conformities/remarks from previous visits, possible changes in the accredited body, internal audit records, management review, documents and records management, complaints, traceability, PT/MLS results, implementation of recommendations for improvement, use of the accreditation mark, etc. shall be checked. The assessment of other elements of the quality management system shall be planned in a way that allows these to be checked at least once in one accreditation cycle.

Prior to each supervisory assessment, the assesors shall plan their activities according to the records and reports from the previous assessment visits, the assessment plan, the information for change of the management system, the information for change of ownership, organizational structure, key personnel, space, equipment, etc. (Assessment visit planning is described in item 2.2.7 of the Assessment Procedure PR 05-01).