INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF NORTH MACEDONIA

Assessment procedure

PR 05-01

CONTENT

1. PURPOSE

This procedure, issued by the Director of the IARNM (Article 23 of the Statute of the IARNM), aims to describe the assessment process, which includes on-site assessment and the activities that precede and follow the assessment. It is an assessment guideline for the IARNM staff directly involved in the assessment process and for IARNM assessors participating in the assessments.

2. DESCRIPTION OF THE PROCEDURE

2.1 Main stages in the assessment procedure

The assessment is a key step in the accreditation procedure, through which the IARNM assesses the competence of the applicant for accreditation (conformity assessment body) or the accredited body, according to the requirements in the appropriate standard/s and/or other normative documents, to define the scope of the accreditation. Regardless of the type of body being assessed (laboratory, certification body, inspection body), the assessment consists of three basic stages, namely:

1. pre-assessment activities
2. assessment
3. activities that follow the assessment

2.2 Pre-assessment activities

2.2.1 Review of the application

After receiving the application for accreditation, the head of the department/section reviews the application in order to check whether:

1. the application is submitted by an related body;
2. contains all the required information;
3. The IARNM may make appropriate assessments in accordance with its own policy and the resources available to it.

The review of the application is confirmed by the signature and date of the accreditation application itself.

If the head of the department/section assesses that the applicant is an related body, he makes an analysis of the impact of the related body on the possible accreditation procedure on form OB 05-61, and the director of the IARNM approves this analysis.

Note: The Head of Department/Section* reviews the Accreditation Applications, and in case of extension of the scope and re-accreditation of accredited bodies.

*As an exception, and in order for the smooth functioning of the current activities in the IARNM, the Director of the IARNM may appoint another person from the ranks of lead assessors, employed in the IARNM, who is competent in the appropriate accreditation scheme.

2.2.2 Selection of an assessment coordinator

After receiving and reviewing the application, the director appoints an assessment coordinator, who on behalf of the IARNM requests additional information and documents from the applicant for accreditation (conformity assessment body) to assess whether the system, organizational level and technical resources of the applicant are sufficient to start the accreditation procedure.

The coordinator coordinates all activities between the IARNM and the service user from the receipt of the application and documents, making a decision to start the accreditation procedure, receipt and submission of the documents, by organizing the assessment, granting accreditation, as well as further activities that follow after granting the accreditation.

2.2.3 Making a decision for starting/ not starting the accreditation procedure

Based on a conclusion of the review of the application and all available information, the director of the IARNM makes a decision for starting/ not starting the accreditation procedure. Assessment coordinator shall prepare a decision (OB 05-09 or OB 05-09-1), the head of the department/ section* approves it and director signs it.

*As an exception, and in order for the smooth functioning of the current activities in the IARNM, the Director of the IARNM may appoint another person from the ranks of leading assessors, employed in the IARNM, who is competent in the appropriate accreditation scheme.

When the director decides that the accreditation procedure can begin, the coordinator notifies the client of the initiation of the accreditation procedure and submits contract for signing (OB 05-26).

2.2.4 Selection of the assessment team

The Director of the IARNM decides on the composition of the assessment team. The selection of the team members is done from the List of assessors and experts of the IARNM in consultation with the heads of department/sections, the professional collegium and, if necessary with assessors. Care is taken to select the optimal and competent assessment team, which can technically cover all areas in the scope of the required accreditation.

The following aspects are taken into account when selecting a lead assessor:

1. ability to work as a lead assessor in the specific accreditation procedure;
2. to have appropriate education, training, experience and personal skills required for a particular assessment depending on the size of the assessment team and the scope of accreditation.

If possible, a lead assessor with technical competence and experience appropriate to the scope of accreditation will be selected.

The following aspects are taken into account when selecting assessors:

- ability to work as assessors,
- experience and appropriate technical knowledge of the scope of the required accreditation,
- Assessors sall be independent of the conformity assessment bodies being assessed and work in an impartial and non-discriminatory manner.

If none of the assessors from list of assessors of IARNM can cover the scope of the required accreditation, then the IARNM selects an assessor with technical experience close to the scope and additionally selects an expert in the field who gives the assessor an interpretation of the specific technical matters.

Involvement of assessors / experts in the assessment teams is usually one accreditation cycle, or four inclusions. If it is not possible to comply with this rule, the risk is analyzed and recorded in the Minutes of the Professional Collegium and the assessment coordinator enters the data in OB 05-63. The assessor / expert is informed about the performed analysis and he/she is subject to mandatory monitoring during the assessment (according to Annex 1 of the Quality Manual, Risk Analysis).

After the selection is made, the director adopts a Decision for establishing an assessment commission (OB 05-58) which states the names of the members of the assessment team and the working organization where they come from.

The selected assessors should be acceptable to the bodies being assessed.

The IARNM shall notify the body that is being assessed of the names, the role and the legal entity where each of the members of the assessment team is employed (Template OB05-08/ OB05-10), whereby a copy of the Decision shall be attached (OB 05-58). Against the Decision, the body has the right to object to the selection of the assessment team within eight days from the receipt of the letter. The complaint must be submitted in printed or electronic form and supported by an appropriate explanation. The merits of the complaint are decided by the director in consultation with the case coordinator and the expert collegium.

If the IARNM decides that a certain number of observers should be present at the assessment, the letter to the assessed body shall state the names of the observers and their role in the assessment. It also informs the members of the assessment team about that. Observers are involved after obtaining the consent of the assessed body and team members.

For each assessment, each external member of the assessment team signs a contract with the IARNM that regulates the mutual obligations between the IARNM and the assessor (Templates: Contracts with assessors/ experts OB03-02, OB03-03). For the employees in the IARNM, the director makes a Decision for performing an assessment (OB 05-59), and they sign a statement of confidentiality and impartiality (OB03-13). With these documents, the assessors are obliged to respect the rules of the IARNM regarding professionalism, confidentiality and independence.

2.2.5 Review of documentation

The lead assessor and members of the assessment team must confirm that the applicant's accreditation documentation has been received and reviewed and provides a good basis for initiating the accreditation process (initial, extension). In cases when the documentation of the applicant for accreditation has significant deviations from the requirements for accreditation, the assessment team submits to the coordinator a Report on the reviewed documentation and the preliminary visit (OB 05-46-1, OB 05-47-1, OB 05-37-1, OB 05-19-1 (2018) or OB 05-21-1-1), which he/she submits to the applicant for accreditation. In this case, further activities are identical to the procedure when conducting a preliminary visit.

If the initial assessment is prolonged after a decision for starting the procedure is made (change of team, for example, unforeseen reasons) a written explanation is submitted to CAB with explanation of reasons.

2.2.6 Preliminary visit

Prior to the first assessment, a preliminary assessment visit can be made if the client stated in the application that he wants to perform it.

It is usually performed by the lead assessor at a specific location (e.g. at the headquarters of the body being assessed) and usually in one day.

No preliminary visit is made before the surveillance and the re-assessment.

This visit aims to:

1. check that the body being assessed works in accordance with the completed application and the submitted documents;
2. certain points of the documentation are discussed;
3. make a brief review of the quality system in order to assess whether the body being assessed generally meets the accreditation requirements and is ready for assessment;
4. the proposed scope of accreditation is harmonized;
5. gather information and discuss the preparation and organization of the assessment program, in the case of multiple locations, persons, on-site assessments (testimony during sampling, testing, calibration, inspection, certification) at the client premises of the body being assessed, etc.;
6. determine the need to involve other assessors and experts.

The lead assessor, after the preliminary visit, prepares and submits to the coordinator the Report on the reviewed documentation and the preliminary visit (for example, OB05-19-1, OB05-37, OB05-46, OB05-47 ...) in which the deviations of the the system of the body for conformity assessment of the accreditation requirements and other criteria of the IARNM (potential non-conformities).

The coordinator submits the report to the client (conformity assessment body). The conformity assessment body should remove them within a period not longer than 6 (six) months.

After the received evidence and written notification that they have been removed, the lead assessor and if necessary the other members of the assessment team review the received documents.

If it is determined that the deviations have been removed, the procedure continues with the planning of the assessment visit.

2.2.7 Planning an assessment visit

The assessment team plans the assessment body for conformity assessment in relation to the assessment of the elements of the management system, selection of locations, selection of staff and assessment of the scope of accreditation in accordance with the Sampling Procedure PR 05-08 / PR 05-07.

For each assessment (from initial to re-accreditation) the lead assessor in cooperation with the members of the assessment team (technical assessors and experts) prepares a four-year assessment plan that plans the assessment (OB 05 - 62-x) taking into account the risks described in the Procedure. PR 05-08 and their analysis is done in OB 05-63 for each assessment separately by the lead assessor in cooperation with the technical assessors for each CAB. Depending on the changes and findings regarding the previous assessment, the expansion or shortening of the scope for accreditation, etc. The plan and risk analysis may change. When changing the plan, if the risk analysis is changed in the register of the body for conformity assessment, the previously prepared

plan and the previous risk analysis are kept, as well as the amended ones, in which the date of revision is stated.

The day of the assessment visit is the subject of an agreement between the assessment body and the assessment team.

In order to assess the performance of on-site conformity assessment bodies, the assessed body may be required to provide a visit to the premises of its clients, where they perform calibration, testing and sampling, or at the place where their auditors/ inspectors (for certification and inspection bodies) work. The conformity assessment body selects clients who can fully cover the scope of the required accreditation and informs the IARNM about the selected clients. The IARNM verifies that the clients selected by the conformity assessment body are eligible. The assessed body has the obligation to inform the selected clients and to ask their consent for the presence of the assessors in their premises.

The day of the assessment visit should be coordinated with the clients of the body being assessed.

When planning the assessment, the following are taken into account: the size of the conformity assessment body, the number of employees, the locations where the conformity assessment activities are performed, the reported/ accredited scope of accreditation.

If IARNM decides to include observers in the assessment, its obligatory to inform the client and other team members about the names and the roles of the observers. The observers will be included in the team after the receiving permission by the client and assessment team.

2.2.8 Schedule of the assessment visit

After planning the visit in cooperation with the other team members and the applicant for accreditation, the lead assessor prepares an assessment program (OB05-11) which accurately lists the locations, activities and persons to be assessed.

The lead assessor calls a meeting with the entire assessment team, or by e-mail, post or other electronic communication requires approval of the proposed program of assessment activities. In doing so, each of the assessors informs the others about certain aspects that may affect the assessment.

After the harmonization of the program, it is delivered to the client and to the members of the assessment team no later than 15 (fifteen) days before the assessment visit. The program contains the following information:

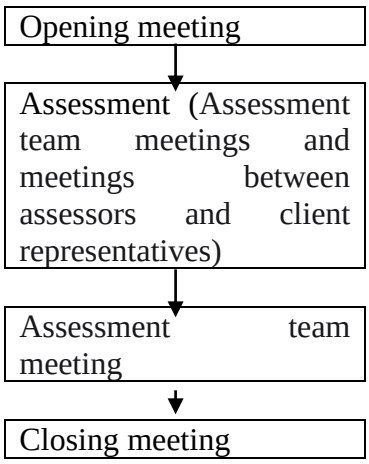
1. Data on the days on which the assessment will be performed;
2. Data on the activities, locations, methods and persons that will be subject to the assessment;
3. Tha activities that are being witnessed;
4. Vertical audit (necessary for surveillance and re-accreditation);
5. Opening and closing meeting time, data for assessment team meetings, for meetings with the management of the body being assessed.

The program should always be coordinated between the assessment team and the assessment body. In that way the evaluation becomes more efficient, good cooperation is achieved, the time of the visit is reduced, interruptions in the regular work of the client are avoided.

Any major deviations from the program (during the assessment visit, locations, scope of accreditation) must be reconciled and agreed upon.

2.3 Assessment visit

The assessment visit is performed in the following steps:



2.3.1 Opening meeting

The assessment team always starts the assessment visit with an opening meeting which confirms the purpose of the visit, the program and the scope of assessment.

The meeting is attended by all members of the assessment team and representatives of the assessed body responsible for the activities to be assessed. The opening meeting is chaired by the lead assessor. At the opening meeting the lead assessor addresses:

a) the representation of the team members and their role in the assessment;
b) the objectives of the assessment, the scope of the assessment and the criteria;
c) matters relating to confidentiality;
d) principles (impartiality, confidentiality, professionalism, neutrality), methods and procedures to be used in conducting the assessment, thereby reminding the representatives of the assessment body that the assessment is based solely on the information available;
e) together with the members of the assessment team and the representatives of the client confirms the assessment program (contract with the representatives of the client, the day and time of the final meeting, breaks, meetings of the assessment team and meetings between the assessment team and the representatives of the client, as well as possible program changes);
f) confirmation that the resources and facilities needed by the assessment team are available to them;

g) manner of reporting and classification of nonconformities;
h) informing about the conditions under which the assessment may be terminated;
i) information related to requested or accredited scope of accreditation.

2.3.2 On-site assessment

Assessment is the main task of the assessment team (see Assessment Methodology - PR 05-02).

The assessment team may also accept an extension of the scope during the on-site assessment if such an extension can be covered by the same assessment team as part of the assessment program. The extension is always subject to agreement with the lead assessor.

During the assessment, each assessor can complete a Checklist, depending on the type of body being assessed (for example, OB05-20, OB05-34, OB05-50, OB05-54, OB05-55, OB05-56...).

The assessment team meets as needed, but at least once during one assessment day. The purpose of these meetings is to coordinate the work of the assessment team, discuss the non-conformities found, agree on possible necessary changes due to unforeseen situations, make a plan for further assessment and prepare for meetings with client representatives.

Meetings between the assessors and the representatives of the assessment body are held at the end of each assessment day. At these meetings, the lead assessor, together with the members of the assessment team, informs the representatives of the assessment body about the progress in the assessment and gives an explanation for the found inconsistencies. If from the available data there are indications that the objectives of the assessment have been missed, the lead assessor talks to the representatives of the assessment body about the reasons why certain activities should be stopped. In that case, a change in the assessment plan, changes in the scope of accreditation or termination of the assessment may be requested.

2.3.3 Assessment team meeting

Prior to the start of the final meeting, the assessment team meets to review the assessors' reports, the on-site assessment, analyze the information and evidence obtained, determine that the conformity assessment body meets the requirements and accreditation criteria, and determine possible nonconformities and to agree on the conclusions of the assessment.

When the assessors cannot make a conclusion after certain findings from the on-site assessment, they will turn to the IARNM for clarification and will inform the representatives of the body being assessed about the decision.

The lead assessor, in cooperation with the assessment team, prepares a Summary report of the assessment team OB 05-14, which lists the identified nonconformities relating to certain points of the standard or other IARNM requirements. If the nonconformity is identified by an expert, the assessor following it shall record the nonconformity, and the assessor and the expert shall sign. Nonconformities are recorded on the spot in the presence of representatives of the body being

assessed. They are required to review the record and the quality manager/ technical manager to confirm nonconformity. The observations can be oraly reported, but shall be written in the assessment reports.

The report contains:

a) clint's name;
b) client's address/ locations;
c) date of the assessment visit;
d) identified nonconformities;
e) team observations or reference to them;
f) possibly a brief report of the results of the assessment with conclusions on the ability of the body being assessed to meet the requirements of the standard.

2.3.4 Final meeting

The final meeting is chaired by the lead assessor in the presence of the assessment team and the representatives of the body being assessed. It reviews the assessment, presents the non-conformities (if the nonconformity is of a technical nature, the technical assessor and/ or the expert may be included in the presentation), observations and conclusions from the assessment and requests the nonconformities to be accepted and confirmed by the client with signing in OB 05-14.

At the final meeting the lead assessor:

a) expresses gratitude for the hospitality and cooperation;
b) summarizes the scope of the assessment and the work done;
c) summarizes the role of each assessor and the assessment methodology used;
d) confirms the scope of accreditation;
e) presents the summary report OB 05-14;
f) requires the client's representatives to confirm the nonconformities and to sign the summary report;
g) gives the opportunity to the representatives of the evaluated body to ask questions to the members of the assessment team, regarding the remarks and non-conformities and their merits.

Based on the nonconformities found, the assessment team assesses whether there will be a need for an additional assessment visit to check the applied corrective measures and to what extent.

At the end of the final meeting the client receives the Summary report of the assessment team and remarks OB 05-14 and a copy is kept by the lead assessor for IARNM.

When there are cases of premature termination of the assessment, nonacceptance of nonconformities by the client, nonacceptance of corrective measures by the assessment team, etc., the information is forwarded to the Accreditation Commission. The Accreditation Commission contacts both the clients and the assessment team and requests additional data and information in order to resolve the case and give a recommendation for further activities to the Director of the IARNM.

2.3.5. *Remote assessment*

The assessment procedure may be performed in part or in full by remote assessment, only in exceptional situations and on the basis of a prior detailed risk analysis.

2.4 Activities that follow the assessment

2.4.1 Corrective measures

After the analysis of the reasons for the nonconformities, the client submits a proposal for corrective measures on his own form (as example, nonconformity form or form for corrective measures), proposing a deadline for their removal (no longer than 3 months), approved by the assessor/ expert who identified them. The client must submit the proposed corrective measures to the IARNM within a period no longer than 14 days from the day of the assessment (final meeting, if possible). Each assessor/ expert should confirm the proposed corrective measure.

2.4.2 Preparation of the assessment report

Lead and technical assessors prepare detailed reports on the outcome of the assessment (for example, OB05-19, OB05-48, OB05-49, OB05-51, OB05-57 ...). Experts also prepare assessment reports (OB 05-14-1).

Assessment reports must contain comments on competence and compliance with the requirements of the standard and must identify nonconformities and observations, if any.

If the report on the outcome of the assessment differs from the outcome achieved at the end of the assessment, i.e. from the report (Summary report of the assessment team OB 05-14), the accreditation body shall give an explanation to the assessed body for conformity assessment, in writing.

The lead assessor, technical assessors and experts submit the Assessment Reports and nonconformities reports to the appropriate coordinator.

The final report of the lead assessor, the technical assessors as well as the reports of the experts, if possible, are distributed to the client within 30 days from the conducted assessment.

2.4.3 Monitoring activities

The client should apply the proposed corrective measures within the agreed period (no longer than 3 months), notify the IARNM and provide evidence for elimination of non-conformities.

The adequacy of the corrective measures taken is verified by the assessment team by examining the submitted evidence or by an assessment visit. If the client's answers are not sufficient, additional information will be requested.

Each assessor approves the application of corrective measures for the nonconformities he has noticed during the assessment visit. If necessary, experts also participate in the approval of corrective measures. Approval is by email. The assessor prepares a Report on verification of the corrective actions (OB 05-16).

If the corrective measures are not applied as agreed or are not fully implemented, the assessment team may propose refusal to grant accreditation, as well as suspension or revocation of accreditation.

If additional assessment is required to approve the corrective action,the lead assessor, if necessary, shall develop a new assessment program that typically involves all or part of the existing team. The IARNM agrees with the client to assess the scope and date of the visit. After additional visit, the technical assessors prepare Report on verification of corrective actions (OB 05-16).

2.4.4 Decision making recommendations

Each member of the assessment team prepares and signs a recommendation (Template OB 05-17) for granting/ rejection/ extension/ maintenance/ suspension/ reduction of the scope of application/ withdrawal/ return to the original position/ continuation of the accreditation surveillance procedure in relation to the area it assesses. The recommendation must clearly refer to a certain part of the scope of accreditation (reference to an appropriate document, for example an application for accreditation, a proposal for a new annex to the accreditation certificate, etc.).

The recommendations are submitted to the appropriate coordinator in the IARNM. The coordinator prepares an accreditation certificate, as well as a proposal of the attachment to the accreditation certificate that he submits to the client for verification and confirmation.

The coordinator collects all the assessment documents such as: assessment reports, all non-conformity reports, reports for verification of corrective measures, recommendations as well as the draft annex to the accreditation certificate and fills in the form Documents from the assessment team OB 05-13.

The coordinator forwards all assessment documents and recommendations from the assessment team to the Accreditation Commission. The Accreditation Commission, based on the received materials, prepares its recommendation which it submits to the director (OB 05-17-1).

The Director, based on the assessment records and the recommendation of the Accreditation Commission, makes a decision on granting, extending, maintaining, suspending, withdrawing or refusing the accreditation (OB 05-13-1).

The coordinator informs the assessed body about the decision by letter and submits the assessment records, reports for verification of corrective measures, attachment to the accreditation certificate (2 copies) and accreditation certificate (1 copy).

The records of the assessments are kept in the register of the assessed body.

2.5 Fraudulent behaviour

If at any stage of the application process or the initial assessment process it is established that:

- there is evidence of fraudulent conduct by the conformity assessment body
- or the body intentionally provides false information

- or conceals information,

the IARNM will reject the application or terminate the assessment process.

2.6 Restrictions

As a rule, corrective measures should be applied for a real period of time, no longer than three months.

The maximum period for elimination of non-conformity can be extended up to 6 months in exceptional cases when there are objective reasons for it, such as when calibration of a measure is required and when objectively it can not be performed within 3 months. The decision to extend the deadline for elimination of non-conformity is made by the director based on the request of the client and the recommendations of the assessment team and the Accreditation Commission. During that period, the conformity assessment body must not endanger the confidence regarding the granted accreditation with its own activities.

Within one assessment there can be a maximum of two assessment visits. If during the additional assessment visit the assessment is negative, the assessment team gives a recommendation for rejection of the application for accreditation or suspension / withdrawal of accreditation.

After granting the accreditation, in accordance with Art.31 of the Rulebook on the accreditation procedure R03, the supervision of the accredited body is planned. The Director of the IARNM includes the accredited body in the term accreditation plan. The implementation of the plan is monitored at the regular meetings of the Professional Collegium and is fully updated once a year.

2.7 Additional criteria for assessment of conformity assessment bodies (CABs) performing internal calibrations

When conformity assessment bodies (CABs) are performing internal calibrations in accordance with the Regulation on ensuring metrological traceability of measurement results (R 11), they shall inform IARNM in advance by filling the field for internal calibrations in corresponding Application for accreditation, with the attention that internal calibrations are not considered as extension of the scope. Also, the internal calibrations shall not be identified as intermediate checks of equipment.

After the application review, the head of department/ section informs the IARNM Director and the accreditation procedure continuous as prescribed in clauses 2.2.1 and 2.2.2.

During the selection of assessment team, for calibration laboratory, IARNM reviews the possibility if already appointed team members have technical competence to cover physical quantity of internal calibration and in the case when internal calibration refers to the physical quantity that is not part of the accreditation scope of calibration laboratory and technical competence of assessment team, then it's obligatory additional technical assessor/ expert for the calibration field to be included in the assessment team. For the other CABs (testing and medical laboratories, inspection bodies), the assessment team shall include technical assessor/ expert for the field/physical quantity of internal calibration.

The planning of assessment is the same as described in clause 2.2.7 and 2.2.8, and assessment of internal calibration is input element of assessment risk analysis (OB 05-63) and the activity is included in the four – year plan for assessment (OB 05-62-x) and assessment programme (OB 05-11).

During the assessment, the technical assessor/expert shall check if the CAB that performs internal calibration has:

1. appropriate procedure/ method for performing calibrations,
2. competent staff to perform the calibrations,
3. traceability of the reference equipment used for calibrations,
4. calculated and expressed measurement uncertainty,
5. participation in appropriate ILCs and use of other internal measures for quality control of the results in accordance with the Regulation on the Requirements for Participation in Proficiency Testing, Interlaboratory Comparisons, and External Quality Assessment Programmes (R 06).

The findings about technical competence for performing internal calibrations of the CAB, shall be included in the assessment report of the assessor/expert.

The activities that follow the assessment and accreditation decision making process are the same as for the other assessment procedures (clause 2.4.1, 2.4.2, 2.4.3, 2.4.4). In the recommendation for accreditation, the technical assessor/ expert appointed for assessing internal calibration shall put the statement about the CAB competence for performing internal calibrations.

For decision making process, the Commission for accreditation shall include lead assessor for calibration in the reviewing of the documentation.