INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF NORTH MACEDONIA

Procedure for risk analysis during assessment planning and sampling during assessment

PR 05-08

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1. PURPOSE

The purpose of this procedure, approved by the Director of IARNM pursuant to Article 23 of the Statute of IARNM, is to define the sampling process in the preparation of the assessment of conformity assessment bodies, taking into account the analysis of defined risks.

2. RISK IDENTIFICATION

Risks related to assessment:

1) Risks in view of the activities related to the accreditation scope:
   - The complexity of the client's activities and their management system such as the maturity of the management system and the effectiveness of the system.
   - The nature of the accreditation scope in various technical areas (e.g. testing techniques and products/calibration matrices, certification schemes and inspection areas). The assessed activities must be representative of the accreditation scope.
   - Technological changes and legislation affecting sampling during assessment.
   - External services (subcontracting) for some activities included in the accreditation scope.
   - Use of flexible scope: Flexible scope management shall be assessed during each assessment.
   - **For testing**: Impact and use of test results, including risks to human health and the environment, sources of measurability, including lack of traceable reference materials/certified reference materials or competency testing schemes.
   - **For certification bodies**: Risks related to impartiality and conflict of interest such as training and consultation provided by the body.
2) Risks related to the locations covered by the accreditation scope such as:
   - The size and number of locations, their geographical location.
   - Activities from the scope for each location such as, different testing area/calibration/ certification/inspection, total number of activities, high volume of activities, low frequency of conformity assessment activities.
   - The number of new locations versus old locations.
   - Cross-border activities.
3) Risks in view of the staff related to the accreditation scope:
   - Experience and knowledge of technical staff,
   - Rotation of technical staff,
   - Sufficient number of employees,
   - Legal requirements regarding staff.
4) Results from previous assessments and the status of effectiveness of corrective measures.
5) Special aspects of sectoral nature. For example for the certification area: specific requirements for schemes such as legal requirements, mandatory documents (guidelines, resolutions, etc.)
6) Other:
   - Complaints submitted for the operation of CAB;
   - Requirements of an appropriate CAB standard, mandatory documents (guidelines, etc.) (such as EA, ILAC, or IAF documents) and resolutions;
   - Is the assessment combined, joint or integrated: for example the opportunity to conduct a combined assessment where several activities are accredited in the same organization (e.g.

testing, calibration, inspection, certification), joint assessment with another organization or competent authority;
- Availability of competent and impartial assessors;
- Results and findings from previous testimonies and vertical assessment.

Prior to each assessment, the leading assessor in collaboration with the members of the assessment team shall analyze the assessment risks. The analysis of the above risks shall be performed in OB 05-63. If during the assessment planning the assessment team identifies an additional risk not listed in the form, it shall be supplemented, analyzed and eliminated/minimized.

3. SAMPLING FOR ASSESSMENT

3.1. TESTING AND CALIBRATION LABORATORIES AND MEDICAL LABORATORIES

Quality Management System Sampling - QMS for Testing and Calibration Laboratories

During the initial assessment and the re-accreditation assessment all elements of the Standard MKC EN ISO/IEC 17025 must be assessed.
During the supervisory assessment of the laboratory, the following elements of the Standard MKC EN ISO/IEC 17025 must be assessed: documentation of the management system, staff, equipment, externally provided products and services, complaints, records (technical records and record control, internal inspections, management review, ensuring the validity of results, metrological traceability, measures related to risk and opportunities. All other elements of the Standard MKC EN ISO/IEC 17025 must be assessed at least once between the first assessment and the re-accreditation assessment. During the supervisory assessment, the assessment team must assess any changes in the laboratory, analyze the effectiveness of corrective action taken due to non-conformities, remarks and comments from the previous assessment and use of the accreditation mark.

Quality management system sampling - QMS for medical laboratories

During the initial assessment and the re-accreditation assessment all elements of the Standard MKC EN ISO15189 must be assessed.
During the supervisory assessment of the laboratory, the following elements of the Standard MKC EN MKC EN ISO15189 must be compulsorily assessed: Quality Management System, Examination in Referral Laboratories (Referral Laboratories), Complaints Resolution, Quality Records and Technical Records, Internal Inspections, Assessment and Inspections, Management Review, Laboratory Equipment, Pre-Analytical Phase, Analytical Test Methods, Quality Assurance of the analytical phase, after the analytical phase, Reporting of results, Issuance of results and Management of laboratory information.
All other elements of the Standard MKS EN ISO15189 must be assessed at least once in the period between the first assessment and the re-accreditation assessment. During the supervisory assessment, the assessment team must assess all changes in the laboratory, analyze the effectiveness of the corrective measures taken due to non-conformities, remarks and comments from the previous assessment and use of the accreditation mark.

Taking samples from the staff

During the initial assessment and re-accreditation assessment, the competence of at least the key staff responsible for the given testing and/or calibration must be assessed.

During the supervisory assessment, authorized staff other than those assessed in the previous assessment must be assessed. Particular attention must be paid to newly recruited staff or staff authorized for the new area. All staff authorized for the accreditation scope must be assessed at least once between the first assessment and the re-accreditation assessment.

Taking samples from locations

When activities are performed at different locations, during the initial assessment and the re-accreditation assessment, the seat/main location shall be assessed and sampling from the other locations where testing and/or calibration of the accreditation scope is performed and their assessment shall be performed on the basis of the performed Risk Analysis (OB 05-63).

Surveillance assessment of individual laboratories, located at multiple locations, shall always be performed at the main site and at least one other site, so that all sites are assessed at least once between the first assessment and the re-accreditation assessment.

Taking samples from the accreditation scope

When taking samples from the accreditation scope, one sample of the accreditation scope shall be assessed at least every two years. Sampling from the accreditation scope shall be performed using the following tools:

- Testimonies,
- Interviews,
- Assessment of results from participation in aptitude tests and in interlaboratory comparisons,
- Vertical inspection,
- Testing and/or calibration of an item with known characteristics.

These tools shall be used according to the table below.

	Initial assessment	Supervisory assessment	Re-accreditation
Testimonies	A representative number of methods must get testimonied in each test area and each unit of physical size in the calibration A representative number of methods can be: – 100% when the accreditation scope is small and when it is	All test methods and/or calibrations shall get testimonied at least once between the initial assessment and the re-accreditation assessment and it shall be noted that during	The principle is identical to the initial assessment, but when choosing the methods, the experiences from the previous cycle shall be taken into account.

	appropriate, – One method from a group of methods, – One method from a type of methods, – One method for each unit of physical size (in calibration)	each supervisory assessment a different type of method and product/material must get testimonied than the one testimonied in the previous assessment.	
Interviews	When: - Testimonies are not possible, - The duration of testing and/or calibration, etc.	When: - Testimonies are not possible, - The duration of testing and/or calibration, etc.	When: - Testimonies are not possible, - The duration of testing and/or calibration, etc.
Results from participation in aptitude tests and interlaboratory comparisons	The competence of the laboratory to perform appropriate tests and/or calibrations can be confirmed without testimonies in the event that the laboratory has participated in aptitude tests or interlaboratory comparisons and obtained positive results.	The competence of the laboratory to perform appropriate tests and/or calibrations can be confirmed without testimonies in the event that the laboratory has participated in aptitude tests or interlaboratory comparisons and obtained positive results.	The competence of the laboratory to perform appropriate tests and/or calibrations can be confirmed without testimonies in the event that the laboratory has participated in aptitude tests or interlaboratory comparisons and obtained positive results.
Vertical inspection	At least one	At least one	At least one
Testing and/or calibration of an item with known characteristics, etc.	If possible	If possible	If possible

3.2 CERTIFICATION BODIES

CERTIFICATION BODIES FOR PRODUCTS AND MANAGEMENT SYSTEMS

Quality management system sampling – QMS. During the initial assessment and the re-accreditation assessment, all elements of the standard MKC EN ISO/IEC 17065, i.e. MKC EN ISO/IEC 17021-1 must be assessed.

During the supervisory visit of the **certification body**, the following elements must be assessed: Management system, Sub-negotiation, Complaints and Objections, Records, Internal checks, Management reviews, staff competence and efficiency of the assessment process. The other elements of the standard must be assessed at least once in the period between the initial assessment and the re-

accreditation assessment. During the supervisory assessment, the assessment team must assess all changes in the certification body, analyze the effectiveness of the corrective measures taken due to non-conformities, remarks and observations from the previous assessment and use of the certification body logo and accreditation mark.

Taking samples from locations

When the **certification body** operates at different locations, during the initial assessment and the re-accreditation assessment, the seat/main location of the body shall be assessed and sampling from the other locations where testing and/or calibration of the accreditation scope is performed and their assessment shall be performed on the basis of the performed Risk Analysis (OB 05-63).

Surveillance assessment of the certification body, located at multiple locations, shall always be performed at the main site and at least one other site, so that all sites are assessed at least once between the first assessment and the re-accreditation assessment.

In the case of **certification bodies for management systems**, key locations are those where the following key activities are performed:

- policy making;
- process and/or procedure development;
- initial approval of auditors, or control of their training;
- ongoing supervision of the work of the auditors;
- review of applications;
- designation of audit teams;
- control of supervisory or certification audits;
- final review of reports or decisions on certification or approval.

In **certification bodies for products**, key locations are those where the following key activities are performed:

- establishing and approving the policy,
- development and approval of a process and/or procedure,
- initial competency assessment, and approval of technical staff and subcontractors,
- control of the process of monitoring the competence of the staff and subcontractors and the results of that process,
- review of contracts, including review of applications and establishment of technical requirements for certification activities in new technical areas or areas with limited, sporadic activities.

Taking samples from the staff

During the initial assessment and re-accreditation assessment, the competence of the authorized personnel to perform the key activities shall be assessed.
The supervisory assessment must assess different authorized personnel from the one assessed in the previous assessment, if possible. Special attention shall be paid to newly hired staff or staff

authorized in the new area. It is recommended to witness an audit/assessment conducted by an audit team/assessment team that has not previously been assessed for a particular area of competence.
All staff authorized for the accreditation scope must be assessed at least once between the first assessment and the re-accreditation assessment.

Taking samples from the accreditation scope

When taking samples from the accreditation scope, one sample of the accreditation scope shall be assessed at least every two years.

The following tools must be used for taking samples from the accreditation scope:

- ***Testimonies,***
- ***Interviews,***
- ***Vertical inspection.***

Testimony of certification bodies

When planning the testimonies, certification and issuance of certificates abroad shall be taken into account, as well as certification of organizations with multiple locations.

The following types of testimonies can be used for **certification body for products**:

- Testimony of factory production control assessment;
- Testimony of sampling of substances, materials or products;
- Testimony of testing substances, materials or products;
- Testimony of process/service assessment (in whole or in part).

The type of testimony shall depend on the certification scheme.
Testimonials must be planned on the basis of the certification body's action plan.

If possible, specific product types shall be grouped together.
The minimal number of certified evaluations/assessments for a product certification body shall be determined as follows:

Number of products or type of products	Minimal number of testimonies
1 to 2	1
3 to 5	2
6 to 9	3
10 to 19	4
20 to 39	5
≥ 40	8

For each group of products, services and process in the accreditation scope, at least one testimony must be given during each accreditation cycle.

Vertical inspection

During the initial assessment and the re-accreditation assessment of the **certification body**, a representative number of certification procedures must be assessed through the vertical inspection, if possible at least 2 certification procedures for each certification scheme. When the assessment team selects certification procedures for vertical inspection, certification and issuance of certificates abroad, certification of multi-location organizations, as well as initial and supervisory checks shall be taken into account. During a regular surveillance visit, at least one vertical inspection must be performed for each certification scheme, taking into account the fact that the entire accreditation scope must be assessed in one accreditation cycle.

Planning and assessment of the **certification body for management systems** shall be realized in accordance with the Procedure for assessment in the office and testimony of certification bodies for management systems PR 05-07.

3.3 INSPECTION BODIES

Quality management system sampling – QMS

During the initial assessment and the re-accreditation assessment, all elements of the MKC EN ISO/IEC 17020 Standard must be assessed.

During the supervisory assessment of the inspection body, the following elements of the Standard MKC EN ISO/IEC 17020 must be assessed:

Standard item	Standard requirements
6.1.9; 6.1.10	Efficient supervision by competent persons (monitoring)
8.1.1	Efficient quality system
8.3	Quality system maintenance
8.6	Internal checks
8.7	Feedback, corrective measures
8.8	Preventive measures
8.5	Review by management
7.1.1	Following the methods prescribed in the conformity assessment requirements
7.1.8	Proper checking of calculations and data transfer
7.3	Inspection records
7.4	Inspection reports/certificates (the entire point)
7.6	Complaints and appeals process

All other elements of the Standard must be assessed at least once in the period from the first assessment and the re-accreditation assessment.

In the case of inspection bodies operating in a regulated area, the requirements of the regulation (administrative requirements, staff, and equipment) must be assessed during each supervision.

If there are changes in terms of staff, documentation, legislation, etc., or changes that would be noticed during the assessment, it is necessary to check the relevant points of the standard to which the changes refer and to update OB 05-62-3 Inspection body assessment plan.

During the supervisory assessment, the assessment team shall analyze the effectiveness of the corrective measures taken on the basis of non-conformities, remarks and comments from the previous assessment, the use of the accreditation mark and changes in the inspection body.

Taking samples from the staff

Testimonies from the performance of accredited activities (usually for one area) is an important element in assessing staff competence, especially when the inspector's professional opinion has a key impact on the inspection outcome.

If possible and appropriately, all inspectors must be certified through each accreditation cycle. The selection of inspectors to testify shall depend on the number and frequency of inspections performed, their experience and competence, the results of previous testimonies, the results of internal monitoring and the legal requirements.

During the initial assessment and the re-accreditation assessment, at least the key certified inspectors must be assessed in relation to their competence to perform the given inspection.

In case accreditation is a precondition for authorization by the competent authorities and the assessed body cannot inspect the clients without authorization, the testimony of the staff performance during the initial assessment must be made by simulating the performance of the inspection activities.

The supervisory assessment must assess staff different from those assessed in the previous assessment. Special attention must be paid to newly recruited staff or staff authorized in a new area. All staff authorized for the accreditation scope must be assessed at least once between the first assessment and the re-accreditation assessment.

Taking samples from locations

When activities are performed at different locations, the seat/main body location must be assessed during the initial assessment and the re-accreditation assessment, whereas sampling from all key locations within the accreditation scope and their assessment shall be performed on the basis of the completed Risks Analysis (OB 05-63).

The supervision assessment of the inspection body, located at several locations, shall always be performed at the main location and at least one other location, in a way that all key locations are assessed at least once in the period between the first assessment and the re-accreditation assessment.

Key locations are those where the following key activities are performed:

- Policy making,
- Development of inspection procedures,

- Selection of inspectors,
- Reviewing contracts and approving inspection reports or other activities affecting the inspection outcome,
- Conformity assessment planning,
- Review and approval of the conformity assessment.

When an inspection body registered as a legal entity in the Republic of North Macedonia performs its activities through different organizational units (in the country or abroad) it shall be clearly distinguished whether these are key locations or only locations through which the inspection body operates (offices, representative offices). This shall be clearly indicated in the accreditation scope (Application, Attachment to the Accreditation Certificate).

In case of key locations, the accreditation scope shall be given for each location separately. The other locations shall be listed in the Attachment of the Certificate with an indication that key activities are not performed at those locations.

The assessor shall check for all locations (through review of contracts, interview and objective evidence/documentation, etc.) whether they are operating under the same management system for the whole scope (e.g. whether they are involved in internal inspections and the management assessment program).

For locations where the same non-key activities are performed, the assessment team shall assess at which locations the performance of the inspection activity shall be checked in one accreditation cycle. If it is a regulated area with defined requirements for locations, it must be checked either by visiting or through documentation.

Taking samples from the accreditation scope

When taking samples from the accreditation scope, one sample of the accreditation scope shall be assessed at least every two years.
The following tools shall be used for sampling from the accreditation scope:

- Testimonies,
- Interviews,
- Vertical inspection.

During the initial assessment and the re-accreditation assessment, each inspection area of the required scope must be assessed through the assessment of staff, equipment, premises, instructions, testimony during the inspection, validation of methods, inspection results, records, etc.

During the preparation of the assessment, the assessors must define a group of items subject to testimony with appropriate similar or identical characteristics.

When different inspection items are bundled in a group with related activities, the grouping and preparation of the testimony plan shall be prepared by the assessment team in collaboration with the head of department/unit.

When an inspection body inspecting different items to which similar or identical inspection procedures apply use the same equipment, inspection shall be carried out by the same personnel, etc. (For example: Respiratory machines cylinder or fire extinguisher cylinder), it shall be considered, at the time of the initial assessment, that it is sufficient to observe one item from the group of items with similar characteristics subject to inspection, while ensuring that more complex items are subject to inspection.
During supervision, the selection of the inspection areas shall be performed in a way that provides an assessment of all areas or related groups of inspection areas, at least once during each accreditation cycle.

The minimum number of testimonies of the inspection methods during the initial assessment shall be performed according to the given table:

Number of inspection methods	Minimal number of testimonies
1 to 5	100%
6 to 10	60%
16 to 25	50%
≥ 26	35%

In some cases (when it is impossible to give testimony of a method) a conversation with the appropriate staff must take place.

At least one vertical check shall be performed during each assessment.

4. ASSESSMENT FOR EXTENSION

The assessment for extension shall include:
- assessment of the changes in the system and the management procedures of the accredited CAB;
- assessment of the technical competence for the requested extension, including analysis of the needs for new competencies (knowledge and skills) and their performance;
- availability and competence of resources, adequacy of equipment and space required for the activities of the requested extension;
- staff authorizations for new testing methods, calibration and inspection, certification schemes or technical areas;
- descriptions of methods and instructions for work related to the new methods/activities;
- validation of new methods and results from participation in PT schemes (testing and calibration);
- performed checks in a new technical area/product/process/service (ST);
- composition of the committee/impartiality committee in relation to the new scope (ST);
- competency needs analysis and access to knowledge sources for checking new technical area/product/process/service (ST).

The extension assessment at a new location shall be carried out in accordance with the sampling requirements from locations given in this procedure (paragraphs 3.1, 3.2, 3.3).

When planning an assessment for extension, the four-year assessment plan must be extended to plan the assessment (OB 05-62-x) and the Risk Analysis (OB 05-63), in accordance with item 2.2.7 Planning an assessment visit (PR 05-01).
In doing so, previous experience from the assessments of the accredited CAB must be taken into account.