INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF NORTH MACEDONIA

Procedure for assessment and accreditation of sampling methods

PR 05-11

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1. PURPOSE

This procedure, issued by the Director of the IARNM (Article 23 of the Statute of the IARNM) sets out the principles of assessment and accreditation of sampling methods.

2. DEFINITIONS

CAB/Organization: A conformity assessment body, in these instances testing laboratories or inspection bodies.

2.1 Sampling terminology:

Method/procedure: the documented criteria for undertaking the sampling activity.
EN ISO /IEC 17025 Clause 7.3.2, "The sampling method shall describe

a) Choice of samples or locations;
b) Sampling plan;
c) Treatment and preparation of the sample from the substance, material or product to obtain information needed for testing and calibration".

Protocol: The sampling protocol is a set of definitive directions which define the operational requirements and/or instructions for the implementation of the sampling plan that shall be followed, without exception, if the analytical results or inspected items shall be accepted for a given purpose.

Plan: The sampling plan shall identify the selection, taking, preservation, transportation and preparation of the primary sample and be based on appropriate statistical methods.

Primary Sample: This is defined as being the collection of one or more increments initially taken from the whole population.

3. IARNM POLICY

3.1 For the accreditation of sampling methods, both EN ISO/IEC 17025 and EN ISO/IEC 17020 standards are applicable and either may be adopted. However, EN ISO/IEC 17025 remains the preferred applicable standard as it includes the most critical criteria for sampling.

3.2 Sampling methods can be accredited as a standalone activity. The preferred standard for the accreditation of sampling methods as stand-alone activity is EN ISO/IEC 17025. EN ISO/IEC 17020 could be considered to be also appropriate provided that all the

corresponding requirements of the preferred standard EN ISO/IEC 17025 shall be used as additional requirements within accreditation process.

3.3 It is IARNM policy to accredit sampling methods that are published as international or national standards, methods specified in European Directives or Regulations and methods specified in national Regulations only; it is IARNM policy not to accredit in-house developed sampling methods or any modified standard methods.

4. GENERAL REQUIREMENTS ABOUT ASSESSMANT OF THE SAMPLING METHODS

EN ISO/IEC 17025 is the standard used by accreditation bodies in the assessment of sampling methods as standalone activity and as an activity accompanied by testing methods, also. EN ISO/IEC 17020 is also relevant, in that inspection bodies shall have and use documented sampling methods in accordance with point 3.3 and to apply additional requirements stated from point 4 to point 11 from this Procedure.

The organization shall verify standard sampling methods/protocols (specified in 3.4) to such an extent that it is capable of demonstrating compliance with the acceptance criteria specified in the standard method and is suitable for its intended purpose. If the standard sampling method refers to additional standards or relevant documents for ensuring validity of the results and/or for verification of the method intended use, the reference documents shall be implemented by the organization and assessed by the assessment team.

The following elements shall be considered in the sampling plan:

- the purpose for which the sample is taken;
- the client's requirements;
- the selection of sampling sites;
- the sampling frequency and timing;
- type of sampling containers, on-site measurements, environmental conditions, sample size, holding conditions, preservatives, the homogeneity and appropriateness of the sample;
- the standard method.

Sufficient knowledge of statistical techniques is required to ensure statistically sound sampling procedures.

5. QUALITY MANAGEMENT SYSTEM

When an organization applies for accreditation of its sampling methods, IARNM shall assess the quality management system which shall be comprehensively documented to fully describe the sampling activities. The organization shall ensure that it has the capability to incorporate its sampling activities within its management structure. With regard to the

technical aspect of sampling, the assessment team will pay particular attention to the relation between the sampling activity and its testing and/or inspection activities.

The management system shall clearly identify technical management responsible for sampling activity and identify those with responsibility for, amongst other things, for decision making, resources allocation, authorisation, training and supervision.

An organisation shall define its sampling policy and clearly identify the scope of its sampling activity.

The terminology, the sampling process and methodology shall be documented with clearly identifiable levels of authority and responsibility associated with each critical phase.

The organization is required to undertake annual audits of sampling activities by an auditor who is independent of the activity being audited.

The assessment team will focus on the organizations' sampling operating principles and procedures to determine whether sampling is an integral part of the testing/ inspection activities or whether it is subcontracted.

Where sampling is subcontracted, this shall clearly be identified within the management system.

6. CONTRACT REVIEW

Organizations seeking accreditation for sampling shall undertake a full review of requests, tenders and contracts to ensure that the organisation responsible for sampling has the capabilities and resources to perform standard sampling methods in accordance with documented plans and protocols.

In addition, the organisation shall ensure that the standard sampling method selected is appropriate and satisfies all testing and inspection requirements.

7. DEVIATING SAMPLES

EN ISO/IEC 17025 specifies a number of requirements for laboratories in the event of deviating samples being identified (clause 7.4.3 and 7.8.1).

The organization shall identify and preserve all samples taken (as appropriate) to avoid any contamination or break in traceability. The organisation shall have documented instructions and records to ensure that the integrity of each sample is maintained from sampling to reporting.

If, at any stage, the organisation has reason to suspect that the sample taken deviates from the sampling plan and method/protocol and thus may jeopardize the validity of the test results, the organisation shall inform the customer immediately of any possible implications to test results generated. Examples of deviations may include incorrect preservation of the sample, maximum preservation time exceeded, date and time of sampling not available, contamination of the sample, etc.

In exceptional circumstances, the customer may request the deviating sample to be analysed. In this instance, the organisation shall include a disclaimer within the report clearly stating that the deviation and that, as a result, the test result(s) may be invalid.

The assessment team will pay particular attention to samples that deviate from the sampling plan and methods/protocols and how the organisation has dealt with the handling and reporting of such samples. Organisations shall have documented procedures with regard to the management of deviating samples.

8. PERSONNEL

The organization shall ensure that it has sufficient competent personnel to undertake sampling activities including those with responsibility for the drawing up of sampling plans and supervision.

The organisation shall ensure that all persons involved in sampling are appropriately qualified, trained and technically competent and shall have a documented training and authorisation procedure to ensure that only authorised and competent personnel undertake sampling and its associated activities.

Supervision of sampling shall be carried out in a systematic and planned manner and shall ensure that sampling plan and method/ protocol are correctly followed. Effective supervision of sampling activity can be claimed only in situations where a supervisor is in a position to review actual observations and sampling decisions or otherwise personally verify that sampling decisions are reliable.

9. ASSESSMENT OF SAMPLING METHODS

The assessment team will review the sampling plan and method/ protocol with particular attention to the organization’s identification of risks and errors (random and systematic), contamination management and traceability of sample identity throughout the sampling process.

The assessment team will also assess the allocation of resources, the competence of the sampling personnel, the availability and adequacy of equipment used for sampling, and the use of subcontractors.

The organisation shall ensure that the sample adequately reflects the properties of interest in the target sample. Particular emphasis will be placed on how the organisation report cases where the sample is not representative but is determined by availability. All contributions to measurement uncertainty which is important and raise from sampling shall be identified and taken into account during its estimation.

Where sampling is performed, the organisation shall have documented procedures for checking that the environment and prevailing conditions do not adversely affect the performance of the sampling equipment.

The organisation shall ensure traceability of all measuring equipment and shall carry out such checks before and after on-site sampling to ensure that equipment remains serviceable and in calibration.

The organization shall ensure that uses procedure for providing validity of sampling results and it shall participate in appropriate proficiency testing scheme and/or interlaboratory comparison other than proficiency testing scheme according to Regulation on Requirements for Proficiency Testing, Interlaboratory comparisons other than Proficiency Testing and External Quality Assessment Programmes – R06.

The technical performance of a sampling method is assessed by paying particular attention to the compatibility of the sampling method and the test method selected.

The assessment team shall document in the report OB 05-19 assessed requirements for sampling methods according to MKC EN ISO/IEC 17025 in the following clauses: 6.2, 6.3, 6.4, 6.5. 6.6, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, accordingly.

10. ASSURING QUALITY OF SAMPLING

An organisation shall have appropriate processes and procedures in place to ensure the quality of sampling activities.

These procedures and processes shall include the following, at a minimum:

- Identifying critical stages to ensure compliance with the related sampling procedure. These critical stages are based upon key steps within the sampling method (e.g. sample criteria required for acceptance or rejection);

▪ Authorized personnel shall carry out checks on sampling reports prior to their approval to ensure that sampling was carried out in accordance any defined critical stages;
▪ Maintaining a register of personnel and ongoing competency records for all personnel involved in the sampling activity;
▪ Define a programme for undertaking independent reviews of all results emanating from sampling activities. The review shall include pertinent data to ensure that sampling activities and requirements are followed;
▪ Review individual sampling techniques to ensure consistency between samplers i.e. on-site witnessing of sampling techniques. A schedule for witnessing individuals undertaking sampling methods shall be designed to ensure that, where appropriate, a representative number is taken, and each individual is witnessed within the accreditation cycle;

▪ The organization shall evaluate on an ongoing basis its sampling plans and methods to ensure compliance with current reference methods.

11. RECORDS

The organization shall retain in accordance with IARNM regulations all original observations, sampling plans, derived data, sampling records, and sampling report.
The records shall contain at least the following:

- Identity of all personnel involved in any stage of sampling;
- Date and time of sampling;
- Precise location of where sample was taken;
- Unique sample identification;
- Reference to sampling plan used;
- Reference to equipment used, including checks on calibration status;
- Relevant environmental conditions at point of sampling and transportation;
- Reference to specific sampling procedure.

12. SAMPLING REPORT/CERTIFICATE

The sampling report/certificate shall be clear, unambiguous and contain all information necessary for the interpretation of the sampling.

The sampling report/certificate shall contain at least the following information:

- Title (“Sampling Report” or similar, “Certificate for sampling” or similar
- Name and address of CAB;
- Name and information for clients contact,

- Unique identification that all components are recognize as a part from complete report and clearly identification of the report end;
- Location of the sampling activities related with sampling, including those which is performed on the clients places or on the places out of permanent CABs facilities or on the temporary or mobile facilities;
- Diagrams, sketches or photographs from each sampling etc.;
- Reference to the sampling plan and sampling method;
- Description - Unambiguous identification of the sample (including the name of the producer, model or tip and serial number if its applicable), and description of the sample condition if it's necessary;
- Date of sampling and date of sample receipt for testing or calibration when it is from crucial importance for validity and usage of the results;
- Date(s) of performing the laboratory activities (if its relevant);
- Date of issuing the Report/ Certificate;
- Statement that results are refer only to the taken samples (if its relevant);
- Results, with measurement units where is appropriate;
- Information needed for measurement uncertainty estimation for subsequent testing/ calibration;
- Additions, deviations or exclusions of the method and sampling plan;
- Identification of the person for approving the Report/ Certificate;
- Clear identification when the result is from external supplier;
- Description of the equipment which is use (if its relevant);
- All environmental condition during sampling which may affect on sampling and interpretation of the results including storage and transport;
- Clear and unambiguous statement for any kind of sample deviation;
- Statement that reproducing the Report/ Certificate is forbidden in whole without organization permission;
- Statement which provides chain of keeping and protecting of the samples.