

Principles for the Assessment and Accreditation of Sampling Methods

PS17

1) Purpose

- 1.1) This statement sets out the policy of the Irish National Accreditation Board with respect to the principles for the assessment and accreditation of sampling methods.

2) Definitions

- 2.1) ISO/IEC 17025: *"General requirements for the competence of calibration and testing laboratories"*.
- 2.2) ISO/IEC 17020: *"General criteria for the operation of various types of bodies performing inspections"*.
- 2.3) ISO/IEC 17025 Clause 5.7.1 under Note 1 describes sampling as *"Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole"* the note goes on to give further clarification when it states that *"Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g. forensic analysis), the sample may not be representative but is determined by availability"*.
- 2.4) CAB: A conformity assessment body.
- 2.5) Sampling terminology:
 - 2.5.1) Method/procedure: the documented criteria for undertaking sampling activity and defines the specific direction necessary to utilise the method (see 4.2 below);
 - 2.5.2) Protocol: The sampling protocol is the set of definitive directions and defines the operational requirements and/or instructions for the implementation of the sampling plan that must be followed, without exceptions, if the analytical results or inspected items are to be accepted for a given purpose.
 - 2.5.3) Plan: The sampling plan shall identify the selection, withdrawal, preservation transportation, and preparation of the primary sample this being the collection of one or more increments initially taken from the whole population.

3) Policy

- 3.1) For the accreditation of sampling methods, both ISO/IEC 17025 and ISO/IEC 17020 standards are applicable and either may be adopted. However, ISO/IEC 17025 remains the leading applicable standard, as it includes the most critical criteria for sampling.
- 3.2) Sampling will only be accredited to ISO/IEC 17025 as a separate standalone activity if it is conducted within the framework of accredited tests as in 3.5 below.
- 3.3) Sampling shall not be accredited as a standalone activity to ISO/IEC 17020, however an applicant or accredited inspection body may be accredited for sampling methods as part of its scope of accreditation.
- 3.4) It is INAB policy to accredit only sampling methods that are published international or national standards or those specified in European Directives or Regulations; it is INAB policy not to accredit in-house developed sampling methods or any in-house variation of a standard method.
- 3.5) It is INAB policy to accredit standard sampling methods, only when the output of sampling is subject to testing undertaken by the CABs own accredited laboratory or an accredited subcontracted laboratory.

4) General Requirements for Sampling

- 4.1) ISO/IEC 17025 is the standard used by accreditation bodies in the assessment of sampling methods used by organisations accredited for testing. ISO/IEC 17020 is also relevant, in that inspection bodies shall have and use documented sampling methods when the absence of such instruction could jeopardise the effectiveness of the inspection process.
- 4.2) ISO /IEC 17025 Clause 5.7.1, Note 2 states:- "*Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information*" and "*Sampling plans shall, wherever, be based on appropriate statistical methods*".
- 4.3) The organisation shall verify or validate standard sampling protocols to such an extent that it is capable of demonstrating compliance with the acceptance criteria specified in the method and is suitable for its intended purpose.
- 4.4) The following elements should 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;
- record of type of sampling containers, on-site measurements, environmental conditions, sample size, holding conditions, preservatives, the homogeneity and appropriateness of the sample;
- the standard method

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

5) Quality Management System

5.1) When an organisation applies for accreditation of its sampling methods, INAB shall assess the quality management system which should be comprehensively documented to fully describe the CABs sampling activities. The organisation should 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 interface between the sampling activities and its testing and/or inspection activities.

5.2) The management system shall clearly identify technical management (e.g. those involved in decision making, the allocation of resources, authorisations, training) responsible for, and those authorised to undertake, sampling activities.

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

5.4) The terminology, the sampling process and methodology shall be described in the sampling and other related documents, with clearly identifiable levels of authority and responsibility associated with each critical phase.

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

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

6) Contract Review

- 6.1) Organisations seeking accreditation for sampling shall undertake a full review of requests, tenders and contracts.
- 6.2) Contract review ensures that the organisation responsible for sampling has the capabilities and resources to perform standard sampling methods in accordance with documented plans and protocols.
- 6.3) In addition, the organisation shall ensure that the standard sampling method selected is appropriate and satisfies all testing and inspection requirements during the contract review process. Associated documents shall be available which convey that an agreement exists between the organisation and its customers for all requirements pertaining to sampling.

7) Deviating samples

- 7.1) ISO/IEC 17025 specifies a number of requirements for laboratories in the event of deviating samples being identified (clause 5.7.2, 5.8.3 and 5.10.1).
- 7.2) The organisation shall identify and preserve all samples taken (as appropriate) to avoid any contamination or break in traceability. The organisation shall make arrangements to ensure that the integrity of each sample is maintained from sampling to reporting.
- 7.3) If, at any stage, the organisation has reason to suspect that the sample taken deviates from the sampling plan and 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 from sampling protocol may include incorrect preservation of the sample, maximum preservation time exceeded, date and time of sampling not available, contamination of the sample during sampling, etc.
- 7.4) In exceptional circumstances, the customer may request for the deviating sample to be analysed. In this instance, the organisation shall include a disclaimer within the report, clearly stating that the sample was deviating and that, as a result, the test result(s) may be invalid.
- 7.5) The assessment team will pay particular attention to samples that deviate from sampling plan and protocols and how the organization has dealt with the handling of such samples and any sampling disclaimers within corresponding test/inspection reports. Organisations shall have documented procedures with regard to the handling of deviating samples and the inclusion of disclaimers in the corresponding test reports.

8) Personnel

- 8.1) The organisation shall ensure that it has sufficient competent personnel undertaking sampling activities including those with responsibility for the drawing up of sampling plans and the appropriate sampling supervision.
- 8.2) 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 procedures to ensure that only authorised and competent personnel undertake sampling and its associated activities.
- 8.3) Supervision of sampling shall be carried out in a systematic and planned manner and should ensure that sampling plan and protocol are correct and 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) The assessment of sampling methods

- 9.1) The assessment team will review the sampling plan and protocol, in particular the organisations identification of risks and critical factors, such as, identifying quantities of random errors in particular the magnitude introduced by heterogeneity of the target, systematic errors introduced by the execution of the sampling plan, any contamination of the sample during sampling by equipment/environment, disturbance factors, etc. and traceability of sample identity throughout the sampling process.
- 9.2) 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.
- 9.3) The organisation shall ensure that the sample resulting from the sampling plan and protocol reflect adequately the properties of interest in the target sample. Particular emphasis will be placed on ensuring how the organisation reports cases where the sample is not representative but is determined by availability.
- 9.4) 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 sampling equipment.
- 9.5) The organisation shall ensure traceability of all measuring equipment and carryout such checks before and after site sampling to ensure that equipment remains serviceable and in calibration.
- 9.6) 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.

10) Assuring the quality of sampling

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

10.2) These procedures / protocols should include the following, at a minimum:

- Specified critical stages shall be identified to ensure compliance with the related sampling procedure. These critical stages are based upon key steps within the sampling method to be carried out (e.g. sample criteria required for acceptance or rejection).
- Authorised personnel should carry out checks on sampling reports prior to their approval to ensure that sampling was carried out in accordance any critical stages defined within the sampling plans and protocol;
- The CAB shall maintain a register of personnel and ongoing competency records for all personnel involved in the sampling activity;
- The CAB shall have a defined programme for undertaking independent reviews of all results emanating from sampling activities. The review should include pertinent data to ensure that sampling activities and requirements are followed;
- Reviews of individual sampling techniques to ensure consistency between samplers i.e. on-site witnessing of sampling techniques. A schedule for witnessing individuals undertaking sampling methods should be designed to ensure that where appropriate a representative number is taken and each individual is witnessed within the normal accreditation cycle;
- The organisation shall evaluate on an ongoing basis its sampling plans and protocols to ensure compliance with current standard methods.

11) Records

11.1) The organisation shall retain in accordance with INAB regulations all original observations, sampling plans, derived data, including sampling records, and sampling report. The records should 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

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

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

- Title ('Sampling Report/Certificate' or otherwise equivalent);
- Name and address of the sampling organisation;
- Unique identification of the report/certificate and of each sample;
- Date time and location of sampling;
- Include any sampling sketches or photographs etc;
- Identification and address of the client;
- Unique identification of the batch which the sample is representative;
- Description of the sample taken, its volume, weight, etc;
- The standard method;
- Unique sampling plan and sampling procedure;
- Equipment used in sampling;
- Any environmental conditions during sampling that could have an effect on the sample taken including storage and transportation;
- Identification of all sampling personnel involved at all stages;
- Identification and signature of person authorising sampling report/certificate;
- Date of issue of sampling report/certificate;
- Clear and unambiguous statement on any deviations in sampling;
- Statement to ensure reproduction of the report/certificate in full is not permitted without authorisation by sampling organisation;
- Statement on assuring the chain of custody of samples taken.

13) Contact

For further information about this statement please contact an INAB officer at **The Irish National Accreditation Board**.

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