# 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.
- 1.2) This policy is not applicable for calibration laboratories accredited to ISO 17025 or laboratories accredited to ISO 15189.

#### 2) Definitions and Reference Standards

- 2.1) ISO/IEC 17025: "General requirements for the competence of calibration and testing laboratories".
- 2.2) CAB: A conformity assessment body, in these instances testing laboratories or inspection bodies.
- 2.3) Sampling terminology:
  - 2.3.1) <u>Method/procedure</u>: the documented criteria for undertaking the sampling of substances, materials or products for subsequent testing activity. ISO /IEC 17025:2017 Clause 7.3 refers.
  - 2.3.2) <u>Plan</u>: The sampling plan shall identify the selection, withdrawal, preservation, transportation and preparation of the primary sample and be based on appropriate statistical methods.
  - 2.3.3) <u>Primary Sample</u>: This is defined as being the collection of one or more increments initially taken from the whole population.

## 3) Policy

- 3.1) Sampling methods will only be accredited to ISO/IEC 17025 as a standalone activity if it is conducted within the framework of accredited tests as in 3.5 below.
- 3.2) It is INAB policy to accredit sampling methods that are published international or national standards or those specified in European Directives or Regulations only; it is INAB policy not to accredit in-house developed sampling methods or any in-house variation of a standard method.
- 3.3) It is INAB policy to accredit standard sampling methods, only when the output of sampling is subject to testing undertaken by the organisation's 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.
- 4.2) The organisation shall verify or validate standard sampling methods/protocols 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.
- 4.3) 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;
- type of sampling containers, on-site measurements, environmental conditions, sample size, holding conditions, preservatives, the homogeneity and appropriateness of the sample;
- the standard method
- 4.4) 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 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 activity and its testing activities.
- 5.2) The management system shall clearly identify technical management responsible for sampling activity and identify those with responsibility for, amongst other things, as decision making, resources allocation, authorisation, training and supervision.
- 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 documented 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 activities or whether it is subcontracted.
- 5.7) Where sampling is subcontracted, this shall clearly be identified within the management system.

## 6) Contract Review

- 6.1) Organisations 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.
- 6.2) In addition, the organisation shall ensure that the standard sampling method selected is appropriate and satisfies all testing requirements. 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) The organisation 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.

- 7.2) 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.
- 7.3) 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 deviation and that, as a result, the test result(s) may be invalid.
- 7.4) 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

- 8.1) The organisation 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.
- 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 procedure 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 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) The assessment of sampling methods

- 9.1) The assessment team will review the sampling plan and method / protocol with particular attention to the organisations identification of risks and errors (random and systematic), contamination management 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 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.
- 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 the 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 and processes should 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);
- Authorised personnel should 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 should 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 should be designed to ensure that, where appropriate, a representative number is taken and each individual is witnessed within the accreditation cycle;
- The organisation shall evaluate on an ongoing basis its sampling plans and methods to ensure compliance with current reference methods.

## 11) Records

- 11.1) The organisation shall retain in accordance with INAB regulations all original observations, sampling plans, derived data, 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( please also refer to ISO17025:2017 7.8.5:-
  - Title ('Sampling Report/Certificate' or otherwise equivalent);
  - Name and address of the organisation;
  - Unique identification of the report/certificate and of each sample;
  - Date, time and location of sampling;
  - 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;

- Any environmental conditions during sampling that could have an effect on the sample taken including storage and transportation;
- Identification of all sampling personnel involved;
- Identification and signature of person authorising sampling report/certificate;
- Date of issue of sampling report/certificate;
- Clear and unambiguous statement on any sample deviations;
- Statement to ensure reproduction of the report/certificate in full is not permitted without authorisation from the organisation;
- Statement on assuring the chain of custody of samples taken.
- Information required evaluating measurement uncertainty for subsequent testing.

#### 13) Contact

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

E-mail: <u>inab@inab.ie</u> Website: <u>www.inab.ie</u>