

Laboratory Guidance On-Site Assessment

1 SCOPE

This document applies to Conformity Assessment - General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies as defined by ISO/IEC 17011:2004(E), to the on-site assessment of laboratories producing environmental data, focused from the laboratory perspective. It includes information on additional requirements and suggested guidance on using ISO/IEC 17011:2004(E) during laboratory assessments.

Volume 2, Module 3 of the TNI standard contains requirements for on-site assessment of environmental laboratories from the perspective of accreditation bodies performing those assessments, and is similarly based on ISO/IEC 17011:2004(E).

2 NORMATIVE REFERENCES

ISO 9000:2000 Quality Management Systems – Fundamentals and Vocabulary
ISO/IEC 17000:2004, Conformity Assessment – Vocabulary and General Principles

3 TERMS AND DEFINITIONS

The terms and definitions used in this document are consistent with those used in the TNI standards.

Note: Accreditation bodies may perform the following types of on-site assessments:

- a) Initial assessments: These are comprehensive and involve reviewing all key activities performed by a laboratory applying for accreditation for the first time. Initial assessments are generally announced.
- b) Reassessments: These are similar in scope to initial assessments except that the experience gained during previous assessments can be taken into account.
- c) Surveillance on-site assessments: These are less comprehensive than reassessments and occur as needed in between an initial assessment and a reassessment or between reassessments.
- d) Follow-up assessments: These are undertaken to verify effective implementation of corrective actions.
- e) Extraordinary assessments: These are conducted as a result of complaints or changes such as ownership, key personnel, location, scope of accreditation, or other matters that may affect the ability of a laboratory to fulfill accreditation requirements.

This document is concerned with conformity assessment bodies commonly known as laboratories providing services in a fixed or mobile setting. The on-site assessment of field sampling and measurement organizations is detailed in Field Sampling and Measurement Organization Sector Volume 1 Modules 1 and 2.

Note: Consultancy means the position and practice of a qualified person paid for advice or services. It does not include information and assistance provided by governmental bodies.

4 ON-SITE ASSESSMENT HUMAN RESOURCES

4.1 Statements of Qualifications and Lack of Conflicts of Interest

An assessor must certify that they will follow the rules of the accrediting body as respects confidentiality and freedom from conflicts of interest.

- 4.1.2** Assessors must sign qualification statements attesting the assessors meet the education and training required by the TNI standard and accrediting body. Accreditation bodies shall provide those statements to laboratories upon request.

Requirements for assessor training, qualifications, and experience are contained in Volume 2, Accreditation Body Requirements, Module 3, On-Site Assessment of this standard. Laboratories interested in these requirements may request this information from accreditation bodies or should refer to Volume 2, Module 3.

- 4.1.3** Before conducting an assessment, an assessor must sign statements certifying the assessor has no conflict of interest with the laboratory to be assessed and provide such statements, upon request, to the laboratory.

It is possible that during the on-site assessment, assessors or laboratory personnel become aware of previously unforeseen conflicts of interest. When this happens, the lead assessor should consult with the accreditation body, as soon as practicable, to determine how to proceed. The accreditation body will determine if the assessment can proceed without compromising its integrity and impartiality, or will request that the assessment team terminate the assessment.

4.2 Assessor's Role in Consultancy and Enforcement

- 4.2.1** If an assessor has provided services to the CAB they must ensure that this does not affect their objectivity. Assessors are employed by or on behalf of accreditation bodies to determine the competence of a laboratory in meeting the TNI standard. The initial accreditation of a laboratory is based primarily on the findings and observations of assessors. Although assessment teams normally make recommendations that are used by other personnel in accreditation bodies to make a determination of the accreditation status of a laboratory, in many accreditation bodies, assessment team members can also be responsible for deciding the accreditation status of a laboratory.

- 4.2.2** While on site, assessment teams may become aware that a laboratory may be in violation of an environmental law or regulation. The assessment team must present this information and any associated documentation to the accreditation body for appropriate action.

Some assessment teams have the ability to act as enforcement agents for their accreditation bodies.

4.3 Standards of Professional Conduct for Assessors

- 4.3.1** The accreditation body must be made aware of any conflicts of interest between the assessor or the organization she/he represents and the CAB.

- 4.3.2** Assessors and experts shall conform to professional and ethical standards of conduct. Assessors and experts shall:

a) Have no interests at play other than those of the accreditation body during the entire accreditation process;

b) Act impartially and not give preferential treatment to any organization or individual;

c) Provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, and disability;

d) Not use their position for private gain;

e) Not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative, or any other affected individual or organization doing business with, or affected by, the actions of the assessor's employer or accreditation body;

- f) Not hold financial interests that conflict with the conscientious performance of their duties;
- g) Not engage in financial transactions using information gained through their positions as assessors to further any private interest;
- h) Not seek or negotiate employment or attempt to arrange contractual agreements with a laboratory that would conflict with their duties and responsibilities as assessors;
- i) Not knowingly make unauthorized commitments or promises of any kind purporting to bind an accreditation body; and
- j) Attempt to avoid any actions that could create the appearance that they are violating any of the standards of professional conduct outlined here.

5.0 FREQUENCY OF ON-SITE ASSESSMENTS

- 5.1 After an initial assessment for accreditation, accreditation bodies perform on-site assessments at intervals of two years plus or minus six months. Once a laboratory is accredited, accreditation bodies reserve the right to assess a laboratory at any time during the accreditation period.
- 5.2 Although most assessments are announced, accreditation bodies have authority to conduct unannounced assessments.

6.0 ASSESSMENT PROCESS

6.1 Preparation for Assessment

- 6.1.1 It is the responsibility of the accrediting body to designate an assessment team which has a lead assessor and other assessors with sufficient expertise in the fields of testing to be able to determine if a CAB is capable of performing the tests for which it is seeking accreditation.
- 6.1.2 Accreditation bodies may conduct unannounced assessments. The requirement to notify the CAB in advance of the names of the members of the assessment team does not apply to unannounced assessments. An unannounced assessment should not be used by an accreditation body to appoint a known objectionable assessment team. The policy established for dealing with objections from a laboratory to the appointment of an assessor or expert to the assessment team should specify the type of objections under which an accreditation body may consider assigning a different assessor or expert. When assembling a team for an unannounced assessment, accreditation bodies should consider previous objections to an assessor made by the CAB. A CAB retains the right to raise an objection to an assessor or expert at the time of the unannounced assessment, but should not raise objections to avoid or delay an unannounced assessment.
- 6.1.3 For environmental laboratories, accreditation bodies should establish procedures for selecting systems, methods, and analytical activities that will be observed during an on-site assessment based on the accreditation scope and complexity of the laboratory to be assessed. Assessors should strike a balance between thoroughness and practicality while determining the extent to which laboratories meet this standard. The examination of the systems, processes, and procedures of the laboratory should give a general sense of its past and present capabilities to perform work of known and documented quality.
- 6.1.4 An on-site assessment must be performed at whatever locations the laboratory will be carrying out testing for which they seek accreditation. Each fixed-base branch or subsidiary of a laboratory with multiple locations is customarily accredited separately by accreditation bodies and require separate initial assessments. Mobile facilities of fixed-base laboratories or mobile laboratories not directed by or attached to a fixed laboratory may be required to maintain distinct accreditations by different accreditation bodies and may require separate initial and surveillance assessments and reassessment.

6.1.5 A date and schedule mutually agreeable to the accreditation body, assessment team and CAB shall be set for assessments. However, accreditation bodies may conduct unannounced assessments. This subsection does not apply to unannounced assessments. Initial assessments are generally announced.

6.2 Document and Record Review

6.2.1 The assessment will include, either before, during or after the on-site, a review of whatever CAB documents are necessary to ensure the requirements of the TNI standards are being met.

6.2.2 The assessment team assigned to the laboratory usually makes a recommendation to the accreditation body to not proceed with an initial assessment when it encounters significant nonconformities during document and record review. Accreditation bodies should inform laboratories of a cancellation of an on-site assessment for those conditions as soon as is feasible. For other types of assessments, nonconformities found while reviewing documents and records before an on-site assessment would not result in cancellation of an on-site assessment.

6.3 Documents Provided to Laboratory

The assessment team shall provide or make available the following types of documents before a scheduled announced on-site assessment, or before the conclusion of the on-site portion of the laboratory assessment:

6.3.1 Assessment Confidentiality Notice – A document advising the laboratory that it has a right to declare information gathered during an assessment as confidential business information according to procedures established by the accreditation body or to restrict access to information requested during an assessment when such information directly affects national security.

6.3.2 Checklists – Any standard forms that the assessment team will use to evaluate conformance with this standard or to document assessment findings.

6.3.3 Assessment Appraisal Form – A document used by the accreditation body to obtain feedback from laboratories about the adequacy and the effectiveness of the assessment process, including the performance of the assessment team.

6.3.4 Notice of Announced Assessment – An appointment letter, an electronic mail message, or a published schedule informing the laboratory about an upcoming assessment and identifying members of the assessment team, with sufficient time to allow for potential objections from a laboratory to members assigned to the assessment team.

6.4 Confidential Business Information

Accreditation bodies shall have documented procedures for processing and evaluating claims made by laboratories of confidential business information (CBI) referencing applicable laws and regulations, the procedures a laboratory must follow to make a claim, the parties that will determine the validity of the claim, and the appeals process to be invoked when a laboratory disagrees with the disposition of a claim.

7.0 PERFORMING ON-SITE ASSESSMENT

7.1 Length of Assessment

Accreditation bodies must assign an adequate number of assessors to complete an assessment within a reasonable period.

The length of an on-site assessment is determined by the scope of accreditation of a laboratory, the number of assessors in an assessment team, the size of a CAB, the number of findings encountered during the assessment, and the cooperativeness of the laboratory staff.

7.2 Opening Conference

- 7.2.1** Attendance at the opening conference must be documented in sheets or forms provided by the assessment team.

Additional items that may be covered or addressed during an opening meeting include: identification of records and operating procedures to be examined, and the responsible laboratory individuals that will provide the assessment team with the necessary documentation; procedures to be followed when a laboratory claims information to be CBI; and safety procedures that the laboratory may think necessary for the protection of the assessment team.

7.3 Assessment Activities

- 7.3.1** An on-site assessment will be performed at each location where accreditation is sought. The assessment team will collect information (i.e. via documents, interviews and observation) that will enable the team to determine if the CAB is capable of performing the tests while adhering to all applicable standards and requirements.

- 7.3.2** The assessors will observe laboratory personnel performing their duties to determine competence. Assessment team members have the authority to conduct interviews with any or all laboratory staff.

It is customary and permissible for assessors to provide instruction or guidance on the meaning of accreditation and method requirements during the on-site assessment process. Offering such instruction and advice does not constitute consultancy. Assessors should not prescribe specific tasks on how to develop or implement management systems or operational procedures to comply with accreditation or method requirements to avoid engaging in consultancy.

- 7.3.3** The assessment team may need to consult with the accreditation body before determining if certain CAB practices are findings.

7.4 Closing Conference

- 7.4.1** At the conclusion of the on-sit, a meeting is held with the assessors and the CAB. The assessors provide a preliminary report of findings, oral or written, to the CAB. The CAB may then make inquiries about the findings or supply additional information to clarify their position.

7.4.2 Attendance at the closing conference must be documented in forms provided by the assessment team.

7.4.3 The assessment team shall provide only preliminary determinations of potential findings and must inform the laboratory that final determinations concerning the number, nature, and extent of assessment findings shall be made by the accreditation body after reviewing reported findings. The assessment team may only provide a preliminary written or oral report at the closing meeting because all final determinations of findings are subject to the approval of the accreditation body.

7.5 Reporting Procedures

- 7.5.1** The accreditation body or its authorized representative shall present to the laboratory, within thirty calendar days of the last day of the on-site assessment, a final assessment report identifying all confirmed findings.

- 7.5.2** The CAB is required to provide a response to the findings, with corrective actions and timeframes for completion, to the accrediting body. Accreditation bodies require documented responses to on-site

assessment reports within specified timeframes. Customarily, a laboratory that does not address all findings satisfactorily within two responses is scheduled for a follow-up evaluation or is subject to administrative procedures that reduce the laboratory's scope of accreditation.

7.5.3 Only accreditation bodies are allowed to release assessment reports initially. An assessment report shall not be released to the public by an accreditation body until the report has been provided to the laboratory, and until the findings of the assessment and the associated corrective actions have been finalized.

The on-site assessment process concludes when a laboratory addresses all findings in the on-site assessment report to the satisfaction of the accreditation body.

8.0 CHANGES IN LABORATORY CAPABILITIES

8.1 A laboratory shall inform the accreditation body within thirty days, of any significant changes relevant to the laboratory's accreditation in any aspect of its status or operation relating to location, ownership, top management, major policies and scope of accreditation.

Bibliography

1. ISO/IEC 17011:2004(E), Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
2. Accreditation of Environmental Laboratories and Related Organizations; INELA Interim Standard, August 2004, Unpublished.
3. National Environmental Laboratory Accreditation Conference, 2003 NELAC Standard. EPA/600/R-04/003, June 2003.