



ENVIRONMENTAL LABORATORY SECTOR

VOLUME 2

GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING ENVIRONMENTAL LABORATORIES

Module 1: General Requirements

TNI Standard

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PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Accreditation Body Committee. The TNI Board of Directors wishes to thank these committee members for their efforts in preparing this Standard as well as those TNI members who offered comments during the voting process.

It is conformant with the requirements of ISO/IEC 17011:2004(E). This publicly available TNI document does not contain the ISO/IEC copyright protected language, but does reference applicable ISO clauses. In these situations, it is useful to read the TNI Standard along with the ISO/IEC standard. Wherever an ISO clause is referenced (*in italics*), the language from that clause is applicable. Any additional TNI language then follows, in plain text, as a NOTE or as an additional numbered standard item.

TNI has an agreement with ASTM International and the American National Standards Institute (ANSI) to provide, to TNI members at a discounted rate, a version of this Standard with the ISO/IEC language included; contact Jerry Parr at TNI for more information.

This Standard may be used by any organization that wishes to implement a program for the accreditation of environmental laboratories.

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VOLUME 2, MODULE 1

General Requirements

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

This TNI Standard is intended as an application of *ISO/IEC 17011-2004(E)* Conformity Assessment - General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies. The ISO/IEC clauses are provided in *italics*, with the additional TNI clauses in normal font.

Users of this Standard should make the following substitutions and recognize that the context may require minor variations to these terms:

For this term:	Substitute this term:
Conformity Assessment Body (CAB)	Laboratory

Unless the contrary is clearly indicated, all references to singular nouns include the plural noun, and all references to plural nouns include the singular.

Some clauses in this Standard contain notes. The notes are used to explain a particular requirement or to provide clarifying examples. The notes do not supersede or modify requirements of the Standard and do not convey any additional requirements.

2.0 NORMATIVE REFERENCES (*ISO/IEC 17011:2004(E)*, Clause 2)

3.0 TERMS AND DEFINITIONS

- 3.1 Accreditation (*ISO/IEC 17011:2004(E)* Clause 3.1)
- 3.2 Accreditation Body (*ISO/IEC 17011:2004(E)* Clause 3.2)
- 3.3 Accreditation Body Logo (*ISO/IEC 17011:2004(E)* Clause 3.3)
- 3.4 Accreditation Certificate (*ISO/IEC 17011:2004(E)* Clause 3.4)
- 3.5 Accreditation Symbol (*ISO/IEC 17011:2004(E)* Clause 3.5)
- 3.6 Appeal (*ISO/IEC 17011:2004(E)* Clause 3.6)
- 3.7 Assessment (*ISO/IEC 17011:2004(E)* Clause 3.7)
- 3.8 Assessor (*ISO/IEC 17011:2004(E)* Clause 3.8)
- 3.9 Complaint (*ISO/IEC 17011:2004(E)* Clause 3.9)
- 3.10 Conformity Assessment Body (CAB) (*ISO/IEC 17011:2004(E)* Clause 3.10)

NOTE: This module is concerned with conformity assessment bodies (CA) commonly know as laboratories providing services in a fixed or mobile setting.

3.11 Consultancy (ISO/IEC 17011:2004(E) Clause 3.11)

NOTE: Consultancy refers to the position or practice of a qualified person paid for advice and services and does not include information and assistance provide by governmental agencies.

3.12 Expert (ISO/IEC 17011:2004(E) Clause 3.12)**3.13 Extending Accreditation (ISO/IEC 17011:2004(E) Clause 3.13)****3.14 Field of Accreditation**

Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation. (see also Scope of Accreditation).

3.15 Interested Parties (ISO/IEC 17011:2004(E) Clause 3.14)**3.16 Lead Assessor (ISO/IEC 17011:2004(E) Clause 3.15)****3.17 Reducing Accreditation (ISO/IEC 17011:2004(E) Clause 3.16)****3.18 Scope of Accreditation (ISO/IEC 17011:2004(E) Clause 3.17)**

(See also Field of Accreditation)

3.19 Surveillance (ISO/IEC 17011:2004(E) Clause 3.18)**3.20 Suspending Accreditation (ISO/IEC 17011:2004(E) Clause 3.19)****3.21 Withdrawing Accreditation (ISO/IEC 17011:2004(E) Clause 3.20)**

NOTE: In the context of this module, withdrawal includes involuntary revocation of accreditation and voluntary relinquishment of accreditation.

3.22 Witnessing (ISO/IEC 17011:2004(E) Clause 3.21)**4.0 ACCREDITATION BODY****4.1 Legal Responsibility (ISO/IEC 17011:2004(E), Clause 4.1)****4.2 Structure****4.2.1 ISO/IEC 17011:2004(E) Clause 4.2.1**

NOTE 1: In all cases, accreditation bodies are governmental organizations at the territory, state or federal levels.

NOTE 2: A territorial, state or federal entity may designate the appropriate agencies or departments as its designated accreditation body for the fields of accreditation for which recognition is being sought.

4.2.2 ISO/IEC 17011:2004(E), Clause 4.2.2**4.2.2.1 An accreditation body shall not delegate authority for granting, maintaining, suspending or revoking a CAB's accreditation to an outside person or body. Portions of the accreditation process may be**

contracted out; however, the authority to grant, maintain, suspend or revoke accreditation shall remain with the accreditation body.

4.2.3 *ISO/IEC 17011:2004(E), Clause 4.2.3*

4.2.4 *ISO/IEC 17011:2004(E), Clause 4.2.4*

4.2.5 *ISO/IEC 17011:2004(E) Clause 4.2.5*

NOTE: In the case of an accreditation body within a government department or entity, top management refers to the management of the organizational unit (and not the department or entity) having authority and responsibility for the accreditation program.

4.2.6 *ISO/IEC 17011:2004(E) Clause 4.2.6*

4.2.7 *ISO/IEC 17011:2004(E) Clause 4.2.7*

4.2.8 *ISO/IEC 17011:2004(E) Clause 4.2.8*

4.3 Impartiality

4.3.1 *ISO/IEC 17011:2004(E) Clause 4.3.1*

4.3.2 *ISO/IEC 17011:2004(E) Clause 4.3.2*

4.3.3 *ISO/IEC 17011:2004(E) Clause 4.3.3*

4.3.3.1 The accreditation body also shall require accredited CAB's to maintain impartiality and integrity.

4.3.4 *ISO/IEC 17011:2004(E) Clause 4.3.4*

4.3.5 *ISO/IEC 17011:2004(E) Clause 4.3.5*

4.3.6 *ISO/IEC 17011:2004(E) Clause 4.3.6*

4.3.7 *ISO/IEC 17011:2004(E) Clause 4.3.7*

NOTE 3: An accreditation body and related bodies within a Government department or entity might not have a distinctive name, logo and or symbol.

4.3.8 Unless required by applicable regulations, accreditation bodies and their contractors shall confine their requirements, assessments and decision making process for an accredited CAB to those matters specifically related to the fields of accreditation being sought or maintained by a CAB.

4.4 Confidentiality (ISO/IEC 17011:2004(E) Clause 4.4)

4.5 Liability and Financing (ISO/IEC 17011:2004(E) Clause 4.5)

4.6 Accreditation Activity (ISO/IEC 17011:2004(E) Clause 4.6)

5.0 MANAGEMENT

5.1 General (ISO/IEC 17011:2004(E) Clause 5.1)

5.2 Management System (ISO/IEC 17011:2004(E) Clause 5.2)

5.3 Document Control (ISO/IEC 17011:2004(E) Clause 5.3)

5.4 Records (ISO/IEC 17011:2004(E) Clause 5.4)**5.5 Non-Conformities and Corrective Actions (ISO/IEC 17011:2004(E) Clause 5.5)****5.6 Preventive Actions (ISO/IEC 17011:2004(E) Clause 5.6)****5.7 Internal Audits (ISO/IEC 17011:2004(E) Clause 5.7)**

5.7.4 One element of the annual internal audit shall be to review the effectiveness of the quality systems required. The internal audit shall include a review of the quality manual and associated written quality procedures. The frequency of internal audits may be reduced if the accreditation body can demonstrate acceptable performance during on-site evaluations. If this audit frequency is extended to a period longer than one year, the accreditation body shall document the frequency in their policies, procedures or quality manual.

5.8 Management Reviews (ISO/IEC 17011:2004(E) Clause 5.8)**5.9 Complaints (ISO/IEC 17011:2004(E) Clause 5.9)**

5.9.1 Accreditation bodies shall have documented policies and procedures for dealing with appeals, complaints and disputes.

6.0 HUMAN RESOURCES (ISO/IEC 17011:2004(E) Clause 6)**7.0 ACCREDITATION PROCESS****7.1 Accreditation Criteria and Information (ISO/IEC 17011:2004(E) Clause 7.1)****7.2 Application for Accreditation (ISO/IEC 17011:2004(E) Clause 7.2)****7.3 Resource Review (ISO/IEC 17011:2004(E) Clause 7.3)****7.4 Subcontracting the Assessment**

7.4.1 *ISO/IEC 17011:2004(E) Clause 7.4.1*

7.4.2 *ISO/IEC 17011:2004(E) Clause 7.4.2*

7.4.2.1 The CAB shall have the right to exclude a third party assessor if there is a conflict of interest.

7.4.3 *ISO/IEC 17011:2004(E) Clause 7.4.3*

7.5 Decision-Making and Granting Accreditation

7.5.1 *ISO/IEC 17011:2004(E) Clause 7.9.1*

7.5.2 *ISO/IEC 17011:2004(E), Clause 7.9.2*

NOTE: An accreditation body, in recognizing the accreditation granted by another accreditation body, which has a law or decision resulting from a legal action, the legal effect of which precludes the accreditation body from granting any accreditation to a particular CAB, would not be required to accept the accreditation of this CAB.

7.5.3 *ISO/IEC 17011:2004(E) Clause 7.9.3*

7.5.4 *ISO/IEC 17011:2004(E) Clause 7.9.4*

7.5.5 *ISO/IEC 17011:2004(E) Clause 7.9.5*

7.5.6 Denial of Accreditation

7.5.6.1 Reasons to deny an initial application shall include, but are not limited to:

7.5.6.1.1 failure to submit a completed application;

7.5.6.1.2 failure to pay fees;

7.5.6.1.3 failure of CAB staff to meet the personnel qualifications of education, training, and experience as required by the Standard;

7.5.6.1.4 failure to successfully analyze and report proficiency testing samples as required;

7.5.6.1.5 failure to respond to an assessment report from an on-site assessment with a corrective action report as required;

7.5.6.1.6 failure to implement the corrective actions detailed in the corrective action report within the required time frame.

7.5.6.1.7 failure to implement a quality system as defined in TNI Environmental Laboratory Sector Volume 1, Module 2 "Management and Technical Requirements for Laboratories Performing Environmental Analysis";

7.5.6.1.8 failure to pass required on-site assessment(s);

7.5.6.1.9 misrepresentation of any fact pertinent to receiving or maintaining accreditation; and/or

7.5.6.1.10 denial of entry during normal business hours for an on-site assessment.

7.5.6.2 No CAB's accreditation shall be denied without the right to due process.

7.6 Appeals

7.6.1 *ISO/IEC 17011:2004(E) Clause 7.10.1*

7.6.2 *ISO/IEC 17011:2004(E) Clause 7.10.2*

NOTE: An independent person, or group of persons, may consist of another group within the accreditation body organization whose responsibility is to handle investigations and appeals. Alternatively, the matter can be addressed by an external group of peers called together for this purpose, and following a documented policy and procedure consistent with this Standard and agreed upon by all participants.

7.7 Reassessment and Surveillance

7.7.1 *ISO/IEC 17011:2004(E) Clause 7.11.1*

7.7.2 *ISO/IEC 17011:2004(E) Clause 7.11.2*

NOTE: "Other surveillance activities" may include, among other things, review by the accreditation body of internal audit reports and managerial reviews or continuing demonstration of corrective actions, or proficiency testing performed by the CAB.

7.7.3 *ISO/IEC 17011:2004(E) Clause 7.11.3*

7.7.4 *ISO/IEC 17011:2004(E) Clause 7.11.4*

7.7.5 *ISO/IEC 17011:2004(E) Clause 7.11.5*

7.7.6 *ISO/IEC 17011:2004(E) Clause 7.11.6*

7.7.7 *ISO/IEC 17011:2004(E) Clause 7.11.7*

7.8 Extending Accreditation (ISO/IEC 17011:2004(E) Clause 7.12)

7.9 Suspending, Withdrawing or Reducing Accreditation

7.9.1 *ISO/IEC 17011:2004(E) Clause 7.13.1*

7.9.2 *ISO/IEC 17011:2004(E) Clause 7.13.2*

7.9.3 *ISO/IEC 17011:2004(E) Clause 7.13.3*

The following are additions as allowed by local laws and regulations.

7.9.4 Suspension, Withdrawal or Reduction of Accreditation

7.9.4.1 Suspension shall not exceed six months or the period of accreditation, whichever is longer. The purpose of suspension is to allow a CAB time to correct deficiencies or an area of non-compliance.

7.9.4.2 Subject to applicable laws, regulations and due process requirements, an accreditation body may suspend, withdraw or reduce a CAB's accreditation if the CAB fails to meet the standards for accreditation. The CAB shall retain accreditation for the scope of accreditation, where it continues to meet the requirements of the Standard. Reasons for suspension, withdrawal or reduction shall include but are not limited to:

7.9.4.2.1 if the accreditation body finds, during the on-site assessment, that the public interest, safety or welfare imperatively requires emergency action;

7.9.4.2.2 failure to complete proficiency testing studies as required;

7.9.4.2.3 failure to notify the accreditation body of any changes in key accreditation criteria as referenced in *ISO/IEC 17011:2004(E) Clause 7.2.1*;

7.9.4.2.4 failure to maintain a Quality System as required;

7.9.4.2.5 failure of the CAB to employ staff that meets qualifications for education, training and experience as required.

7.9.4.2.6 Misrepresentation of any fact pertinent to receiving or maintaining accreditation;

7.9.4.2.7 Denial of entry to an accreditation body's assessment team during normal business hours for the purpose of conducting an on-site assessment;

7.9.4.2.8 Failure to pass an on-site assessment conducted by an accreditation body;

7.9.4.2.9 Failure to complete responses or corrective actions from an accreditation body's assessment report.

7.9.4.2.10 Failure to pay fees.

- 7.9.4.3 A suspended CAB shall not continue to perform conformance assessment services for the affected scope of accreditation.
- 7.9.4.4 The accreditation body shall change the CAB's accreditation status from suspended to accredited when the CAB demonstrates to the accreditation body that it complies with the relevant requirements.
- 7.9.4.5 A suspended CAB shall not have to reapply for accreditation if the cause/causes for suspension are corrected within six months or before the end of the period of accreditation, whichever is longer.
- 7.9.4.6 If the CAB fails to correct the causes of suspension within six months after the effective date of the suspension or by the end of the period of accreditation (whichever is longer), the accreditation body shall withdraw or reduce the CAB's accreditation and the CAB is required to reapply for accreditation.
- 7.9.4.7 No CAB's accreditation shall be suspended, withdrawn or reduced without the right to due process as set forth by the Accreditation Body.

7.10 Records on CAB's

7.10.1 *ISO/IEC 17011:2004(E) Clause 7.14.1*

7.10.2 *ISO/IEC 17011:2004(E) Clause 7.14.2*

NOTE: The confidentiality of documents and records may be challenged in specific instances by public information requests under state or federal laws.

7.10.3 *ISO/IEC 17011:2004(E) Clause 7.14.3*

7.10.4 The accreditation body shall have a policy and procedure for retaining accreditation records for a minimum length of time as required by contractual obligations or pertinent territorial, state or federal laws and regulations.

7.11 Proficiency Testing and Other Comparisons for CABs

7.11.1 *ISO/IEC 17011:2004(E) Clause 7.15.1*

7.11.2 *ISO/IEC 17011:2004(E) Clause 7.15.2*

7.11.3 *ISO/IEC 17011:2004(E) Clause 7.15.3*

NOTE 3: Proficiency testing can occur and be administered by assessors during an on-site assessment of a CAB.

8.0 Responsibilities of the AB and the CAB (ISO/IEC 17011:2004(E) Clause 8)