ENVIRONMENTAL LABORATORY SECTOR

VOLUME 2

General Requirements for Accreditation Bodies Accrediting Environmental Laboratories

TNI Standard

P.O. Box 2439
Weatherford, TX 76086
817-598-1624
www.nelac-institute.org

PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Proficiency Testing 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.

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

Standard Revision History

Module	Action	Date
1	Working Draft Standard Published	January 14, 2007
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Environmental Laboratory Sector

Volume 2

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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 2

GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING ENVIRONMENTAL LABORATORIES

Module 1: General Requirements

TNI Standard

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

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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*)

ENVIRONMENTAL LABORATORY SECTOR

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Module 2: Proficiency Testing

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Sections 5.1.2, 5.2.1 c), 5.2.1 e), 5.2.1.f), 7.3 a), and 7.3 d) of this document have been processed in accordance with the TNI requirement for a Tentative Interim Amendment. The same or similar amendment will undergo the consensus standards development process within the time-frame specified in SOP 2-100.

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VOLUME 2, MODULE 2

Proficiency Testing

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VOLUME 2, MODULE 2

Proficiency Testing

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

1.1 Introduction

Volume 2, Module 2 provides the requirements that shall be used by an accreditation body (AB) to assess a laboratory to meet the proficiency testing requirements set forth in this Standard.

1.2 Scope

The TNI Proficiency Testing program (PT Program) is established to provide for a primary accreditation body (Primary AB) to evaluate a laboratory's performance under specified conditions relative to given set of criteria in a specific area of testing through analysis of samples provided by an external source yielding PT data that are technically defensible on the basis of the type and quality of the PT samples provided.

1.3 Applicability

1.3.1 Volume 2, Module 2 is applicable to any accreditation body (AB) that uses this Standard as the basis for accreditation of laboratories regardless of the number of personnel or the extent of testing performed by that laboratory.

2.0 NORMATIVE REFERENCES

Not applicable.

3.0 TERMS AND DEFINITIONS

For the purpose of this Standard, the relevant terms and definitions conform to *ISO/IEC 17011* and *ISO/IEC 17025*. Additional relevant terms are defined below.

3.1 **Analysis Date:** The calendar date of analysis associated with the analytical result reported for an accreditation or experimental field of proficiency testing.

3.2 **Experimental Field of Proficiency Testing (Experimental FoPT):** Analytes for which a laboratory is required to analyze a PT sample if they seek or maintain accreditation for the field of accreditation, but for which successful analysis is not required in order to obtain or maintain accreditation.

3.3 **Field of Accreditation:** Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

3.4 **Field of Proficiency Testing (FoPT):** Analytes for which a laboratory is required to successfully analyze a PT sample in order to obtain or maintain accreditation, collectively defined as: matrix, technology/method, and analyte.

3.5 **Primary Accreditation Body (Primary AB):** The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

3.6 **Proficiency Testing (PT):** A means to evaluate a laboratory's performance, under controlled conditions, relative to a given set of criteria, through analysis of unknown samples provided by an external source.

3.7 **Proficiency Testing Program (PT Program):** The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of results and the collective demographics and results summary of all participating laboratories.

3.8 **Proficiency Testing Provider (PTP):** A person or organization accredited by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.

3.9 **Proficiency Testing Provider Accreditor (PTPA):** An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.

3.10 **Proficiency Testing Sample (PT Sample):** A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.

3.11 **Proficiency Testing Study (PT Study):** A single complete sequence of circulation of proficiency testing samples to all participants in a proficiency test program.

3.12 **PT Study Closing Date:** The calendar date for which analytical results for a PT sample shall be received by the PT provider from the laboratory

3.13 **PT Study Opening Date:** The calendar date that a PT sample is first made available to any laboratory by a PT provider.

3.14 **Secondary Accreditation Body (Secondary AB):** An accreditation body that grants laboratory accreditation for a field of accreditation based on recognition of accreditation from a Primary Accreditation Body for the same field of accreditation.

3.15 **Study:** This term refers to a PT Study or Supplemental PT Study.

3.16 **Supplemental Proficiency Testing Study (Supplemental PT Study):** A PT sample that may be from a lot previously released by a PT Provider that meets the requirements for supplemental PT samples given in Volume 3 of this Standard but that does not have a pre-determined opening date and closing date.

3.17 **Supplemental PT Study Closing Date:** The calendar date for which analytical results for a PT sample shall be received by the PT provider from the laboratory.

3.18 **Supplemental PT Study Opening Date:** The calendar date that a PT sample is shipped from the PT provider to a laboratory.

3.19 **TNI PT Board:** A board consisting of TNI members or affiliates, appointed by the TNI Board of Directors, which is responsible for the successful implementation and operation of the TNI Proficiency Testing Program. The duties of the TNI PT Board are defined in the TNI PT Board Charter.

3.20 **Suspension:** The temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed six (6) months or the period of accreditation, whichever is longer, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard.

3.21 **Revocation:** The total or partial withdraw of a laboratory's accreditation by an accreditation body.

4.0 ACCREDITATION BODY REQUIREMENTS

4.1 Primary Accreditation Body (Primary AB)

4.1.1 The Primary AB shall ensure the laboratory meets the proficiency testing requirements for initial and continued accreditation as specified in this Standard. In this capacity the Primary AB shall have procedures in place to:

a) receive final evaluation reports from any PTPA-accredited PT provider;

b) assess a laboratory to ensure that the analysis of PT samples is performed in accordance with the requirements set forth in this Standard;

c) evaluate final evaluation reports as specified in this Standard;

d) deny, suspend or revoke a laboratory's accreditation when the laboratory has not met the requirements of the proficiency testing program as specified in this Standard;

e) maintain the current accreditation status of laboratories in their program in the National Database, when the database is established; and

f) notify all Secondary ABs of revocation of accreditation of any laboratory in their program.

4.1.2 The Primary AB shall allow a laboratory to withdraw from a study for any FoPT on or before the close date of the study. Withdrawing from a study shall not exempt the laboratory from meeting the semi-annual analysis requirement necessary for continued accreditation.

4.1.3 The Primary AB shall accept evaluation reports from any PTPA-accredited PT Provider.

4.1.4 The Primary AB shall accept results from non-PTPA-accredited PTPs when the FoPT is not available from any accredited PTP.

4.2 Secondary Accreditation Body (Secondary AB)

4.2.1 The Secondary AB shall accept the assessment decisions made by the Primary AB regarding a laboratory's performance and compliance with the proficiency testing requirements set forth in this Standard.

4.2.2 The Secondary AB shall not impose additional requirements for proficiency testing that are not included in this Standard as a requisite for initial or continued accreditation.

5.0 REQUIREMENTS FOR ACCREDITATION

5.1 Initial Accreditation

5.1.1 The Primary AB shall require that a laboratory seeking initial accreditation for a field of accreditation successfully analyze two (2) PT samples for the corresponding FoPT for which the laboratory seeks accreditation.

5.1.2 The Primary AB shall require that the PT samples for initial accreditation be obtained from any PTPA-accredited PT provider as part of a TNI-compliant PT study, unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

5.1.3 The analysis date of the PT samples for an accreditation FoPT shall be no more than eighteen (18) months prior to the application date for accreditation, with the analysis date of the most recent PT sample for an accreditation FoPT having been no more than six (6) months prior to the application date for accreditation.

5.1.4 There shall be at least fifteen (15) calendar days between the analysis dates of successive PT samples for the accreditation FoPT.

NOTE 1: The requirements for successful performance are described in Section 6.0.

NOTE 2: The requirements for supplemental PT samples are specified in Volume 3 of this Standard.

NOTE 3: The TNI PT Board maintains the official listing of FoPT and experimental FoPT on the TNI website.

5.2 Continued Accreditation

5.2.1 In order to maintain accreditation, the Primary AB shall have procedures in place that track the following requirements:

a) The laboratories analyze at least two (2) TNI-compliant PT samples per year for each accreditation FoPT for which the laboratory holds accreditation with the Primary AB.

b) The laboratories maintain a history of at least two (2) successful performances out of the most recent three (3) PT samples analyzed for the same accreditation FoPT.

c) The laboratories obtain PT samples from any PTPA accredited PTP unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

d) Ensure that the analysis dates of successive PT samples for the same accreditation FoPT are at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation or is being used to reinstate accreditation after suspension, in which case the analysis dates of successive PT samples for the same accreditation FoPT shall be at least fifteen (15) days apart.

e) Whole Effluent Toxicity testing laboratories shall analyze at least one (1) TNI-compliant PT sample per calendar year for each accredited FoPT for which the laboratory holds accreditation with the primary AB. The primary AB shall require corrective action when a PT study has been failed. Corrective action shall include:

i. A written corrective action report,

ii. A copy of the raw data used for the study,

iii. A copy of the current Standard Reference Toxicant (SRT) control chart relevant to the PT study, and

iv. Other documentation the laboratory deems necessary to support the conclusions of the report.

f) For Whole Effluent Toxicity Testing fields of proficiency testing, the study closing date for non DMR-QA Studies shall be no more than ninety (90) calendar days after the opening date of the study. For DMR-QA Studies, the laboratory must meet the time frames as stated in the Announcement letter.

5.2.2 When PT samples are not available for the FoPT from any PTPA recognized PT provider at least twice per year, the Primary AB shall require the laboratory to analyze the PT samples in the minimum time frame in which the PT samples are available from any PTPA recognized PT provider.

5.2.3 If the laboratory holds accreditation that is designated an experimental FoPT, the primary AB shall require the laboratory to analyze two (2) PT samples for the experimental FoPT per year using the same time frames specified for accreditation FoPT. However, successful performance of the experimental PT is not a requisite for initial or continued accreditation.

NOTE: A Primary AB may specify the month(s) in which laboratories within its accreditation authority shall participate in PT studies and if the Primary AB chooses to specify such, then the Primary AB shall adhere to the semi-annual schedule.

6.0 REQUIREMENTS FOR ASSESSMENT OF PT SAMPLE ANALYSIS

6.1 The Primary AB shall assess the laboratory to ensure that PT samples are tracked, prepared, and analyzed in the same manner as routine samples.

The Primary AB shall require the laboratory demonstrate through their records that:

a) PT samples are tracked through the laboratory in the same manner as routine samples;

b) PT samples are prepared according to the PT provider's instructions and subsequently handled as a routine sample;

c) PT samples are analyzed under the same analytical conditions and instrument calibrations as used for routine samples;

d) the type, composition, concentration, and frequency of quality control samples analyzed with the PT samples are the same as with routine samples;

e) PT samples are not analyzed multiple times unless routine samples are analyzed multiple times and results from multiple analyses are calculated in the same manner as routine samples;

f) the laboratory has procedures in place for the analysis of environmental and PT samples when the concentration range of the samples is outside of its normal range of measurement;

g) the laboratory has performed corrective action for any unacceptable evaluation received from the PT provider for any FoPT.

6.2 If a Primary AB discovers that a PTP has suggested or directed a laboratory to purchase QC standards that are specifically designed for a given PT sample or that the PT provider has given the laboratory analysis instructions beyond those specified in this Standard, the Primary AB shall report the results of their findings to the PTP's PTPA.

6.3 The Primary AB shall allow the laboratory to analyze the same PT sample using different technologies and/or multiple test methods for any FoPT. If a laboratory reports more than one test method per technology per FoPT, an unacceptable score for either test method shall result in an unacceptable score for both test methods for that FoPT.

7.0 REQUIREMENTS FOR ASSESSMENT OF FINAL EVALUATION REPORTS

7.1 The Primary AB shall complete the assessment of the final evaluation report within sixty (60) days of receipt of each study report and determine the accreditation status for any field of accreditation for which Not-acceptable evaluations were assigned for the corresponding FoPT.

7.2 The Primary AB shall consider the analytical result for a FoPT acceptable when the result reported by the laboratory for a FoPT is evaluated acceptable by the PT provider.

7.3 The Primary AB shall consider the analytical result for a FoPT not acceptable when:

a) the result reported by the laboratory does not meet the criteria for "acceptable" as specified in V3, Section 10.3 and associated subsections of this Standard. If the criteria in V3, Section 10.3 are met, and the result for the FoPT was scored "not acceptable" by the PTP, the AB shall overturn the performance evaluation and score the analytical result "acceptable";

b) the laboratory does not report results for an accredited FoPT within the timeframes specified in this Standard;

c) the laboratory makes any reporting error or omission that results in a non-specific match between the analytical result for the FoPT and any criterion that identifies the laboratory or the field of accreditation for which the PT sample was analyzed for the purpose of initial or continued accreditation; or

d) the laboratory submits analytical results for a FoPT from a PT provider that is not accredited by the PTPA unless there are not any PTPA-accredited PTP for the FoPT in which case the PT sample may be purchased from any PTP and the AB shall accept the results from the PTP selected by the laboratory.

8.0 REQUIREMENTS FOR ASSESSMENT OF CORRECTIVE ACTION

8.1 The Primary AB shall assess the laboratory to ensure that the laboratory has performed corrective action for each FoPT for which the laboratory receives an evaluation of not acceptable from the PT provider.

8.2 The Primary AB shall accept the results of a proficiency testing (PT) sample used for corrective action when the laboratory follows these requirements:

a) The PT sample used for corrective action shall be obtained from any PTPA recognized PT provider. A scheduled or a supplemental proficiency testing sample may be used for corrective action.

b) The laboratory shall notify the PT provider that the PT sample is for corrective action to ensure that the PTP provides a PT sample that meets the requirements for supplemental PT samples as specified in Volume 3 of this Standard.

c) There shall be at least fifteen (15) calendar days between the closing date of a previous study and the analysis date of any subsequent study for the same FoPT.

d) The subsequent PT sample shall be analyzed and reported in accordance with the requirements described in this Standard.

9.0 REQUIREMENTS FOR COMPLAINT RESOLUTION

9.1 The Primary AB shall submit questions about PT samples or performance evaluations made by the PTP to the PTP. If the PTP is unable or unwilling to resolve the questions, the Primary AB shall refer those questions to the PTP's PTPA.

9.2 The Primary AB shall have procedures to resolve a laboratory's question about the validity of a not acceptable evaluation made by the Primary AB for a FoPT in any PT sample or when the validity of

an entire study from a PTP may be questionable based on complaints, failure rates or data provided by the PTP.

10.0 SUSPENSION OR REVOCATION OF ACCREDITATION

10.1 The Primary AB shall suspend the accreditation of a laboratory for a FoPT when:

a) the laboratory receives an unacceptable score for the FoPT in two (2) out of the three (3) most recent studies attempted for the FoPT, or

b) the laboratory does not provide a corrective action report to the Primary AB within thirty (30) calendar days of request of such report.

10.2 To reinstate accreditation for a FoPT after suspension, the primary AB shall ensure that the laboratory meets the requirements for continued accreditation as described in this Standard.

10.3 The Primary AB shall revoke the accreditation of a laboratory for a FoPT when:

a) the laboratory does not participate in the PT program as required by this Standard, or

b) the laboratory submits results for PT samples that were generated by another laboratory.

10.4 To reinstate accreditation after revocation, the primary AB shall require the laboratory to meet the requirements for initial accreditation as described in this Standard.

NOTE: The Primary AB may have regulatory processes for revocation and/or suspension that supersede the conditions under which suspension or revocation of accreditation is taken by this Standard.

ENVIRONMENTAL LABORATORY SECTOR

VOLUME 2

GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING ENVIRONMENTAL LABORATORIES

Module 3: On-Site Assessment

TNI Standard

P.O. Box 2439
Weatherford, TX 76086
817-598-1624
www.nelac-institute.org

PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) On-Site Assessment 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 ISOI/IEC copyright protected language, but does reference applicable ISO clauses. In these situations, it is useful to read the TNI Standard along with the ISOI/IEC Standard. Wherever an ISO clause is referenced *(in italics),* the language from that clause is applicable. Any additional TNl 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.

Standard Revision History

Action	Date
Working Draft Standard Published	January 14, 2007
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Draft Interim Standard Published	December 15, 2007
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On-Site Assessment

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

This 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 *(ISO/IEC 17011:2004(E), Clause 3 Introduction)*

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)*

NOTE 2: Accreditation bodies perform the following types of on-site assessments:

a) Initial assessments: These are comprehensive and involve reviewing all key activities performed by a CAB applying for accreditation for the first time. Initial assessments are announced.

b) Reassessments: These are similar in scope to initial assessments except that the experience gained during previous assessments may 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 CAB to fulfill accreditation requirements.

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 2: This module is concerned with conformity assessment bodies (CAB) 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 *TNI Field Sampling and Measurement Organization Sector, Volume 2*.

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

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 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 Interested Parties *(ISO/IEC 17011:2004(E), Clause 3.14)*

3.15 Lead Assessor *(ISO/IEC 17011:2004(E), Clause 3.15)*

3.16 Reducing Accreditation *(ISO/IEC 17011:2004(E), Clause 3.16)*

3.17 Scope of Accreditation *(ISO/IEC 17011:2004(E), Clause 3.17)*

3.18 Surveillance *(ISO/IEC 17011:2004(E), Clause 3.18)*

3.19 Suspending Accreditation *(ISO/IEC 17011:2004(E), Clause 3.19)*

3.20 Withdrawing Accreditation *(ISO/IEC 17011:2004(E), Clause 3.20)*

3.21 Witnessing *(ISO/IEC 17011:2004(E), Clause 3.21)*

4.0 ON-SITE ASSESSMENT HUMAN RESOURCES

4.1 General Provisions

4.1.1 *ISO/IEC 17011:2004(E), Clause 6.1.2*

4.1.2 The accreditation body shall have documented procedures for assigning assessors to CABs. Such procedures shall consider the scope of accreditation and the complexity of operations of the CABs.

4.1.3 *ISO/IEC 17011:2004(E), Clause 6.1.3*

4.1.4 *ISO/IEC 17011:2004(E), Clause 6.1.4*

4.1.5 The accreditation body shall require assessors employed directly or under contract to affirm this commitment before they participate in their first assessment for the accreditation body or whenever the rules of the accreditation body pertaining to the accreditation of CABs change.

4.2 Education and Training Requirements for Assessors

4.2.1 *ISO/IEC 17011:2004(E), Clause 6.2.1*

4.2.2 *ISO/IEC 17011:2004(E), Clause 6.2.2*

4.2.3 An assessor shall hold at least a Bachelor's degree in a scientific discipline or have commensurate experience acquired by having performed verified assessments of environmental CABs.

4.2.4 An assessor shall have completed and attained a passing score on the written examination of courses approved by the employing accreditation body on assessing quality systems and all technical disciplines comprising a technology or combination of method and technology that the assessor will assess.

NOTE: Technical disciplines applicable to the environmental sector include microbiology, toxicity testing, inorganic non-metals, metals, organics, asbestos, radiochemistry, and field activities.

4.2.5 Before an assessor is allowed to perform unsupervised assessments for an accreditation body, the assessor shall have performed a minimum number of assessments under the supervision of an assessor whose competence has been qualified by the accreditation body. The qualified assessor shall observe the candidate assessor performing:

a) at least one assessment, for those assessors that have previous documented experience performing environmental CAB assessments; or

b) at least two assessments, for those assessors that have no documented experience performing environmental CAB assessments.

NOTE: A qualified assessor may evaluate the ability of an assessor to perform unsupervised assessments by: direct observation, observing the assessor perform an assessment in its entirety; or by limited observation, observing the assessor performing parts of an assessment and allowing the assessor to conduct some parts of the assessment independently.

c) The supervising qualified assessor shall document his or her conclusions to the accreditation body employing the candidate assessor. The accreditation body shall use the qualified assessors' conclusions to determine if an assessor candidate may perform unsupervised assessments or if additional supervised assessments beyond the minimum specified in this Standard are required to qualify the candidate assessor.

4.2.6 *ISO/IEC 17011:2004(E), Clause 6.2.3*

4.2.7 *ISO/IEC 17011:2004(E), Clause 6.2.4*

NOTE 2: Assessors that are able to communicate effectively through a translator or interpreter are considered to have complied with this requirement.

4.3 Records on Assessors

4.3.1 *ISO/IEC 17011:2004(E), Clause 6.4.2*

NOTE: These records are available to outside parties, upon request, subject to the rules of confidentiality of personnel records and the open records laws of an accreditation body.

4.3.2 Assessors shall sign qualification statements attesting the assessors meet the education and training required by this Standard. Accreditation bodies shall provide those statements to CABs upon request.

4.3.3 Before conducting an assessment, an assessor shall sign statements certifying the assessor has no conflict of interest with the CAB to be assessed and provide such statements, upon request, to the CAB.

4.3.4 It is possible that during the on-site assessment, assessors or CAB personnel become aware of previously unforeseen conflicts of interest. When this happens the lead assessor shall consult with the accreditation body, as soon as practicable, to determine how to proceed. The accreditation body shall take action to ensure that the assessment can proceed without compromising its integrity and impartiality or shall request that the assessment team terminate the assessment. If it is necessary to appoint a new assessment team, the accreditation body shall appoint it as soon as practicable without jeopardizing the CAB's request for accreditation.

4.3.5 *ISO/IEC 17011:2004(E), Clause 7.5.3 a*

NOTE: Assessors are employed by or on behalf of accreditation bodies to determine the competence of a CAB in meeting this Standard. The initial accreditation of a CAB is based primarily on the findings and observations of assessors. In many accreditation bodies, assessment team members can also be responsible for deciding the accreditation status of a CAB.

4.4 Standards of Professional Conduct for Assessors

4.4.1 *ISO/IEC 17011:2004(E), Clause 7.5.3 b*

4.4.2 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 CAB, CAB 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 CAB 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.

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

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

5.0 FREQUENCY OF ON-SITE ASSESSMENTS

5.1 After an initial assessment for accreditation, accreditation bodies shall perform reassessments at intervals of two years plus or minus six months. Once a CAB is accredited, accreditation bodies reserve the right to assess a CAB at any time during the accreditation period.

5.2 Accreditation bodies have authority to conduct unannounced assessments. Initial on-site assessments are announced.

6.0 ON-SITE ASSESSMENT PROCESS

6.1 Resource Review *(ISO/IEC 17011:2004(E), Clause 7.3)*

6.2 Subcontracting the Assessment

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

NOTE 2: External individual assessors and experts become part of the accreditation body assessment team and using them in this manner is not considered subcontracting. Hiring an external organization to perform entire assessments on behalf of an accreditation body is considered subcontracting.

6.3 Preparation for Assessment

ISO/IEC 17011:2004(E), Clause 7.5.1 is not applicable.

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

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

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

NOTE: 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 CAB 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.

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

6.3.5 *ISO/IEC 17011:2004(E), Clause 7.5.6*

NOTE: 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 CAB to be assessed. Assessors should strike a balance between thoroughness and practicality while determining the extent to which CABs meet this Standard. The examination of the systems, processes and procedures of the CAB should give a general sense of its past and present capabilities to perform work of known and documented quality.

6.3.6 *ISO/IEC 17011:2004(E), Clause 7.5.7*

NOTE 2: Each fixed-base branch or subsidiary of a CAB with multiple locations is customarily accredited separately by accreditation bodies and requires separate initial assessments. Mobile facilities of fixed-base CABs or mobile facilities not directed by or attached to a fixed-base CAB may be required to maintain distinct accreditations by different accreditation bodies and may require separate initial assessments.

6.3.7 *ISO/IEC 17011:2004(E), Clause 7.5.8*

NOTE: Each fixed-base branch or subsidiary of a CAB with multiple locations is customarily accredited separately by accreditation bodies and requires separate surveillance and reassessments. Mobile facilities of fixed-base CABs or mobile facilities not directed by or attached to a fixed-base CAB may be required to maintain distinct accreditations by different accreditation bodies and may require separate surveillance and reassessments.

6.3.8 *ISO/IEC 17011:2004(E), Clause 7.5.9*

NOTE: 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 CAB 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.

6.3.9 *ISO/IEC 17011:2004(E), Clause 7.5.10*

6.4 Document and Record Review

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

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

NOTE: The assessment team assigned to the CAB 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 CABs of a cancellation of an initial on-site assessment for those conditions as soon as 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.

6.5 Documents Provided to CAB

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 CAB assessment:

a) Assessment Confidentiality Notice: a document advising the CAB that it has the 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.

b) Checklists: any standard forms that the assessment team will use to evaluate conformance with this Standard or to document assessment findings.

c) Assessment Appraisal Form: a document used by the accreditation body to obtain feedback from CABs about the adequacy and the effectiveness of the assessment process, including the performance of the assessment team.

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

6.6 Confidential Business Information

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

6.7 Length of Assessment

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

NOTE: The length of an on-site assessment is determined by the scope of accreditation of a CAB, 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 CAB staff.

6.8 Opening Conference *(ISO/IEC 17011:2004(E), Clause 7.7.1)*

Attendance at the opening conference shall be documented in sheets or forms provided by the assessment team.

NOTE: 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 CAB individuals that will provide the assessment team with the necessary documentation, procedures to be followed when a CAB claims information to be confidential business information (CBI), and safety procedures that the CAB may think necessary for the protection of the assessment team.

6.9 Assessment Activities

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

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

NOTE: Assessment team members have the authority to conduct interviews with any or all CAB staff.

6.10 Analysis of Findings and Assessment Report

6.10.1 *ISO/IEC 17011:2004(E), Clause 7.8.1*

NOTE: 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.

6.10.2 *ISO/IEC 17011:2004(E), Clause 7.8.2*

6.11 Closing Conference

6.11.1 *ISO/IEC 17011:2004(E), Clause 7.8.3, Introduction*

a) Attendance at the closing conference shall be documented in sheets or forms provided by the assessment team.

b) The assessment team shall provide only preliminary determinations of potential findings and shall inform the CAB that final determinations concerning the number, nature and extent of assessment findings shall be made by the accreditation body after reviewing reported findings.

NOTE: 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.

6.12 Reporting Procedures

6.12.1 *ISO/IEC 17011:2004(E), Clause 7.8.3.b*

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

6.12.3 *ISO/IEC 17011:2004(E), Clause 7.8.3.c*

6.12.4 The CAB shall provide to the accreditation body a plan of corrective action to address findings in the assessment report within thirty calendar days from its receipt.

NOTE: Customarily, a CAB that does not address all findings satisfactorily within two responses is scheduled for a follow-up evaluation or is subject to administrative procedures that deny accreditation to the CAB or that reduce its scope of accreditation.

6.12.5 *ISO/IEC 17011:2004(E), Clause 7.8.4*

6.12.6 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 CAB, and until the findings of the assessment and the associated corrective actions have been finalized.

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

6.12.7 *ISO/IEC 17011:2004(E), Clause 7.8.5*

NOTE: The accreditation body may consult with the assessment team while reviewing CAB responses to nonconformities and before arriving at decisions on the accreditation status of a CAB.

6.12.8 *ISO/IEC 17011:2004(E), Clause 7.8.6*

6.13 Reassessment and Surveillance

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

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

ISO/IEC 17011:2004(E), Clause 7.11.3 is not applicable.

6.13.3 After an initial assessment for accreditation, accreditation bodies shall perform reassessments at intervals of two years plus or minus six months. Once a CAB is accredited, accreditation bodies reserve the right to assess a CAB at any time during the accreditation period.

6.13.4 Although most assessments are announced, accreditation bodies have authority to conduct unannounced assessments.

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

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

NOTE: A strict timeline defines enforceable deadlines commensurate with the severity of a finding.

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

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

NOTE: Extraordinary assessments may be performed when accreditation bodies receive complaints about CABs or when CABs experience changes in ownership, key personnel, location, and scope of accreditation.

7.0 CHANGES IN CAB CAPABILITIES

ISO/IEC 17011:2004(E), Clause 8.1.2 Introduction is not applicable.

A CAB shall inform the accreditation body within thirty days of any significant changes relevant to the CAB's accreditation in any aspect of its status or operation relating to:

a) *ISO/IEC 17011:2004(E), Clause 8.1.2.a*

b) *ISO/IEC 17011:2004(E), Clause 8.1.2.b*

c) *ISO/IEC 17011:2004(E), Clause 8.1.2.c*

d) *ISO/IEC 17011:2004(E), Clause 8.1.2.d*

e) *ISO/IEC 17011:2004(E), Clause 8.1.2.e*

f) *ISO/IEC 17011:2004(E), Clause 8.1.2.f*