



FIELD SAMPLING AND MEASUREMENT ORGANIZATION SECTOR

VOLUME 2

GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING FIELD SAMPLING AND MEASUREMENT ORGANIZATIONS

~~TNI Standard~~ Working Draft Standard

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

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PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Field Activities 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 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 organizations performing sampling or field measurements.

Standard Revision History

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VOLUME 2 GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING FIELD SAMPLING AND MEASUREMENT ORGANIZATIONS

Table of Contents

1.0	INTRODUCTION, SCOPE AND APPLICABILITY.....	1
1.1	Scope	1
2.0	NORMATIVE REFERENCES.....	1
3.0	TERMS AND DEFINITIONS.....	1
3.1	Accreditation.....	1
3.2	Accreditation Body.....	1
3.3	Accreditation Body Logo.....	1
3.4	Accreditation Certificate.....	1
3.5	Accreditation Symbol.....	1
3.6	Appeal	1
3.7	Assessment.....	1
3.8	Assessor.....	1
3.9	Complaint	2
3.10	Conformity Assessment Body.....	2
3.11	Consultancy.....	2
3.12	Expert.....	2
3.13	Extending Accreditation.....	2
3.14	Interested Parties	2
3.15	Lead Assessor.....	2
3.16	Reducing Accreditation.....	2
3.17	Scope of Accreditation.....	2
3.18	Surveillance.....	2
3.19	Suspending Accreditation.....	2
3.20	Withdrawing Accreditation	2
3.21	Witnessing.....	2
3.22	Field.....	2
3.23	Field Measurement	2
3.24	Field Sampling	2
3.25	Finding	2
3.26	FSMO	2
3.27	Matrix.....	2
3.28	Preservation	3
3.29	Proficiency Testing	3
3.30	Sampling	3
4.0	ACCREDITATION BODY.....	3
4.1	Legal Responsibility.....	3
4.2	Structure.....	3
4.3	Impartiality	4
4.4	Confidentiality.....	5
4.5	Liability and Financing.....	5
4.6	Accreditation Activity	5
5.0	MANAGEMENT.....	5
5.1	General.....	5
5.2	Management System.....	5
5.3	Document Control.....	5

5.4 Records 5

VOLUME 2
GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING FIELD
SAMPLING AND MEASUREMENT ORGANIZATIONS

Table of Contents cont.

5.5	Nonconformities and Corrective Actions.....	6
5.6	Preventive Actions.....	6
5.7	Internal Audits.....	6
5.8	Management Reviews.....	6
5.9	Complaints.....	6
6.0	HUMAN RESOURCES.....	6
6.1	Personnel Associated with the Accreditation Body.....	6
6.2	Personnel Involved in the Accreditation Process.....	6
6.3	Monitoring.....	10
6.4	Personnel Records.....	10
7.0	ACCREDITATION PROCESS.....	10
7.1	Accreditation Criteria and Information.....	10
7.2	Application for Accreditation.....	11
7.3	Resources Review.....	14
7.4	Subcontracting the Assessment.....	14
7.5	Preparation for Assessment.....	14
7.6	Document and Record Review.....	15
7.7	On-Site Assessment.....	15
7.8	Analysis of Findings and Assessment Report.....	20
7.9	Decision-Making and Granting Accreditation.....	22
7.10	Appeals.....	27
7.11	Reassessment and Surveillance.....	28
7.12	Extending Accreditation.....	29
7.13	Suspending, Withdrawing or Reducing Accreditation.....	29
7.14	Records on CABs (FSMOs).....	29
7.15	Proficiency Testing and Other Comparisons for Laboratories.....	30
8.0	RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB.....	31
8.1	Obligations of the CAB.....	31
8.2	Obligations of the Accreditation Body.....	31
8.3	Reference to Accreditation and Use of Symbols.....	31

VOLUME 2

GENERAL REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING FIELD SAMPLING AND MEASUREMENT ORGANIZATIONS

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

This TNI Standard includes requirements applicable to Accreditation Bodies (AB) engaged in accrediting field sampling and measurement organizations (FSMO).

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.

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.

1.1 SCOPE (*ISO/IEC 17011:2004(E), Clause 1*)

NOTE 2: The term FSMO under this TNI Standard corresponds to Conformity Assessment Bodies under *ISO/IEC 17011*. The term Accreditation Bodies under this TNI Standard corresponds to Accreditation Bodies under *ISO/IEC 17011*.

NOTE 3: This Standard specifies the essential requirements and processes that relate to an accreditation body and to a FSMO in the granting of, and application for, accreditation, respectively for environmentally-related field sampling and measurements.

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 2: This TNI Standard is concerned with conformity assessment bodies commonly known as field sampling and measurement organizations.

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 provided by government 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)

Additional Terms and Definitions

NOTE: The relevant definitions listed in the referenced ISO documents apply when using this document. Definitions related to this document, which are used differently or do not exist in the ISO references are defined below.

3.22 Field: Any location outside the controlled environment of a laboratory.

3.23 Field Measurement: The quantitative determination of physical, chemical, biological or radiological properties of a matrix by measurements made in the field.

3.24 Field Sampling: The process of obtaining a representative portion of an environmental matrix suitable for laboratory or field measurement or analysis.

3.25 Finding: An assessment conclusion referenced to an accreditation standard and supported by objective evidence that identifies compliance with and/or a deviation from an accreditation standard requirement.

3.26 FSMO: Field Sampling and Measurement Organization, See Clause 1.0.

3.27 Matrix: The substance within which a measurement is made or from which a ~~separate~~ sample is collected. The matrix includes the physical, chemical, biological or radiological characteristics of the

substance ~~which may interfere with the measurement of some desired characteristic of the substance.~~

3.28 Preservation: Physical or chemical treatment of a sample to prevent the gain or loss of target analytes before analysis; filtration, refrigeration and addition of chemical reagents are examples of preservation techniques.

3.29 Proficiency Testing (PT): A means of evaluating an organization's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by ~~a an external source~~ Proficiency Test Provider.

3.30 Sampling: See (*ISO/IEC 17025; 2005(E), Clause 5.7.1, NOTE 1*)

3.31 Proficiency Testing Provider: Any private party or government entity accredited by the TNI recognized PTPA that meets the stringent criteria to produce and distribute TNI samples, evaluate study results, against published FOPT performance criteria and report the results to FSMOs, ABs, and their PTPA.

3.32 Proficiency Testing Provider Accreditor (PTPA): An organization with technical expertise, administrative capacity and financial resources sufficient to implement and operate a program of PTP evaluation and oversight that meets the responsibilities and requirements established by the TNI FSMO and NELAC Standard.

3.33 Measurement: ISO/IEC Guide 99:2007 Clause 2: Process of experimentally obtaining one or more quantity values that can be reasonably attributed to a quantity.

4.0 ACCREDITATION BODY

4.1 Legal Responsibility (*ISO/IEC 17011:2004(E), Clause 4.1*)

4.1.1 An accreditation body shall seek recognition for its accreditation activities from ~~an applicable standards setting authority~~ The NELAC Institute (TNI) that shall use this Standard as the basis for granting recognition.

NOTE 1: An accreditation body for an FSMO may be a government authority or non-government organization engaged in specifically assessing conformity to these Standards.

NOTE 2: A governmental authority, having the authority, rights and responsibilities necessary to carry out an FSMO accreditation program, may be a territory, state, or federal entity.

NOTE 3: A government authority may designate the appropriate agencies or departments as its recognized accreditation body for the accreditation for which recognition is being sought by the FSMO.

NOTE 4: A government accreditation body may contract with a non-government organization to be its recognized agent for all or part of its accreditation activities for the accreditation for which recognition is being sought by a FSMO provided that the government authority retains final authority over the agent in all matters relating to FSMO accreditation activities as defined within this Standard and agreed contract terms.

4.2 Structure

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

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

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 federal or state 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*

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

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*

4.3.2.1 The accreditation body, within the scope and applicability of its policies and applicable rules and regulations for government ABs~~of its prevailing rules and regulations~~, shall also establish one or more committees for assistance in interpretation of requirements and for advising the accreditation body on the granting of accreditation and on any technical matters relating to the operation of its accreditation program.

NOTE 1: Members of advisory committees who may have a conflict of interest shall not have access to information about granting accreditation to a specific FSMO.

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

4.3.3.1 The accreditation body shall have no rules, regulations, procedures or practices that:

- a) impose any financial conditions or restrictions for participation in the accreditation program other than any accreditation fees; or that
- b) conflicts with any territorial, state or federal laws governing discrimination.

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

4.3.4.1 The accreditation body shall have a policy or arrangements to ensure that its management and technical staff are subject to the same conflict of interest disclosure requirements (designed to identify and eliminate potential conflict-of interest problems) as for the parent organization itself or for those government programs, units, divisions, bureaus etc., housing the accreditation body.

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: The requirement that an accreditation body and its related bodies have a distinctive name, logo and or symbol may not be applicable or practical for government accreditation bodies.

~~4.3.7.1 For the instance of an Accreditation Body and FSMOs that are organizational units of the same department or agency of a government authority which is an accreditation body, or that have other organizational conflicts of interest, the AB shall:~~

~~a) demonstrate by organizational structure, that the accreditation body's accreditation program manager and FSMO's technical director (however named) do not report within the same chain-of-command; and~~

~~b) demonstrate by policies and procedures, that conflicts of interest do not exist; or~~

~~c) direct the FSMO to apply for accreditation through any other recognized accreditation body.~~

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

4.5 Liability and Financing

4.5.1 *ISO/IEC 17011:2004(E), Clause 4.5.1*

NOTE 1: A government accreditation body shall have the same arrangements to cover liabilities and workman's compensation claims arising from its operations and activities as all other programs, units, divisions, bureaus, etc., in the department or agency in which the accreditation body is located.

NOTE 2: A non-government accreditation body shall have appropriate coverage for liabilities and workman's compensation claims arising from its accreditation activities.

4.5.2 *ISO/IEC 17011:2004(E), Clause 4.5.2*

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*)

~~NOTE: The requirements within TNI Standard "General Requirements for Field Sampling and Measurement Organizations", Volume 1, and ISO/IEC 17025 or ISO/IEC 9001 could serve as the basis for a quality manual.~~

~~5.2.4 Quality Manual~~

~~The accreditation body shall have a quality manual appropriate to the type, range and volume of work performed as part of its accreditation activities and that addresses all requirements of this Standard.~~

~~NOTE: The requirements within TNI Standard "General Requirements for Field Sampling and Measurement Organizations", Volume 1, and ISO/IEC 17025 or ISO/IEC 9001 could serve as the basis for a quality manual.~~

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

5.4.3.31 The accreditation body shall maintain in hard copy, electronic media or other means, a controlled document or documents describing its environmental FSMO accreditation program including:

- a) at a minimum, all information required of an FSMO to acquire and maintain accreditation through the accreditation body; and
- b) additional documentation requirements as described in sections 4.6, 6.2 and 7.1.2 of this volume.

5.4.3.42 The accreditation body shall review such documents annually.

- a) A written record of this review shall be readily available for inspection upon request from the applicable registrar or other standards setting authority.
- b) When the review of such document or documents reveals that the accreditation body's FSMO accreditation program has changed or is otherwise different from the accreditation program described in such documents, the document or documents shall be updated within thirty (30) calendar days of completion of the review.

5.4 Records (ISO/IEC 17011:2004(E), Clause 5.4)

~~5.4.3~~ The accreditation body shall maintain in hard copy, electronic media or other means, a controlled document or documents describing its environmental FSMO accreditation program including:

- ~~a)~~ at a minimum, all information required of an FSMO to acquire and maintain accreditation through the accreditation body; and
- ~~b)~~ additional documentation requirements as described in sections 4.6, 6.2 and 7.1.2 of this volume.

~~5.4.4~~ The accreditation body shall review such documents annually.

- ~~a)~~ A written record of this review shall be readily available for inspection upon request from the applicable registrar or other standards setting authority.
- ~~b)~~ When the review of such document or documents reveals that the accreditation body's FSMO accreditation program has changed or is otherwise different from the accreditation program described in such documents, the document or documents shall be updated within thirty (30) calendar days of completion of the review.

5.5 Nonconformities 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

5.7.1 ISO/IEC 17011:2004(E), Clause 5.7.1

5.7.1.1 Internal audits shall include a review and effectiveness assessment of the accreditation body's quality manual.

~~5.7.1.2~~ When applicable, the accreditation body shall use the same policies and procedures for internal audits as used by all other programs, units, divisions, bureaus, etc., in the department or agency or organization in which the accreditation body is located.

5.7.2 ISO/IEC 17011:2004(E), Clause 5.7.2

NOTE: The frequency of internal audits, normally at least once per year, should not be less than once every twenty-four (24) months if augmented (to demonstrate effective management systems) by alternate-year-audit by external agents.

5.7.3 *ISO/IEC 17011:2004(E), Clause 5.7.3*

5.8 Management Reviews (ISO/IEC 17011:2004(E), Clause 5.8)

m) proficiency testing program

5.9 Complaints (ISO/IEC 17011:2004(E), Clause 5.9)

6.0 HUMAN RESOURCES

6.1 Personnel Associated with the Accreditation Body

6.1.1 *ISO/IEC 17011:2004(E), Clause 6.1.1*

~~6.1.1.1 — The accreditation body shall have physical and human resources required for the operation of its accreditation program, necessary to complete action on an application within nine (9) months from the time a completed application is first received from the FSMO. This time period shall not apply if delays are caused by the FSMO responses to the accreditation process, on-site assessment or proficiency testing requirements beyond the required time limits set forth in this Standard.~~

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

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

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

NOTE: Rules defined by the accreditation body should include ethics policies and compliance requirements. See Clause 6.2.5.2, Note 3.

6.2 Personnel Involved in the Accreditation Process (ISO/IEC 17011:2004(E), Clause 6.2)

6.2.5 Assessor's Roles and Responsibilities

6.2.5.1 Accreditation program management

In addition to the management system representative (see Clause 5), the accreditation body shall identify an individual or individuals responsible for day-to-day management of the accreditation program(s). This individual shall:

- a) be an employee of the accreditation body, and
- b) have the technical expertise necessary to:
 - i. plan and manage the matrix-specific FSMO accreditation program;
 - ii. coordinate various facets of the FSMO accreditation program with territory, state, and federal or non-government accreditation bodies, as applicable; and
 - iii. provide input on the technical competence and performance of contractors or employees involved in the accreditation process.

6.2.5.2 Standards of professional conduct for assessors

NOTE 1: Professional standards apply to every assessor, whether a government or non-government employee or an employee of a third party organization (agent), conducting assessments under an agreement with an accreditation body.

NOTE 2: Assessors that knowingly engage in unprofessional activity may be liable for punitive actions as initiated by the assessor's accreditation body.

NOTE 3: The Standards for Professional Conduct, as outlined in this Clause, are based upon US 5 CFR 2635, "Standards of Ethical Conduct for Employees of the Executive Branch."

a) Assessors shall:

- i. have no interest at play other than that of the accreditation body during the entire accreditation process;
- ii. act impartially and not give preferential treatment to any organization or individual;
- iii. provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, and/or disability;
- iv. not use their position for private gain; nor solicit or accept any gift or other item of monetary value from any FSMO, FSMO representative, or any other affected individual or organization doing business with, or affected by, the actions of the assessor's employer or accreditation body;
- v. not hold financial interests that conflict with the conscientious performance of their duties;
- vi. not engage in financial transactions using information gained through their positions as assessors to further any private interest;
- vii. not engage in employment activities (seeking or negotiating for employment) or attempt to arrange contractual agreements with a FSMO that would conflict with their duties and responsibilities as an assessor;
- viii. not knowingly make unauthorized commitments or promises of any kind purporting to bind the affected accreditation body; and shall
- ix. attempt to avoid any actions that could create even the appearance that they are violating any of the standards of professional conduct outlined in this clause.

b) Assessors shall report to the accreditation body any personal issues or activities that constitute a conflict of interest before an assessment occurs.

- i. If an unforeseen conflict becomes apparent during an assessment, the lead assessor shall consult, as soon as practicable, with the accreditation body to determine how to proceed with the assessment.
- ii. The accreditation body shall determine if the reported issues and activities regarding a specific assessor constitute, or can be construed as, conflicts of interest.
- iii. 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.

- iv. The accreditation body shall have in place an independent appeals process in the event the FSMO and the accreditation body cannot achieve resolution on the conflict.

6.2.6 Basic On-Site Assessment Personnel Qualifications and Training

6.2.6.1 Qualifications

An assessor shall be qualified by the accreditation body prior to conducting an assessment.

- a) Each assessor shall complete or comply with the following:
 - i. Sign a statement before conducting an assessment certifying that no conflict of interest exists;
 - ii. Provide any supporting information as required by the accreditation body. Failure to provide this information makes the proposed assessor ineligible to participate in the assessment program; and
 - iii. Be an experienced professional and hold at least a Bachelor's degree in a scientific discipline or have equivalent experience in environmental sampling and measurement.

iv. judged proficient by accreditation body.

~~b) Each assessor shall participate in at least four actual on-site assessments under the supervision of a qualified assessor (see following exception, item c).~~

~~c) For a newly recognized accreditation body, assessors shall not be required to complete assessments under the supervision of a qualified assessor provided:~~

~~i. they have completed at least four other FSMO on-site assessments;~~

~~ii. they have been judged proficient by the accreditation body; and~~

~~iii. documentation of completion of the assessments and a statement of proficiency by the accreditation body is available.~~

6.2.6.2 Training

- a) Each assessor shall satisfactorily complete a training program approved by the accreditation body responsible for on-site assessments. The training program shall include ongoing changes to or adoption of applicable regulations, standards and sampling and measurement methods and technologies.
- b) Each accreditation body shall be responsible for ensuring that the training course used to train its assessors meets this Standard. This training program requires assessors to participate in a **TNI Approved Assessor** Basic Training Course, including attainment of a passing score on the written examination for the course.
- c) Assessors shall complete Technical Training requirements for at least one technical discipline addressing sampling (grab or composite) or measurement technologies or a combination of technology and method in areas of accreditation, such as, for example:
 - i. air matrices (ambient, indoor and outdoor air, point source and fugitive emissions, soil atmospheres, air and continuous emissions monitoring);

- ii. solids, including soil, sediment, sludge and solids monitoring;
 - iii. water, including surface, waste, drinking and groundwater;
 - iv. biological samples including, for example, whole animals, fish, shell, plant or animal tissue and microorganisms.
- d) Assessors shall complete annual refresher/update training in order to:
- i. be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;
 - ii. have a thorough knowledge of the relevant assessment methods and assessment documents;
 - iii. be thoroughly familiar with the various forms of records described in Clause 7.6, Document and Record Review;
 - iv. be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;
 - v. have a working knowledge and be conversant with specific sampling and measurement techniques or types thereof for which the accreditation is sought and, where relevant, with any associated sampling preservation procedures; and
 - vi. be able to communicate effectively, both orally and in writing.

NOTE 1: Technical disciplines may be related to regulatory programs such as the CAA, RCRA, TSCA, SARA, FIFRA, CWA, CERCLA and SDWA.

NOTE 2: The assessor training program can be implemented by either an accreditation body, assessor bodies, or other approved entities.

NOTE 3: The purpose of technical training is to ensure consistency of knowledge and techniques among the assessors. The technical training assumes a level of basic knowledge of the subject and concentrates on the elements of the sampling and measurement technology or methods that are key to properly assuring FSMO competency to deliver data of known and documented quality.

6.2.7 Expert Roles and Responsibilities

The accreditation body shall identify experts capable of performing specific tasks within assessment teams based on their education, training, technical knowledge, skills and experience. See *ISO/IEC 17011:2004(E) Clauses 6.2.1 through 6.2.4*.

NOTE 1: Experts perform specific and limited tasks within assessment teams by witnessing FSMO activities within the expert's field of competence and reporting to the lead assessor. See *ISO/IEC 17011:2004(E) Clause 6.1.3*.

NOTE 2: Experts have the same ethical responsibilities as all other personnel associated with the accreditation body. See *ISO /IEC 17011:2004(E) Clause 6.1.4*.

6.3 Monitoring

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

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

6.3.2.1 Notwithstanding *ISO/IEC 17011:2004(E) Clause 6.3.2*, each assessor conducting assessments of FSMOs shall be observed on-site at least once in every three years. Supporting evidence (see the referenced ISO clause) is not sufficient in itself to define the continued competence of an assessor.

NOTE: The process or system to evaluate assessor performance should be sufficient to demonstrate compliance with this Standard and be consistent with the organization's employee evaluation program.

6.4 Personnel Records

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

NOTE: Personnel involved in the accreditation process may include, but are not limited to, assessors, experts, individuals evaluating accreditation applications or assessment reports and individuals making accreditation decisions.

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

- h) number of assessments completed; and
- i) date of most recent updating of record.

7.0 ACCREDITATION PROCESS

7.1 Accreditation Criteria and Information

7.1.1 *ISO/IEC 17011:2004(E), Clause 7.1.1*

7.1.1.1 The criteria for accreditation of FSMOs (conformity assessment bodies) shall be based on ISO/IEC Guide 17011, and relevant modifications for application to Field Sampling and Measurement Organizations as given in this TNI Standard, General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations, Volume 2.

7.1.1.2 General Applicability

- a) Accreditation shall apply to the FSMO (organization) and not to any one individual or group of individuals within an organization.
- b) Accreditation shall be granted as follows:
 - i. an Umbrella Accreditation: To a parent FSMO operating under a single common Management system (e.g., at a corporate or divisional level), and providing field sampling and measurements across various jurisdictions from multiple non-contiguous fixed-based locations; or
 - ii. an Individual Accreditation: To a single fixed-base FSMO entity or to each non-contiguous entity of a parent FSMO, each with its own management system, providing sampling and measurements across various jurisdictions.
- c) The accreditation body shall determine whether a FSMO qualifies for an umbrella accreditation or for an individual accreditation, taking into account the presence or absence of a common management system, ownership/management, technical oversight, and scope of accreditation as detailed in the FSMO accreditation application.

NOTE 1: FSMO activities, whether from a fixed or mobile base, that encompass multiple field sampling and measurement locations, do not require separate accreditations.

NOTE 2: A mobile sampling and measurement unit, operating under the FSMO management system, does not require a separate accreditation.

7.1.2 *ISO/IEC 17011:2004(E), Clause 7.1.2*

7.1.3 Accreditation Applicability

7.1.3.1 Types of FSMOs and Applicability

Accreditation shall apply to those FSMOs engaged in environmental field sampling and measurement activities (for example, research, development, monitoring and regulatory compliance) and reporting under federal, state, and local (mandated or not) testing programs, or for other purposes.

NOTE: Field sampling and measurement activities may be related to regulatory programs such as the CAA, RCRA, TSCA, SARA, FIFRA, CWA, CERCLA, SDWA and CEM monitoring or may be a result of other provisions or specialty areas promulgated as a result of action by a local, state or federal authority.

7.1.3.2 ~~Scope of Accreditation~~~~Types of Matrices and Applicability~~

~~————7.1.3.2.1 Accreditation shall be granted for Field Sampling by Matrix/Technology, and/or for Field Measurements by Matrix/Technology.~~

~~NOTE: Accreditation may also be granted for Field Sampling/Measurement Methods, or analyte as specific to programs listed in 7.1.3.1.~~

~~7.1.3.2.2 The accreditation body shall make publicly available a list of scopes they are competent to assess. Accreditation may be granted by Matrix (either sampling or measurement) such as:~~

~~a) air matrices (ambient, indoor, outdoor air, point source and fugitive emissions, soil atmospheres, air monitoring, and continuous emissions monitoring);~~

~~b) solids, including soil, sediment, sludge and solids monitoring;~~

~~c) water, including surface, waste, drinking and groundwater; and~~

~~d) biological samples, including, for example, whole animals, fish, shell, animal or plant tissue and microorganisms.~~

~~NOTE: Accreditation may also be granted by Field Sampling/Measurement methods, or analyte/analyte group as specific to those programs defined previously under "Types of FSMOs" and "Types of Matrices".~~

7.2 Application for Accreditation

7.2.1 *ISO/IEC 17011:2004(E), Clause 7.2.1*

7.2.1.1 Components of Accreditation

7.2.1.1.1 Initial Application

An Accreditation body shall require a FSMO seeking accreditation to complete and submit a formal application package to the accreditation body to include:

- a) legal name and contact mailing address;
- b) billing address (if different from a);
- c) name and address of owner(s) if privately held;
- d) a scope of accreditation including:
 - i. field sampling and field ~~measurement technologies analytical methods~~ for which accreditation is being requested;
 - ii. ~~a complete listing of sampling and measurement methods employed including analytes to be~~; and
 - iii. address(s) of all FSMO entities under the scope of the accreditation, and address(s) of the field sampling and measurement locations, if applicable, for selection of on-site assessment observations.
 - 1. ~~The accreditation body shall have in place a procedure for mutually selecting and agreeing, with the FSMO, the field sampling and measurement locations and sampling/measurement personnel for observations in accordance with the scope of the requested accreditation.~~
 - 2. ~~The accreditation body shall have in place a procedure for selecting field sampling and measurement locations that provide a representative sampling of such locations and a representative sampling across field sampling and analytical methods and FSMO locations, such that all activities are assessed within an agreed timeframe not to exceed three accreditation cycles.~~
- e) name and contact information of the responsible person(s) and or quality assurance officer, however named;
- f) normal hours of operation for each FSMO entity included in the Scope;
- g) a description of the FSMO type (for example, commercial, federal, hospital or health care, state, academic institute, public water system, public wastewater system, industrial/industry with discharge permits, mobile, consulting or engineering firm);
- h) ~~job description summaries of management and supervisory positions responsible for field sampling and measurement activities, with reporting relationships between positions;~~
- i) ~~job description summaries of field sampling and measurement positions, with reporting relationships between positions;~~

NOTE: Documentation of representative individual field sampling and measurement personnel along with their qualifications and any applicable personal certifications will be examined by the accrediting body during on site assessments (see 7.7.3).

- jh) a summary of mobile units, listed by function, that are integral to field sampling and measurement activities and are employed by the FSMO facilities being considered for accreditation;
- ki) a description of the FSMOs proficiency testing program, and copies of the results of the previous proficiency testing three Proficiency Testing samples/programs performed, if applicable;
- lj) other documents as requested by the accreditation body or approved assessment team.
 - i. Examples of documents that shall be provided include those related to the quality manual and evidence of its application across the FSMO locations.
 - ii. Examples of documents that may be requested include representative Standard Operating Procedures, Work Instructions, copies of calibration and maintenance records, field notebooks/records, internal or external quality audits, corrective/preventive action reports, and organization charts, etc.
 - iii. Examples of documents that verify the implementation of section 5.9.1 of ISO 17025 and the Vol. 1 TNI-FSMO Standard

7.2.1.1.2 Personnel qualifications/certifications statements

- a) As part of the application package, the accreditation body shall request from the FSMO a summary table of the qualifications, experiences, training, and any certifications of designated supervisory personnel in their areas of responsibilities, specifically those related to the technical and quality aspects of sampling and measurement activities.
- b) Educational standards, experience, and training for these designated personnel shall be at the discretion of the FSMO management, but typical of industry standards. The accreditation body and/or assessment team may provide feedback on the adequacy of the designated personnel to carry out their assigned FSMO responsibilities, but shall not deny accreditation status based on perceived inadequacies in this area.
- c) The accreditation body and/or on-site assessment team shall review the qualifications, training, and experiences of selected FSMO personnel actually engaged in field sampling and measurement as part of assessment activities, including observations of sampling and measurement methods.
- d) The accreditation body or assessment team shall have the option to request information on or observe staff not originally indicated in the application package if such inclusion is pertinent to the scope of the accreditation or on-site assessment.

NOTE: Applicable certifications may include, for example, Registrations or Certifications to professional standards (e.g., registered geologist, Professional Engineer).

7.2.1.1.3 Accreditation fee

The accreditation body shall determine the applicability, frequency, and level of any fees.

NOTE: If accreditation is sought from more than one accreditation body, each accreditation body may assess the FSMO an applicable accreditation fee.

7.2.2 *ISO/IEC 17011:2004(E), Clause 7.2.2*

7.2.3 *ISO/IEC 17011:2004(E), Clause 7.2.3*

7.3 Resources Review (ISO/IEC 17011:2004(E), Clause 7.3)

7.3.3 The accreditation body shall document the procedure for conducting an internal audit of its ability to assess a FSMO (CAB) and document the audit results.

7.3.4 The accreditation body shall initiate processing of completed applications for accreditation in the chronological order that the applications were received.

7.4 Subcontracting the Assessment (ISO/IEC 17011:2004(E), Clause 7.4)

7.5 Preparation for Assessment

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

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

NOTE: Experts are not eligible to conduct staff interviews, observe, or cite deficiencies in the absence of an assessor.

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

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

7.5.4.1 Upon request, the accreditation body shall provide the FSMO with all forms and records pertaining to the assessor team member's credentials and qualifications, including certification of freedom from conflicts of interest that may impact the assessors' objectivity and impartiality. Such information shall be provided to the FSMO management even if the request is made after the conclusion of the on-site visit.

7.5.4.2 The accreditation body shall request the FSMO to provide written consent or objections on the choice of a particular assessor.

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

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

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

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

7.5.8.1 The accreditation body shall have in place a procedure for mutually selecting and agreeing, with the FSMO, the field sampling and measurement locations and sampling/measurement personnel for observations in accordance with the scope of the requested accreditation.

7.5.8.2 The accreditation body shall have in place a procedure for selecting field sampling and measurement locations that provide a representative sampling of such locations and a representative sampling across field sampling and analytical methods and FSMO locations, such that all activities are assessed within an agreed timeframe not to exceed three accreditation cycles.

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

7.5.9.1 The AB shall provide notice and scope of an announced on-site assessment, for example, by letter, email, telephone call, or published schedule, on the agreed date and schedule and shall request the FSMO respond with the acceptance of the proposed time, date and location.

7.5.9.2 The on-site assessment shall occur during normal business hours unless prior arrangements have been made or extenuating circumstances intervene.

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

7.6 Document and Record Review

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

7.6.1.1 Pre-Assessment Documents

After receipt of an accreditation application, the assessment team shall:

- a) request in writing any additional information, such as pertinent quality and training records, operating procedures, documents, and methods to be examined, if not part of the application package, necessary for a successful assessment, including a rationale for the request;
- b) review other relevant accreditation correspondence, status and any pending actions and determine:
 - i. whether site access or security advance planning/notification is required;
 - ii. whether any special site safety procedures may be required of the assessment team.

7.6.1.2 Assessment Documents

Prior to an announced assessment (for items a) and b)), or at the conclusion of an on-site assessment (for items c) to e)), the lead assessor shall provide the FSMO with:

- a) notice and scope of an announced on-site assessment, for example, by letter, email, telephone call, or published schedule, and the FSMO acceptance of the proposed time, date and location;
- b) copies of any checklists used to evaluate conformance with this Standard and to document assessment findings if not already provided by the AB;
- c) an effectiveness/adequacy appraisal form (for feedback from the FSMO to the assessors on the processes employed);
- d) an assessment confidentiality notice, allowing the FSMO to:
 - i. claim confidential business information on information/documents gathered during the assessment; and
 - ii. restrict access to requested information/documents for national security reasons;
- e) opening and closing session attendance sheets;

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

NOTE: Nonconformities found during document and records review may include inadequate documentation to support the scope of accreditation, a quality manual that does not comply with TNI Standard Volume 1, General Requirements for Field Sampling and Measurement Organizations, absence of evidence of qualified personnel or standard operating procedures for the requested accreditation or absence of applicable PT data (but see Clause 7.9.2.1.2, Interim Accreditation for an exception to PT sample data).

7.7 On-Site Assessment

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

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

7.7.2.1 Conducting an On-Site Assessment

The lead assessor shall advise the accreditation body as soon as possible if and when an FSMO refuses admittance to the site and shall advise the FSMO that such refusal is grounds for automatic failure to receive accreditation or loss of an existing accreditation, unless extenuating circumstances are accepted by and documented with the accreditation body.

- a) The opening conference shall include:
- i. agreement on the scope, purpose, duration and locations (if both fixed-base and field locations are part of the assessment) of the assessment;
 - ii. the introduction and identification of each assessor along with their qualifications and areas of responsibilities;
 - iii. the identification of the FSMO's processes and personnel to be examined, including those selected for field observations;
 - iv. a discussion of the responsibilities of the FSMO's key managers and field sampling and measurement personnel;
 - v. a discussion concerning procedures related to business confidential information;
 - vi. a review of any safety considerations, necessary for assessor protection while in certain parts of the FSMOs' facilities.

NOTE 1: The FSMO shall not request the assessors to sign any waiver of responsibility on the part of the FSMO for injuries incurred during an assessment or simply being on the FSMO site.

NOTE 2: The Accreditation body should request that the FSMO provide (or pre-advise the assessors of such requirements) any necessary safety gear and instructions for safe use during the site visit.

- vii. a review of the appropriate accreditation standards for assessment and/or checklists used to judge compliance;
 - viii. an opportunity to raise and discuss any assessment issues or procedures; and
 - ix. the time and place of the closing conference and a review of the post assessment timeline.
- b) The closing conference shall include:

- i. a discussion and informal debriefing with the FSMO's representative(s) to provide preliminary findings, potential impacts and their criticality and severity, and the deficiencies and their relationship to the accreditation standards;
- ii. a discussion of the process whereby the accreditation body makes the final determination of the assessment based upon reported findings which may include additional findings not discussed in the closing conference;
- iii. a discussion of any deficiencies which may be the subject of additional actions, such as FSMO improper or potentially illegal activities;
- iv. a discussion of any contested assessor findings which, if not resolved during the closing conference, shall be identified and included in the preliminary report to the accreditation body for final resolution on the validity of the contested finding; and
- v. informing the FSMO that a final assessment report will be issued within thirty (30) days, encompassing all relevant information concerning the FSMO's accreditation status and conformance with these Standards.

NOTE: The on-site assessor may use a variety of tools in the assessment process including prior experiences of the assessor, his/her observations or interviews with the FSMO staff, examination of SOPs, raw data, and the FSMO's documentation and records.

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

7.7.3.1 Staff Interviews and Observations

Any deficiencies in the interviews or observations shall be discussed with the effected staff and summarized during the closing conference.

The assessment team shall conduct staff interviews and/or observations:

- a) to the extent necessary, and if appropriate, for determining compliance with these Standards, either at the FSMO's fixed base, field location(s) or a combination of both; and
- b) with a selected cross section to judge FSMO and staff competency across the scope of the accreditation, including, for example, sampling and measurement activities and procedures, calculations, data reductions, transfers and reporting, data verification and validation, calibrations, quality control and assurance practices, and adherence to standard operating procedures, standard methods and the FSMO quality manual.

NOTE 1: The assessment team may request selected sampling and measurement personnel conduct or describe in detail a sampling or measurement event, to demonstrate knowledge of, for example, the procedure or method and equipment used, QA/QC procedures, and calibrations.

NOTE 2: ~~Proficiency Testing Sample(s)~~~~Performance Evaluation sample(s)~~, or Certified Standard(s), if available, may be used to physically demonstrate competence for the selected scope of accreditation for matrix/technology/analyte.

NOTE 3: The accreditation of a particular FSMO depends primarily upon the assessment team's findings, and much of the on-site assessment depends upon the assessor's observations of existing conditions. See *ISO/IEC 17011:2004(E), Clause 3.21, Witnessing: Observation of the CAB carrying out conformity assessment services within its scope of accreditation* (i.e., observing operations and processes).

7.7.4 On-Site Assessment Safety

The accreditation body shall have procedures in place to address compliance with any regulatory or FSMO requirements for assessor safety during an on-site assessment, including but not limited to:

- a) security clearances and site access;
- b) on-site identification, badging and escorting;
- c) safety briefings, site safety issues review;
- d) site emergency procedures; and
- e) use of safety equipment.

NOTE 1: As a general expectation, the accreditation body should have the FSMO provide assessors with any required safety equipment and work with the FSMO to ensure assessor safety.

NOTE 2: Safety requirements include those that may also be required by the site owner, if not the FSMO or by law.

7.7.5 Areas of Assessment

The assessor shall perform a review of all documents provided in the FSMO application package prior to arrival at the site/facility.

NOTE: Assessment activities while on site should be limited to activities which can only be verified through on-site observation, or which were not satisfactorily documented for the assessor prior to arriving on the site, or for spot checking actual practice/procedures versus information provided in the application package.

The following essential areas shall be reviewed and or observed during the on-site assessment.

- a) Adherence to published test methods and internal standard operating procedures;
- b) Observed field sampling and measurement practices;
- c) Verification of implemented, functional quality manual elements;
- d) Personnel – experience, training and demonstration of competency records;
- e) Physical facilities – accommodation and environment;
- f) Sampling and measurement equipment and reference materials;
- g) Measurement traceability and calibration;
- h) Associated field records and data reductions;
- i) Subcontracting of sampling or measurement activities;
- j) Outside support services;
- k) Records of preventive, corrective actions and complaint resolution; and

l) Proficiency Monitoring Plan which describes how the FSMO will demonstrate and/or measure proficiency, and shall include any available records.

7.7.6 Frequency and Types of Assessments

The assessment shall include an appraisal at the FSMO's fixed-base location(s) and/or field operations location in accordance with the accreditation requested (Umbrella or Individual), as appropriate and as pre-determined by the accreditation body.

For field sampling and measurement, the assessment shall include field observations of selected personnel and procedures representative of the area(s) of accreditation being sought.

7.7.6.1 Routine Assessments

The accreditation body shall conduct a comprehensive on-site assessment of the applicable FSMO's fixed base(s) of operations, including field operations:

- a) prior to granting accreditation, except as allowed by interim accreditation (see Clause 7.9);
- b) thereafter at least typically once every two (2) years, except that assessments for cause may be conducted more frequently, at the option and direction of the accreditation body;
- c) to verify correction of previously identified (via audit) deficiencies;
- d) to determine the merit of a formal appeal to a previous audit finding or accreditation recommendation;
- e) when warranted by a change in a FSMO's ownership, location, key personnel, major instrumentation, or new area or additional fields of accreditation;
 - i. Notification by the FSMO to the accreditation body is required within thirty (30) days of such changes.
 - ii. The accreditation body shall evaluate the significance of such change for any alteration or impact on the FSMO's capability and quality manuals, and so indicate to the FSMO the results of their evaluation in writing within thirty (30) days.
 - iii. The accreditation body shall retain records to indicate that such an evaluation was conducted.
- f) either announced or unannounced at the discretion of the accreditation body;

NOTE: Advance notification of an on-site assessment is not required, unless site access or security clearance is a pre-requisite for the assessment team.

- g) of reasonable duration sufficient to demonstrate compliance with these Standards dependent upon a balance of practicality and thoroughness, including:
 - i. the complexity and scope of the accreditation being sought;
 - ii. availability of resources, either of the accreditation body or assessment team; and
 - iii. logistical constraints of field locations vs. fixed base of operation or sampling/ measurement schedules.

7.7.6.2 Follow Up and For Cause Assessments

If directed by an accreditation body, an assessment team shall conduct follow-up assessments at FSMO facilities where a deficiency was identified by the previous assessment. When deficiencies are of such severity as to possibly warrant the downgrading of a FSMO's accreditation status, any follow-up assessment that is planned or conducted shall be completed and reported within 180 calendar days after the receipt of the FSMO's plan of corrective action.

NOTE 1: Nothing in this clause should be construed as requiring an accreditation body to reassess a facility prior to taking a regulatory or administrative action affecting the status of the facility's accreditation.

NOTE 2: Nothing in this clause should be construed as limiting in any way the accreditation body's ability to revoke or otherwise limit a FSMO's accreditation upon the identification of such deficiencies as to warrant such action.

Follow Up and For Cause assessments may be, but are not necessarily limited to:

- a) determining whether a FSMO has corrected its deficiency(s);
- b) determining the merit of a formal appeal from the FSMO from a previous assessment; and
- c) responding to knowledge that the FSMO is no longer in compliance with these Standards.

7.7.7 On-Site Records Review and Collection

The assessment team members shall review FSMO pertinent records and quality manuals for completeness, accuracy, and compliance with standard, internal operating procedures and published methods, including any records of any proficiency testing and results. Such reviews shall use established accreditation body checklists, correlated to the pertinent standards.

- a) The accreditation body shall advise the FSMO to mark any confidential business information as such (e.g., "trade secret", "proprietary", or confidential") and the assessors shall treat such information as required by law or regulation until the accreditation body or legal authority determines otherwise.
- b) The accreditation body shall have in place a procedure for handling receipt of such confidential business information (as designated by the FSMO or if the assessors become aware of such information during the course of an assessment) that is compliant with applicable government laws or regulations.

7.8 Analysis of Findings and Assessment Report

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

NOTE: Analysis may include the use of a check sheet that is used to gather assessment results. A copy of the check sheet either in raw or final form should be provided, if requested, at the conclusion of the on-site assessment or at a later date.

7.8.1.1 Assessment Reporting

Since the recommendation not to accredit or to change a FSMO's accreditation status is based on factual information and not upon subjective evaluations, it is crucial that the on-site assessor has a clear understanding of the FSMO's procedures and policies and that the assessor documents any deficiencies in the assessment report of the on-site assessment.

- a) All deficiencies shall include a specific reference(s) to a clause in the relevant assessment standards, a clause in a method, a section or clause in the FSMO's own management system documentation, or to an accreditation body's own policies/procedures. The assessment team shall use specific documentation in its reporting of deficiencies (e.g., a checklist).
 - i If during the assessment, sufficient information becomes available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report, the assessor shall thoroughly and accurately document the information or activity (since further action may be necessary).
 - ii In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team shall present such information to the accreditation body for appropriate action(s) as soon as practical.

NOTE: The issues under i and ii above, at the discretion of the accreditation body, may or may not be subjects of or become issues for discussion at the closing conference. However the assessor must continue to gather the information necessary to complete the assessment process.

- b) The assessment report shall be presented to the FSMO within thirty (30) days of the last day of the on-site assessment.
- c) The accreditation body shall allow the FSMO thirty (30) days after receipt of the report to provide a corrective action plan on any identified deficiencies to the accreditation body. An extension to this thirty-day period may be agreed if possible enforcement actions have been indicated.
- d) The accreditation body shall respond in writing within thirty (30) days of receipt of the corrective action plan as to the acceptability of the proposed corrective action plan(s).
- e) If a second corrective action response including objective evidence of implementation plan is found unacceptable, the accreditation body shall consider denial of initial accreditation or re-accreditation status (see Clause 7.9).

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

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

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

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

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

7.8.7 Report Format

- a) The final assessment report shall be written in a narrative format describing the adequacy of the FSMO as it relates to this assessment Standard.
- b) Documentation of existing conditions at the FSMO shall be included in each report to serve as a baseline for future contacts with the facility.
- c) The assessment report shall contain sufficient evidence to support all assessment findings and the overall evaluation of the FSMO.
- d) In addition to the requirements under *ISO/IEC 17011:2004(E), Clause 7.8.6*, the assessment report(s) shall contain:

- i. the unique address of each location assessed;
 - ii. date(s) of the each assessment by location;
 - iii. the affiliation of each assessor team member or expert;
 - iv. the identification of FSMO participants in the assessment process;
 - v. a statement of the objective of the assessment; and
 - vi. a summary and assessment of audit findings (deficiencies), such as on a check sheet.
- e) Within the report (or check sheet) any “Findings” shall be referenced to the applicable Standard so that the finding (deficiency) and the specific requirement are understood, defined and linked (e.g. by use of the specific clause number and language).
- f) The lead assessor shall assure that the results within the final assessment report conform to established standards for the evaluated parameters.
- g) The accreditation body may include a section in the assessment report for comments and recommendations in order to convey suggestions aimed at helping the FSMO improve operations.

7.8.8 Distribution and Release of an On-Site Assessment

7.8.8.1 Interim Report

After submittal of the assessor’s interim assessment report, the accreditation body shall:

- a) make a final determination of the potential findings, including the validity, severity and impact on accreditation status;
- b) attempt to resolve any contested findings (See Clause 7.10);
- c) communicate the confirmed findings in writing (the Report), either directly or through an authorized third party, within thirty (30) days of the completion of the on-site assessment to the FSMO;
- d) indicate whether any possible enforcement investigations or actions have or will be initiated as a result of the assessment;
- e) request the FSMO, upon receipt of the findings, to provide a corrective action plan to the accreditation body, within thirty (30) days, with priority for self-compliance given to correcting critical findings identified in the report; and
- f) provide the FSMO with an extension to the thirty-day requirement if possible enforcement actions have been indicated or if extenuating circumstances warrant it (e.g. acts beyond the control of the FSMO).

7.8.8.2 Final Report and Assessment Closure

- a) The lead assessor shall be responsible for drafting, compiling, editing and submitting the final report to the accreditation body.

- b) The accreditation body shall be responsible for the release and distribution of the final assessment report to the responsible FSMO representative.
- c) The accreditation body shall not release the assessment report to any accreditation database or the public:
 - i. until findings of the assessment and the corrective actions have been finalized and agreed by the FSMO and accreditation body;
 - ii. unless all confidential business information and information related to national security has been stricken from the report in accordance with prescribed procedures;
 - iii. unless any documents or information adjudged to be proprietary, financial and/or trade confidential or relevant to an ongoing enforcement investigation, have been removed and,
 - iv. before the report has been provided to the FSMO.

7.9 Decision-Making and Granting Accreditation

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

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

NOTE: Other relevant information may include documentation or practices that demonstrate conformity to TNI Field Sampling and Measurement Sector Volume 1, General Requirements for Field Sampling and Measurement Organizations.

7.9.2.1 Types of Accreditation

7.9.2.1.1 Initial accreditation

- a) When the accreditation body has determined the FSMO has completed all of the requirements for accreditation as given under this Standard, the accreditation body shall issue to the FSMO an official certificate of accreditation including:
 - i. an official signature from the accreditation body;
 - ii. a clear indication of the effective dates of accreditation;
 - iii. name and address(s) of the FSMO and all its entities covered by the scope of accreditation;
 - iv. the scope of the field sampling and/or field analytical methods subjected to accreditation; and
 - v. any addenda or attachments (also considered as official documents).
- b) The accreditation body shall issue the FSMO a separate certificate for each different or change in scope of accreditation. Each certificate shall:
 - i. note that continued accredited status depends on successful ongoing participation in the program;
 - ii. urge a customer to verify the FSMO's current accreditation standing;

- iii. be returned to the accreditation body upon loss of accreditation. A certificate that has simply expired does not need to be returned; and
 - iv. be reissued if an accredited FSMO changes its scope of accreditation, subject to meeting any new accreditation requirement.
- c) The initial accreditation shall remain in effect for a period of time (typically two years as determined initially by the accreditation body to accommodate applicable regulatory or government fiduciary cycles), from the initial date of notification of accreditation unless suspended or revoked by the accreditation body, or withdrawn at the written request of the FSMO to the accreditation body.

NOTE: The accreditation body should determine, after the initial period of accreditation, an accreditation cycle. This may typically be a two-year cycle.

7.9.2.1.2 ~~Preliminary Interim~~-accreditation

- a) If the accreditation body has determined that a FSMO has completed all of the requirements for accreditation except that the accreditation body cannot schedule an on-site assessment, the accreditation body may issue a ~~preliminary interim~~ accreditation.
- b) ~~Preliminary Interim~~-accreditation may also be granted in the event the FSMO completes all the accreditation requirements, except for the successful completion of any applicable PT sample(s).
- c) ~~Preliminary Interim~~-accreditation status shall not exceed twelve (12) months from the date of issuance of the ~~preliminary interim~~-accreditation.

NOTE 1: ~~Preliminary Interim~~-accreditation allows a FSMO to perform sampling and measurement analyses and report results with the same status as an accredited FSMO until the on-site assessment or PT requirements have been completed.

NOTE 2: Revocation of ~~preliminary interim~~-accreditation may be initiated for due cause as described in Clause 7.9.2.1.5

7.9.2.1.3 Denied accreditation

Reasons to deny an initial application shall include:

- a) failure to submit a completed application;
- b) failure to pay required fees;
- c) failure to successfully ~~demonstrate competency analyze and report applicable proficiency testing samples within a twelve month period;~~
- d) failure to respond to an assessment report from the on-site assessment with a corrective action report within the required thirty (30) calendar days after receipt of the assessment report;
- e) failure to implement the corrective actions detailed in the corrective action report within the time frame as approved by the accreditation body;

- f) failure to implement a management system and quality manual as defined in Clause 5 of this Standard;
- g) failure to pass the on-site assessment(s) as specified in Clause 7.7 of this Standard;
- h) misrepresentation of any fact pertinent to receiving or maintaining accreditation; and

~~i) denial of entry during normal business hours for an on-site assessment.~~

Once denied, the accreditation body shall require the FSMO to wait six months before again reapplying for accreditation and the FSMO may be subject to additional fees as determined by the accreditation body.

NOTE 1: Denied means to refuse to accredit, in total or in part, a FSMO applying for initial accreditation or resubmission of an initial application.

NOTE 2: The accreditation body should not deny the FSMO's accreditation without the right to due process as set forth by the accreditation body.

7.9.2.1.4 Suspended accreditation

- a) An accreditation body may suspend an FSMO's accreditation in total or in part. Accreditation shall be retained by the FSMO for those areas where it continues to meet the requirements of this Standard.
- b) The accreditation body shall inform the FSMO that, if suspended:
 - i. the FSMO shall not have to reapply for accreditation (and pay any fees) if the cause(s) for suspension is corrected within six (6) months after written notification of the suspension (the effective date);
 - ii. the FSMO cannot continue to sample or measure or report data in the affected areas of accreditation, during the period of suspension;
 - iii. the FSMO's suspended accreditation status for any impacted area shall change to accredited when it demonstrates to the accreditation body that it once again complies with these Standards and,
 - iv. the FSMO's accreditation shall be revoked in total or in part if the FSMO fails to correct the causes of suspension within six (6) months after the effective date of the suspension..

NOTE 1: Suspension means the temporary removal of a FSMO's accreditation for a defined period of time, not to exceed six (6) months. The purpose of suspension is to allow a FSMO time to correct deficiencies or an area of non-compliance with these Standards.

NOTE 2: The accreditation body should not suspend the FSMO's accreditation without the right to due process as set forth by the accreditation body.

- c) Reasons for suspension include failure to continue to meet the requirements of accreditation including but not limited to:~~shall include:~~

- i. failure to successfully complete applicable proficiency testing studies within any interim accreditation period (twelve months), failure to complete at least one applicable PT sampling program during the accreditation period (typically two years) and failure to maintain a two out of three passing record on applicable PT studies, or failure to demonstrate the required degree of competency in the absence of applicable and available PT programs;
- ii. failure to notify the accreditation body of any changes in key accreditation criteria required to maintain accreditation; as per Clause 8;
- iii. failure for cause based on information made available to and verified by the accreditation body;
- iv. failure to maintain a Quality manual (see TNI Standard Volume 1, General Requirements for Field Sampling and Measurement Organizations);
- v. failure to employ staff that meet the qualifications for education, training and experience as required; and
- vi. a finding by the accreditation body during an on-site assessment that the public interest, safety or welfare imperatively requires such emergency action.

7.9.2.1.5 Revoked accreditation

- a) The accreditation body may revoke a FSMO's accreditation, in part or in total, for failure to correct the deficiencies as identified during the on-site assessment, Clause 7.7 of this Standard and for failure to correct the reasons for being suspended. Accreditation shall be retained by the FSMO for those matrices, field sampling or measurement/ analytical methods where it continues to meet the requirements of this Standard.
- b) Reasons for revocation, in part or in total, shall include:
 - i. failure to submit an acceptable corrective action report, in response to an assessment report and failure to implement corrective action(s) related to any deficiencies found during an assessment. The FSMO may submit two corrective action reports within the time limits specified in Clause 7.8;
 - ii. ~~if after being suspended due to failure of two consecutive proficiency testing samples, the FSMO's analysis of the next proficiency testing study results in a further failed proficiency test study. Revocation shall apply only to each affected accredited scope of accreditation;~~
 - iii. failure to respond with a corrective action report within the required thirty (30) calendar days;
 - iv. ~~failure to participate in the ongoing proficiency testing program (if applicable and available) or maintain a two out of three passing PT record;~~
 - v. ~~submission of proficiency test sample results generated by another FSMO as its own;~~
 - ii.vi. misrepresentation of any material fact pertinent to receiving and maintaining accreditation;

- ~~vii~~ denial of entry during normal business hours for an on-site assessment;
- viii. conviction of charges relating to the falsification of any report relating to a sampling or measurement activity; or
- ~~vix~~. failure to remit the accreditation fees, if applicable, within the time limit as established by the accreditation body.

NOTE 1: Revocation means the in part or total withdrawal of a FSMO's accreditation by the accreditation body. After correcting the reason/cause for revocation and satisfying any legal remedies, the FSMO may reapply for accreditation.

NOTE 2: The accreditation body should not revoke the FSMO's accreditation without the right to due process as set forth by the accreditation body.

7.9.2.1.6 Renewal or continuation of accreditation.

The accreditation body shall:

- a) Notify the FSMO that its accreditation status may be suspended or revoked upon receipt of information that the FSMO has failed to maintain, revise, or replace any of the key FSMO management system components or as specified elsewhere in Sections 7.9.2.1.4 and 7.9.2.1.5 of this Standard unless the FSMO has notified the accreditation body of any changes in key accreditation criteria within thirty (30) calendar days of the change. This written notification includes, but is not limited to, changes in the FSMO ownership, locations, key personnel, and major sampling and measurement methods or instrumentation.

NOTE 1: The accreditation body may approve transfer of the FSMO's accreditation when the legal or ownership status of the FSMO changes with no impact on the components of accreditation.

NOTE 2: The accreditation body, at its discretion, may impose a "transfer fee" and/or require a follow up on-site assessment to verify any effects on continued FSMO compliance with these Standards.

- b) maintain all records on FSMOs, associated with accreditation parameters, for a minimum of five (5) years unless otherwise designated for a longer period by regulation or regulatory authority.
- c) ensure traceability of the FSMO's accreditation number(s) or FSMO ownership changes for a minimum of five (5) years.

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

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

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

- e) for field sampling and measurement organizations:
 - 1. the types of sampling procedures and matrices sampled and where appropriate, the methods used;
 - 2. the types of field tests performed and matrices tested and where appropriate, the methods used.

7.9.6 Delegation of Authority

An accreditation body shall not delegate authority for granting, maintaining, suspending or revoking a FSMO's accreditation to another person or body.

- a) If portions of the accreditation process are contracted out (e.g. for on-site assessments) the accreditation body shall:
 - i. take full responsibility for such contracted work;
 - ii. ensure that the contractor/employees is/are competent and comply with these Standards and any confidentiality agreements with the accreditation body; and
 - iii. ensure that the contractor/employees does/do not have any conflicts of interest related to the subcontracted work.

7.10 Appeals

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

7.10.1.1 The accreditation body shall also have documented standard operating procedures for dealing with complaints and disputes arising from denial, suspension or revocation of FSMO accreditation, or from users of the services of the FSMO or for any other matters impacting accreditation status.

7.10.1.2 The accreditation body shall have a documented policy or procedure for resolving conflicts regarding interpretation of standards that arise between the accreditation body and a FSMO and shall:

- a) communicate the final consensus interpretation of the Standard to the relevant FSMO, and
- b) make the consensus interpretation available and easily accessible to other interested parties.

7.10.1.3 Due Process

As a matter of course, the accreditation body shall document in writing and clearly communicate to the FSMO any decisions and supporting information, such as citations from this Standard, impacting the FSMO accreditation status.

NOTE: Regardless of the language in this Standard concerning actions such as denial, suspension and revocation of accreditation, a FSMO is always entitled to the right of due process. Due process rights are delineated in the appropriate state laws and regulations. Since these laws and regulations may vary from state to state, FSMO's seeking accreditation are encouraged to become familiar with the specific laws and regulations governing due process.

7.10.2 *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 provided that this arrangement is agreed by all parties. 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.

7.11 Reassessment and Surveillance

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

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

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

NOTE: Notwithstanding *ISO/IEC 17011:2004(E), Clause 7.11*, FSMOs are subject to an initial qualification assessment followed by reassessments typically every two (2) years for re-qualification. Additional surveillance assessments (extraordinary assessments) may be triggered for cause provided that regulatory authority and a documented procedure exists for conducting such assessments.

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

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

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

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

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

7.12.1 Extending the Scope of Accreditation

The accreditation body may grant a request for an extension of the scope of accreditation from the FSMO provided the FSMO completes or complies with all relevant clauses of this Standard and as agreed with the accreditation body. Failure to complete or comply with these elements shall be cause for denying the scope extension as specified in Clause 7.9 of this Standard.

7.12.2 Changes in Accreditation Scope

An accreditation body may approve a FSMO's application to add an analyte or sampling/ measurement method to its scope of accreditation by performing a data review without an on-site assessment.

The addition to the scope of accreditation via a data review of PT performance, if applicable, or other measure of competency demonstration~~proficiency testing performance (if available)~~, quality control performance, and written standard operating procedure shall be at the discretion of the accreditation body, but shall be in accordance with a defined written policy.

NOTE: An addition of a new technology or test method requiring specific equipment may require an on-site assessment at the discretion of the accreditation body, in accordance with a defined written policy.

7.13 Suspending, Withdrawing or Reducing Accreditation

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

NOTE 2: The term withdrawal is synonymous with revocation.

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

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

7.14 Records on CABs (FSMOs)

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

7.14.1.1 The accreditation body shall have a policy and procedure concerning access to records as prescribed by the territorial, state or federal authority or organization in which the accreditation body resides with due regard to designated FSMO confidential information.

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

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

7.14.4 Checklists/Records

- a) Accreditation bodies shall use standardized checklists for the on-site assessment to assist in conducting a thorough and efficient assessment.

NOTE 1: The use of checklists does not replace the need for assessor observations and staff interviews.

NOTE 2: A checklist is not a substitute for assessor training and experience.

- b) Any checklists used by the assessors during the assessment shall become a part of the permanent file kept by the accreditation body for each FSMO accredited location.
- c) The assessor shall specify the requirements of any Standards for the records, documents, equipment, procedures, or staff evaluated, and record the observations that contributed to the evaluation of "No" for each assessment checklist item and document this information in the comments section or provide reference to the checklist item.

7.14.5 Record Retention Time

Copies of all assessment reports, checklists, and FSMO responses shall be retained by the accreditation body for a period of at least five (5) years or longer, if required by specific state or federal laws or regulations.

7.15 Proficiency Testing and Other Comparisons for Laboratories

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

7.15.1.1 Available Proficiency Testing Programs

- a) ~~Each FSMO seeking accreditation shall receive, analyze, and achieve a passing score on an applicable and available PT sample(s) from an TNI PTPA approved PT provider for each scope of accreditation as outlined in the FSMO PT Plan (7.7.5. I). Each FSMO seeking accreditation shall receive, analyze, and achieve a passing score on an applicable and available PT sample(s) from an approved PT provider for each scope of accreditation being sought.~~
- b) The accreditation body shall consider the results of the PT sample(s) in determining accreditation status (initial, ~~interim~~ preliminary, denied, suspended or revoked ~~—See Sections 7.9.2.1.4 and 7.9.2.1.5 of this Standard~~).

7.15.1.2 Proficiency Testing Program is Not Available

If an appropriate PT program is not applicable or available for the field sampling or analytical method for which the FSMO is seeking accreditation, then the accrediting body shall consider other evidence that demonstrates FSMO proficiency, for example that the FSMO:

- ~~a) maintains a quality manual that meets the requirements of Clause 5 of this Standard to demonstrate sampling and measurement procedure competency;~~
- ba) employs the use of other types of internal quality control check samples or programs to demonstrate sampling/measurement procedure competency;
- eb) has conducted method detection limit studies, precision and accuracy studies and demonstrations of analyst capability.
- ec) employs an internal self-monitoring and audit system (e.g., of processes, procedures, field observations) to demonstrate sampling/measurement competency;
- ed) participates in applicable inter-organization comparison studies such as round robins; and
- fe) employs various combinations of the aforementioned examples or other techniques to demonstrate competence in the requested scope of accreditation.

NOTE: The requirements within TNI Standard “General Requirements for Field Sampling and Measurement Organizations”, Volume 1, and *ISO/IEC 17025* or *ISO/IEC 9001* could serve as the basis for a quality manual.

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

The accreditation body accrediting to the TNI FSMO Standard shall use a TNI PTPA approved PTP for applicable and available PTs.

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

8.0 RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB

8.1 Obligations of the CAB (*ISO/IEC 17011:2004, Clause 8.1*)

8.2 Obligations of the Accreditation Body

8.2.1 *ISO/IEC 17011:2004(E), Clause 8.2.1*

8.2.2 *ISO/IEC 17011:2004(E), Clause 8.2.2*

NOTE: Traceability of measurement results should be referenced to National or International Standards where applicable.

8.2.3 *ISO/IEC 17011:2004(E), Clause 8.2.3*

8.2.4 *ISO/IEC 17011:2004(E), Clause 8.2.4*

8.2.5 Enforcement

An accreditation body shall take any enforcement actions independently.

The enforcement component of the accreditation authorities shall be based on explicit values, or principles, with which all participants concur including:

- a) the program is equitable to all participants;
- b) the rules are well publicized;
- c) the program needs of the participating regulatory agencies shall be upheld; and
- d) the due process rights of participating FSMOs shall be protected.

8.3 Reference to Accreditation and Use of Symbols (*ISO/IEC 17011:2004(E), Clause 8.3*)