



[SECTOR]

[VOLUME 1, MODULE 2]

**GENERAL REQUIREMENTS FOR AN ACCREDITOR OF
STATIONARY SOURCE AUDIT SAMPLE PROVIDERS**

TNI Voting Draft Standard

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PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Stationary Source Audit Sample Expert 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 drafting process.

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GENERAL REQUIREMENTS FOR AN ACCREDITOR OF STATIONARY SOURCE AUDIT SAMPLE PROVIDERS

1.0 INTRODUCTION, SCOPE, AND APPLICABILITY

1.1 Introduction

This Standard (Volume 1, Module 2) provides the requirements for an organization to function as a TNI-approved Stationary Source Audit Sample Provider Accreditor, hereafter referred to as "Provider Accreditor."

1.2 Scope

The TNI Stationary Source Audit Sample Program (SSAS Program) includes the following elements:

- a) The production and supply of stationary source audit samples, hereafter referred to as "audit samples," that challenge the critical components of each analytical procedure, from initial sample collection to final data analysis;
- b) The production and supply of audit samples that are as similar to real-world samples as are reasonably possible and are representative of materials analyzed for environmental regulatory programs, regulatory agencies, and communities;
- c) The yielding of audit sample data that are technically defensible on the basis of the type and quality of the audit samples provided; and
- d) The preparation of audit samples that pose equivalent difficulty and challenge, regardless of the manner in which they are designed and manufactured by the Stationary Source Audit Sample Providers, hereafter referred to as "Providers."
- e) Establishment of requirements for Facilities, Regulatory Agencies, Stationary Source Testers, Laboratories, Providers, and Provider Accreditors participating in the SSAS Program.

1.3 Applicability

1.3.1 This Standard (Volume 1, Module 2) is applicable to any organization seeking to function as a TNI-approved Provider Accreditor. The requirements define the responsibilities of the TNI-approved Provider Accreditor. These requirements assume that monitoring is an essential part of accreditation, and so the accreditation and monitoring functions are seen as part of the same process. It is also recognized that the Provider Accreditor may have other requirements and mutual recognition agreements that may need to be included in the TNI accreditation process. These requirements are outside the TNI consensus process, except that the PT Board must approve them as applicable to TNI accreditations. In addition, these recognitions allow Providers to offer their services in regions where TNI accreditation may not be recognized.

1.3.2 Included in this Standard are some of the responsibilities of the PT Board regarding the determination of audit sample availability (as defined in the SSAS Table), SSAS Program content, Provider Accreditor evaluation criteria, and oversight.

- 1.3.3 This is not intended as a complete set of requirements or procedures for the PT Board; rather, it is intended to assure (1) that these functions are controlled by the TNI consensus process, and (2) that there is an impartial selection process for the Provider Accreditor(s).

2.0 REFERENCES

- 2.1 *ISO/IEC 17011 General requirements for accreditation bodies accrediting conformity assessment bodies.*

3.0 TERMS AND DEFINITIONS

For the purpose of this Standard (Volume 1, Module 2), the relevant terms conform with *ISO/IEC 17011:2004(E), Clause 3* and *ISO/IEC 17025:2005(E), Clause 3*. Additional relevant terms are defined below.

- 3.1 **Acceptance Limits:** The range of values that constitute acceptable performance for a Participant providing results for an audit sample material.
- 3.2 **Assigned Value:** Value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose.
- 3.3 **Facility:** The responsible owner or operator for the stationary source test or their authorized representative.
- 3.4 **Laboratory:** The organization that analyzes the samples collected during the stationary source test to determine emissions. This organization may be (1) the Stationary Source Tester or analytical chemist contractor analyzing the samples at the facility being tested or in a mobile laboratory or (2) an analytical laboratory or Stationary Source Tester analyzing the samples in their laboratory facility.
- 3.5 **Participants:** The Facilities, Regulatory Agencies, Stationary Source Testers, Laboratories, and Providers participating in a stationary source test.
- 3.6 **Referee Laboratory:** An independent laboratory that analyzes samples to provide a second opinion.
- 3.7 **Regulatory Agency:** The federal, state, local, or tribal agency having responsibility and accountability for overseeing testing of atmospheric emissions from stationary sources.
- 3.8 **Stationary source:** Any building, structure, facility, or installation that emits or may emit any air pollutant.
- 3.9 **Stationary Source Audit Sample (audit sample):** A sample, the composition of which is unknown to the Stationary Source Testers and Laboratory, and that is provided to evaluate whether the Stationary Source Testers and/or Laboratory can produce measurement results within specified acceptance criteria. The audit sample is analyzed, or collected and analyzed, as part of the batch of field test samples using the same personnel, procedures, and materials.
- 3.10 **Stationary Source Audit Sample Program (SSAS Program):** The procedures and operations for providing rigorously controlled and standardized environmental samples, analyzing or collecting and analyzing them, reporting measured values, and reporting evaluations of the accuracy of the measured values.
- 3.11 **Stationary Source Audit Sample Provider (Provider):** A person or organization that offers an SSAS Program in accordance with Section 6.0 of this Standard.

- 3.12 Stationary Source Audit Sample Provider Accreditor (Provider Accreditor):** An organization that is evaluated and approved by TNI to accredit and monitor the performance of Providers.
- 3.13 Stationary Source Audit Sample Table (SSAS Table):** Table in which the analytes and acceptance limits for audit sample materials are defined.
- 3.14 Stationary Source Test:** The determination of the qualitative and/or quantitative composition of atmospheric emissions from a stationary source.
- 3.15 Stationary Source Tester:** Person or persons testing a stationary source for atmospheric emissions.
- 3.16 TNI Proficiency Testing Board (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 SSAS Program. The duties of the PT Board are defined in the PT Board Charter.

4.0 REQUIREMENTS FOR OVERSIGHT OF THE SSAS PROGRAM

4.1 Audit Sample Availability

The PT Board shall determine the content of the approved TNI SSAS Program and performance expectations for Laboratories and/or Stationary Source Testers. These determinations shall be based on sound technical, professional, and statistical judgment.

The SSAS Expert Committee shall determine concentration ranges, expected values, and acceptance criteria that shall, where appropriate, be consistent with public health needs and best international practices.

To this end, the SSAS Expert Committee shall:

- 4.1.1 Define audit sample requirements for content, including:
- a) matrix or collection media, as appropriate;
 - b) measurement technologies;
 - c) analytes or classes of analytes; and
 - d) required concentration range.
- 4.1.2 Determine acceptance limits for each analyte. The SSAS Table, containing all analyte acceptance limits established by the SSAS Expert Committee, shall be publicly available.
- 4.1.3 Review audit sample data and the acceptance limits at least biennially to revise existing evaluation criteria and establish new criteria, as needed.
- 4.1.4 Establish criteria for the Provider to document the inclusion of analytes or ranges that are not in the SSAS Table.

Note: This can include, for example, justification for the additional analyte or range, its relation to or effect on other analytes in the audit sample, and criteria for acceptable performance.

4.2 Selection of Provider Accreditor

The PT Board shall select an organization or organizations to serve as Provider Accreditor. To accomplish this, the PT Board shall:

- 4.2.1 Assure that the prospective Provider Accreditor meets all requirements in Section 5.0 of this Standard (Volume 1, Module 2).
- 4.2.2 Approve all policies and procedures used by the Provider Accreditor for the purposes of accreditation and oversight of Providers. This shall include approval of any additional (non-TNI) requirements from the Provider Accreditor that are related to their policies for compliance with ISO/IEC 17011 and international agreements.
- 4.2.3 Conduct appropriate biennial onsite assessments of any organization designated as a Provider Accreditor.

4.3 Determining Criteria for Oversight

- 4.3.1 The PT Board shall determine criteria for ongoing oversight of Provider activities, including activities and objectives for the Provider Accreditor review consistent with this Standard (Volume 1, Module 2).
- 4.3.2 The PT Board shall have arrangements to ensure that the Provider Accreditor has access to sufficient data to allow oversight of Providers, as described in Section 6.3.1 of this Standard.
- 4.3.3 The PT Board shall serve as final arbiter for:
 - a) complaints about the Provider Accreditor that come from Regulatory Agencies or from Providers; and
 - b) disputes between Provider Accreditors.

5.0 REQUIREMENTS FOR APPROVAL OF PROVIDER ACCREDITORS

These requirements apply to the approval of the accreditation and oversight body. The requirements in this Section can serve as guidance for PT Board procedures for those functions, or as requirements that the Provider Accreditor shall meet in order to be approved.

5.1 Technical and Administrative Qualifications

- 5.1.1 An organization shall demonstrate to the PT Board that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of Provider accreditation and oversight.
- 5.1.2 The organization shall be recognized by a national or international cooperation of accrediting bodies for the accreditation of environmental laboratories, and shall demonstrate the following:
 - a) Compliance with *ISO/IEC 17011*;
 - b) Have, or have access to, technical expertise in *ISO Guide 34* and/or *ISO 17025* as appropriate, for the preparation and/or analysis of the types of reference materials being prepared by the Providers;
 - c) Expertise in statistical applications used for interlaboratory comparison programs;
 - d) Capability to conduct onsite assessments of Providers that are consistent with this Standard (Volume 1, Module 2);

- e) Capability to conduct technical reviews of initial applications;
- f) Having or have access to technical expertise in the relevant requirements of *ISO/IEC Guide 43a* or *ILAC G-13*, in regard to audit samples.

5.2 RESPONSIBILITIES REGARDING ASSESSMENT OF PROVIDERS

- 5.2.1 The assessment and oversight activities of the Provider Accreditor shall be designed to ensure that any accredited Provider meets the requirements specified in the Provider Standard (Volume 1, Module 1) and in Section 6.0 of this Standard (Volume 1, Module 2).
- 5.2.2 Any variations from these requirements or additions to these requirements shall be approved by the PT Board prior to use by the Provider Accreditor.

5.3 Development of Standard Operating Procedures and Forms

The Provider Accreditor shall develop procedures to conduct the Provider evaluation. These procedures shall be based upon the requirements of this Standard (Volume 1, Module 2).

- 5.3.1 The Provider Accreditor shall develop and implement procedures including, but not limited to:
 - a) Initial application submittal and review process;
 - b) Onsite assessment;
 - c) Accreditation process;
 - d) Obtaining information for oversight;
 - e) Revoking a Provider's accreditation; and
 - f) Appealing accreditation determinations.
 - 5.3.2 The Provider Accreditor shall develop procedures for the initial application process to be followed by Providers applying for accreditation. The application shall include information about the qualifications of the organization seeking accreditation.
 - 5.3.3 The Provider Accreditor's procedures shall require acceptance of other accreditations, recognitions, calibrations, etc., if they are current and are issued by organizations that have a mutual recognition agreement with the Provider Accreditor for that activity, product, or characteristic. To the extent feasible, the Provider Accreditor shall not assess those activities that are so recognized.

NOTE: By mutual recognition agreement, the Provider Accreditor is allowed to find nonconformances in activities that have recognized accreditation.
 - 5.3.4 The Provider Accreditor shall develop procedures for conducting consistent and effective onsite assessments of Providers. The procedures shall include a description of the circumstances for conducting any additional assessments or unannounced assessments.
 - 5.3.5 The Provider Accreditor shall develop standard, concise, and unambiguous checklist(s) to be used during all assessments of Providers.
- 5.4** The Provider Accreditor shall have arrangements to allow oversight of Providers as described in Section 6.3.1 of this Standard (Volume 1, Module 2).

5.5 List of Accredited Providers

- 5.5.1 The Provider Accreditor shall maintain a list of accredited Providers and the audit samples they are accredited to provide. The list shall be maintained on a continuing basis, in an electronic bulletin board or similar means, and shall be readily available to Facilities, Stationary Source Testers, Laboratories, Regulatory Agencies, and other interested parties.
- 5.5.2 The Provider Accreditor shall ensure that all accredited Providers abide by the provisions of the PT Board and the Provider Accreditor regarding the advertising and marketing of their accreditation approval status.

5.6 Provider Accreditor Ethics

- 5.6.1 The Provider Accreditor shall serve as an impartial body designed to objectively evaluate information about Providers and use this information to make sound determinations regarding a Provider's accreditation status.
- 5.6.2 The Provider Accreditor shall be able to demonstrate to any interested party that it is free of any organizational or financial conflict of interest, which would prevent it from complying with the requirements of this Standard (Volume 1, Module 2).
- 5.6.3 The Provider Accreditor shall remain unbiased in evaluating information gathered and received including assessment reports, referee laboratory sample results, complaints, and any other information obtained regarding a Provider.
- 5.6.4 The Provider Accreditor shall evaluate all information about Providers related to providing the SSAS Program, determine which information is relevant to the Provider's accreditation status, and provide that information to the appropriate parties, consistent with all confidentiality agreements.

5.7 Confidentiality

- 5.7.1 A portion of the information provided to the Provider Accreditor by the Provider in the course of its assessment and oversight activities shall be proprietary in nature. The Provider Accreditor shall agree to maintain the confidentiality of proprietary information provided to it by the Providers.
- 5.7.2 The Provider Accreditor shall treat all audit sample data, formulation process information, analysis techniques, and other proprietary information as confidential and not accessible to any other entity; except as described in this Standard (Volume 1, Module 2). This information shall not be released without prior written permission from the Provider.

6.0 REQUIREMENTS FOR ACCREDITATION OF PROVIDERS

The accreditation process shall be repeated every two (2) years, and shall include all stages of initial review, onsite assessment, and oversight.

Timelines for application review, conducting assessments, and follow-up activities shall not cause undue delay in processing a request for accreditation.

NOTE: These timelines will be consistent with the Provider Accreditor's internal policies, as approved by its mutual recognition partners.

6.1 Initial Application Review

The Provider Accreditor shall conduct the reviews described in this Section for the applications from any new candidates or existing Providers renewing their application. This review shall include:

- a) Initial application documents for compliance with the Provider qualifications described in this Standard (Volume 1, Module 2);
- b) Audit sample designs used by the Provider for compliance with this Standard;
- c) Audit sample analyte and scoring procedures used by the Provider for compliance with this Standard;
- d) Procedures used to validate that new audit sample formulations are fit for their intended purpose, prior to use of such materials. This review shall ensure, at a minimum, that audit samples have assigned values within the specified ranges for every technology used to report results;
- e) Adequacy of data processing and analysis techniques, including statistical procedures used on audit sample sets with fewer than twenty (20) laboratories;
- f) Confirmation of the absence of conflicting interests with subscribing Laboratories, including:
 - i) Any financial interest in a Laboratory seeking or having accreditation to this Standard; and
 - ii) Sharing of personnel, facilities, or instrumentation with a Laboratory seeking, or having, accreditation to this Standard.
- g) Providing Providers with checklist(s) to be used during the assessment as part of the initial application process. The checklist shall include all requirements that may be necessary for the Provider Accreditor to comply with their own policies and external agreements.

6.2 Onsite Assessment

- 6.2.1 An onsite assessment of the Provider shall follow the initial review and shall include, at a minimum:
- a) A review of the quality management system for adherence to the requirements of this Standard (Volume 1, Module 2);
 - b) A review of staff qualifications and technical expertise necessary to produce acceptable audit samples;
 - c) A review of the audit sample manufacturing and analytical verification procedures and data to ensure the requirements of this Standard are met;
 - d) A review of the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for Providers and confidentiality of assigned values and Participant results;
 - e) A review of data reporting systems to ensure that the requirements of this Standard are met within the defined time periods; and
 - f) An exit meeting, which shall include delivery of the final report from the assessment and a discussion of all assessment findings.
- 6.2.2 The Provider Accreditor shall provide a written final report to the Provider during the exit briefing. The final report may only contain findings identified during the onsite assessment and discussed during the exit briefing, as defined in the Provider Accreditor's procedures.

6.2.3 The Provider Accreditor shall allow the Provider to submit its response to the report. In order for the Provider's response to be considered acceptable, it shall include a description of any corrective actions necessary to meet the criteria of this Standard (Volume 1, Module 2) and, as appropriate, objective evidence of successful implementation of any corrective action.

6.2.4 The Provider Accreditor shall follow its procedure for determining accreditation. This procedure shall include use of the appropriate final assessment report and associated documents submitted by the Provider.

6.3 Responsibilities for Ongoing Monitoring of Providers

6.3.1 The Provider Accreditor shall have procedures to acquire data as needed, for example, in response to a complaint, or periodically as directed by the PT Board, to review Provider performance with regard to the following:

- a) Assurance that concentrations are within the specified analyte ranges;
- b) Confirmation that analytes and ranges are as defined in the SSAS Table;
- c) Proper documentation when providing analytes that are not in the SSAS Table;
- d) Confirmation of the correct use of acceptance limits, as appropriate, per analyte;
- e) Review of acceptance rates for each audit sample manufacturing lot;
- f) Review of audit sample stability over time;
- g) Check report times; and
- h) Confirm Provider records during their onsite assessment.

6.3.2 When prompted by a complaint or when monitoring indicates that the Provider's audit sample is of unacceptable quality, the Provider Accreditor may use an accredited referee laboratory to verify the assigned values of the concentrations.

- a) The determination of unacceptable quality shall use the same acceptance criteria that were used in the manufacture of the audit sample (e.g., one standard deviation for verification or the approved criteria for homogeneity and stability).
- b) The Provider Accreditor shall provide each Provider with a report describing the results for any required referee laboratory analyses.

6.3.3 Provider Accreditor monitoring shall include review of critical operational parameters of the Provider, such as changes in ownership or senior management, and the evidence of internal assessments and management review.

6.3.4 Unscheduled onsite assessments of the Provider may be conducted for exceptional circumstances, such as persistent complaints from Participants, failure to adequately respond to inquiries from the Provider Accreditor, or other evidence of persistent nonconforming activity. The causes and resolution of exceptional visits shall be fully documented.

6.3.5 Any possible problems indicated by the monitoring shall be discussed with the Provider. Complete records shall be maintained of all contacts and responses from the Provider.

6.3.6 Based upon the results of its ongoing monitoring and its internal appeals process, the Provider Accreditor may determine that the Provider's accreditation status should be suspended or withdrawn.

6.4 Complaints and Corrective Action

6.4.1 The Provider Accreditor shall evaluate all complaints that it receives regarding accredited or candidate Providers. If the Provider Accreditor determines that a complaint warrants investigation, it shall notify the Provider of the complaint. The Provider is required to resolve the complaint to the satisfaction of the Provider Accreditor.

6.4.2 The Provider Accreditor shall provide to the PT Board a summary of all Provider complaints received the previous year.

6.4.3 Complaints made to Providers and the resultant corrective actions shall be reviewed by the Provider Accreditor in the following manner:

- a) Review of a written summary of all complaints regarding the technical aspects of the audit sample and the resulting corrective actions; and
- b) Review of all complaints that are unresolved after ninety (90) days.

6.4.4 The Provider Accreditor shall review any complaints about Providers received from Regulatory Agencies, and work with the Provider, the Regulatory Agency, and the PT Board to resolve the complaints.

6.5 Suspension or Revocation of Provider Accreditation

6.5.1 Based on their review of audit sample data, onsite assessments, and corrective actions associated with complaints or other nonconformances, the Provider Accreditor may determine that the Provider fails to meet the requirements of this Standard (Volume 1, Module 2) on a continuing basis.

6.5.2 The Provider Accreditor shall provide formal written notice to the Provider of any action to revoke or suspend the Provider's accreditation for any reason.

6.5.3 The Provider Accreditor shall inform the Provider of the reasons for proposed revocation or suspension and the procedures for appeal of such a decision.

6.5.4 The Provider Accreditor shall respect the due process rights of the Provider during any revocation or suspension proceedings, including the Provider's right to appeal the decision to the PT Board after completion of the Provider Accreditor's appeals process.