



# **STATIONARY SOURCE AUDIT SAMPLE PROGRAM**

**[VOLUME 1, MODULE 1]**

**GENERAL REQUIREMENTS FOR 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 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.

Sections 3.19 (added section), 8.3(f) (added section), and 11.2.2(l) (added section) of this document have been processed in accordance with the TNI requirement for a Tentative Interim Amendment. The same or similar amendment will undergo the consensus standards development process within the time-frame specified in SOP 2-100.

TNI developed these standards to fulfill the requirements established by EPA in Federal Register Vol. 75 No. 176 (75 FR 55636) September 13, 2010 "Restructuring the Audit Sample Program."

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## [VOLUME 1, MODULE 1]

# GENERAL REQUIREMENTS FOR STATIONARY SOURCE AUDIT SAMPLE PROVIDERS

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## 1.0 INTRODUCTION, SCOPE, AND APPLICABILITY

### 1.1 Introduction

This Standard (Volume 1, Module 1) specifies the requirements for providers of stationary source audit samples (hereafter referred to as “audit samples”) used for the confirmation of stationary source air emissions testing results.

### 1.2 Scope

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

- a) The production and supply of audit samples that challenge the critical components of each source test procedure, from sample collection to sample analysis;
- b) The production and supply of audit samples, the matrices of which, to the extent possible, resemble the matrices which Participants routinely analyze;
- c) The yielding of audit sample data that are technically defensible on the basis of the type and quality of the audit samples provided;
- 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”); and
- e) Establishment of requirements for Facilities, Regulatory Agencies, Stationary Source Testers, Laboratories, Providers, and Stationary Source Audit Sample Provider Accreditors (hereafter referred to as “Provider Accreditors”) participating in the SSAS Program.

### 1.3 Applicability

This Standard (Volume 1, Module 1) does not address issues of laboratory accreditation.

## 2.0 REFERENCES

- 2.1 *ISO 9001 Quality Management Systems – Requirements.*
- 2.2 *ISO PAS 17005 Conformity Assessment - Use of Management Systems in Conformity Assessment - Principles and Requirements.*
- 2.3 *ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories.*
- 2.4 *ISO/IEC 17011 General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.*
- 2.5 *ISO Guide 34 General Requirements for the Competence of Reference Material Producers.*

~~2.6~~ ILAC G-13 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes.

2.6 *ISO/IEC 17043 Conformity Assessment - General Requirements for Proficiency Testing, most recent revision.*

2.7 Federal Register Vol. 75 No. 176 (75 FR 55636) September 13, 2010 "Restructuring the Audit Sample Program"

### 3.0 TERMS AND DEFINITIONS

For the purpose of this Standard (Volume 1, Module 1), the relevant terms and definitions conform to *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 **Analyte of Interest:** Target analyte that is spiked into the audit sample, as requested by the Participants.

3.3 **Assigned or True Value:** Value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose.

Note: See Section 6.4 of this Standard for further discussion of assigned values.

3.4 **Facility:** The responsible owner or operator for the stationary source or their its authorized representative.

3.5 **Laboratory:** The organization that analyzes the samples collected during the stationary source test. 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.

3.6 **Manufacturing Lot:** A group of audit samples made at one particular time in one particular place for one particular method at one particular concentration.

3.7 **Participants:** The Facilities, Regulatory Agencies, Stationary Source Testers, Laboratories, and Providers participating in a stationary source test.

3.8 **Referee Laboratory:** An independent laboratory that analyzes samples to provide a second opinion.

3.9 **Regulatory Agency:** The federal, state, local, or tribal agency having responsibility and accountability for overseeing testing of atmospheric emissions from stationary sources.

3.10 **Stationary source:** Any building, structure, facility, or installation that emits or may emit any air pollutant.

3.11 **Stationary Source Audit Sample (audit sample):** A blind sample, the composition of which is known only to the Provider, and that is provided to evaluate whether, during a particular test event, the Stationary Source Tester and/or Laboratory can produce measurement results within specified acceptance criteria. Audit samples are not analyzed on a regular schedule, but they are analyzed only during the particular event (e.g. a compliance test) that is being audited. Audit samples are analyzed, or collected and analyzed, as part of the batch of field test samples using the same personnel, procedures, and materials.

- 3.12 Stationary Source Audit Sample Central Database (SSAS Central Database):** Repository for data related to audit performance and any field sample concentration measurements that are being evaluated in accordance with the TNI SSAS Program.
- 3.13 Stationary Source Audit Sample Number (SSAS Number):** A unique number assigned by the Provider to identify each audit sample shipped to a particular Facility for a stationary source test.
- 3.14 Stationary Source Audit Sample Program (SSAS Program):** The procedures and operations for providing rigorously controlled and standardized audit samples, analyzing or collecting and analyzing them, reporting measured values, and reporting evaluations of the accuracy of the measured values.
- 3.15 Stationary Source Audit Sample Provider (Provider):** A person or organization that offers audit samples in accordance with the requirements of the Provider Standard (Volume 1, Module 1). This term is synonymous with Accredited Audit Sample Provider (AASP).
- 3.16 Stationary Source Audit Sample Provider Accreditor (Provider Accreditor):** An organization that is evaluated and approved by TNI, in accordance with the requirements of the Provider Accreditor Standard (Volume 1, Module 2), to accredit and monitor the performance of Providers. This term is synonymous with Audit Sample Provider Accreditor (ASPA).
- 3.17 Stationary Source Audit Sample Table (SSAS Table):** Table in which the **methods**, **analytes**, and acceptance limits for audit sample materials are defined.
- 3.18 Stationary Source Test:** The determination of the qualitative and/or quantitative composition of atmospheric emissions from a stationary source.
- 3.19 Stationary Source Test Start Date:** The initial date that a stationary source test sample is collected for subsequent analysis.
- 3.20 Stationary Source Tester:** ~~Person or persons testing~~ **A person or organization that tests or collects samples at** a stationary source ~~of for~~ atmospheric emissions.
- 3.21 TNI Proficiency Testing Executive Committee (PT Executive Committee):** A committee 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 Executive Committee are defined in the PT Executive Committee Charter.

## 4.0 PROVIDER ACCREDITATION

- 4.1** The Provider shall be accredited by a TNI-approved Provider Accreditor for every audit sample (as listed in the SSAS Table) they will offer in the SSAS Program.
- 4.2** In order to receive and maintain accreditation for any **method and** analyte per matrix, the Provider shall demonstrate compliance with all requirements of this Standard (Volume 1, Module 1) during onsite assessments and ongoing oversight conducted by the Provider Accreditor, per Volume 1, Module 2.
- 4.3** Providers shall be subject to biennial onsite assessments conducted by their chosen TNI-approved Provider Accreditor. They may also be subject to unannounced assessments for cause.
- 4.4** Providers shall submit data from each of their audit sample manufactured lots to the Provider Accreditor for review to determine compliance with this Standard, in a format and frequency determined by the Provider Accreditor.

- 4.5 Upon request by the Provider Accreditor, the Provider shall supply to the Provider Accreditor, at no charge, audit samples specified by the Provider Accreditor and which are included in the Provider's scope of accreditation, for submission to a referee laboratory.
- 4.6 If conflicts with the Provider Accreditor arise, Providers shall follow the Provider Accreditor's appeals process.
- 4.7 Unresolved conflicts with the Provider Accreditor shall be submitted to the PT Executive Committee.

## 5.0 MANAGEMENT REQUIREMENTS

### 5.1 Quality System and Technical Requirements

- 5.1.1 The Provider's quality management system shall meet the requirements of ISO 9001 for the design, production, testing, and distribution of audit samples, and the evaluation of audit sample analyses results or measurements.

NOTE: This requirement can be met by demonstrating compliance with the Management System requirements of a standard that complies with ISO PAS 17005, such as ISO/IEC 17025 or ISO/IEC 17043.

- 5.1.2 The Provider's manufacturing system shall meet the requirements of ISO Guide 34.
- 5.1.3 The design and operation of the Provider's participation in the SSAS Program shall meet the relevant requirements of ~~ILAC G-13 until replaced by~~ ISO/IEC 17043, ~~when approved~~.
- 5.1.4 The testing facilities used to support the verification, homogeneity, and stability testing required in this Standard (Volume 1, Module 1) shall meet the requirements of ISO/IEC 17025.
- 5.1.5 Provider Accreditors are not required to re-assess current accreditations applicable to this Standard that were granted to a Provider by other TNI-approved Provider Accreditors, though they may choose to do so.
- 5.1.6 Providers shall maintain all records related to each audit sample manufacturing lot for a minimum of five (5) years.

### 5.2 Provider Conflict of Interest and Confidentiality

Providers seeking to obtain or maintain accreditation shall:

- a) Document and certify to the satisfaction of the Provider Accreditor that they do not have any conflict of interest with any Participant in the SSAS Program;

NOTE: Such a conflict of interest could take the form of a financial interest or sharing of personnel, facilities, or equipment with any Participant in the SSAS Program.

- b) Inform all internal and contract personnel who perform work on the SSAS Program of the Provider's obligation to report personal and organizational conflicts of interest to the Provider Accreditor;
- c) Have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of the SSAS Program;

- d) Immediately make a full written disclosure to the Provider Accreditor of any identified actual or potential organizational conflict of interest. The disclosure shall include a description of any action that the Provider has taken or proposes to take after consultation with the Provider Accreditor to avoid, mitigate, or neutralize the actual or potential conflict of interest;
- e) Have written procedures to ensure that the confidentiality of data associated with audit samples and the SSAS Program is not compromised;
- f) Not release the assigned values or acceptance limits of any audit sample prior to the reporting of the audit sample analyses results; and
- g) Not disclose specific Facility, Laboratory, or Stationary Source Tester results or evaluations to any parties other than as specified in Section 11.1.2 without written release from the Facility for Facility data, from the Laboratory for Laboratory data, or from the Stationary Source Tester for Stationary Source Tester data.

NOTE: Providers may release, without permission of participant Laboratories, summaries of participant Laboratory results that do not identify individual Laboratories, Stationary Source Testers, or Facilities.

### **5.3 Provider Facilities and Personnel**

- 5.3.1 Providers shall have appropriate facilities, equipment, and analytical instrumentation in place to produce, analytically verify, distribute, and provide data evaluation and reporting functions for every audit sample for which they wish to obtain or maintain accreditation.
- 5.3.2 Providers shall employ sufficient technical and support staff to design, produce, analyze, distribute, and provide data evaluation and reporting functions for every audit sample for which they wish to obtain or maintain accreditation.
- 5.3.3 No portion of the design, production, testing, distribution, data collection, data evaluation, or data reporting functions may be outside the direct control of the Provider for any particular manufacturing lot. For the purposes of this Standard (Volume 1, Module 1), "direct control" means that these functions are performed in the Provider's facilities by the Provider's staff or are subcontracted by means of a written agreement with defined Provider supervision to ensure that all requirements of this Standard are met.
- 5.3.4 Any subcontracted function related to the design, production, testing, distribution, data collection, data evaluation, or data reporting shall be assessed by the Provider Accreditor and shall meet the applicable requirements of this Standard.

### **5.4 Complaints Handling**

- 5.4.1 Providers shall have written procedures for handling both written and verbal complaints from Participants who receive audit sample reports.
- 5.4.2 Providers shall record all complaints received concerning the SSAS Program, including any remedial or corrective actions taken. This record shall be provided to the Provider Accreditor upon request.
- 5.4.3 Any complaint received by a Provider that remains unresolved after forty-five (45) **calendar** days shall be submitted to the Provider Accreditor. For additional information, refer to the Participants Standard (Volume 1, Module 3), Section 6.0.

### **5.5 Notification of Sample Integrity**



If any audit sample or analyte used in the SSAS Program is found not to meet any of the requirements of this Standard (Volume 1, Module 1), the Provider shall notify (with full disclosure as to the scope and nature of the nonconformance) **the SSAS Expert Committee**, all affected Participants, and the Provider's Provider Accreditor within seven (7) calendar days of the discovery of the nonconformance.

## **6.0 AUDIT SAMPLE DESIGN AND MANUFACTURE**

### **6.1 Design Review**

Providers shall demonstrate to the satisfaction of the Provider Accreditor that their audit sample design and manufacturing processes:

- a) Permit Participants, conforming to the calibration and quality control requirements of the analytical method(s) for which the audit sample was designed, to generate results that fall within the acceptance limits defined in the SSAS Table;
- b) Provide equivalent challenge to all Participants; and
- c) Result in Participant acceptable/not acceptable rates that are consistent with historical norms.

### **6.2 Audit Sample Matrices**

The matrices of all audit samples shall, to the extent possible, resemble the matrices which Participants routinely analyze.

### **6.3 Audit Sample Analytes**

- 6.3.1 Providers shall prepare audit samples that are compliant with the criteria defined by the SSAS Expert Committee and published in the SSAS Table on the TNI website. **If requested by the Regulatory Agency and/or the Facility, analytes that are not listed in the SSAS Table may be included in an audit sample if the purpose and technical justification are documented, and if, where appropriate, the Regulatory Agency and/or Facility are notified in advance.**
- 6.3.2 When the SSAS Expert Committee makes changes to the audit sample design criteria, Providers shall comply with the revised requirements per the SSAS Expert Committee's implementation schedule.
- 6.3.3 The Provider shall spike the analytes of interest into the audit sample according to the SSAS Table.
- 6.3.4 The Provider shall produce audit samples that conform to the method being tested.
- 6.3.5 The Provider shall be allowed to add interferences (not to be reported), normally present in the matrix being tested, to the audit sample, subject to approval by the Provider Accreditor in accordance with the requirements of Section 6.1 of this Standard (Volume 1, Module 1).

## 6.4 Audit Sample Concentration Ranges

- 6.4.1 Providers shall supply audit samples that are within reflect the concentration ranges in the SSAS Table. If requested by the Regulatory Agency and/or the Facility, ranges that are not listed in the SSAS Table may be included in an audit sample if the purpose and technical justification are documented, and if, where appropriate, the Regulatory Agency and/or Facility are notified in advance.

**NOTE:** A Provider may, upon request, supply samples, similar in composition to audit samples, which have concentrations outside the ranges in the SSAS Table. By definition, such samples would not be considered audit samples, and are, therefore, outside the scope of this Standard.

- 6.4.2 Assigned values for audit sample analytes that are measured (chemical concentrations, isotope activities, etc.) shall:
- Be equal to the made-to values of the analytes based on gravimetric and volumetric measurements of a starting material of known concentration if possible, and if not possible, shall be set to the mean of the determined measured value; and
  - Be presented in three (3) significant figures.

## 7.0 AUDIT SAMPLE TESTING

### 7.1 Verification of Assigned Value

- 7.1.1 Providers shall analytically verify the assigned value of all analytes in all manufacturing lots of audit samples prior to use.
- 7.1.2 Providers shall verify the assigned value by direct analysis against a calibration standard made from, or traceable to, a primary reference material (e.g., National Institute of Standards and Technology), if available.
- 7.1.3 If a primary reference material is not available, then verification shall be performed against an independently prepared calibration material.

**NOTE:** An independently prepared calibration material is one prepared from a raw material source independent of the source used to prepare the audit sample or one prepared and documented by a source external to the Provider.

- 7.1.4 The assigned value verification analytical event shall also include the analysis of a second source reference material from a source independent of the calibration standard and the audit sample being verified.
- 7.1.5 The Provider shall have documented criteria for the acceptance of the results of the second source reference material.
- 7.1.6 The analytical method used by the Provider for assigned value verification shall have a repeatability relative standard deviation of not more than one-sixth of the acceptance limits for the participant Laboratories.
- 7.1.7 For test methods listed in the SSAS Table, where the method performance precludes the use of the one-sixth limit defined in Section 7.1.6, the Provider shall document the technical justification that the method used to verify the audit sample assigned value is adequate to ensure that it meets data user requirements. This shall be reviewed and approved by the Provider Accreditor.

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- 7.1.8 The relative standard deviation of the Provider's verification method shall be established by a method validation study for each method and instrument.
- 7.1.9 For analytes in aqueous media, the assigned value of an analyte is verified if the mean of the Provider's verification analyses is within one-third of the Laboratory acceptance limits, as defined in the SSAS Table, to a maximum of 10% of either:
- The assigned value, if an unbiased verification method is used; or
  - The expected mean value for the analyte, if a biased method is used.
- 7.1.10 For analytes contained on or in sampling media, the assigned value of an analyte is verified if the mean of the Provider's verification analyses is within one-half of the Laboratory acceptance limits, as defined in the SSAS Table, of either:
- The assigned value, if an unbiased verification method is used; or
  - The expected mean value for the analyte, if a biased method is used.
- 7.1.11 The standard deviation of the verification analyses shall be less than one standard deviation, as calculated for the participant Laboratories.
- 7.1.12 Any manufacturing lot that fails to meet the requirements of this Section shall not be used as an audit sample.
- 7.2 Homogeneity Testing**
- 7.2.1 Providers shall analytically verify that all analytes in all manufacturing lots of audit samples are sufficiently homogenous, according to the requirements of Section 7.2, prior to their use as an audit sample.
- 7.2.2 Homogeneity shall be verified using a procedure, approved by the Provider Accreditor, to verify that differences between audit samples will not impact the evaluation of the stationary source test.
- 7.2.3 Homogeneity testing shall be performed on a representative selection of audit samples randomly selected from each final packaged audit sample batch prior to shipment.
- 7.2.4 Any manufacturing lot that fails to meet the requirements of this Section shall not be used as an audit sample.
- 7.3 Stability Testing**
- 7.3.1 Providers shall verify the expiration date of the audit sample manufacturing lot and shall verify that all analytes in all audit samples remained stable.
- 7.3.2 Providers shall conduct stability testing of each lot of audit sample material or have data showing, to the satisfaction of the Provider Accreditor, that the sample was stable during the time period of use in the SSAS Program
- 7.3.3 If appropriate according to the sample design, Providers shall retain samples from each audit sample manufacturing lot for use in confirmation of the lot assigned values and subsequent analytical verification.
- 7.3.4 The Provider shall use a stability verification procedure approved by the Provider Accreditor.

7.3.5 Audit samples or analytes that fail to meet the criteria of this Section shall be invalidated, and all sample recipients notified with a detailed discussion report.

#### 7.4 Verification, Homogeneity, and Stability Testing Reporting

7.4.1 Upon request, and only after the Provider has released their evaluation of the audit sample analyses results, the Provider shall release, to a designated Participant, the results of the Provider's assigned value verification, homogeneity, and stability testing for any audit sample/analyte for which the Participant has reported or received data.

7.4.2 Upon request, and only after the Provider has released their evaluation of the audit sample analyses results, the Provider shall release to the PT Executive Committee the results of the Provider's assigned value verification, homogeneity, and stability testing for any audit sample/analyte.

7.4.3 To protect the blind nature of the audit sample, the Provider shall ensure the manufacturing lot number does not appear on any labels or documentation they provide to Participants and the PT Executive Committee, for assigned value verification, homogeneity, or stability testing.

7.5 Providers shall label each audit sample with a unique identifier, the SSAS Number.

### 8.0 ORDERING AND REPORTING INSTRUCTIONS

8.1 The Provider shall receive an audit sample order from a Facility or its authorized representative. The Provider shall contact the appropriate Regulatory Agency within five (5) business days to request any specific requirements (e.g., changes to the audit sample concentration and/or shipment address) prior to shipment of the audit sample. The Provider may ship the audit sample if response is not received from the Regulatory Agency within fifteen (15) calendar days of such request.

- a) Providers assign audit samples based on Laboratory-specific information received during the initial audit sample order.
- b) The Provider shall ensure that the audit sample is sealed such that opening or tampering will be apparent.
- c) The Provider shall ship the audit sample to the Facility, unless the Regulatory Agency requests that it be shipped, instead, to the Regulatory Agency.
- d) If the Facility cancels or modifies an audit sample order at any time, including modification of the Stationary Source Tester and/or Laboratory selected by the Facility, the Provider shall notify the Regulatory Agency of such cancellation or modification within two (2) business days of the receipt of such notice.

8.2 The Provider shall provide instructions with each audit sample shipment, describing:

- a) How to handle, store, dilute or otherwise prepare the audit sample;
- b) How to report the data. The following attestation statement must be signed and submitted with the data:

*"By affixing my signature below, I attest that the audit sample analyses results have met the following criteria:*

- 1) *I have no prior knowledge of the concentration of target analyte(s) in the audit sample. No additional information was solicited or received concerning the assigned values or acceptance ranges for the audit sample.*
  - 2) *The audit sample(s) I am reporting was/were analyzed in the same laboratory under the same calibration, utilizing the same quality control standards, by the same analysts following audit sample instructions as the stationary source test samples.*
  - 3) *The stationary source test laboratory results and the audit sample analyses results have been reported to the appropriate regulatory agency.”*
- c) The expiration date or valid time frame of the audit sample being provided;
  - d) A warning that the TNI Standard requires audit samples to be analyzed at the same time as the stationary source test samples utilizing the same analysts, methods, and quality control procedures; and
  - e) A warning that the TNI Standard requires audit samples that test the field stack sampling process (e.g., for EPA Method 25), to be collected before, during, or after the collection of the field samples, or as directed by the Regulatory Agency, utilizing the same methods and quality control procedures.

### 8.3 The Provider shall not:

- a) Provide inappropriate assistance to the Participants, nor encourage the non-routine analysis of audit samples;
  - b) Suggest or direct that Laboratories use additional quality control samples or quality control samples designed specifically for a given audit sample, in conjunction with any audit sample;
  - c) Provide excessive volume of any audit sample that may encourage non-routine analyses;
- NOTE: The Provider Accreditor, in consultation with the PT Executive Committee, will determine what constitutes excessive volume based on method requirements and common Provider practices within the industry.
- d) Provide actual concentrations of audit sample to the Facility;
  - e) Ship an audit sample past its established expiration date; and
  - f) Send an audit sample from the same manufacturing lot to the same Facility or Laboratory consecutively, or more than once in a calendar month, or more than eight (8) times in a twelve month period.

## 9.0 SYSTEM FOR REPORTING

The Provider shall:

- a) Have procedures and systems in place to ensure the accurate, timely, and secure transmission of audit sample data to the Provider;
- b) Have a reporting mechanism that ensures the results received by the Provider are consistent with those submitted;

- c) Ensure that results reported are not delayed or lost due to the Provider's reporting mechanism;
- d) Ensure that data are kept secure and that they are not subject to unauthorized dissemination either during or after data reporting to the Provider; and
- e) Evaluate only the analytes of interest for each audit sample, as reported.

## 10.0 AUDIT SAMPLE DATA ANALYSIS

### 10.1 Data Review

On a periodic basis to be determined by the Provider Accreditor, the Provider shall review the data reported for the following conditions:

- 10.1.1 Providers shall review all audit sample data for bimodal or multi-modal distributions and/or situations where results from a given method have disproportionately large failure rates or reporting anomalies.
- 10.1.2 If a multi-modal distribution is found related to an analytical method, this data shall be reported to the SSAS Expert Committee.
- 10.1.3 Providers shall review all audit sample data for disproportionately high or low failure rates compared to historical norms.

### 10.2 Evaluation of Individual Participant Results

- 10.2.1 The Provider shall evaluate a result as "Acceptable" if it falls within the SSAS Table-defined acceptance limits.
- 10.2.2 The Provider shall evaluate a result as "Not Acceptable" if it falls outside the SSAS Table-defined acceptance limits.
- 10.2.3 The Provider shall evaluate a result as "Not Acceptable" if it cannot be evaluated (e.g., alpha characters for a quantitative test or reported as a less than or greater than value).
- 10.2.4 If the Provider invalidates an analyte in the audit sample, all evaluations for data reported for that analyte shall be "No Evaluation" and a discussion of the situation leading to the invalidation shall be included in the final report to Participants.

## 11.0 GENERATION OF REPORTS

### 11.1 Schedule

- 11.1.1 The Provider shall submit the evaluation reports defined in Section 11.2 to the required parties no later than three (3) business days after the reporting of the audit sample data, with the following exception:
  - 11.1.1.1 Audit samples are Laboratory-specific. In the event that the Provider receives audit sample results from a Facility whereby the Stationary Source Tester and/or Laboratory associated with the audit sample results are different from those previously identified in the audit sample order, the Provider shall, within two (2) business days of receipt of the audit sample results, request approval from the Regulatory Agency to submit the evaluation reports to the required parties. The Provider shall allow three (3) business days following the notification to the Regulatory Agency to receive a response from the

**Regulatory Agency. After that three (3) business-day waiting period, if the Regulatory Agency has approved reporting the results or has not responded to the notification, the Provider shall then submit the evaluation reports to the required parties no later than three (3) business days following the end of the waiting period.**

- 11.1.2 The Provider shall submit evaluation reports to Facilities, Facility-requested Regulatory Agencies, Stationary Source Testers that performed the test and test method audited, Laboratories that analyzed the audit samples, other parties requested by the Facility, and to the SSAS Central Database within the same twenty-four (24) hour period.

NOTE: Evaluation reports may be submitted in hardcopy or electronic form.

## **11.2 Evaluation Report**

- 11.2.1 The Provider shall include the following information in the evaluation report:

- a) Provider name
- b) Provider accreditation number
- c) Participant Facility name
- d) Participant Facility physical address
- e) Name, title, and telephone number of Facility point of contact, as provided
- f) Laboratory's or Stationary Source Tester's name, address, and other contact information (e.g., telephone, email, and fax)
- g) Date evaluation report was prepared
- h) Date evaluation report was amended, if applicable

- 11.2.2 The Provider shall include the following information for each audit sample/analyte in the final evaluation report:

- a) SSAS Number
- b) Analyte name
- c) Analyte code defined in the SSAS Table
- d) Identification of any analytes not included in the Provider's accreditation
- e) Assigned value
- f) Laboratory value, as reported
- g) Method name or description, as reported
- h) Matrix description

- i) Analysis dates, as reported by the participating Laboratory
- j) Evaluation, per Section 10.2 above
- k) Stationary Source Test Start Date

11.2.3 Each page of the final evaluation report shall include an indication of the length of the report, presented by either "Page X of Y" or the total number of pages with each page consecutively numbered.

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