2008

[SECTOR]

[VOLUME X]

GENERAL REQUIREMENTS FOR AN ACCREDITOR OF STATIONARY SOURCE AUDIT SAMPLE PROVIDERS

TNI Working Draft Standard

Drafted December 15, 2008

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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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1.0 INTRODUCTION, SCOPE, AND APPLICABILITY

1.1 Introduction

This Volume provides the requirements for an organization to function as a TNI-approved Stationary Source Audit Sample Provider Accreditor (SSAS PA).

1.2 Scope

The TNI SSAS program includes the following elements:

a) the production and supply of SSASs that challenge the critical components of each analytical procedure, from initial sample preparation to final data analysis;

b) the production and supply of SSASs 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 SSAS data that are technically defensible on the basis of the type and quality of the SSASs provided; and

d) the preparation of SSASs that pose equivalent difficulty and challenge, regardless of the manner in which the SSASs are designed and manufactured by the SSAS providers.

1.3 Applicability

1.3.1 This Volume is applicable to any organization seeking to function as a TNI-approved SSAS PA. The requirements define the responsibilities of the TNI-approved SSAS PA(s). 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 SSAS PA 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 TNI PT Board must approve them as applicable to TNI accreditations. In addition, these recognitions allow TNI SSAS providers to offer their services in regions where TNI accreditation may not be recognized.

1.3.2 Included in this Volume are some of the responsibilities of the TNI PT Board regarding the determination of SSAS availability (as defined in the TNI FoPT tables), SSAS program content, SSAS PA evaluation criteria, and oversight.

1.3.3 This is not intended as a complete set of requirements or procedures for the TNI 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 SSAS PA(s).

2.0 NORMATIVE REFERENCES

Not Applicable.

3.0 TERMS AND DEFINITIONS

For the purpose of this Standard, 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 Field of Proficiency Testing (FoPT) Table: Table in which the analytes and acceptance limits for SSAS materials are defined.

3.2 Stationary Source Audit Sample (SSAS): 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 SSAS is analyzed, or collected and analyzed, as part of the batch of field test samples using the same personnel, procedures, and materials.

3.3 Stationary Source Audit Sample Program (SSAS Program): The procedures 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. The program establishes requirements for facilities, stationary source testers, and laboratories for field collection (if applicable), analysis, reporting of measurement results, and reporting of SSAS analyses results.

3.4 Stationary Source Audit Sample Provider (SSAS Provider): A person or organization accredited by the TNI-approved SSAS PA.

3.5 Stationary Source Audit Sample Provider Accreditor (SSAS PA): An organization that is evaluated and approved by TNI to accredit and monitor the performance of SSAS providers.

3.6 TNI PT Board (PT Board): A board consisting of TNI members or affiliates, appointed by the TNI Board of Directors (BOD), 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 PT BOARD OVERSIGHT OF THE SSAS PROGRAM

4.1 SSAS 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. Content of SSAS programs, concentration ranges, expected values, and acceptance criteria shall, where appropriate, be consistent with public health needs and best international practices.

To this end, the PT Board shall:

4.1.1 Define SSAS requirements for content, including:

a) the appropriate matrix;
b) measurement technologies;
c) analytes or classes of analytes;
d) required concentration range;

4.1.2 Determine acceptance limits for each analyte. The tables containing all analyte acceptance limits established by the PT Board shall be publicly available.

4.1.3 Review SSAS data and the acceptance limits at least biennially to revise existing evaluation criteria and establish new criteria, as needed.

4.2 Selection of SSAS PA

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

4.2.1 Assure that the prospective SSAS PA meets all requirements in Section 5 of this Volume.

4.2.2 Approve all policies and procedures used by the SSAS PA for the purposes of accreditation and oversight of SSAS providers. This shall include approval of any additional (non-TNI) requirements from the SSAS PA that are related to their policies for compliance with ISO/IEC 17011 and international agreements.

4.2.3 Conduct appropriate biennial on-site assessments of any organization seeking to be an SSAS PA.

4.3 Determining Criteria for Oversight

4.3.1 The PT Board shall determine criteria for ongoing oversight of SSAS provider activities, including activities and objectives for the SSAS PA review consistent with this Standard.

4.3.2 The PT Board shall have arrangements to develop and maintain a database for oversight of SSAS providers. The database shall include the following:

a) data on verification, homogeneity, and stability testing;

b) summary information about each SSAS manufacturing lot, including

i. means and standard deviations
ii. number of results
iii. information about unacceptable rates
iv. any other information requested by the SSAS PA to meet the requirements of Section 6.3.

4.3.3 The PT Board shall serve as final arbiter for:

a) complaints about the SSAS PA that come from regulatory agencies or from SSAS providers;

b) disputes between SSAS PAs.

5.0 REQUIREMENTS FOR APPROVAL OF SSAS PA

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 SSAS PA 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 SSAS 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, General requirements for accreditation bodies accrediting conformity assessment bodies;*

b) have, or have access to, technical expertise that conforms with *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 SSAS providers;

c) expertise in statistical applications used for interlaboratory comparison programs;

d) the capability to conduct on-site assessments of SSAS providers that are consistent with this Standard;

e) the capability to conduct technical reviews of initial applications.

5.2 Responsibilities Regarding Assessment of SSAS Providers

5.2.1 The assessment and oversight activities of the SSAS PA shall be designed to ensure that any accredited SSAS provider meets the requirements specified in Volume 3 of this Standard, and in Section 6 of this Volume.

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 SSAS PA.

5.3 Development of Standard Operating Procedures and Forms

The SSAS PA shall develop procedures to conduct the SSAS provider evaluation. These documents shall be based upon the requirements of this Standard.

5.3.1 The SSAS PA shall develop and implement procedures including, but not limited to:

a) the initial application submittal and review process;
b) on-site assessment;
c) accreditation process;
d) submittal of oversight information to the SSAS PA;
e) revoking a SSAS provider's accreditation;
f) appealing accreditation determinations.

5.3.2 The SSAS PA shall develop procedures for the initial application process to be followed by SSAS providers applying for accreditation. The application shall include information about the qualifications of the organization seeking accreditation.

5.3.3 The SSAS PA'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 SSAS PA for that activity, product, or characteristic. To the extent feasible, the SSAS PA shall not assess those activities that are so recognized.

NOTE: By mutual recognition agreement, the SSAS PA is allowed to find non-conformances in activities that have recognized accreditation.

5.3.4 The SSAS PA shall develop procedures for conducting consistent and effective on-site assessments of SSAS providers. The procedures shall include a description of the circumstances for conducting any additional assessments or unannounced assessments.

5.3.5 The SSAS PA shall develop standard, concise, and unambiguous checklist(s) to be used during all assessments of SSAS providers.

5.4 Development and Maintenance of a Comprehensive SSAS Database

5.4.1 The SSAS PA shall maintain a comprehensive SSAS database that contains summaries of participant results and results of all verification, homogeneity, and stability determinations.

5.4.2 The SSAS PA shall instruct SSAS providers on procedures for submitting data to the database.

5.5 List of Accredited SSAS Providers

5.5.1 The SSAS PA shall maintain a list of accredited SSAS providers and the SSASs 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 SSAS PA shall ensure that all accredited SSAS providers abide by the provisions of the PT Board and the SSAS PA regarding the advertising and marketing of their accreditation approval status.

5.6 SSAS PA Ethics

5.6.1 The SSAS PA shall serve as an impartial body designed to objectively evaluate information about SSAS providers and use this information to make sound determinations regarding a provider's accreditation status.

5.6.2 The SSAS PA 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.

5.6.3 The SSAS PA shall remain unbiased in evaluating information gathered and received including assessment reports, referee sample results, complaints, and any other information obtained regarding an SSAS provider.

5.6.4 The SSAS PA shall evaluate all information about SSAS providers related to providing the SSAS program, determine which information is relevant to the SSAS 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 SSAS PA by the SSAS provider in the course of its assessment and oversight activities shall be proprietary in nature. The SSAS PA shall agree to maintain the confidentiality of proprietary information provided to it by the SSAS providers.

5.7.2 The SSAS PA shall treat all SSAS 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. This information shall not be released without prior written permission from the SSAS provider.

6.0 REQUIREMENTS FOR ACCREDITATION OF SSAS PROVIDERS

The accreditation process shall be repeated every two (2) years, and shall include all stages of initial review, on-site 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 SSAS PA's internal policies, as approved by its mutual recognition partners.

6.1 Initial Application Review

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

a) the initial application documents for compliance with the SSAS provider qualifications described in this Standard;

b) the SSAS designs used by the SSAS provider for compliance with this Standard;

c) the SSAS analyte and scoring procedures used by the SSAS provider for compliance with this Standard;

d) procedures used to validate that new SSAS formulations are fit for their intended purpose, prior to use of such materials. This review shall ensure, at a minimum, that SSASs have assigned values within the specified ranges for every technology used to report results;

e) the adequacy of data processing and analysis techniques, including statistical procedures used on SSAS 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;

ii the sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, accreditation to this Standard.

g) providing SSAS 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 SSAS PA to comply with their own policies and external agreements.

6.2 On-Site Assessment

6.2.1 An on-site assessment of the SSAS 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;

b) a review of staff qualifications and technical expertise necessary to produce acceptable SSASs;

c) a review of the SSAS 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 SSAS 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 SSAS PA shall provide a written final report to the SSAS provider during the exit briefing. The final report may only contain findings identified during the on-site assessment and discussed during the exit briefing, as defined in the SSAS PA's procedures.

6.2.3 The SSAS PA shall allow the SSAS provider to submit its response to the report. In order for the SSAS provider's response to be considered acceptable, it shall include a description of any corrective actions necessary to meet the criteria of this Standard, and, as appropriate, objective evidence of successful implementation of any corrective action.

6.2.4 A SSAS PA shall follow its procedure for determining accreditation. This procedure shall include use of the appropriate final assessment report and associated documents submitted by the SSAS provider.

6.3 Responsibilities for Ongoing Monitoring of SSAS Providers

6.3.1 The SSAS PA shall conduct ongoing monitoring of all accredited SSAS providers. This shall include a review of SSAS verification and SSAS data to assure that every SSAS meets the criteria defined in this Standard. The review shall also include:

a) assurance that concentrations are distributed throughout the specified analyte ranges;

b) confirmation of the required number of analytes included in groups;

c) approval of documentation for any change in the initial assigned value;

d) confirmation of the correct calculation of assigned values and acceptance limits as appropriate per analyte;

e) verification of the prepared or assigned value;

f) appropriate homogeneity testing;

g) appropriate stability testing.

6.3.2 The SSAS PA shall investigate any situation where the SSAS provider's overall or analyte pass/fail rate is statistically different from the national average at a 95% level, as determined by appropriate statistical techniques.

6.3.3 The SSAS PA may use an accredited referee laboratory to verify the assigned values of the concentrations when monitoring indicates that the SSAS provider's SSAS is of unacceptable quality.

a) The determination of unacceptable quality shall use the same acceptance criteria that were used in the manufacture of the SSAS (for example, one standard deviation for verification or the approved criteria for homogeneity and stability).

b) The SSAS PA shall provide each SSAS provider with a report describing the results for any required referee analyses.

6.3.4 The monitoring shall provide verification of the SSAS provider's adherence to the appropriate standards for the following:

a) correct and complete analyte lists as per SSAS provider accreditation;

b) a process for handling complaints;

c) compliance with defined nomenclature (codes) for methods, analytes and technologies;

d) timeliness of reports to customers, regulatory agencies, and the SSAS PA.

6.3.5 SSAS PA monitoring shall include review of critical operational parameters of the SSAS provider, such as changes in ownership or senior management, and the evidence of internal assessments and management review.

6.3.6 Unscheduled on-site assessments of the SSAS provider may be conducted for exceptional circumstances, such as persistent complaints from SSAS program participants or regulatory agencies, failure to adequately respond to inquiries from the SSAS PA, or other evidence of persistent non-conforming activity. The causes and resolution of exceptional visits shall be fully documented.

6.3.7 Any possible problems indicated by the monitoring shall be discussed first with the SSAS provider. Complete records shall be maintained of all contacts and responses from the SSAS provider.

6.3.8 Based upon the results of its ongoing monitoring and its internal appeals process, the SSAS PA may determine that the SSAS provider's accreditation status should be suspended or withdrawn.

6.4 Complaints and Corrective Action

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

6.4.2 The SSAS PA shall provide to the TNI PT Board a summary of all SSAS provider complaints received the previous year.

6.4.3 Complaints made to SSAS providers and the resultant corrective actions shall be reviewed by the SSAS PA in the following manner:

a) review of a written summary of all complaints regarding the technical aspects of the SSAS and the resulting corrective actions; and

b) review of all complaints that are unresolved after ninety (90) days.

6.4.4 The SSAS PA shall review any complaints about SSAS providers received from regulatory agencies, and work with the SSAS provider, the regulatory agency, and the PT Board to resolve the complaints.

6.5 Suspension or Revocation of SSAS Provider Accreditation

6.5.1 Based on their review of SSAS data, on-site assessments, and corrective actions associated with complaints or other non-conformances, the SSAS PA may determine that the SSAS provider fails to meet the requirements of this Standard on a continuing basis.

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

6.5.3 The SSAS PA shall inform the SSAS provider of the reasons for proposed revocation or suspension and the procedures for appeal of such a decision.

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