TNI Stationary Source Audit Sample Expert Committee Teleconference
March 26, 2012

Attendance:

| | | |
|---|---|---|
| Maria Friedman – Chair<br>TestAmerica (Laboratory) | Committee member | present |
| Mike Hayes<br>Linde (Provider) | Committee member | absent |
| Michael Klein<br>New Jersey DEP (State government) | Committee member | present |
| Theresa Lowe<br>CCI Environmental | Committee member | absent |
| Paul Meeter<br>Weston Solutions (Stationary Source Tester) | Committee member | present |
| Gregg O'Neal,<br>North Carolina DAQ (State government) | Committee member | present |
| Michael Schapira<br>Enthalpy (Laboratory) | Committee member | present |
| Jim Serne<br>TRC Solutions (Stationary Source Tester) | Committee member | present |
| Richard Swartz, Vice-chair<br>Missouri DNR (State government) | Committee member | absent |
| Stanley Tong<br>EPA Region 9 (Federal government) | Committee member | present |
| Ken Jackson<br>TNI (Program Administrator) | Program Administrator | present |
| Ty Garber<br>Wibby (Provider) | Associate member | absent |
| Shawn Kassner<br>ERA (Provider) | Associate member | present |
| Mike Miller<br>(Member at large) | Associate member | absent |
| William Mills<br>Mills Consulting (NELAC Assessor) | Associate member | absent |
| William Daystrom<br>TNI (Webmaster) | Guest | present |

1) Double-check receipt of documents to be referenced in this teleconference.

All present confirmed receipt of the documents e-mailed March 23, 2012.

2) Review and approve minutes from teleconference on March 19, 2012.

It was moved by Gregg and seconded by Jim to approve the minutes. Since only 5 members were in favor (there was one abstention), it was decided to complete the vote by e-mail.

3) Chair update

Maria reported that ERA's information has been posted on the EPA website, and she has received approval for it to be posted on the TNI website. Shawn will send a draft of the ERA scope of accreditation to Maria, and they will decide how it should be presented. She has also written an article for the TNI newsletter.

4) Review draft SOP re. SSAS Table Update (last updated on 3-22-2012)

Prior to the meeting, Maria had circulated an updated draft SOP incorporating the language discussed during the previous week's call. This is attached, with the new text highlighted. Further changes were discussed.

In the second sentence of Section 4.5, it was questioned what "6 months thereafter" means. If it is 6 months after the approval date, does it mean there will be a 6-month delay before anyone can order the new analytes? Maria said if providers can get them out sooner, they could be made available, but cannot be called TNI audit samples before the 6-month time schedule unless all the providers agree it can be accelerated (e.g., in the case of just a concentration range change). There were two suggestions to change the sentence to read: either "The effective date of approved modifications will be set by the SSAS Expert Committee and shall not exceed 6 months", or "The effective date of approved modifications will be 6 months or a date set by the SSAS Expert Committee, whichever is first".

It was discussed whether the SSAS Expert Committee or the SSAS Table Subcommittee should drive the review process in the subsections of 5.2.2. It was said subsections 5.2.2.4 and 5.2.2.5 should be driven by the Expert Committee before going to the Table Subcommittee, since they are policy decisions. However, subsections 5.2.2.2 and 5.2.2.3 should not go to the Expert Committee until the Table Subcommittee has made its recommendation. It was asked if a step is needed to send the modified table to EPA for approval, but that is already in Section 4.5. However, the first sentence of Section 4.5 should be modified to read: "Modifications to the SSAS Table, when deemed necessary, must be first approved by the SSAS Expert Committee and the approved modifications must then also be approved by EPA." Gregg suggested re-ordering the 5.2.2 subsections as follows: 5.2.2.1; 5.2.2.10; 5.2.2.6; 5.2.2.7; 5.2.2.8; 5.2.2.3; 5.2.2.2; 5.2.2.4; 5.2.2.5; and 5.2.2.9.

In Section 5.3.1, Shawn said the number of data points should not be specified. It is better to state "sufficient data". However, Maria explained it means 20 points per concentration range, and there needs to be more language to say this. The subcommittee should look at the 20 points and use that information to establish the acceptance criteria. However, EPA has not said what are sufficient data, so maybe 20 points should not be specified as a minimum. It was discussed whether fewer than 20 points will sometimes be sufficient, and it was suggested that the Expert Committee should be allowed to recommend smaller or larger data sets, depending on what is statistically valid. The TNI SOP for PT acceptance criteria states 10 studies with 10 participants in each; i.e.,100 data points. It was suggested that would be too much work for an audit sample, and maybe 20 points is more realistic.

Shawn stated that, in section 6.1.1, removal of a method or analyte(s) should require a sponsor.

The Stationary Source Audit Sample Table Change Request Application (attached) was briefly reviewed. It was questioned why, in Section 3, method needs to be there. It was pointed out that if method is there and there is no method code, TNI can create one.

At this point the discussion ended and Maria asked the call participants to let her know before the next call if they see anything else in the SOP that may need changing.

5) Adjournment

The meeting was adjourned at 3:15 pm EDT.

The next meeting is scheduled for April 9, 2012, at 2:00 pm EDT

TNI Stationary Source Audit Sample Expert Committee Teleconference Agenda for March 26, 2012:

1) Double-check receipt of documents to be referenced in this teleconference

2) Review and approve minutes from teleconference on March 19, 2012

3) Chair update

4) Review draft SOP re. SSAS Table Update (last updated on 3-22-2012)


| | |
|---|---|
| **SOP TITLE:** | **SSAS Table Management** |
| **SOP NO.:** | **x-xxx** |
| **REVISION NO:** | **0.0** |

| | | | |
|---|---|---|---|
| **Committee:** | SSAS Expert Committee | **Approved Date:** | [Enter date here] |
| **Program Board:** | NA | **Approved Date:** | NA |
| **Policy Committee Reviewed Date:** | | | [Enter date here] |
| **TNI Board of Directors Endorsed Date:** | | | [Enter date here] |
| **SOP Effective Date:** | | | [Enter date here] |

# Table of Contents

## 1.0 Purpose and Applicability

This Standard Operating Procedure (SOP) delineates procedures for updating the Stationary Source Audit Sample (SSAS) Table. The procedures described herein apply to all methods and analytes used in the TNI SSAS Program.

## 2.0 Summary

A request is made to modify the SSAS Table. The SSAS Expert Committee reviews all requests, such as adding or removing methods or analytes, setting or changing concentration ranges and acceptance criteria, and correcting typographical and formatting errors. When any modification is approved, a new revision number and effective date are established according to defined timelines.

## 3.0 Definitions

Audit Sample Reporting Limit (ASRL): The lowest result that could be obtained from the lowest spike level for an analyte, provided in the SSAS Table as guidance to laboratories analyzing SSAS samples.

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

SSAS Table: Table in which the analytes and acceptance limits for audit sample materials are defined.

Sponsor: A Regulatory Agency that agrees with the need to add a method, analyte, or group of analytes to the SSAS Table. A sponsor is not required when requesting the removal of a method, analyte, or group of analytes from the SSAS Table.

## 4.0 General Procedure for SSAS Table Modification

4.1 Requests to modify the SSAS Table may be made by a Participant in the TNI SSAS Program, namely, a Regulatory Agency, Provider, Provider Accreditor, Laboratory, Stationary Source Tester, or Facility. Modifications requested may be any one or more of the types listed below:

4.1.1 Addition or removal of a method

4.1.2 Addition or removal of an analyte

4.1.3 Changes to NELAC (TNI) Analyte Codes

4.1.4 Changes to concentration ranges, units, acceptance criteria, and ASRLs

4.1.5 Changes to footnotes

4.1.6 Changes to group headers

4.1.7 Changes to effective dates

4.1.8 Changes as a result of the biennial SSAS Table review per the TNI SSAS Standard

4.1.9 Corrections to typographical or formatting errors

4.1.9.1 Changes to numerical values or acceptance criteria are not considered typographical errors.

4.1.9.2 Corrections to typographical or formatting errors do not require a change in the SSAS Table's Effective Date.

4.2 Request for typographical or formatting corrections must be sent to the SSAS Expert Committee Chair, whose contact information is available on the TNI SSAS Expert Committee page on the TNI website.

4.3 Request for modifications other than typographical or formatting corrections must be initiated using the SSAS Table Change Request Application (CRA) and submitted electronically to the SSAS Expert Committee Chair.

4.3.1 A CRA must be filled out for each type of modification requested. See Attachment 1.

4.3.2 If the modification requested is for the addition of a method, analyte, or group of analytes, a Sponsor is required (see Section 5.1.1). All other modifications do not require a Sponsor.

4.4 Depending on the type of modification requested, the SSAS Expert Committee may direct the SSAS Table Subcommittee to review requested modification and prepare formal recommendations for consideration by the SSAS Expert Committee voting members. The SSAS Expert Committee will work with the subcommittee to set acceptable timetable goals for completion of their review and proposal.

4.5 Modifications to the SSAS Table, when deemed necessary, must be first approved by the SSAS Expert Committee and then by EPA. Approved modifications will be effective 6 months, thereafter.

4.6 The newly modified SSAS Table will reflect a new effective date and a new revision number.

4.6.1 When the SSAS Table undergoes modifications not related to typographical or formatting corrections, the assigned revision number follows a progression of Rev.1.0, 2.0, 3.0, and so on.

4.6.2 When the SSAS Table undergoes modifications related to typographical or formatting corrections, the assigned revision number follows a progression of Rev. 1.1, 1.2, 1.3, and so on.

4.7 Public notice will be posted on the TNI website as notification that an updated SSAS Table has been approved.

4.8 In the event of default acceptance criteria having been assigned to new analytes due to insufficient historical data, the SSAS Expert Committee shall monitor the SSAS Central Database until which time that at least 20 data points have been collected for the new analyte. At that time, the SSAS Expert Committee shall evaluate the collected data to assign new acceptance criteria based upon the historical data.

## 5.0 Addition of Methods or Analytes

### 5.1 Requirements for Requests

5.1.1 Requests to add a method, analyte, or group of analytes to the SSAS Table must be sponsored by at least one Regulatory Agency. If the requestor is a Regulatory

Agency, an additional sponsor is not required.

5.1.2 The CRA submittal shall include:

5.1.2.1 The method(s) and/or analyte(s) being requested

5.1.2.2 The requestor's reason(s) for adding the method(s) or analyte(s)

5.1.2.3 The proposed spiking concentration and initial acceptance criteria

5.1.2.4 The required supporting documentation noted on the CRA

## 5.2 Review Procedure

5.2.1 The SSAS Expert Committee notifies EPA, within 14 days of receipt of the request, to ascertain whether or not the EPA would consider allowing the addition of the requested method, analyte, or group of analytes.

5.2.2 If EPA deems the request appropriate, the SSAS Expert Committee will initiate a review of the request within 14 days of notification from EPA. When deemed necessary, the SSAS Table Subcommittee will be requested to review the request and submit a recommendation, within agreed upon timelines, to the SSAS Expert Committee. Whether the review is undertaken by the SSAS Expert Committee or by the SSAS Table Subcommittee, the review shall include, but not be limited to, the following elements:

5.2.2.1 The CRA and supplied documentation

5.2.2.2 Availability of SSAS Providers to provide an audit sample compatible with the proposed method(s) and spiked with the proposed analyte(s)

5.2.2.3 Cost impact assessment to Providers, Laboratories, and Facilities

5.2.2.4 TNI SSAS Program risk assessment – Is addition of the method(s) or analyte(s) really necessary?

5.2.2.5 Regulatory need

5.2.2.6 Technical feasibility – This must include one or more method validation studies showing that the analyte(s) can be measured at the required concentration range by the specified SSAS method. SSAS Providers may be requested to provide input, based on their experience with the requested new method, analyte, or group of analytes.

5.2.2.7 Concentration range – The requested concentration range will be evaluated for suitability based on input from Participants. A default concentration range appropriate to the method will be assigned, if necessary, based on a reasonable expectation of method and analyte performance.

5.2.2.8 Initial acceptance criteria – When historical data do not exist, default acceptance criteria of 10% to 200% Recovery will be assigned unless more appropriate acceptance criteria can be derived from data supplied with the CRA.

5.2.2.9 NELAC (TNI) Method or Analyte Code – Does one exist?

5.2.2.10 Historical data availability

5.2.3 The request review process shall be documented, including, but not limited to, minutes of relevant meetings, checklists, data pertaining to the request, calculations, graphs, and other information used in the decision-making process. Documentation shall be submitted to TNI for posting and archiving.

5.2.4 The review shall be completed within 60 days of the initiation of the review. The SSAS Expert Committee Chair will notify the requestor of the SSAS Expert Committee's decision within 14 days thereafter.

### 5.3 Follow-up

5.3.1 In the event of default acceptance criteria having been assigned to new analytes due to insufficient historical data, the SSAS Expert Committee shall monitor the SSAS Central Database until which time that at least 20 data points have been collected for the new analyte. At that time, the SSAS Expert Committee shall evaluate the collected data to assign new acceptance criteria based upon the historical data.

## 6.0 Removal of Methods or Analytes

### 6.1 Requirements for Requests

6.1.1 Requests to remove a method, analyte, or group of analytes from the SSAS Table does not require a sponsor.

6.1.2 The CRA submittal shall include:

6.1.2.1 The method(s) or analyte(s) to be removed

6.1.2.2 The requestor's reason(s) for removing the method(s) or analyte(s)

6.1.2.3 The required supporting documentation noted on the CRA.

### 6.2 Review Procedure

6.2.1 The SSAS Expert Committee notifies EPA, within 14 days of receipt of the request, to ascertain whether or not the EPA would consider allowing the removal of the requested method, analyte, or group of analytes.

6.2.2 If EPA deems the request appropriate, the SSAS Expert Committee will initiate a review of the request within 14 days of notification from EPA. When deemed necessary, the SSAS Table Subcommittee will be requested to review the request and submit a recommendation, within agreed upon timelines, to the SSAS Expert Committee. Whether the review is undertaken by the SSAS Expert Committee or by the SSAS Table Subcommittee, the review shall include, but not be limited to, the following elements:

6.2.2.1 The CRA and supplied documentation

6.2.2.2 Impact on other SSAS Table – Does this change impact other methods or analytes?

6.2.2.3 TNI SSAS Program risk assessment – Is an audit sample for this method(s) or analyte(s) necessary?

6.2.2.4 Regulatory need – Does a Regulatory Agency currently collect/use data resulting from the analysis of the audit sample method(s) or analyte(s)?

6.2.3 The request review process shall be documented, including, but not limited to, minutes of relevant meetings, checklists, data pertaining to the request, calculations, graphs, and other information used in the decision-making process. Documentation shall be submitted to TNI for posting and archiving.

6.2.4 The review shall be completed within 60 days of the initiation of the review. The SSAS Expert Committee Chair will notify the requestor of the SSAS Expert Committee's decision within 14 days thereafter.

## 7.0 References

7.1 TNI Standard, Stationary Source Audit Sample Program, Volume 1, Module 1: General Requirements for Stationary Source Audit Sample Providers, current revision

7.2 TNI Standard, Stationary Source Audit Sample Program, Volume 1, Module 2: General Requirements for an Accreditor of Stationary Source Audit Sample Providers, current revision

7.3 TNI Standard, Stationary Source Audit Sample Program, Volume 1, Module 3: Requirements for Participation in the TNI Stationary Source Audit Sample Program, current revision

## 8.0 SOP Approved Changes

| Previous SOP No. | New SOP No. | Date of Change | Description of Change |
|---|---|---|---|
| | x-xxx | xx/xx/2012 | New Document. |
| | | | |
| | | | |

## 9.0 Tables, Figures, Diagrams, Charts, Examples, Checklists, and Appendices


**Stationary Source Audit Sample (SSAS) Table**
**Change Request Application**

SUBMISSION DATE: _____

## SECTION 1 – Requestor/Organization Information

Requestor: _____

Organization: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Facsimile: _____

Email:_____

## Section 2 – Change Request

Instructions: Check the corresponding box below to indicate the type of change you are requesting, and complete the corresponding section as instructed. Requests for multiple types of changes must be submitted using separate applications.

☐ **Add Method(s) or Analyte(s); complete Sections 3 and 3A**

☐ **Remove Method(s) or Analyte(s); complete Sections 3 and 3B**

☐ **Change concentration ranges, units, or acceptance criteria; complete Section 4**

☐ **Change footnotes; complete Section 4**

☐ **Other (specify) _____; complete Section 4**

## Section 3 – Add or Remove Method(s) or Analyte(s)

Instructions: Supply all requested information below. Attach additional sheets if necessary. If requesting addition, also complete Section 3A. If requesting removal, also complete Section 3B.

**Method(s) to be added or removed:**

| TNI Method Code | Method Name/Description |
|---|---|
| | |
| | |

**Analyte(s) to be added or removed:**

| TNI Analyte Code | Analyte Name |
|---|---|
| | |
| | |
| | |
| | |
| | |

**Reason(s) for adding or removing the method(s) and/or analyte(s):**

_____
_____
_____
_____
_____
_____
_____
_____
_____

**Requests for adding a new method, analyte, or group of analytes must be sponsored by at least one Regulatory Agency (including the requestor).**

Sponsor Regulatory Agency: _____

Official Contact: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Facsimile: _____

Email: _____

**Note here if reference to any additional Regulatory Agency sponsors is being provided.**

**Additional sponsors? No** ☐

**Yes** ☐ Other Sponsors : _____

_____

If yes, provide contact information on additional sponsors as an attachment to the application.

## Section 3A – Addition of Method(s) and/or Analyte(s)

Do any TNI approved SSAS Providers currently offer the analyte(s) in a product suitable for use as a SSAS audit sample?

**No** ☐ **Yes** ☐ **Unknown** ☐

If yes, attach a list of products known to be currently available (specify each SSAS Provider, SSAS Provider's product name, and SSAS Provider's catalog reference.)

The following documentation must also be provided as attachments to this application when requesting addition of new analyte(s):

1) Proposed spiking concentration and initial acceptance criteria
2) Information on technical feasibility – This must include one or more method validation studies showing that the analyte(s) can be measured at the required concentration range by the specified SSAS method.

## Section 3B – Removal of Method(s) and/or Analyte(s)

Do any Regulatory Agencies currently collect /use data resulting from the analysis of the audit sample method(s) or analyte(s)?

**No** ☐ **Yes** ☐ **Unknown** ☐

The following documentation must also be provided as attachments to this application when requesting removal of method(s) and/or analyte(s):

1) Copies of any supporting documents that were referenced in Section 3 in the reason(s) provided for removing the method(s) and/or analyte(s).

## Section 4 – Miscellaneous Changes

**Describe in details the changes requested. Provide attachments as needed.**

_____
_____
_____
_____
_____
_____
_____
_____
_____

## Section 5 – Submittal of Application

All applications (including attachments) must be submitted electronically via email to the TNI SSAS Expert Committee Chair. No paper copies will be accepted. Contact information is posted on the SSAS Expert Committee page on the TNI website at http://nelac-institute.org.

Please complete the application and provide the supporting documentation as instructed. Incomplete applications will delay the review process and may be returned to the requestor.