TNI Stationary Source Audit Sample Expert Committee Teleconference
March 19, 2012

Attendance:

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

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

All present confirmed receipt of the documents e-mailed March 16, 2012.

2) Review and approve minutes from teleconference on March 12, 2012.

Under item #3 (chair update), the second and third sentences were modified to read "However, ERA's list of available audit samples will be posted on the TNI website, and then on the EPA website when

two (or more) accredited SSAS Providers become available. EPA will only post those method/analyte combinations when there are 2 or more accredited providers."

With this change in effect it was moved by Gregg and seconded by Michael Schapira to approve the minutes. All were in favor.

3) Review draft SOP re. SSAS Table

Prior to the meeting, Maria had circulated a draft SOP incorporating the language discussed during the previous week's call, together with proposals from Jim Serne and Mike Schapira. These are attached. Before continuing the discussion Maria reminded Committee Members to let everyone know if they see anything else that needs bringing in from the PT Executive Committee SOP.

Jim Serne's comments. Jim had proposed a phase-in period for gathering data to set acceptance criteria for new analytes and types of audit sample. It was discussed how funding might be obtained for generating the data and designing the new audit samples. Asking EPA for funding, perhaps through a grant, was considered, and Stan volunteered to informally contact EPA about this possibility. However, any formal request would need to be routed through the TNI Board of Directors. The cost would obviously depend on the analytes and methods. The providers may be able to estimate how much it would cost, and it was speculated the providers might be prepared to do this work at their expense if it would lead to sufficient demand for the new samples; especially if they already produced PT samples with the same analytes. A set of top-performing laboratories might be needed to generate the data voluntarily. The PT program used 20 samples, which may be acceptable at one concentration level, so it was suggested 50 samples may be appropriate if a spread of concentrations needs to be established. However, this might take too long to get enough data, since there might not be a high level of reporting when it is not yet a required audit sample. The experimental PT requirement in the environmental laboratory standard was described, with its pitfalls such as the difficulty persuading laboratories to run the PTs when they would not be scored. Maria suggested finding a pool of laboratories prepared to do the work at no cost and a provider who will sponsor the new audit sample. It was asked if we need an idea in advance of how close to the true value they would need to report (e.g., 10%).

Ken described a process used by the New York PT program when the first solid waste samples were prepared and distributed. They were scored right away by using consensus robust statistics; i.e., laboratories passed if they reported a result within 2 standard deviations of the mean, so approximately 95% of the laboratories passed. With the first round of samples the standard deviation was very high, but this quickly dropped with successive rounds as the laboratories gained more experience. It was thought a similar process might be feasible, since EPA has nothing in its rules about how to handle new analytes/samples. Therefore, a tentative plan will be to first propose a concentration range and acceptance criteria, e.g.,10%-200%R, or other limits, and then ask providers if they can do it. A passing score on the new audit sample would then be required immediately, and the passing requirements could then be updated when sufficient historical data had been obtained. It was suggested there might also be existing data from PTs that could be used to establish the initial limits.

In light of the above discussion, Maria will update the draft SOP, depending on any feedback from Stan's communication with EPA. It was suggested having a provider on the next call, to ask if they would have the incentive to make new samples, and Mike Hayes added it would depend how big the demand would be. William will draft a SSAS Table Change Request Application.

4) Adjournment

The meeting was adjourned at 3:00 pm EDT.

The next meeting is scheduled for March 26, 2012, at 2:00 pm EDT

TNI Stationary Source Audit Sample Expert Committee Teleconference Agenda for March 19, 2012:

1) Double-check receipt of documents to be referenced in this teleconference
2) Review and approve minutes from teleconference on March 12, 2012
3) Review draft SOP re. SSAS Table Update

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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

The SSAS Expert Committee reviews all requests to make modifications to the SSAS Table, 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 SSAS Table Modification

4.1 Types of modifications:

- 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 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.

4.3 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.

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

4.4.1 When the SSAS Table undergoes non-typographical or formatting modifications, the assigned revision number follows a progression of Rev.1.0, 2.0, 3.0, and so on. When the SSAS Table undergoes a typographical or formatting correction, the assigned revision number follows a progression of Rev. 1.1, 1.2, 1.3, and so on.

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

5.0 Reviewing Requests to Add New Methods or Analytes to the SSAS Table

5.1 Requests to add a method, analyte, or group of analytes to the SSAS Table may be made by a Participant in the SSAS Program, namely, a Regulatory Agency, Provider, Provider Accreditor, Laboratory, Stationary Source Tester, or Facility. A request must be sponsored by at least one Regulatory Agency. If the requestor is a Regulatory Agency, an additional sponsor is not required.

5.2 To request a new method, analyte, or group of analytes, a SSAS Table Change Request Application (CRA) shall be completed by the requestor and submitted electronically to the SSAS Expert Committee Chair. The CRA submittal shall include:

5.2.1 The method(s) and/or analyte(s) being requested.

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

5.2.3 The proposed spiking concentration and initial acceptance criteria.

5.2.4 The required supporting documentation noted on the CRA.

5.3 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.

5.4 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:

5.4.1 The CRA and supplied documentation

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

5.4.3 Cost impact assessment to Providers, Laboratories, and Facilities

5.4.4 SSAS Program risk assessment - Is addition of the method(s) or analyte(s) really necessary?

5.4.5 Regulatory need

5.4.6 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.

5.4.7 Concentration range and initial acceptance criteria. When historical data do not exist, default acceptance criteria based on a reasonable expectation of method and analyte performance is used unless more appropriate acceptance criteria can be derived from data supplied with the CRA.

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

5.4.9 Historical data availability

5.5 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.

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

6.0 Reviewing Requests to Remove Methods or Analytes from the SSAS Table

6.1 Requests to remove a method, analyte, or group of analytes to 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.

6.2 To request removal of a method, analyte, or group of analytes, a SSAS Table Change Request Application (CRA) shall be completed by the requestor and submitted electronically to the SSAS Expert Committee Chair. The CRA submittal shall include:

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

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

6.2.3 The required supporting documentation noted on the CRA.

6.3 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.

6.4 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:

6.4.1 The CRA and supplied documentation

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

6.4.3 SSAS Program risk assessment - Is an audit sample for this method(s) or analyte(s) necessary?

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

6.5 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.

6.6 The review shall be completed within 60 days of the initiation of the review. The SSAS Expert Committee Chair, or designee, 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

Prev. 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

Proposal from Jim Serne

TNI SSAS PROCEDURE FOR DEVELOPING AND IMPLEMENTING NEW ANALYTES AND TYPES OF AUDITS

SECTION XX:
NEW ANAYLTE AND NEW AUDIT TYPE PHASE-IN PROCESS

The acceptance criteria for SSAS audits must be established (at least in part) based on historical data. In order to obtain historical data, a "phase-in period" is needed for gathering a statistically meaningful number of analyses of the new audits to be analyzed by well qualified laboratories.
The phase-in period may need to be several months to one year in order to gather an adequate number of data at low and high concentrations since it will be necessary to set audit concentration ranges as well as the acceptance criteria across the audit concentration range.
During the phase-in period, there will be no acceptance criteria and therefore, a pass or fail determination for the new analyte or type of audit will not apply. These new audits will only be used to gather data that TNI may use for developing new analytes or types of audits for use in the SSAS Program.

ISSUES TO DISCUSS:
The approximate number of samples needed at each concentration is 50 (???) (Need input from acceptance table subcommittee and/or statistician)
Need TNI database set up to accept data so it later can be used to seta acceptance criteria.
Need Provider input on how they would handle developing audits for new analytes or types of audits, and how many concentrations would they want to try (low, mid, high) to see if the acceptance criteria are linear.
Need Regulator and Tester input on the what new analytes or types of audits are needed.

Phase In

Proposal from Mike Schapira

In the event that an analyte of interest for a project is not listed in the current TNI SSAS table the agency representative should contact the EPA (Candace ?) to request a new analyte be funded for testing, so that sufficient data can be collected to get the analyte added to the table. The agency would then insist that the samplers do the work of 'collecting' or 're-shipping' (as appropriate) the audit sample, and EPA would be responsible for the billing of the audit sample (perhaps directly by the labs while doing the project - or as a refund to testers upon report completion if they simply pay for the extra sample)?