

TNI Stationary Source Audit Sample Expert Committee Teleconference
April 23, 2012, 2:00 pm EDT

Attendance:

Maria Friedman – Chair TestAmerica (Laboratory)	Committee member	present
Mike Hayes Linde (Provider)	Committee member	absent
Michael Klein New Jersey DEP (State government)	Committee member	present
Theresa Lowe CCI Environmental	Committee member	absent
Paul Meeter Weston Solutions (Stationary Source Tester)	Committee member	absent
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	absent
Richard Swartz, Vice-chair Missouri DNR (State government)	Committee member	absent
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	present
Mike Miller (Member at large)	Associate member	present
William Mills Mills Consulting (NELAC Assessor)	Associate member	absent
William Daystrom TNI (Webmaster)	Guest	present
Wayne Stollings	Guest	present

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

All present confirmed receipt of the documents e-mailed April 20, 2012.

- 2) Review and approve minutes from the teleconference on April 9, 2012.

It was moved by Gregg to approve the minutes (there was no second). It was decided to conduct the review and vote by e-mail. It was noted that the previous minutes (March 26) had been approved by e-mail.

3) Review draft SOP re. SSAS Table Update (last updated on 4-20-2012)

Maria described the further changes to the SOP, highlighted in yellow on the attached copy. She also noted that Sections 5.2.4 and 5.2.5 had been reversed, as had sections 6.2.4 and 6.2.5. There were no further comments on the SOP.

The Stationary Source Audit Sample Table Change Request Application (CRA; attached) was also briefly reviewed. Only one extra change had been made (highlighted in yellow) and there were no further comments.

4) Review TNI SOP 4-101; Recommendation and Calculation of Acceptance Limits for Chemical, Radiochemical, and Microbiological Components of Proficiency Tests

This SOP is used in the TNI laboratory accreditation proficiency test program, and it was examined whether it can be used in the SSAS program. It was questioned whether Section 5.3.1 in the draft SOP re. SSAS Table Update would then need to be changed to reflect the use of this SOP. Mike Miller recommended adding to Section 5.3.1 that the TNI Field of Proficiency Testing committee should monitor when enough data points have been accumulated and should then recommend acceptance limits to the SSASEC. Mike also cautioned that SOP 4-101 requires a strong statistical approval that needs a lot of data points to establish the acceptance limits, and it needs to be decided if this is needed for audit samples. Maria commented that could then mean months or even years before there are enough data, so timing would be a problem. She added that we are bound by the EPA Final Rule to only use historical data. Mike Miller pointed out that Section 5.2.3.6 provides for default acceptance criteria until sufficient historical data have been collected.

Maria noted that the version of SOP 4-101 available and distributed to all in the SSAS Expert Committee was marked as a draft. Maria added that if SOPs like this are to be referenced in the SSAS SOPs, they should be in the final approved version. Shawn concurred.

Maria will work on revised language for the section on Review Procedure for additions of methods and analytes. The language will not reference specific SOPs like 4-101 but will be more of a general statement that will enable use of SOPs like SOP 4-101, as long as the SOP followed meets the requirements of the Final Rule. The draft SSAS Table Management SOP will be e-mailed for the Committee to review.

Maria asked for any comments on SOP 4-101 to be sent to her before the next call.

5) Other business

Ken will find out the numbering system to be used by SSASEC for its SOPs.

Shawn reported that the subcommittee has made a recommendation on Method 25. Maria will distribute it to the Committee and she announced this will be the main topic of the next call.

It was reported that ERG is not planning to participate in the privatized SSAS Program. Maria will follow up on any progress with the second provider.

6) Adjournment

The meeting was adjourned at 2:40 pm EDT.

The next meeting is scheduled for May 8, 2012, at 2:00 pm EDT

TNI Stationary Source Audit Sample Expert Committee Teleconference Agenda for April 23, 2012:

- 1) Double-check receipt of documents to be referenced in this teleconference
- 2) Review and approve minutes from teleconference on April 9, 2012
- 3) Review draft SOP re. SSAS Table Update (last updated on 4-20-2012)
- 4) Review TNI SOP 4-101; Recommendation and Calculation of Acceptance Limits for Chemical, Radiochemical, and Microbiological Components of Proficiency Tests



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]

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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 by a Participant 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.

Participant: The Facility, Regulatory Agency, Stationary Source Tester, Laboratory, and Provider participating in a stationary source test.

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.

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. Modifications requested may be 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 or removal 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, or on the date approved by the SSAS Expert Committee, whichever is sooner.
- 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 **completes** a preliminary review of the request, within **21** days of receipt of the request, to determine whether to proceed with a formal review. Factors that may determine whether to proceed include, but are not limited to, regulatory need and impact to the TNI SSAS Program.

5.2.2 If the SSAS Expert Committee determines that the request merits a formal review, the SSAS Expert Committee notifies EPA to ascertain whether or not EPA would consider allowing the addition of the requested method, analyte, or group of analytes. If the SSAS Expert Committee determines that the request is without merit, the SSAS Expert Committee Chair shall notify the requestor of the SSAS Expert Committee's decision within 14 days thereafter.

5.2.3 If EPA deems the request appropriate, the SSAS Expert Committee will initiate a formal 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 formal review is undertaken by the SSAS Expert Committee or by the SSAS Table Subcommittee, the formal review shall include, but not be limited to, the following elements:

5.2.3.1 The CRA and supplied documentation

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

5.2.3.3 Historical data availability

5.2.3.4 Technical feasibility – This must include one or more method validation studies showing that the analyte(s) can be measured at the **requested** 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.

5.2.3.5 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.

5.2.3.6 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.

5.2.3.7 Cost impact assessment to Providers, Laboratories, and Facilities

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

5.2.4 The SSAS Expert Committee Chair shall notify the requestor of the SSAS Expert Committee's decision within 14 days **of completion of the formal review.**

5.2.5 The entire 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.

5.3 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 20 data points, or other number as determined appropriate by the SSAS Expert Committee, 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 must be sponsored by at least one Regulatory Agency. If the requestor is a Regulatory Agency, an additional sponsor is not required.

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 **completes** a preliminary review of the request, within **21** days of receipt of the request, to determine whether to proceed with a formal review. Factors that may determine whether to proceed include, but are not limited to, regulatory need and impact to the TNI SSAS Program.

6.2.2 If the SSAS Expert Committee determines that the request merits a formal review, the SSAS Expert Committee notifies EPA to ascertain whether or not EPA would consider allowing the removal of the requested method, analyte, or group of analytes. If the SSAS Expert Committee determines that the request is without merit, the SSAS Expert Committee Chair will notify the requestor of the SSAS Expert Committee's decision within 14 days thereafter.

6.2.3 If EPA deems the request appropriate, the SSAS Expert Committee will initiate a formal 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 formal review is undertaken by the SSAS Expert

Committee or by the SSAS Table Subcommittee, the formal review shall include, but not be limited to, the following elements:

- 6.2.3.1 The CRA and supplied documentation
- 6.2.3.2 Impact on other SSAS Table – Does this change impact other methods or analytes?
- 6.2.4 The SSAS Expert Committee Chair shall notify the requestor of the SSAS Expert Committee’s decision within 14 days **of completion of the formal review.**
- 6.2.5 The entire 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.

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 or removing a 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.