



SOP TITLE:	SSAS Table Management
SOP NO.:	6-101
REVISION NO:	0
PROGRAM	Stationary Source Audit Sample

SOP Approval Dates

	Initial Approval	Last Revision Date	Last Review Date
Committee: SSAS	9/4/2012		
Program			
Policy Committee Review			
TNI Board of Directors Endorsement			
Effective Date	9/4/2012		

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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 audit 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

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- 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 As required in the EPA Final Rule [75 FR 55636, September 13, 2010], "Restructuring of the Stationary Source Audit Program," historical audit sample data must be used when considering requests to change acceptance criteria for existing methods and analytes.
- 4.5 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.
- 4.6 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.
- 4.7 The newly modified SSAS Table will reflect a new effective date and a new revision number.
 - 4.7.1 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.
 - 4.7.2 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.
- 4.8 Public notice will be posted on the TNI website as notification that an updated SSAS Table has been approved.
- 4.9 In the event of initial acceptance criteria, derived from sources other than historical audit sample data, having been assigned to new analytes, 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.

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 30 calendar 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 calendar 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 calendar 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

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necessary, based on a reasonable expectation of method and analyte performance.

5.2.3.6 Initial acceptance criteria – When historical audit sample data do not exist, acceptance criteria will be established using one or more of the following sources, unless more appropriate acceptance criteria can be derived from data supplied with the CRA:

5.2.3.6.1 Results of a pilot study, if available

5.2.3.6.2 Historical data from samples other than audit samples, using the same sample matrix and method as would be used with audit samples. Acceptable sources include, but are not limited to, data from the EPA Office of Water, the EPA Office of Solid Waste, or the EPA Office of Air and Radiation.

5.2.3.6.3 An expert evaluation of the capabilities of the method, based on calibration requirements and prior experience with other samples, recorded in 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 calendar 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 initial acceptance criteria, derived from sources other than historical audit sample data, having been assigned to new analytes, 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 30 calendar 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 calendar 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 calendar 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 calendar 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

Revision No.	Effective Date	Description of Change
0	9-4-2012	New Document. (Renumbered from SOP 2-104)

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

Attachment 1: SSAS Table Change Request Application

TNI SSAS Table Change Request Application (CRA)
Effective: 9-4-2012

Revision 1.0



**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**

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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):

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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.

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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.