

SOP TITLE:	SSAS Table Management
SOP NO.:	2-102
<b>REVISION NO:</b>	1.0

Committee:	SSAS Expert Committee	Approved Date:	9-4-2012
Program Board:	NA	Approved Date:	NA
Policy Committee R	Reviewed Date:		[Enter date here]
TNI Board of Direct	ors 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

<u>Audit Sample Reporting Limit (ASRL)</u>: 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.

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

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

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

<u>Sponsor</u>: 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 Attachment1.
  - 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

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

Previous SOP	New SOP	Date of	Description of Change
No.	No.	Change	
None	2-102	9-4-2012	Approved by SSAS Expert Committee

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

## Attachment 1: SSAS Table Change Request Application

Stationary So Char	THE NELAC INSTITUTE Purce Audit Sample (SSAS) Tab nge Request Application	Revision 1.0
SUBMISSION DATE:		
SECTION 1 – Requestor/Organizat	ion Information	
Requestor:		
Organization:		
Address:		
City:	State:	Zip:
Telephone:	Facsimile:	
Section 2 – Change Request		
requesting, and complete the corresp of changes must be submitted using s		
requesting, and complete the corresp	omplete Sections 3 and 3A	
requesting, and complete the corresp of changes must be submitted using a Add Method(s) or Analyte(s); co Remove Method(s) or Analyte(s	omplete Sections 3 and 3A s); complete Sections 3 and 3B	
requesting, and complete the corresp of changes must be submitted using s Add Method(s) or Analyte(s); co	omplete Sections 3 and 3A s); complete Sections 3 and 3B units, or acceptance criteria; c	
<ul> <li>requesting, and complete the corresp of changes must be submitted using a</li> <li>Add Method(s) or Analyte(s); co</li> <li>Remove Method(s) or Analyte(s)</li> <li>Change concentration ranges,</li> </ul>	omplete Sections 3 and 3A s); complete Sections 3 and 3B units, or acceptance criteria; c ection 4	omplete Section 4

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TNI SSAS Table Change Effective: 9-4-2012	Request Application (CRA)	Revision 1
Section 3 – Add o	r Remove Method(s) or Analyte(s)	
	ly all requested information below. Attach addit , also complete Section 3A. If requesting remo	
	dded or removed:	
TNI Method Code	Method Name/Description	
Analyte(s) to be a	dded or removed:	
TNI Analyte Code	Analyte Name	
Reason(s) for add	ling or removing the method(s) and/or analy	te(s):
Reason(s) for add	ling or removing the method(s) and/or analy	te(s):
Reason(s) for add	ling or removing the method(s) and/or analy	te(s):
Reason(s) for add	ling or removing the method(s) and/or analy	te(s):
Reason(s) for add	ling or removing the method(s) and/or analy	te(s):
Reason(s) for add	ling or removing the method(s) and/or analy	te(s):
Reason(s) for add	ling or removing the method(s) and/or analy	te(s):

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Effective: 9-4-2012		
Requests for adding or removing a meth sponsored by at least one Regulatory Ag		
Sponsor Regulatory Agency:	10 1010 A2 1040	200 - 100 
Official Contact:		
Address:		
City:		
Telephone:	Facsimile:	22 NJ 1022 - 10
Email:		
Note here if reference to any additional F	Regulatory Agency s	ponsors is being provided.
Additional sponsors? No		
Yes Other Spor	ISOTS	
	- 65	
If we are a stated as the state of a state o		
If yes, provide contact information on addition	onal sponsors as an a	ttachment to the application.
If yes, provide contact information on addition	onal sponsors as an a	ttachment to the application.
adoli – a anch i e ne kochanye ingeriosekken ola akterakinek ola akteraki		ttachment to the application.
Section 3A – Addition of Method(s) and/o	or Analyte(s)	
adoli – a anch i e ne kochanye ingeriosekken ola akterakinek ola akteraki	or Analyte(s)	
Section 3A – Addition of Method(s) and/o Do any TNI approved SSAS Providers curro use as a SSAS audit sample?	or Analyte(s)	
Section 3A – Addition of Method(s) and/o Do any TNI approved SSAS Providers curre	or Analyte(s) ently offer the analyte( currently available (sp	s) in a product suitable for becify each SSAS Provider,
Section 3A – Addition of Method(s) and/o Do any TNI approved SSAS Providers curre use as a SSAS audit sample? No Yes Unknown I If yes, attach a list of products known to be	or Analyte(s) ently offer the analyte( currently available (sp Provider's catalog refe	s) in a product suitable for becify each SSAS Provider, erence.)
Section 3A – Addition of Method(s) and/o Do any TNI approved SSAS Providers curre use as a SSAS audit sample? No Yes Unknown I If yes, attach a list of products known to be SSAS Provider's product name, and SSAS The following documentation must also be p	or Analyte(s) ently offer the analyte( currently available (sp Provider's catalog refe provided as attachmer	s) in a product suitable for becify each SSAS Provider, erence.)
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Section 3A – Addition of Method(s) and/o Do any TNI approved SSAS Providers curre use as a SSAS audit sample? No Yes VINKnown I If yes, attach a list of products known to be SSAS Provider's product name, and SSAS The following documentation must also be p requesting addition of new analyte(s): 1) Proposed spiking concentration and 2) Information on technical feasibility –	or Analyte(s) ently offer the analyte( currently available (sp Provider's catalog refe provided as attachmer initial acceptance crite This must include one an be measured at the	s) in a product suitable for becify each SSAS Provider, erence.) Ints to this application when eria or more method validation
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Section 3A – Addition of Method(s) and/o Do any TNI approved SSAS Providers curre use as a SSAS audit sample? No Yes VINKnown I If yes, attach a list of products known to be SSAS Provider's product name, and SSAS The following documentation must also be p requesting addition of new analyte(s): 1) Proposed spiking concentration and 2) Information on technical feasibility – studies showing that the analyte(s) c	or Analyte(s) ently offer the analyte( currently available (sp Provider's catalog refe provided as attachmer initial acceptance crite This must include one an be measured at the	s) in a product suitable for becify each SSAS Provider, erence.) Ints to this application when eria or more method validation
Section 3A – Addition of Method(s) and/o Do any TNI approved SSAS Providers curre use as a SSAS audit sample? No Yes VINKnown I If yes, attach a list of products known to be SSAS Provider's product name, and SSAS The following documentation must also be p requesting addition of new analyte(s): 1) Proposed spiking concentration and 2) Information on technical feasibility – studies showing that the analyte(s) c	or Analyte(s) ently offer the analyte( currently available (sp Provider's catalog refe provided as attachmer initial acceptance crite This must include one an be measured at the	s) in a product suitable for becify each SSAS Provider, erence.) Ints to this application when eria or more method validation
Section 3A – Addition of Method(s) and/o Do any TNI approved SSAS Providers curre use as a SSAS audit sample? No Yes Unknown I If yes, attach a list of products known to be SSAS Provider's product name, and SSAS The following documentation must also be p requesting addition of new analyte(s): 1) Proposed spiking concentration and 2) Information on technical feasibility – studies showing that the analyte(s) c	or Analyte(s) ently offer the analyte( currently available (sp Provider's catalog refe provided as attachmer initial acceptance crite This must include one an be measured at the	s) in a product suitable for becify each SSAS Provider, erence.) Ints to this application when eria or more method validation

TNI SSAS Table C Effective: 9-4-2012	Change Request Application (CRA) 2	Revision 1.0
Section 3B -	Removal of Method(s) and/or Analyte(s)	
	atory Agencies currently collect /use data resulting find(s) or analyte(s)?	rom the analysis of the audit
No 🗌 Yes	Unknown	
	documentation must also be provided as attachmen noval of method(s) and/or analyte(s):	ts to this application when
	of any supporting documents that were referenced is ad for removing the method(s) and/or analyte(s).	n Section 3 in the reason(s)
Section 4 – N	/iscellaneous Changes	
Describe in d	letails the changes requested. Provide attachme	nts as needed.
Section 5 – S	submittal of Application	
All application		nically via email to the TNI . Contact information is
All application SSAS Expert posted on the Please comple	submittal of Application s (including attachments) must be submitted electro Committee Chair. No paper copies will be accepted	nically via email to the TNI . Contact information is t http://nelac-institute.org.