



<b>SOP TITLE</b>	<b>SSAS Table Management</b>
<b>SOP NO.</b>	<b>6-101</b>
<b>REVISION NO.</b>	<b>1.0 (Provisional)</b>
<b>PROGRAM</b>	<b>SSAS</b>

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**1.0 Purpose and Applicability**

The purpose of this Standard Operating Procedure (SOP) is to delineate procedures for updating the TNI Stationary Source Audit Sample (SSAS) Table.

The procedures described herein apply to all methods and analytes found in the most current TNI SSAS Table, to the addition of new method/analyte combinations to the TNI SSAS Table, or to the deletion of methods or analytes from the TNI SSAS Table.

**2.0 Summary**

This SOP details the management of the SSAS Table used in the Stationary Source Audit Program (SSAP). Procedures for approval of changes to the TNI Analyte Code, additions of analytes/methods, approval of removal of analytes/methods, approval of changes in concentration ranges, and approval of changes in acceptance criteria are described.

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 of the SSAS Table are established according to defined timelines.

Requestors are notified within 14 calendar days of the receipt of the Change Request Application (CRA). The merit of the request is determined by the SSAS Expert Committee. If the request is deemed non-persuasive, the requestor is notified within 14 calendar days of the determination of merit, and a reason for the determination of non-persuasiveness is given. If the request is deemed persuasive, the Committee must notify the requestor of the determination of merit within 14 calendar days, and a description of the Committee’s future plans to resolve the request is given. A formal review of all requests deemed to be persuasive is initiated within 60 calendar days of the determination of merit. If necessary, the SSAS Table is then updated based on the outcome of the formal review and any subsequent actions conducted by the SSAS Expert Committee. (See Appendix B).

**3.0 Related Documents**

- 3.1 SOP 1-109: Establishing, Validating, and Maintaining Analyte and Method Codes, Revision 1.
- 3.1 TNI Standard, Stationary Source Audit Sample Program, Volume 1, Module 1: General Requirements for Stationary Source Audit Sample Providers, current revision
- 3.3 TNI Standard, Stationary Source Audit Sample Program, Volume 1, Module 2: General Requirements for an Accreditor of Stationary Source Audit Sample Providers, current revision
- 3.4 TNI Standard, Stationary Source Audit Sample Program, Volume 1, Module 3: Requirements for Participation in the TNI Stationary Source Audit Sample Program, current revision.

**4.0 Definitions**

Term	Definition
Audit Sample Matrix	The substrate of an audit sample. If the audit sample is manufactured in any state other than a whole sample, the Audit Sample Matrix is the substrate in which the audit sample is prepared for use.
Audit Sample Reporting Limit (ASRL)	A statistically derived value that represents the lowest acceptable concentration for an analyte in an Audit sample.
LAMS	Laboratory Accreditation Management System

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Term	Definition
Participant(s)	The Facility, Regulatory Agency, Stationary Source Tester, Laboratory, or Provider participating in a stationary source test.  Note: "Participant" is analogous of "Stakeholder" as defined by TNI.
Quality System Matrix - Air and Emissions	Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device.
Regulatory Agency	The federal, state, local, or tribal agency having responsibility and accountability for overseeing testing of atmospheric emissions from stationary sources.
Should	Indicates that an associated element is recommended but not mandatory and is synonymous with "may".
Sponsor	A Regulatory Agency that agrees with the need to add or remove a method, analyte, or group of analytes to the SSAS Table.
SSAS Table	Table in which the methods, analytes and acceptance limits for audit samples are defined.

## 5.0 Procedure

### 5.1 Submission of Requests:

5.1.1 Requests must be made by a Participant in the TNI SSAS Program.

5.1.2 Modifications requested must be one or more of the types listed below:

- 5.1.2.1 Addition or removal of one or more methods.
- 5.1.2.2 Addition or removal of one or more analytes.
- 5.1.2.3 Changes to TNI Analyte Codes.
- 5.1.2.4 Changes to concentration ranges, units, acceptance criteria, and ASRLs.
- 5.1.2.5 Changes to footnotes.
- 5.1.2.6 Changes to group headers.
- 5.1.2.7 Changes to effective dates.
- 5.1.2.8 Corrections to typographical or formatting errors.

Note 1: Corrections to typographical or formatting errors do not require a change in the SSAS Table's Effective Date.

Note 2: The Quality Systems Matrix for audit samples ("Air & Emissions") must not change.

5.1.3 Requests for typographical or formatting corrections must be submitted electronically to the SSAS Expert Committee Chair. Contact information is posted on the SSAS Expert Committee page on the TNI website at <http://nelac-institute.org>.

5.1.4 Requests 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 (see Appendix A). Contact information is posted on the SSAS Expert Committee page on the TNI website at <http://nelac-institute.org>.

- 5.1.4.1 A separate CRA must be submitted for each type of modification requested.
- 5.1.4.2 Each CRA must be added to the SSAS Committee Action Table.

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- 5.1.5 A Sponsor is required for the addition or removal of a method, analyte, or group of analytes, or to change the concentration range or acceptance limits of an analyte (see Sections 5.1.6 and 5.1.7). All other modifications do not require a Sponsor.

The SSAS table contains the following elements:

- 5.1.5.1 Matrix.
- 5.1.5.2 TNI Analyte Code.
- 5.1.5.3 Analyte.
- 5.1.5.4 Concentration Range.
- 5.1.6.5 Acceptance Criteria.
- 5.1.5.6 Audit Sample Reporting Limit (ASRL)

- 5.1.6 Addition of Methods or Analytes, or changes in concentration range for existing analytes:

5.1.6.1 Requests to add a method, analyte, or group of analytes, or to change the concentration range of an existing analyte, must be sponsored by at least one Regulatory Agency. If the requestor is a Regulatory Agency, an additional sponsor is not required.

5.1.6.2 The CRA submittal must include:

- a) The method(s) and/or analyte(s) being requested;
- b) The requestor's reason(s) for adding the method(s) or analyte(s);
- c) The proposed spiking concentration and initial acceptance criteria; and,
- d) The required supporting documentation noted on the CRA.

- 5.1.7 Removal of Methods or Analytes:

5.1.7.1 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.

5.1.7.2 The CRA submittal must include:

- a) The method(s) and/or analyte(s) to be removed;
- b) The requestor's reason(s) for removing the method(s) or analyte(s); and
- c) The required supporting documentation noted on the CRA.

- 5.2 Consideration of requests by the SSAS Expert Committee:

5.2.1 If a CRA is submitted, the Committee must consider the merits and possible actions needed to address the request.

5.2.2 Determination of Merit:

The committee may determine to find the comment non-persuasive and make no change, or, find the comment persuasive and take appropriate action(s). The SSAS Expert Committee must complete a preliminary review of the request within 30 calendar days of receipt. Factors that may determine merit include, but are not limited to, regulatory need and impact to the TNI SSAS Program. The Committee Chair must notify the requestor within 14 calendar days of the determination of merit.

If the request is deemed non-persuasive, the notification must include the reason(s).

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If the request is deemed persuasive, the notification must include potential actions the Committee may take, and the Committee must initiate a formal review within 60 calendar days of notification.

- 5.2.3 Depending on the type of modification requested, the SSAS Expert Committee may direct a SSAS Table subcommittee to review the requested modification and prepare formal recommendations for consideration by the SSAS Expert Committee voting members. The SSAS Expert Committee may work with the subcommittee to set an acceptable schedule for completion of the review and proposal.
- 5.2.4 Changing TNI Analyte code: The SSAS Expert Committee will review the validity of the Change Request Application with the TNI LAMS Administrator.
- 5.3 Formal Review Process:
  - 5.3.1 Existing Acceptance Limits: 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* concentrations, methods, and analytes. Historical data must be analyzed following the statistical analyses described in SOP 6-100. The Committee must request and formally review the statistical analysis of historical data prior to proceeding with any changes to existing analytes.
  - 5.3.2 Addition of Methods and Analytes, Expansion of Concentration Range:
    - 5.3.2.1 For additions of new methods and/or analytes, the SSAS Expert Committee must begin the formal review within 60 calendar days of receipt of the Change Request Application. While not required or mandated, the Committee Chair should notify the EPA of the request.
    - 5.3.2.2 For expansion of the concentration range for an existing method or analyte, statistical analysis of a data set must be formally reviewed by the Committee prior to any changes to the SSAS Table. The statistical analyses of these data sets may consist of Pilot Study data or historical data (e.g., PT data). Data may be provided as part of the original CRA or may be generated or provided at the request of the SSAS Committee. All statistical analyses must be as described in TNI SOP 6-100. The Committee must begin the formal review within 60 calendar days of receipt of the Change Request Application.
  - 5.3.3 Removal of Methods and Analytes: The SSAS Expert Committee must notify the EPA of the request and seek written guidance (electronic or otherwise).
  - 5.3.4 The formal review must include, but not be limited to, the following elements:
    - 5.3.4.1 The CRA and any other supplied documentation.
    - 5.3.4.2 Availability of SSAS Providers to provide an audit sample compatible with the proposed method(s) and spiked with the proposed analyte(s).
    - 5.3.4.3 Data availability, if applicable.
    - 5.3.4.4 Cost impact assessment to Providers, Laboratories, and Facilities.
    - 5.3.4.5 Impact on other methods or analytes in the SSAS Table, if any.
    - 5.3.4.6 Presence or absence of a TNI Method or Analyte Code.
    - 5.3.4.7 Technical feasibility:
      - a) If the CRA pertains to the addition of a new analyte or method, or to the expansion of the concentration range of existing methods or analytes, technical feasibility considerations must include one or more method

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validation studies showing that the analyte(s) can be measured at the requested concentration range by the specified reference method. The requested concentration range will be evaluated for suitability based on input from Participants.

- b) An evaluation of the capabilities of the method must include alternative technologies, where feasible. A default concentration range appropriate to the method will be assigned, if necessary (such as expanding concentration ranges as with Pilot Studies), based on a reasonable expectation of the reference method and analyte performance. SSAS Providers may be requested to provide input, based on their experience with the requested method, analyte, or group of analytes.

5.3.4.8 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:

- a) Historical data from samples other than audit samples, using the same audit sample matrix and method as would be used with audit samples.

Note: Acceptable sources include, but are not limited to the EPA Office of Air and Radiation, or historical data from PT samples for the specific method and analyte combination of interest.

- b) Results of a pilot study performed following TNI SOP 6-100.

5.3.5 The SSAS Expert Committee Chair must notify the requestor of the SSAS Expert Committee's review findings within 14 calendar days of completion of the formal review.

5.3.6 The entire review process must be documented, including, but not limited to, minutes of relevant meetings, checklists (see Appendix C), data pertaining to the request, calculations, graphs, communications, and other information used in the decision-making process. Documentation must be submitted to TNI for posting and archiving.

## 5.4 Modifications to the SSAS Table:

5.4.1 Modifications to the SSAS Table must be approved by the SSAS Expert Committee. All accredited Audit Providers and the EPA must be notified by the SSAS Expert Committee Chair within 14 calendar days.

5.4.2 The newly modified SSAS Table will be assigned a new effective date and a new revision number. The effective date must be determined based upon audit availability by the Accredited Provider(s).

5.4.2.1 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.

5.4.2.2 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.

5.4.2.3 The updated SSAS Table will be sent to the TNI Webmaster to replace the current SSAS Table on the TNI website.

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

5.5 Follow-up:

To confirm acceptability, the SSAS Expert Committee must evaluate any new concentration range or acceptance limit in the SSAS Table after the new range or limit has been in effect for 6 months or has returned 20 data points, whichever comes first.

**6.0 References**

SOP-6-100: Conducting Pilot Studies for New Concentration Ranges and Acceptance Limits for Source Sampling Audit Samples

**7.0 SOP Approved Changes**

Revision No.	Effective Date	Description of Change
0	9/4/2012	New Document (Originally SOP 2-104)
1.0	1/19/21	Added sections on changing TNI Analyte Code, changing concentration ranges and changing acceptance limits. Clarified "Effective Date" definition. Reorganized Section 5 to follow chronological order of events. Added timelines for replies to requestor. Added Pilot Study (SOP 6-100) as an acceptable source of data to support changing the SSAS Table.



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Appendix A: SSAS Table Change Request Application



**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, and statistical analysis of Pilot Studies, if any.
- 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 detail the changes requested. Provide attachments, data, and statistical analysis, as needed.**

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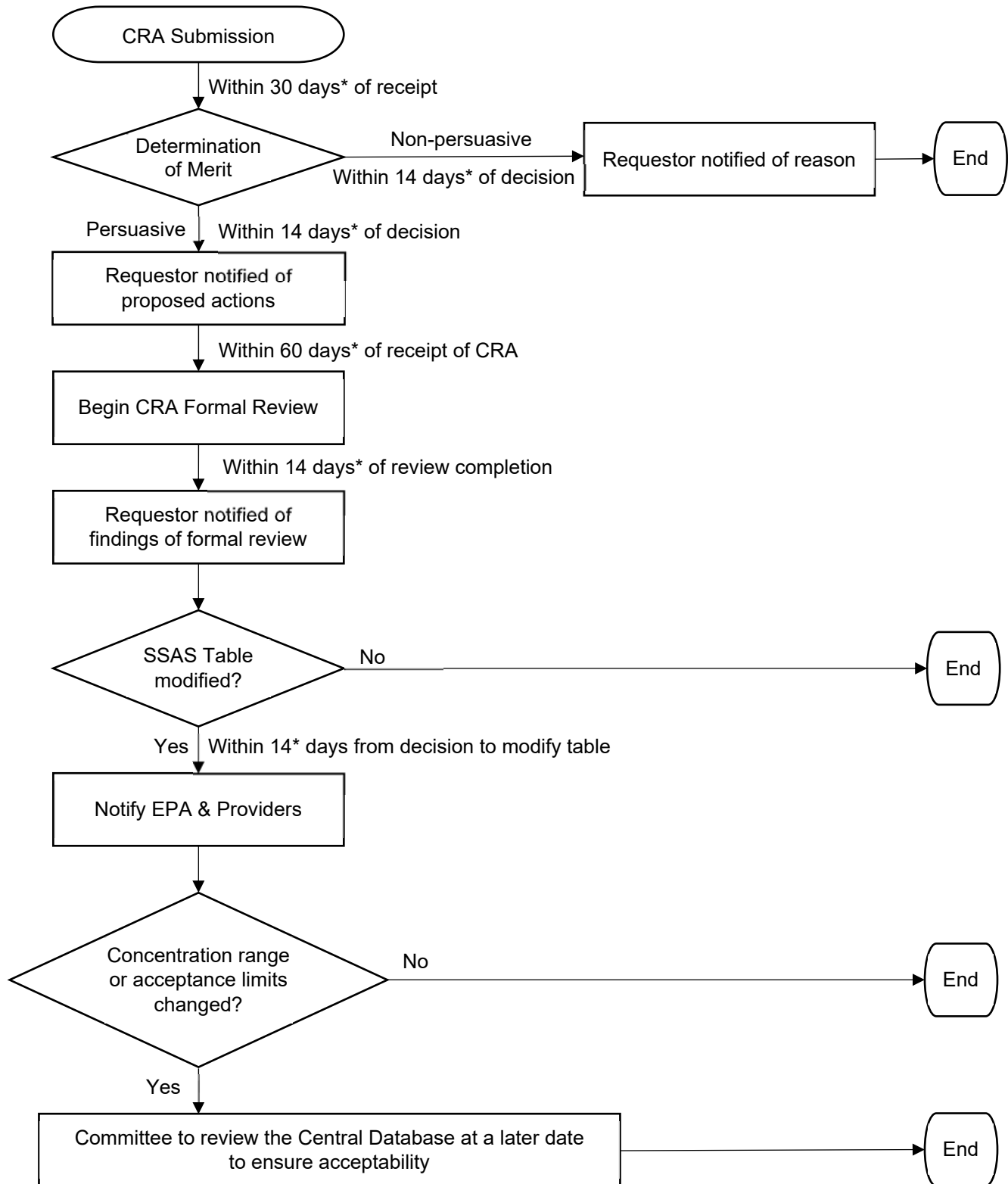
**Section 5 – Submittal of Application**

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.

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Appendix B: SSAS Table Management Summary and Timeline  
 (\*all days refer to Calendar days)



Appendix C: SSAS Table Change Request Formal Review Checklist

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	Item	Yes	No	N/A
1.	CRA complete? (If no, indicate missing requirement)			
2.	If required, is Sponsor a Regulator?			
3.	SSAS Providers able to provide audit sample?			
4.	Supporting Data available from Requestor or Provider?			
5.	Cost of change reasonable for Providers, Laboratories and Facilities?			
6.	Does change impact other methods or analytes?			
7.	Does a NELAC Method or Analyte Code exist?			
8.	If a new Audit Sample, is it technically feasible to be measured at the requested concentration range by the specified reference method?			
9.	Is there a regulatory need for the change?			
10.	Will the change negatively impact the TNI SSAS Program?			