TNI Stationary Source Audit Sample Expert Committee Teleconference
March 12, 2012

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	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 9, 2012.

2) Review and approve minutes from teleconference on February 21, 2012.

It was moved by Michael Schapira and seconded by Jim Serne to approve the minutes as presented. All were in favor.

3) Chair update

Prior to the Chair update, Jim provided a summary of what were presented re. SSAS during last week's SES Conference: Jim presented an overview of the SSAS Program, showed where to find information from either the TNI or EPA websites, and distributed the registration form for Stationary Source Testers to sign-up for the SSAS Central Database. Shawn presented how acceptance criteria in the SSAS Table were determined and what Providers do to demonstrate validity, homogeneity, etc. of the audit samples they provide. Charles presented the results of the Method 25 studies conducted in collaboration with Wayne's lab.

Maria reported that EPA has not yet posted ERA as an accredited provider but will do so. 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. Maria is also writing an article for the TNI newsletter. Regarding Method 25, she mentioned that Shawn Kassner had reported that a formal recommendation is soon to be voted on, and will then be sent to Maria. Charles Simon sent Maria some information on his Method 25 presentation at the SES Conference. and requested his permission to share his presentation, during the SES Conference, to the SSAS committee members; still waiting for Charles' response. Maria will contact ERG to learn their plans for audit samples. The SSAS Table is now posted on the TNI website. It was reported that ACLASS has completed its checklist, which will be sent to the PT Executive Committee soon. Rob Adams' organization, Liquid Technology, is interested in becoming a provider through ACLASS for Method 25 only.

4) Review draft SOP from TNI PT Executive Committee

Maria had circulated a copy of the SOP titled "FoPT Table Management" (attached). She pointed out this is still in draft form and has not yet gone through the approval process. This SOP was reviewed with a view to developing a separate SOP for the SSAS Program. It was noted that the TNI SOP for developing SOPs will also need to be looked at.

All references to the PT Executive Committee and FoPTs will be replaced accordingly when the SOP is written for the SSAS Program.

Section 2.0. Formulations and concentration ranges need to be included as well as how additional items such as samples outside normal concentration ranges will be added.

Section 3.0. Accreditation Body definition is wrong, and needs to be changed to the ISO definition.

Section 4.0. The header needs changing to SSAS table. Addition of analyte by method is required for new and existing methods. It was noted that EPA might be expanding the range for what some methods can be used. A similar change will be needed for removal of an analyte. PTRL will need changed to ASRL.

In the first paragraph after the bulleted list, the subcommittee needs to be specified.

In the second paragraph, EPA approval needs adding. There should be no reference to non-TNI programs.

Section 4.1. There was extensive discussion on the timeframe, and whether 6 months after approval is appropriate for the effective date. It was pointed out the effective date will be when EPA approves the Table. The effective date should not be based or held waiting for when Providers can provide samples since this could take a long time. However, everybody understands that time has to be allotted for Providers to comply with the requirements of an updated Table. The statement re. Providers having to prepare for the new Table does not explicitly need to be in the SOP but all still agreed that 6 months will be appropriate.

Sections 4.2 & 4.3. These sections need no changes other than the global changes (discussed above). However, there was discussion on ownership of the table. Maria offered to inquire whether the table will be the responsibility of EPA or TNI; specifically who will post the table and who will link to it.

Section 4.4. It was agreed to skip this section.

A discussion followed on concentration range, specifically whether providers should have to provide the range. It was commented they should not be accredited if they cannot meet the range in the table. They may not have to make every range routinely available provided they have the capability to provide the full range.

Section 5.0. This section should specify analyte/method combinations. For new analyte method combinations, it was pointed out that acceptance criteria can only be set in cases where historical data are available. There should be a section that addresses providers making new types of audit sample, but with a phase-in period until historical data have been obtained to establish pass/fail or acceptance criteria.

Time did not permit further discussion, and Maria asked the committee to look at Section 5.0 and later sections to be ready to discuss them during the next meeting.

5) Adjournment

The meeting was adjourned at 3:30 pm EDT.

The next meeting is scheduled for March 19, 2012, at 2:00 pm EDT

TNI Stationary Source Audit Sample Expert Committee Teleconference Agenda for March 12, 2012:

1) Double-check receipt of documents to be referenced in this teleconference
2) Review and approve minutes from teleconference on February 21, 2012
3) Chair update
4) Review draft SOP from TNI PTEC

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SOP TITLE:	**FoPT Table Management**
SOP NO.:	4-107
REVISION NO:	0.0

Committee:	PTP Executive Committee	**Approved Date:**	**December 15, 2011**
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:			

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1.0 Purpose and Applicability

This SOP provides procedures for the Proficiency Testing (PT) Executive Committee to manage and update Fields of Proficiency Testing (FoPT) tables. These procedures apply to all current FoPT tables and any proposed FoPT tables.

2.0 Summary

This SOP includes procedures for the PT Executive Committee to review requests to add new analytes to and remove analytes from the TNI FoPT Tables. The procedures address FoPT table modification, setting effective dates and revision numbers, and fixing typos in the tables, as well as how to add FOPT analytes when PT data does not exist. The timeframe for FoPT table modification and implementation is also covered.

3.0 Definitions

Fields of Proficiency Testing Tables – tables that contain the matrices, analytes, analyte codes, concentration ranges, acceptance criteria, and proficiency testing reporting limits (PTRL) adopted by the PT program.

Sponsor – An Accreditation Body that agrees with the need to add an analyte or group of analytes to a FoPT table. A sponsor is not required when requesting the removal of an analyte or group of analytes from a FoPT table.

Accreditation Body – The territorial, state, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

4.0 FoPT Table Modification

FoPT table changes that constitute a modification include the following:

- Addition of an analyte
- Removal of an analyte
- Changes to analyte codes (EPA or NELAC)
- Changes to concentration ranges, units, acceptance criteria, and PTRLs
- Changes to foot notes
- Changes to group headers
- Changes to effective dates

Necessary changes forwarded to a subcommittee for resolution will be added to the subcommittee's agenda. The subcommittee will work with the PT Executive Committee to set acceptable timetable goals for completion of the change(s) and FoPT table update.

When FoPT table modifications are necessary, the modified FoPT table must be approved by both the PT Executive Committee and any other TNI Program (NELAP, NEFAP, etc) that requires the use of that FoPT table. Certain non-TNI Programs, such as certain EPA programs, may also need to be contacted for review and/or approval of changes. A listing of each currently effective FoPT table and the Program it supports (NELAP, NEFAP, etc) is provided in Attachment A.

4.1 Setting a FoPT Table Effective Date

Once the FoPT table has been modified, a suggested Effective Date will be set for the table at the beginning of the final approval process. The table's Effective Date will be finalized after all required Program approvals for the table have been obtained by the PT Executive Committee. The final Effective Date will be set to a date approximately six months after the date the approval process has been

completed. Sufficient time must be allowed for PT provider implementation. Public notice will be posted on the TNI website as notification that the FoPT table will change.

4.2 Fixing FoPT Table Typos

Formatting errors and spelling errors are considered typos. Changes to numerical values or acceptance criteria are not considered typos. The PT Executive committee may edit FoPT tables for typos at any time, without having to obtain approval to do so from other Programs. A FoPT table's Effective Date is not required to be changed when a FoPT table is edited and updated for typos only.

4.3 Setting FoPT Table Revision Numbers

Revision numbers are assigned to FoPT tables upon update. FoPT tables that undergo modifications (as described in section 4.0) are assigned a revision progression of Rev.1.0, 2.0, 3.0 etc. FoPT tables that undergo typo corrections (as described in section 4.2) are assigned a revision progression of Rev. 1.1, 1.2, 1.3, etc.

4.4 FoPT Table Electronic File Naming Convention

File names are structured as follows –

NAME_FOPT_EffectiveYear_EffectiveMonth_EffectiveDay_Rev+number

Example: DW_FOPT_2012_01_03_Rev3.0

Example: NEFAP Pb in Paint_FOPT_2012_01_03_Rev1.0

5.0 Reviewing Requests to Add New Analytes to the FoPT Tables

Requests to add an analyte or group of analytes to an FoPT table may be made by an individual or on behalf of Accreditation Bodies, federal government agencies, laboratories, TNI Programs, or PT Providers. A request submitted by an individual or on behalf of a laboratory or PT Provider must be sponsored by at least one Accreditation Body.

To request a new analyte or group of analytes, a FoPT Analyte Request Application (ARA) shall be completed by the requestor and submitted electronically to the PT Executive Committee Chair. The ARA submittal shall include:

1) The analyte(s) being requested.
2) The requestor's reason(s) for adding the analyte(s).
3) The proposed spiking concentration and initial acceptance criteria.
4) The additional required supporting documentation noted on the application.

The PT Executive Committee will initiate a review of the request within 30 days of receipt of the request. The Executive Committee review shall include a review of the following:

- The Analyte Request Application (ARA) and supplied documentation
- Availability of PT providers to provide a PT spiked with the proposed analyte(s).
- Cost impact assessment to PT providers and laboratories.
- PT program risk assessment - Is addition of the analyte(s) really necessary?
- Regulatory need

    - The appropriate TNI Program (NELAP Accreditation Council, NEFAP, etc) is notified of the request, and asked to confirm whether or not that Program would approve of having that parameter added.
- 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 at least one published method.
- PT range and initial acceptance criteria. The PT Executive Committee may elect to postpone a review of this information until after a FoPT table subcommittee has submitted a recommendation for this criteria. When historical PT data does not exist, a default PT acceptance criteria of study mean +/- three standard deviations is used unless more appropriate acceptance criteria can be derived from data supplied with the Analyte Request Application.
- NELAC (TNI) Analyte Code – Does one exist?
- PT data availability
- Subcommittee availability to process request

The request review process shall be completed in 60-90 days. Upon completion of the review, the PT Executive Committee shall determine whether or not to assign the task of FoPT analyte addition to a FoPT table subcommittee.

The requestor will be notified of the PT Executive Committee's decision on whether or not to proceed with modification of the FoPT table(s) to add the analyte(s).

6.0 Reviewing Requests to Remove Analytes from the FoPT Tables

Requests to remove an analyte or group of analytes from a FoPT table may be made by an individual or on behalf of Accreditation Bodies, federal government agencies, laboratories, TNI Programs, or PT Providers.

To request removal of an analyte or group of analytes, a FoPT Analyte Request Application (ARA) shall be completed by the requestor and submitted electronically to the PT Executive Committee Chair. The ARA submittal shall include:

1) the analyte(s) to be removed.
2) the requestor's reason(s) for removing the analyte(s).
3) the additional required supporting documentation noted on the application.

The PT Executive Committee will initiate a review of the request within 30 days of receipt of the request. The review shall include a review of the following:

- The Analyte Request Application (ARA) and supplied documentation
- Impact on other FoPT tables – Does this change impact more than one FoPT table?
- PT program risk assessment - Is a PT for this analyte(s) necessary?
- Regulatory need
    - The appropriate TNI Program (NELAP Accreditation Council, NEFAP, etc) is notified of the request, and asked to confirm whether or not that Program would approve of having that parameter removed.
    - Does an AB or regulatory agency currently collect/use data resulting from the analysis of the PT analyte(s)?

The review shall be completed in 60 -90 days. Upon completion of the review, the PT Executive Committee shall determine whether or not to revise the associated FoPT table(s).

The requestor will then be notified of the PT Executive Committee's decision on whether or not to remove the analyte(s) from the FoPT table(s).

7.0 Timeframe For Implementation of Modifications

The minimum timeframe that the PT Executive Committee must be allowed to process an approved request is one year. This may be in addition to the time it takes the PT Executive Committee to approve a request. Additional time may also be needed depending on:

- the scope of the request
- whether PT data is readily available when a request for a new analyte is made
- whether a subcommittee is needed to work on updating the FoPT table
- whether a subcommittee is available or would need to be established
- whether all steps are able to be completed successfully without having to go back and repeat any steps

An example of the timeline for implementation of a FoPT Table modification is as follows –

1) Review of request is initiated – 30 days
2) Review of the request is performed by PT Executive Committee – 60 to 90 days
3) PT Executive or subcommittee makes change– 90 days (or longer)
4) PT Executive committee reviews, approves change, and forwards to appropriate TNI Program – 60 days
5) TNI Program reviews and approves of FoPT table change – 30 to 60 days.
6) The PT Executive Committee sets a FoPT table effective date approximately six months from the end of the approval process. PT Providers accredited to provide PTs and TNI PT Provider Accreditors are forwarded a copy of the updated FoPT table(s). The requestor is notified by the PT Executive Committee Chair that the FoPT table update/approval process has been completed and informed of the new FoPT table effective date. – 30 days
7) The FoPT table is posted on the TNI website at least one month before the effective date and posted in a manner that appropriately categorizes/identifies the FoPT table by program (i.e. NELAP, NEFAP, EPA, etc). A notice is placed in the "News" section of the TNI website. Color coding within the FoPT table highlights how the FoPT table has been modified.

8.0 SSAS Tables

SSAS Tables are handled separately from FoPT tables. Management of SSAS Tables does not fall under the PT Executive Committee's responsibilities. Modifications and updates to SSAS Tables are the responsibility of the SSAS Committee. The SSAS Committee forwards any modified SSAS Tables to the PT Executive Committee for review and approval prior to implementation. The SSAS Committee posts SSAS Tables separately on the TNI's SSAS webpage.

9.0 References

TNI PT Executive Committee SOP 4-101 – Recommendation and Calculation of Acceptance Limits for Chemical, Radiochemical, and Microbiological Components of Proficiency Tests

10.0 SOP Approved Changes

Original SOP
Approved by the PT Executive Committee: December 15, 2011
Reviewed by the Policy Committee:
Endorsed by the Board of Directors:

Prev. SOP	New SOP	Date of	Description of Change

Revision	Revision	change	

11.0 Tables, Figures, Diagrams, Charts, Examples, Checklists, and Appendicies

Appendix A
List of TNI FOPT Tables

Name of Table	TNI or EPA Program
Drinking Water (Chemistry & Microbiology)	**NELAP**
Drinking Water (RadioChemistry)	**NELAP**
Non-Potable Water (Chemistry & Microbiology)	**NELAP**
Non-Potable Water (WET)	**NELAP**
Solid and Chemical Materials	**NELAP**
Protozoa	**EPA Cryptosporidium Laboratory Approval Program**
FSMO	**NEFAP**