



<b>SOP TITLE</b>	<b>FoPT Table Management</b>
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<b>PROGRAM</b>	<b>Proficiency Testing (PT)</b>

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**The NELAC Institute (TNI)**  
 P.O. Box 2439  
 Weatherford, TX 76086  
[www.nelac-institute.org](http://www.nelac-institute.org)

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## 1.0 Purpose and Applicability

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

This SOP is not applicable to Stationary Source Audit Sample (SSAS) table management.

## 2.0 Summary

The PTPEC reviews all proposals and requests for FoPT table editorial changes, modifications, additions, and removals. FoPT table updates are reviewed and completed in compliance with the procedures outlined within this SOP. FoPT tables are assigned effective dates and revision numbers by the PTPEC and applicable stakeholders are notified of updates via the PTPEC or TNI website.

## 3.0 Related Documents

SOP 1-109: Establishing, Validating, and Maintaining Analyte and Method Codes  
SOP 4-105: PT Program Executive Committee Voting Process

## 4.0 Definitions

For the purpose of this SOP, the relevant terms and definitions conform to ISO/IEC 17000:2004. Additional relevant terms are defined below.

<b>Sponsor</b>	A governmental Accreditation Body that supports the addition of a new FoPT table or an analyte or group of analytes to an existing FoPT table.
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## 5.0 FoPT Tables

FoPT tables are designed to provide a central location for analyte specific information relating to PT manufacture, composition, and scoring to be used by all applicable stakeholders in support of the Proficiency Testing Program. The analytes selected for inclusion within a FoPT table depend on the need of a Sponsor. Manufacture, composition, and scoring criteria are derived in PTPEC FoPT subcommittees using historical data compiled by Proficiency Testing Providers.

FoPT tables include a title/header, footer, columns with analyte-specific information, and footnotes. The various sections of the FoPT tables are described below.

- Title/Header – includes the applicable program, matrix, and effective date.
- Footer – includes the electronic file name of the table document, which incorporates the table effective date and revision number.
- Column Headings for all tables except the WET table (see below) include:
  - Matrix – drinking water, nonpotable water, solids, etc...
  - EPA Analyte Code – an analyte-specific unique number assigned by EPA.
  - TNI Analyte Code – an analyte-specific unique number assigned by TNI.
  - CAS #
  - Analyte – the name of the analyte. This column also provides guidance on potential groupings of analytes for inclusion within one PT sample. Grouping requirements are defined via footnotes.

## FoPT Table Management

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- Concentration Range – defines the concentration range within which the analyte must be manufactured in a PT sample.
- Acceptance Criteria – defines the variables or means of generating acceptance limits, typically used in conjunction with specific instructions included via footnotes.
- NELAC Proficiency Test Reporting Limit (PTRL) – a statistically derived value that represents the lowest acceptable theoretical concentration for an analyte in a PT sample, if the analyte is spiked into the PT sample at the lowest concentration as specified in the TNI FoPT tables.
- Column Headings for the WET table include:
  - Matrix – drinking water, nonpotable water, solids, etc...
  - EPA Test Code - a test-specific unique number assigned by EPA.
  - EPA Reference Method
  - EPA Analyte Code – an analyte-specific unique number assigned by EPA.
  - Technology – Organism and Test type. This section includes information on assigned value and acceptance criteria in the footnotes.
  - Analyte – the name of the analyte.
  - Reference Toxicants and Concentration – defines the parameters by which the analyte must be manufactured in a PT sample.
- Footnotes – provide additional details, specific instructions, and/or guidance on PT composition/manufacture, reporting results, and scoring.
- Change Log – a second tab in the Excel file which documents changes made to the table. Each row contains two columns:
  - Effective Date: the date the table was made effective.
  - Change –summary of the changes made associated with the effective date.

### 6.0 FoPT Table Review Types

There are five types of FoPT Table reviews - line item, targeted, failure rate, full, and follow up. These reviews are determined/scheduled by the PTPEC and performed by the FoPT table subcommittee. Documentation of FoPT Table reviews is maintained in the PTPEC minutes

- 6.1 Line item review:** This is a review of individual analyte(s) in the FoPT table based on an identified need for a specific update. Frequency- as needed.
- 6.2 Targeted review:** This is a review of certain sections and/or multiple analytes in the FoPT table. It may be based on an identified need for a specific set of updates or based on a routine periodic review (frequency noted below) of sections/analytes. The sections/ analytes selected as part of a periodic review are determined by the PTPEC after consultation with the FoPT table subcommittee. Frequency – At least once within five years after completion of the last Full review of the FoPT table, a selection of sections of analytes in the FoPT table will be reviewed.
- 6.3 Failure rate review:** This is a review to examine the failure rates for all analytes across a two year period worth of data for each table to ensure failure rates are not excessive. Frequency – Every two years.
- 6.4 Full review:** This is a complete review of all sections/analytes in the FoPT table. A FoPT table will undergo a full review at least once every ten years. When determining which FoPT table will undergo a full review, priority should be given to the FoPT table with the oldest effective date.
- 6.5 Follow up review:** Performed on analytes where recent changes to acceptance criteria have been made. This is performed one year after the FoPT table has been made effective. TNI pulls PT results from the one year window since the FoPT table went into effect. The impact of changes are evaluated by the PTPEC and corrective action taken where determined necessary.

### 7.0 FoPT Table Review Triggers

Certain events may trigger the need for the PTPEC to consider initiating one of the FoPT Table review types (as outlined in section 6). These include:

- Atypically performing analytes that may have high failure rates identified, based on
  - PTPEC reviews
  - A Follow up review (see section 6.5)
  - Other sources
- A new Analyte Request Application (ARA) is submitted to the PTPEC
- Complaints received regarding acceptance limits or concentration ranges
- Changes in methods, improved technology, updated regulations
- Periodic Targeted review due
- Periodic Full review due
- Follow up review due

## **8.0 FoPT Table Update Types**

### **8.1 Editorial Changes to Existing FoPT Tables**

Formatting, transcription, and spelling errors are considered typographical errors and only require an editorial change. Editorial changes do not require the full review and approval process and updates may be posted immediately upon correction. Editorial changes are summarized in the change log. The FoPT table effective date is not changed.

### **8.2 Modifications to Existing FoPT Tables**

A modification is any change that is not considered an editorial change. Examples of FoPT table updates that constitute a modification include the following:

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

### **8.3 Creation of New FoPT Tables**

New FoPT tables may be added when the requested additions do not fit into any of the existing FoPT tables such as for different programs or matrices.

### **8.4 Removal of FoPT Tables**

FoPT Tables may be removed when no longer in use for regulatory purposes and this change is approved by the appropriate program(s).

## **9.0 FoPT Table Update Processes**

### **9.1 Editorial Changes**

Editorial changes presented to the PTPEC will be made by the PTPEC. The appropriate FoPT subcommittee will be consulted, as necessary, to confirm the change as editorial. Once this is confirmed, the PTPEC will make the change, update the change log, and send the updated table to the TNI webmaster to replace the current one posted on the TNI website.

### **9.2 Modifications to Existing Information**

Proposed changes presented to the PTPEC are forwarded to the appropriate FoPT subcommittee for resolution. The subcommittee will review the proposed changes and will provide their recommendation to the PTPEC for final review and approval.

When FoPT table modifications are necessary, the modified FoPT table must be approved by the PTPEC and the decision communicated in writing to any applicable program (EPA, NELAP, NEFAP, etc) that requires the use of that FoPT table. The PTPEC will set a FoPT table effective date (Section 10.0) and the updated table will be sent to the TNI webmaster to replace the current one posted on the TNI website.

### **9.3 Addition of New Analyte(s) to Existing or New FoPT Table**

Requests to create a new FoPT table or add an analyte or group of analytes to an existing FoPT table may be made by an individual or on behalf of Accreditation Bodies (TNI ABs, EPA, other regulatory 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 governmental Accreditation Body. A request submitted by a regulatory authority or a governmental Accreditation Body does not require sponsorship.

Note: A sponsor is only required for additions, not removals.

To request a new table, analyte or group of analytes, the requestor shall complete sections I, II, and IIIA of the TNI FoPT Analyte Request Application (ARA) (see appendix A or the TNI Website). The application shall be submitted electronically to the PTPEC Chair.

Submitting an incomplete application, or failure to supply the required documentation, may delay the process while the PTPEC tries to gather the required information.

An Analyte Request Application may be withdrawn or rescinded by its originator or a higher authority at the originating organization. Notice of the withdrawal must be provided electronically to the PTPEC Chair within 90 days of the submittal of the ARA to the PTPEC. Once withdrawn or rescinded, submittal of a new ARA would be required to restart the process.

A sponsorship of an ARA may also be withdrawn or rescinded by the sponsor or a higher authority at the sponsor's organization. Notice of the withdrawal must be provided electronically to the PTPEC Chair within 90 days of the submittal of the ARA to the PTPEC. If a required sponsorship of an ARA is withdrawn or rescinded and there are no other sponsors listed in the ARA, submittal of a new ARA would be required to restart the process.

#### **9.3.1 Review of ARA**

The PTPEC will initiate a review of the request within 30 days of receipt of the ARA. The PTPEC will review the following:

- The ARA and supplied documentation.
- Regulatory need:
  - Confirmation of AB sponsorship.
  - Confirmation that the applicable Program (NELAP Accreditation Council, NEFAP, etc) will consider the request.
- Availability of historical PT data.
- Feasibility of producing a PT for the requested FoPT.
- Cost impact assessment to ABs, PT Providers and laboratories.
- PT concentration range and initial acceptance criteria. The PTPEC may elect to postpone a review of this information until after the FoPT subcommittee has submitted their recommendation.

- Technical feasibility – this must include at least one method validation study, compliant to TNI Volume 1 Module 2, showing that the analyte(s) can be measured throughout the proposed concentration range by at least one published method. Note: Additional method validation studies may be necessary upon PTPEC review.
- Existence of a TNI Analyte Code.

The ARA review process shall be completed within 90 days of receipt. Upon completion of the review, the PTPEC shall determine whether or not to pursue the request and assign the task of FoPT table and/or analyte addition to a FoPT subcommittee.

The requestor will be notified in writing of the PTPEC's decision on whether or not to pursue the FoPT table and/or analyte(s) additions.

The requestor will also be notified in writing by the PTPEC if:

- the ARA is withdrawn or rescinded by a higher authority of the requestor's organization.
- a sponsorship of the ARA is withdrawn or rescinded by a sponsor or a higher authority at the sponsor's organization.

### 9.3.2 Processing and Implementation

If pursued, the PTPEC will make every effort to complete the implementation process within 18 months. If this is not possible, the requestor will be notified of an estimated completion date. Processing and implementation include:

- PTPEC submits the ARA to the appropriate FoPT subcommittee for FoPT table or analyte addition recommendations.
- If a new TNI analyte code is required, the PTPEC will work with the TNI IT Committee to create one.
- PTPEC reviews, approves, sets an effective date (see Section 10.0), and forwards written notice of any additions to the applicable TNI Program(s).
- Comments will be evaluated as received prior to the effective date of the FoPT table.
- The requestor is notified by the PTPEC Chair that the FoPT table update/approval process has been completed.
- All affected parties are notified of the FoPT table additions (see section 12.0).
- 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).

## 9.4 Removal of Analyte(s)

Requests to remove a FoPT table or analyte or group of analytes from an existing FoPT table may be made by an individual or on behalf of Accreditation Bodies (TNI ABs, EPA, and other regulatory agencies), laboratories, TNI Programs, or PT Providers.

To request a removal of a FoPT table, analyte or group of analytes, the requestor shall complete sections I and IIIB of the TNI FoPT Analyte Request Application (ARA) (see appendix A or the TNI Website). The application shall be submitted electronically to the PTPEC Chair.

Submitting an incomplete application, or failure to supply the required documentation, may delay the process while the PTPEC tries to gather the required information.

An Analyte Request Application may be withdrawn or rescinded by its originator or a higher authority at the originating organization. Notice of the withdrawal must be provided electronically to the PTPEC Chair within 90 days of the submittal of the ARA to the PTPEC. Once withdrawn or rescinded, submittal of a new ARA would be required to restart the process.

A sponsorship of an ARA may also be withdrawn or rescinded by the sponsor or a higher authority at the sponsor's organization. Notice of the withdrawal must be provided electronically to the PTPEC Chair within 90 days of the submittal of the ARA to the PTPEC. If a required sponsorship of an ARA is withdrawn or rescinded and there are no other sponsors listed in the ARA, submittal of a new ARA would be required to restart the process.

#### **9.4.1 Review of ARA**

The PTPEC will initiate a review of the request within 30 days of receipt of the ARA. PTPEC shall review the following:

- The ARA and supplied documentation.
- Impact on other FoPT tables.
- Regulatory need:
  - Confirmation that the applicable Program (NELAP Accreditation Council, NEFAP, etc) will consider the removal.

The ARA review process shall be completed within 90 days of receipt. Upon completion of the review, the PTPEC shall determine whether or not to pursue the request and remove the proposed FoPT table and/or analyte(s).

The requestor will be notified in writing of the PTPEC's decision on whether or not to pursue the FoPT table and/or analyte(s) removal.

The requestor will also be notified in writing by the PTPEC if:

- the ARA is withdrawn or rescinded by a higher authority of the requestor's organization.
- a sponsorship of the ARA is withdrawn or rescinded by a sponsor or a higher authority at the sponsor's organization.

#### **9.4.2 Processing and Implementation**

If pursued, the PTPEC will make every effort to complete the implementation process within 18 months. If this is not possible, the requestor will be notified of an estimated completion date. Processing and implementation include:

- PTPEC submits the ARA to the appropriate FoPT subcommittee for FoPT table or analyte deletions
- PTPEC reviews, approves, sets an effective date (see Section 10.0), and forwards written notice of any removals to the applicable TNI Program(s).
- Comments will be evaluated as received prior to the effective date of the FoPT table.
- The requestor is notified by the PTPEC Chair that the FoPT table update/approval process has been completed.
- All affected parties are notified of the FoPT table removals (see section 12.0).
- 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).



## **10.0 Setting FoPT Table Effective Date**

Once the FoPT table has been created or modified, a target Effective Date will be set for the table as part of the PTPEC approval process. The final Effective Date will be set approximately six months after the date of PTPEC approval to allow sufficient time for PT Provider implementation.

## **11.0 FoPT Table Document Control**

### **11.1 Setting FoPT Table Revision Numbers**

Revision numbers are assigned to FoPT tables upon creation and update. New FoPT tables are assigned a revision number starting with Rev. 0. FoPT tables that undergo modifications (as described in section 8.2) are assigned a revision progression of Rev.1.0, 2.0, 3.0 etc. FoPT tables that undergo editorial changes (as described in section 8.1) are assigned a revision progression of Rev. 1.1, 1.2, 1.3, etc.

### **11.2 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

## **12.0 Notification of FoPT Table Updates**

The PTPEC Chair notifies PT Providers, PTPAs, and applicable TNI Program(s) by email anytime there is a change to a FoPT table.

Additionally, a notice is placed in the “News” section of the TNI website every time a FoPT table is changed, and subscribers to direct email notifications will receive information alerting them to the posting of an updated FoPT table.

## **13.0 Records Management**

Records associated with FoPT Table management shall be handled in accordance with TNI SOP 1-104, Control of TNI Documents. SOP 1-104, Control of TNI Documents, discusses retention of draft versions, current finalized versions, and retired previous versions of FoPT tables for the historical record. SOP 4-101, Recommendation and Calculation of Acceptance Criteria for Chemical, Radiochemical, and Microbiological Components of Proficiency Tests, describes in detail the record management procedures for draft FoPT tables.

## **14.0 Quality Control**

This SOP will be reviewed every three years or whenever the PTPEC requires, whichever occurs first. The TNI PT Program Administrator will initiate this review. This review must be documented and any changes deemed necessary must be made with the vote of the PTPEC. If the document is revised, the revisions will be posted on the TNI website.

## **15.0 References**

SOP 4-101 Recommendation, Evaluation, and Calculation of Acceptance Criteria and Applicable Concentration Ranges for Proficiency Tests

SOP 1-204: Control of TNI Documents

**16.0 SOP Approved Changes**

Revision No	Effective Date	Description of Change
0	12/15/11	
1	11/21/13	Reformatted to current TNI SOP template. Updated flow of document to make it easier to follow. Clarified types of table updates, how to do notifications of updates, etc.
2	5/28/20	Updated Related Documents section. Clarified Sponsor definition to reference governmental. Added CAS number to FoPT table column headings list. Separated out WETT table column headings list. Added Change Log information to section 5. Created new section 6 on FoPT table review types. Created new section 7 on FoPT table review triggers. Renamed section 8. Referenced change log in section 8.1. Referenced change log in section 9.1. Clarified that a governmental AB doesn't require a sponsor to submit an ARA for new analytes. Added language on the ARA and sponsorship withdrawal processes. Added language to method validation study requirements. Updated Records Management and References sections. Updated notification language in sections 9.2, 9.3.2, 9.4.2, and 12. Updated setting effective date language in section 10.

**Appendix A: TNI Fields of Proficiency Testing FoPT Analyte Request Application (ARA):**



**TNI Fields of Proficiency Testing (FoPT) Analyte Request Application**

SUBMISSION DATE: \_\_\_\_\_

**SECTION I – REQUESTOR/ORGANIZATION INFORMATION**

Requestor: \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone: \_\_\_\_\_ Facsimile: \_\_\_\_\_

Email: \_\_\_\_\_

**SECTION II – Sponsor (if applicable)**

**Required for applications submitted by individuals or on behalf of laboratories or Proficiency Testing Providers**

Sponsor Accreditation Body: \_\_\_\_\_

Official Contact: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone: \_\_\_\_\_ Facsimile: \_\_\_\_\_

Email: \_\_\_\_\_

**Note here if reference to any additional AB sponsors is being provided.**

**Additional sponsors?** No   
Yes  Other Sponsor ABs: \_\_\_\_\_  
\_\_\_\_\_

If yes, provide contact information on additional AB sponsors as an attachment to the application.

**Section III – Analyte Request**

Instructions: If requesting addition of a new FoPT table or analyte(s) to an existing FoPT table, please complete section IIIA. If requesting removal of a FoPT table or analyte(s) from an existing FoPT table, please complete section IIIB. Requests for additions and removals cannot be submitted on the same application; separate applications are required.

**Section IIIA – Addition of New FoPT Table or Analyte(s)**

FoPT table and/or analyte(s) to be added (please specify program and matrix for new FoPT table):

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For analyte(s) additions only, FoPT table(s) on which the analyte(s) should be added (if more than one analyte, clearly annotate which analytes to add to which existing FoPT tables):

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Reason(s) for adding the FoPT table and/or analyte(s):

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Do any TNI approved PT Providers currently offer the analyte(s) in a PT product?

No  Yes  Unknown

If yes, attach a list of PT products currently available (specify each PT Provider, PT Provider's product name, and PT 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 range and initial acceptance criteria.
- 2) Information on technical feasibility – this must include one or more method validation study showing that the analyte(s) can be measured throughout the proposed concentration range by at least one published method.

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**Section IIIB – Removal of FoPT Table or Analyte(s)**

FoPT table and/or analyte(s) to be removed:

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For analyte removals only, FoPT table(s) from which the analyte(s) should be removed (if more than one analyte, clearly annotate which analytes to remove from which FoPT tables):

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Reason(s) for removing the FoPT table and/or analyte(s):

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The following documentation must also be provided as attachments to this application when requesting removal of analyte(s):

- 1) Copies of any supporting documents that were referenced above in the reason(s) provided for removing the analyte(s).

**Section IV – Submittal of Application**

All applications (including attachments) must be submitted electronically via email to the PT Program Executive Committee Chairperson. No paper copies will be accepted.

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.

***For PTPEC use only***

Date ARA Received:	
Date ARA Review Initiated:	
Date ARA Review Completed:	
Date Requestor notified of PTPEC's decision to pursue or dismiss the request:	
If pursued, Date Request submitted to FoPT Subcommittee:	
Date Request Completed:	