TNI Fields of Proficiency Testing (FoPT) Change Process

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Jacksonville, Florida
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Agenda

- Introduction to Fields of Proficiency Testing
- The FoPT Change Process
- Analyte Request Applications (ARAs)
- How ARAs are Processed
- History of an ARA

Introduction to FoPTs

Introduction to FoPTs

Fields of Proficiency Testing (FoPTs) are…

- Matrix, technology/method, and analyte combinations for which the composition, spike concentration ranges and acceptance criteria have been established by the PTPEC
- Published in FoPT tables (spreadsheet and PDF), one table per matrix
- Used by PT Providers to design PT samples and determine concentration ranges and acceptance criteria
- Used by Accreditation Bodies and Laboratories to determine which analytes (sometimes called Fields of Accreditation) require PTs

NELAC PT for Accreditation
Fields of Proficiency Testing with PTRLs
Drinking Water
Effective: July 1, 2019

Blue = New Analyte Magenta = Changes

Matrix	EPA Analyte Code	NELAC Analyte Code	Analyte[2]	Conc Range	Acceptance Criteria[3,4,5,6] a	b	c	d	NELAC PTRL[7]
			Nutrients	mg/L					
Drinking Water	0009	1810	Nitrate as N[1]	3 to 10	±10% fixed acceptance limit				2.7
Drinking Water		1820	Nitrate + Nitrite as N	3 to 10	±15% fixed acceptance limit				2.6
Drinking Water	0092	1840	Nitrite as N[1]	0.4 to 2	±15% fixed acceptance limit				0.34
Drinking Water	0261	1870	Orthophosphate as P	0.5 to 5.5	±15% fixed acceptance limit				0.43
			Minerals	mg/L					mg/L
Drinking Water	0287	1575	Chloride	20 to 160	±15% fixed acceptance limit				17
Drinking Water	0010	1730	Fluoride[1]	1 to 8	±10% fixed acceptance limit				0.90
Drinking Water	0145	2000	Sulfate	25 to 250	±15% fixed acceptance limit				21
Drinking Water	0286	1125	Potassium	10 to 40	±15% fixed acceptance limit				8.5
Drinking Water	0029	1155	Sodium	12 to 50	±15% fixed acceptance limit				11
Drinking Water	0283	1035	Calcium	30 to 90	±15% fixed acceptance limit				26
Drinking Water	0285	1085	Magnesium	2 to 20	±15% fixed acceptance limit				1.7
Drinking Water	0025	1550	Ca Hardness as $CaCO_3$	75 to 225	±15% fixed acceptance limit				64
Drinking Water		1755	Total Hardness as $CaCO_3$	83 to 307	±15% fixed acceptance limit				71
			Inorganic Disinfection By-Products	µg/L					µg/L
Drinking Water	0193	1535	Bromate[1]	7 to 50	±30% fixed acceptance limit				4.9
Drinking Water	0260	1540	Bromide	50 to 300	±15% fixed acceptance limit				42
Drinking Water	0194	1570	Chlorate	60 to 180	±30% fixed acceptance limit				42
Drinking Water	0195	1595	Chlorite[1]	100 to 1000	±30% fixed acceptance limit				70
			Misc Analytes	mg/L					mg/L
Drinking Water	0027	1505	Alkalinity as $CaCO_3$/L	25 to 200	±10% fixed acceptance limit				22
Drinking Water	0253	1520	Asbestos[1]	1.5 to 20 MF/L	study mean		0.2971	0.4164	1 MF/L
Drinking Water		1620	Corrosivity[13i]	-4 to +4 SI units	± 0.4 SI units fixed acceptance				Not Applicable
Drinking Water	0146	1635	Cyanide[1,13b]	0.1 to 0.5	±25% fixed acceptance limit				0.075
Drinking Water		1710	Dissolved Organic Carbon (DOC)	1.3 to 13	0.9744	0.0960	0.0402	0.0700	1.1
Drinking Water		1895	Perchlorate	4 to 20 µg/L	±20% fixed acceptance limit				3.2 ug/L
Drinking Water	0026	1900	pH	5 to 10 units	± 0.2 units fixed acceptance limit				Not Applicable
Drinking Water	0022	1945	Residual Free Chlorine	0.5 to 3.0	1.0000	0.0004	0.0776	0.0246	0.37
Drinking Water		1990	Silica as SiO_2	5 to 75	±15% fixed acceptance limit				4.2
Drinking Water	0288	1610	Specific Conductance	130 to 1300 µmhos/cm	±10% fixed acceptance limit				117 µmhos/cm
Drinking Water		2025	Surfactants - MBAS	0.1 to 1.0	0.9804	0.0054	0.0673	0.0348	0.020
Drinking Water		1940	Total Residual Chlorine	0.5 to 3.0	1.0000	-0.0048	0.0723	0.0065	0.40
Drinking Water	0024	1955	Total Filterable Residue	100 to 1000	±20% fixed acceptance limit				80
Drinking Water	0263	2040	Total Organic Carbon	1.3 to 13	±20% fixed acceptance limit				1.0
Drinking Water	0023	2055	Turbidity[1,13c]	0.5 to 8 NTU	0.9755	0.0593	0.0565	0.0661	0.36 NTU
Drinking Water		2060	UV 254 Absorbance	0.05 to 0.7 cm-1	0.9919	0.0043	0.0872	0.0034	0.038 cm-1

Introduction to FoPTs

FoPT Tables are…

- Used by more than just TNI Accreditation Bodies and Laboratories – a true "National Program"
  - DMR-QA
  - Many state programs

Introduction to FoPTs

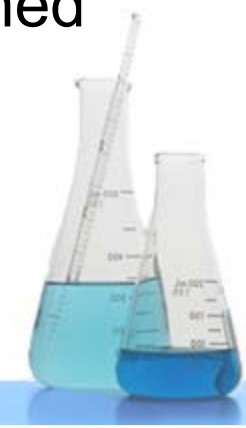
Fields of Proficiency Testing (FoPTs) Tables actively used:

- Drinking Water
  - Chemistry and Microbiology (7-1-2019)
  - Radiochemistry (10-1-2007)
- Non-Potable Water (NPW)
  - Chemistry and Microbiology (7-24-2017)
  - Whole Effluent Toxicity (7-31-2016)
- Solid and Chemical Materials (SCM) (7-24-2017)

Introduction to FoPTs

How are acceptance limits determined?

- Calculated using summary PT study statistics obtained from PT Providers through TNI
- For regulated analytes (e.g. 40 CFR Part 141, National Primary Drinking Water Regulations), limits in FoPT tables may not be wider than US EPA limits
- Many FoPT limits adopt linear regression model used by US EPA prior to externalization of PT program
- Other limits are fixed percentage around the assigned value (e.g., +/- 20%)



Introduction to FoPTs

- Limits must provide suitable challenge to labs
- Example: If limits are 50-150% of assigned value and the concentration range is narrow, e.g., 100-200 ug/L, then the resultant PT provides no suitable challenge to laboratories. The laboratory conceivably could report 150 ug/L each PT study for the analyte and never fail.
- SOP for calculating limits: PTPEC SOP 4-101, available on TNI website

FoPT Change Process

When are FoPTs Changed?

- FoPTs are changed through FoPT Review Process
- Two categories of review
  - Reviews initiated by PTPEC
  - Reviews initiated by PT Participants
    - Laboratories
    - ABs
    - PT Providers
    - PT Provider Accreditors

Review Initiated by PTPEC

5 Reviews Types:

- Full Review
  - Complete review of an FoPT Table
  - Frequency: Every 10 years
- Follow-Up Review
  - Review of analytes with recent changes to acceptance criteria
  - Frequency: One year after FoPT effective date

Review Initiated by PTPEC

5 Reviews Types – Cont'd:

- Failure Rate Review
  - Examination of failure rates for all analytes across 2-year period of data to ensure failure rates are not excessive
  - Frequency: Every 2 years
- Targeted Analyte Review
  - Review of section or multiple analytes based on identified need
  - Frequency: Within 5 years after last full review of FoPT table
- Line Item Review
  - Review of individual analyte based on identified need
  - Frequency: As Needed

Review Initiated by PTPEC

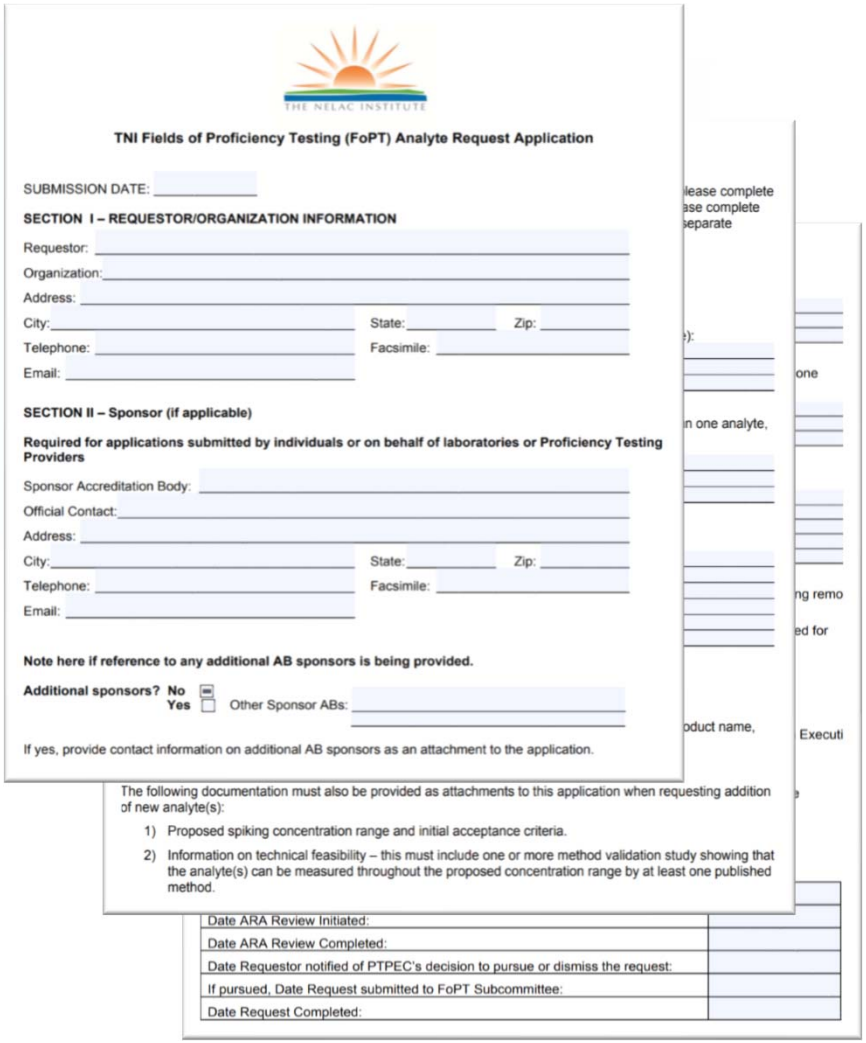
Certain events that may trigger Targeted or Line Item FoPT reviews:

- Problematic analytes or high failure rates are identified for specific analytes
- Complaints received regarding acceptance limits or concentration ranges
- Changes in methods, improved technology, updated regulations

Review Initiated by PT Participants

Analyte Request Application (ARA) submitted to the PTPEC

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.

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.

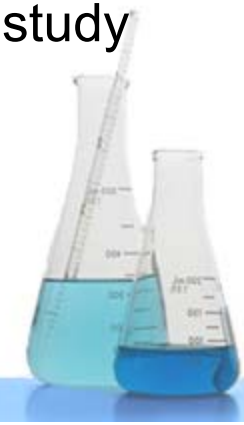
Date ARA Review Initiated:
Date ARA Review Completed:
Date Requestor notified of PTPEC's decision to pursue or dismiss the request:
If pursued, Date Request submitted to FoPT Subcommittee:
Date Request Completed:

- Form posted on TNI website
- Can be used to request new FoPTs or removal of existing FoPTs
- May be submitted to PTPEC by any PT participant at any time

Analyte Request Application (ARA)

ARA Form includes:

- Requestor contact information
- Governmental AB Sponsor(s)
  - Required for ARAs not submitted by governmental AB
- Identification of FoPT to be added or removed
- Reason(s) for requested addition or removal
- For additions:
  - Proposed concentration range and initial acceptance criteria
  - Information on technical feasibility with method validation study
  - List of matching PT products, if available
- Other supporting docs as needed



Analyte Request Application (ARA)

PTPEC initiates review within 30 days of receipt of ARA for the following:

- Regulatory need
  - Confirmation of at least one governmental AB sponsor
  - 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

Analyte Request Application (ARA)

- 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
  - 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
  - Additional method validation studies may be necessary upon PTPEC review
- Existence of a NELAC (TNI) Analyte Code

ARA Processing

- Review completed within 90 days of receipt
- Upon completion of the review, PTPEC determines whether or not to continue processing the ARA
- The requestor will be notified of the PTPEC's decision

ARA Processing

- If decision is to pursue, PTPEC assigns the ARA to the appropriate FoPT subcommittee for their recommendation
  - Subcommittee may request PT data from PT Providers to calculate acceptance criteria
- If a new NELAC (TNI) analyte code is required, the PTPEC will work with the TNI IT Committee to create one
- PTPEC reviews, approves, and forwards recommended additions to the applicable TNI Program

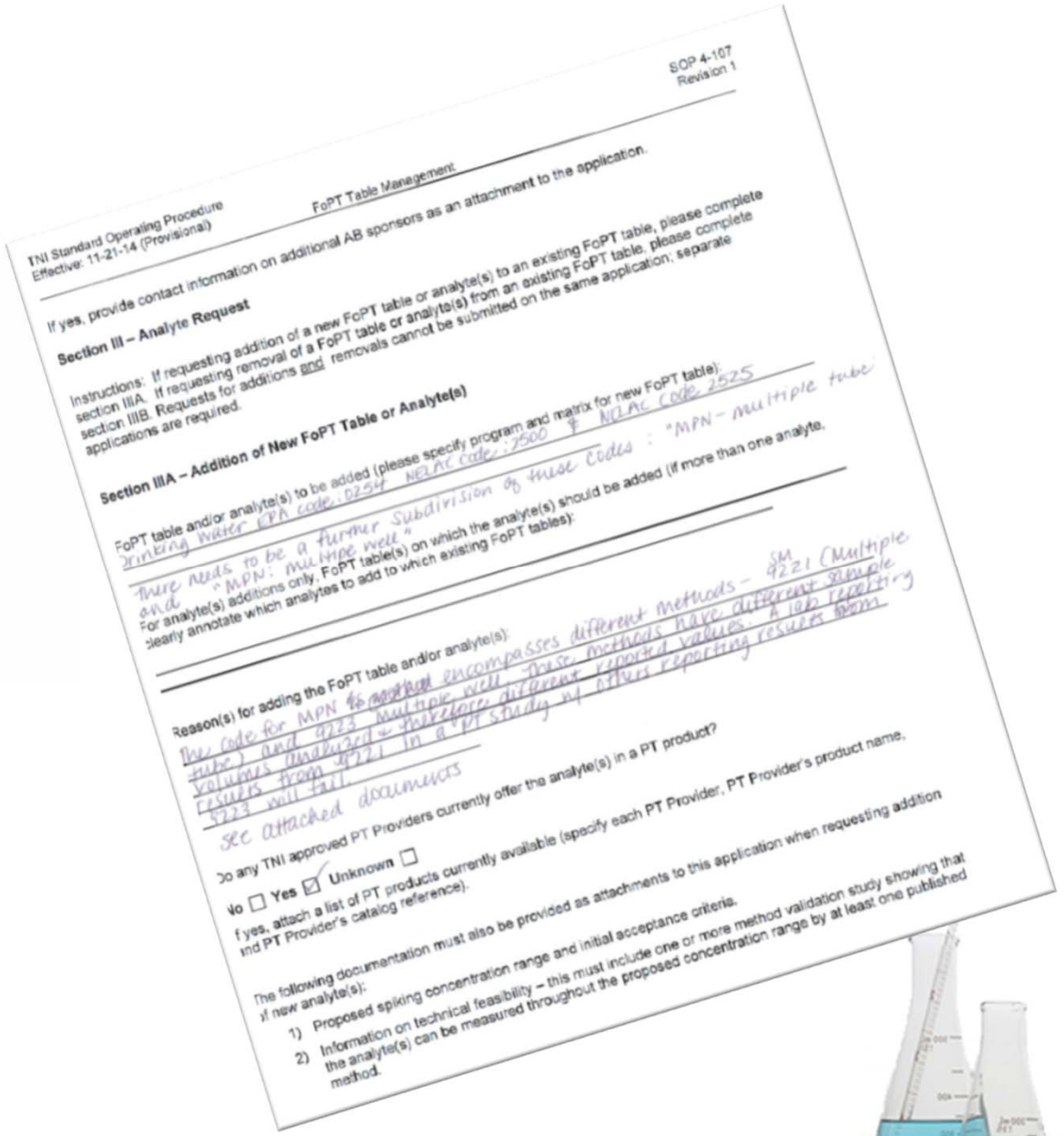
ARA Processing

- Requestor is notified by the PTPEC Chair that the FoPT table update/approval process has been completed
- PTPEC sets a FoPT table effective date
  - Date typically 6 months from Program approval
- All affected parties are notified of the FoPT table update
- FoPT table is posted on the TNI website side-by-side with the current (outgoing) table at least one month before the new effective date
- PTPEC will make every effort to complete the implementation process within 18 months

Voluntary ARA Withdrawal

- ARA may be withdrawn or rescinded by its originator or a higher authority at the originating organization or sponsor(s)
- 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

History of an ARA



TNI Standard Operating Procedure
Effective: 11-21-14 (Provisional)

FoPT Table Management

SOP 4-107
Revision 1

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):
Drinking Water EPA code: 0254 NELAC code: 2500 & NELAC code 2525
There needs to be a further subdivision of these codes: "MPN - multiple tube and "MPN: multiple well"

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):

Reason(s) for adding the FoPT table and/or analyte(s):
The code for MPN is omitted encompasses different methods - SM 9221 (Multiple tube) and 9223 Multiple well. These methods have different sample volumes analyzed & therefore different reported values. A lab reporting results from 9221 in a PT study by others reporting results from 9223 will fail.
See attached documents

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.

ARA Timeline

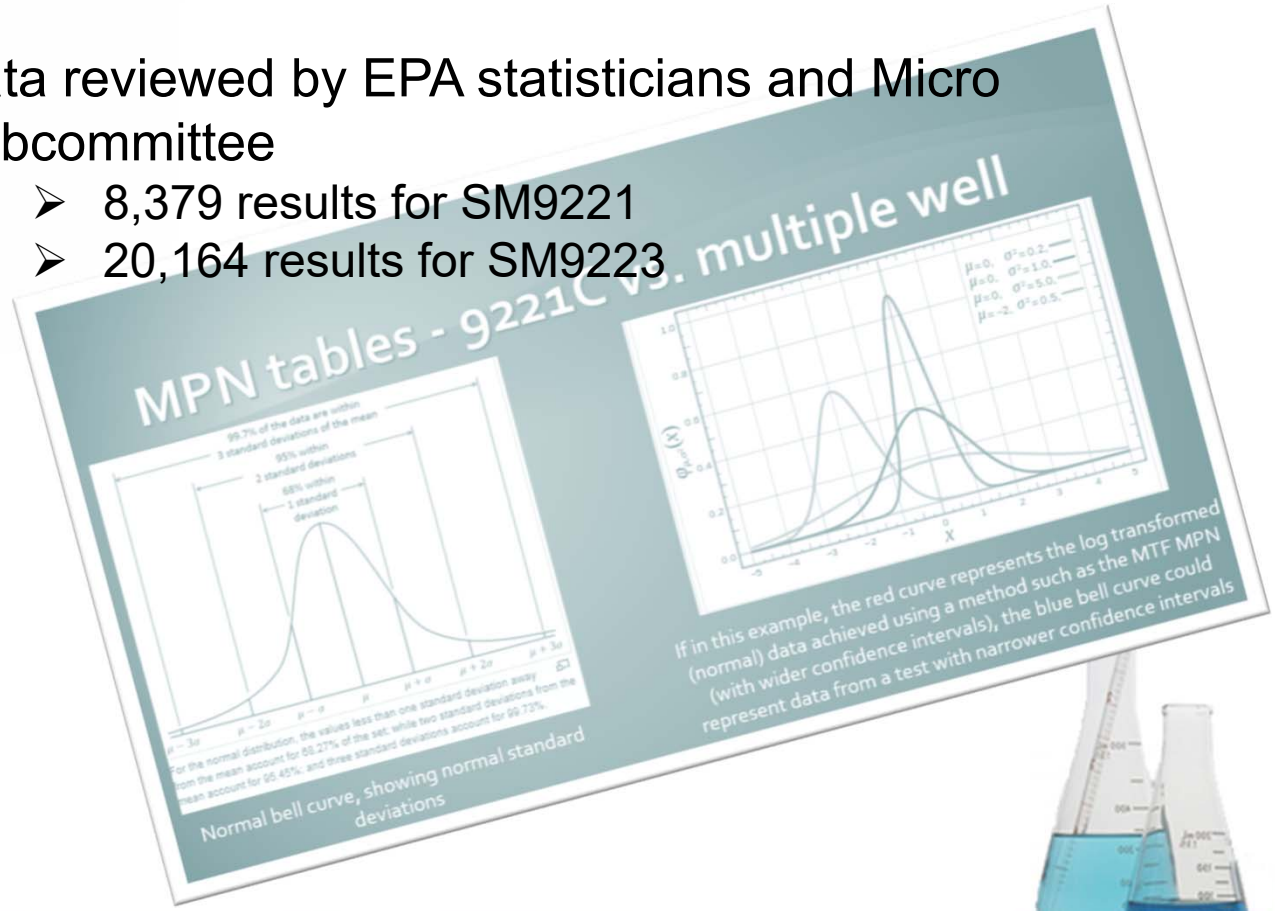
Dec 2014	ARA submitted by US EPA to subdivide existing FoPTs for DW and NPW Most Probable Number (MPN) Coliforms into "MPN-Multiple Tube" and "MPN-Multiple Well" ➢ Rationale given: MPN is analyzed by different methods (SM9221 and SM9223) having different numbers of sample portions analyzed and using different MPN tables, therefore they have different reported values ➢ A lab reporting SM9221 in a PT study with others reporting SM9223 will fail
Feb 2015	PTPEC initiates review of ARA PTPEC forwards ARA to NELAP AC for their consideration
Apr 2015	NELAP AC responds to PTPEC with questions

ARA Timeline

May 2015	PTPEC responds to NELAP AC questions
Sep 2015	NELAP AC informs PTPEC they have no objections to ARA
Oct 2015	PTPEC updates scope of Microbiology (Micro) Subcommittee to investigate ARA and make recommendations to PTPEC
Mar 2016	Micro Subcommittee drafts letter to PT Providers to request MPN PT study data
May 2016	PTPEC requests MPN PT study data from PT Providers

ARA Timeline

Aug 2016	Data received from PT Providers and submitted to Micro Subcommittee for review
2017-2018	Data reviewed by EPA statisticians and Micro Subcommittee ➢ 8,379 results for SM9221 ➢ 20,164 results for SM9223

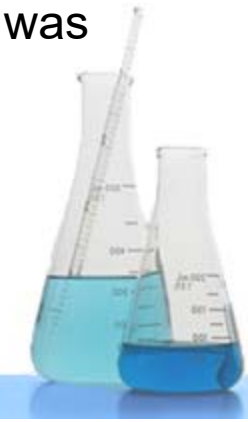


ARA Timeline

Dec 2018	Micro Subcommittee completes review of PT data and recommends approving ARA
Jan 2019	PTPEC votes to approve ARA and produces updated draft FoPT tables with approved changes
Feb 2019	PTPEC requests NELAP AC to review and approve draft FoPT tables

ARA Timeline

Mar 2019	NELAP AC reviews proposal ➢ Concerns that there would likely be too few PTs using the "tube" technology to provide adequate statistical power for scoring the PTs, since very few labs still use that older technology. This would result in a situation where PT failure never happened ➢ Consensus was that the revised FoPT tables would not provide a "suitable challenge" as proposed, due to the limited number of labs using that technology
Apr 2019	NELAP AC reviews information from Micro Subcommittee Chair regarding their analysis of PT data to support the determination that MPN subdivision was warranted



ARA Timeline

May 2019

NELAP AC votes to reject updated draft FoPT tables with MPN subdivision

- Consensus that the tube method should not be separated from the well methods simply because the tube method more often fails PT samples

Latest FoPT Developments

- July 2019: New revision of SOP 4-107 governing FoPT Table Management approved by PTPEC; to be sent to Policy Committee
- ARA in progress: Isomer Groups (e.g., Xylenes), proposal to add individual isomers to DW and SCM FoPT tables (note: already present in NPW)

Thank You!