TNI PT Program Executive Committee Meeting Summary

August 7, 2017

1. Roll call and approval of minutes:

Chair, Maria Friedman, called the TNI PT Program Executive Committee (PTPEC) meeting to order on August 7, 2017, at 9am Eastern in Washington, DC. Attendance is recorded in Attachment A – there were 9 members present.

Maria confirmed that everyone received the meeting information she sent by email on August 6th.

The July meeting minutes will be reviewed during the next regular meeting.

2. Overview

Maria provided an overview of the PTPEC mission and activities over the last 6 months – see Attachment D.

Maria also reviewed PTPEC's activities on FoPT Tables and Old and New PTPEC business—see Attachment D.

3. Subcommittee Reports

Maria asked each of the subcommittees to report on their activities.

FoPT Table Format Subcommittee

Craig Huff: The subcommittee has added CAS numbers to the FoPT tables. This was completed last year. They are now reviewing the consistency between LAMS and the FoPT tables. All the comparison tables are now done except for WETT. They have issues in consistency in naming and some spelling issues.

Craig reviewed the Solid and Chemical Materials (SCM) FoPT table that the subcommittee prepared. The items shaded in blue are the differences between LAMS and the FoPT table. All CAS numbers are highlighted because CAS numbers are not included in LAMS. Craig asked whether the FoPT tables need to be changed or will LAMS make changes.

Maria thanked Craig and his committee for all the work to put the tables together and for the excellent review. The subcommittee included Craig, Nicole, Shawn Kassner, Andy Valkenberg and Stephen Arpie.

The PTPEC will begin discussion with the NELAP AC to understand how the tables are used and get input on where the changes should occur. The NELAP AC is planning to put this topic on their agenda in September.

Matt noted that there are also issues with all the different State deliverables.

Chemistry FoPT Subcommittee

Carl Kircher: The subcommittee will begin reviewing the Radiochemistry FoPT table at the end of the month. They will also be working on requesting data for the ARA for qualitative PCBs.

SOP Subcommittee

Gil Dichter: The subcommittee is reviewing SOP 4-101 – Acceptance Criteria SOP. Section 6 is very involved and they have split up the responsibility for different sections so that experts are looking at the sections that need more expertise. They expect to have a DRAFT version of the SOP by the winter meeting.

The PTPEC has talked about ways to streamline the process of how FoPT updates are done. It took almost 7 years to do the last major update. Recommendations from the PTPEC have been given to the SOP Subcommittee for incorporation into SOP 4-101.

Microbiology FoPT Subcommittee

Jennifer Best: The EPA statisticians have gotten through some of the data received from the PT Providers. She needs to go through it before she can give a more detailed report. She also reviewed the ARA that the subcommittee is working on.

4. Training

Matt Sica (PTPA – ANAB) and Shawn Kassner (PTPA – A2LA) provided training to all attendees on PTPA roles in the PT Program. Both presenters hoped that their presentations would make it clear what information they can and cannot provide. The presentations can be found in Attachments E and F.

Comments:

- Nicole noted that the new Standard builds in what PT Providers need to give to TNI. The PTPAs only monitor the data.

- A question came up about comparison of data between the PTPAs. Will the PTPAs work together?
- Another question was about preparatory methods. The ABs are pushing back because tracking this would cause huge changes to their databases. Nicole noted that everyone in TNI would have to be on board to make this change. Labs can report prep methods, but not everyone uses this option. For the most part, labs don't report this information.

5. PTPA Reports

The reports presented by ANAB and A2LA can be found in Attachments G and H.

Comments:

ANAB

The last PT Provider assessments were in Feb 2017, Sept 2017 and July 2017.

The only studies of concern were DW studies: TSS, TDS, Total Phosphorus (18.4% failure rate at low end of the FoPT range – they looked at data over 6 months and 1 year), Nitrite as N, and Ammonia as N.

A2LA

Shawn described the rules for reporting and discussed data challenges.

If failures were consistently one provider, he planned to do more research. No problems like this were found.

WPChem – Chloride, pH, Non-Filterable, TKN, Orthophosphate, Benxo(a)anthracene, Aroclor 1016, 1,2,4-Trimethylbenzene

WSChem – Bromide, Fluoride, Dissoved Organic Carbon (DOC), Turbidity, chromium VI, Copper. Bromoform, 1,1-Dichloroethene, 2,2-Dichloropropane, Isopropylbenzene

Nicole asked both PTPAs what should the PTPEC be looking at? Is there other data they should be requesting? The PTPAs don't think there is more to give than what they already provide.

ANAB would prefer to look at a year's worth of data instead of 6 months. They don't have as much data because the "n" is not always big enough.

Matt noted that when the data is reviewed, they need to understand whether it is really something that can be improved upon. Sometimes there are limitations they can do nothing about.

6. PT Database

William Daystrohm (TNI Staff – IT) provided a presentation to update attendees on the status of the PT Database – see Attachment I.

William walked through example screen shots of the database. It provides user management, ability to load PT data into a database and allows another person to retrieve anonymized information.

PT Providers should use the Standard Format to upload their data.

PTPAs need access to the TNI database also. They need to contact William. Everyone has signed confidentiality statements.

7. New Business.

- None

8. Action Items

The action items can be found in Attachment B. Updates are added as notes in the table.

9. Next Meeting

The next PTPEC teleconference will be August 24, 2017 at 1pm Eastern. Ilona will send out Webex notifications within 24 hours of the meeting time.

Action Items are included in Attachment B and Attachment C includes a listing of reminders.

Maria adjourned the meeting at noon Eastern.

Attachment A

Participants TNI Proficiency Testing Program Executive Committee

Members	Rep	Affiliation	Contact Information
Maria Friedman (2020)	AB	California Water	949-307-0949
, ,		Board	Maria.Friedman@waterboards.ca.gov
Present			
Ilona Taunton,		TNI	828-712-9242
Program Administrator Present			tauntoni@msn.com
Eric Smith (2019)	Lab	ALS Environmental	904-394-4415
Life cimar (2010)	Lab	/ Leo Environmental	eric.smith@alsglobal.com
Absent			
Susan Jackson (2018)	AB	South Carolina	(803)896-0978
		DHEC	jacksosb@dhec.sc.gov
Present (2010)	1 - 1-	NIV OLA LA DOLL	(540) 470 0000
Nicole Cairns (2018)	Lab	NY State DOH	(518) 473-0323
Present			nicole.cairns@health.ny.gov
Jennifer Duhon (2019*)	Other	Millipore Sigma	307-3897218
, (2010)	0	poro oigina	jennifer.duhon@sial.com
Present			,
Matt Sica (2020)	AB	ANAB, ANSI-ASQ	msica@anab.org
		National	
Present		Accreditation Board	
Dixie Marlin (2018*)	Other	Marlin Quality	513-309-3593
Absent		Management, LLC	marlinquality@gmail.com
Gil Dichter (2018*)	Other	IDEXX Water	207-556-4687
on bienter (2010)	Otrici	IDEXX Water	gil-dichter@idexx.com
Present			gii dionioi (giidoraliooni
Patrick Garrity (2019*)	AB	Kentucky DEP	502-319-4040
			patrick.garrity@ky.gov
Present			
Michella Karapondo	Other	USEPA	513-569-7141
(2019*)			karapondo.michella@epa.gov
Absent			
Fred Anderson (2020*)	Other	Advanced Analytical	Fred@advancedqc.com
,		Solutions, LLC	
Present			
Jennifer Mullins (2020*)	Lab	Upper Occoquan	jennifer.mulllins@uosa.org
Drocent		Service Authority	
Present Scott Haas (2020*)	FSMO	Environmental	405-401-7344
30011 1 1 aas (2020)	FSIVIO	Testing, Inc.	shaas@etilab.com
	1	1 00th 19, 1110.	Chaaca Chab.

Attachment B

Action Items – TNI PT Executive Committee

	Action Items		Date		Actual
	A stion Itom	VVI b 0		Expected	
257	Action Item	Who	Added	Completion	Completion
257	Email to SOP Subcommittee	Maria		12/12/14	Maria
	regarding clarification on				prepared it, but
	how limit updates due to				is waiting for a
	issues should be addressed.				chair for this
					subcommittee.
					4/20/17: Ilona
					will look back
					in minutes to
					find the
					original issue
					and send to
					Maria.
295	Moved from Backburner:	Shawn		7/15/17	In Progress
	PTPA Evaluation Checklist	Ilona			(will use 2009
	needs to be updated prior to				TNI Standards
	next round of evaluations.				and current
	(Originally discussed 8/6/13)				SSAS
					Standards)
343	Notify PT Providers and	Maria		TBD	Add 348 back
	PTPAs about delay of				in?
	Volume 3 and 4				
	implementation.				
2.10					
349	Review LAMS/FoPT Table	ALL	4/20/17	4/25/17	In Progress
	Differences document.				
	Provide comments by email				
	and next meeting.				
			- / / -		
352	Moved from Backburner	All	2/20/14	TBD	
	(originally discussed				
	2/20/14):				
	When new limits are				
	established for the FoPTs,				
	what is considered to be a				
	statistically significant				
	change to the old rates? At				
	what point is it appropriate to				
	question new limits? This				
	lends to the TSS discussion a				
	few months ago.				

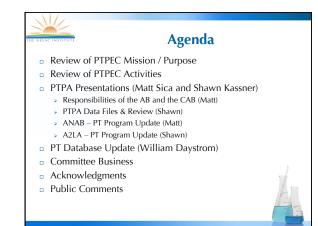
Action Item	Who	Date Added	Expected Completion	Actual Completion
Patrick commented that it would make sense to look at changes to pass/fail rates 6 months after new limits are effective. This possible addition to procedures should be evaluated when updating the limit acceptance SOP.				
Discuss possible procedural changes to how limits are updated. Maria talk to SOP Subcommittee. (Need to look at PT database implications.)	All		TBD	
Send request to SOP subcommittee to consider what happens when ARA's are rescinded. There is no formal process.	Maria	6-29-17	7/19/17	
Send DRAFT PTPA report format to Shawn and Matt.	Maria	6-29-17	7/5/17	Complete
Send SOP 4-102 to Policy Committee.	Ilona	6-29-17	7/19/17	Complete
	would make sense to look at changes to pass/fail rates 6 months after new limits are effective. This possible addition to procedures should be evaluated when updating the limit acceptance SOP. Discuss possible procedural changes to how limits are updated. Maria talk to SOP Subcommittee. (Need to look at PT database implications.) Send request to SOP subcommittee to consider what happens when ARA's are rescinded. There is no formal process. Send DRAFT PTPA report format to Shawn and Matt. Send SOP 4-102 to Policy	Patrick commented that it would make sense to look at changes to pass/fail rates 6 months after new limits are effective. This possible addition to procedures should be evaluated when updating the limit acceptance SOP. Discuss possible procedural changes to how limits are updated. Maria talk to SOP Subcommittee. (Need to look at PT database implications.) Send request to SOP subcommittee to consider what happens when ARA's are rescinded. There is no formal process. Send DRAFT PTPA report format to Shawn and Matt. Send SOP 4-102 to Policy Ilona	Patrick commented that it would make sense to look at changes to pass/fail rates 6 months after new limits are effective. This possible addition to procedures should be evaluated when updating the limit acceptance SOP. Discuss possible procedural changes to how limits are updated. Maria talk to SOP Subcommittee. (Need to look at PT database implications.) Send request to SOP subcommittee to consider what happens when ARA's are rescinded. There is no formal process. Send DRAFT PTPA report format to Shawn and Matt. Send SOP 4-102 to Policy Ilona 6-29-17	Patrick commented that it would make sense to look at changes to pass/fail rates 6 months after new limits are effective. This possible addition to procedures should be evaluated when updating the limit acceptance SOP. Discuss possible procedural changes to how limits are updated. Maria talk to SOP Subcommittee. (Need to look at PT database implications.) Send request to SOP subcommittee to consider what happens when ARA's are rescinded. There is no formal process. Send DRAFT PTPA report format to Shawn and Matt. Send SOP 4-102 to Policy Ilona All TBD TBD TBD TBD TBD TBD TBD T

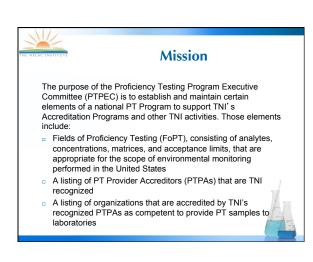
Attachment C

Backburner / Reminders – TNI PT Executive Committee

	Item	Meeting Reference	Comments
7	Add the Field PT Subcommittee to the limit update SOP during its next update.	3/4/10	In Progress
11	Evaluate how labs are accredited for analytes that co-elute.	5-19-11	
13	Charter needs to be updated in November.	Ongoing 2017	
18	Shawn noted that PTPEC should have some specific measurements. This should be passed along to the PTP SOP Subcommittee. Nicole noted that we need to determine which items to measure.	6-29-17	

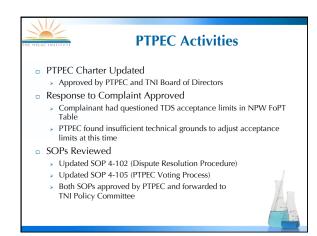


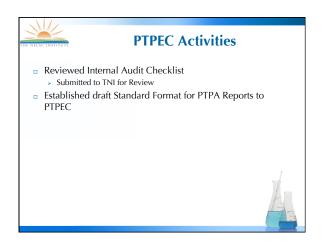


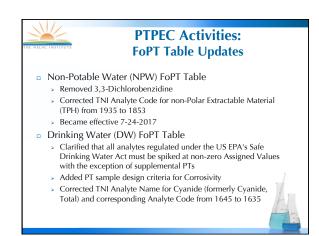




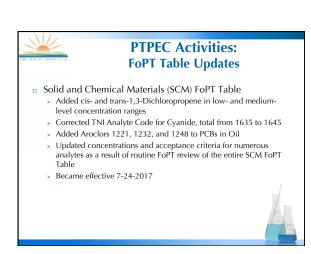




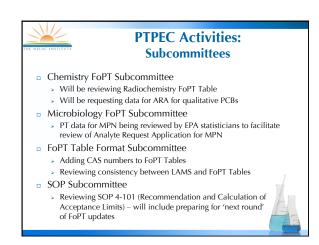




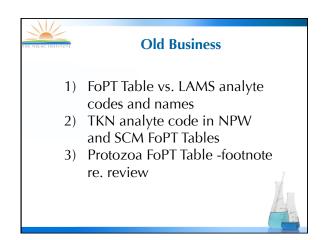




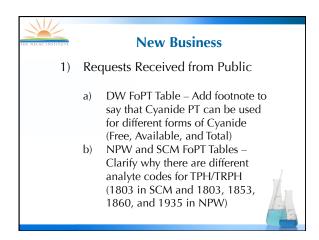


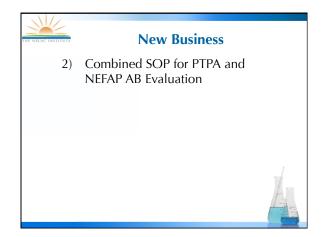






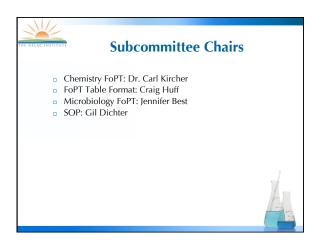
















Responsibilities of the AB and the CAB Understanding AB & customer relationships



ISO/IEC 17011

- Specifies general requirements for:
 - Accreditation bodies
 - · Conformity assessment bodies (CABs)
- Identifies Responsibilities and Obligation of each
 - Typically addressed in terms and conditions of application
 - Signed Application is a Contract
 - · Contract Law prevails

Impartiality of AB

- Safeguard the objectivity and impartiality of its activities
- Policies and procedures:
 - non-discriminatory
 - · administered in a non-discriminatory way
- Make its services accessible to all applicants whose requests for accreditation fall within the activities
- Ensure that each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment

Impartiality of AB

- The accreditation body shall not offer or provide any service that affects its impartiality:
 - Conformity assessment services that CABs perform
 - Ex. AB shall not provide services such as a lab, RMP or PTP
 - Consultancy
 - Training is not consultancy (often misunderstood in accredited community)

Impartiality of AB

- Activities of its related bodies do not compromise:
 - Confidentiality, objectivity, and impartiality of its accreditations
 - Related bodies may:
 - Provide consultation or conformity assessment services (for which AB accredits)
 - Different management, personnel (making decisions), no possibility of influence (outcome of assessment), different names logos, symbols

Confidentiality

- Adequate arrangements to safeguard the confidentiality of the information obtained in the process of its accreditation activities at all levels of the accreditation body
- Shall not disclose confidential information about a particular CAB outside the accreditation body without written consent

Example: DOD ELAP

Liability and Financing

- · Arrangements to cover liabilities arising from its activities
- Financial resource required for operation

Obligations of the CAB

- CAB shall commit to fulfill the requirements for accreditation set by the AB for the areas where accreditation is sought or granted

 This includes agreement to adapt to changes in the requirements for accreditation
- CAB shall accommodate and cooperate as is necessary to enable the AB to verify fulfillment of requirements for accreditation
 This applies to all premises where the conformity assessment services take place
- CAB shall provide access to information, documents and records as necessary for the assessment and maintenance of the accreditation

Obligations of the CAB

- CAB shall provide access to those documents that provide insight into the level of independence and impartiality of the CAB from its related bodies, where applicable
- CAB shall arrange the witnessing of CAB services when requested by
- · CAB shall claim accreditation only with respect to the scope for which it has been granted accreditation

Obligations of the CAB

- CAB shall not use its accreditation in such a manner as to bring the AB into disrepute
- CAB shall pay fees as shall be determined by the AB
- AB shall require that it is informed by the accredited CAB, without delay, of significant changes relevant to its accreditation, in any aspect of its status or operation

Obligations of the AB

- AB shall make publicly available information about the current status of the accreditations that it has granted to CABs
- AB shall provide the CAB with information about suitable ways to obtain traceability of measurement results in relation to the scope for which accreditation is provided
- AB shall, where applicable, provide information about international arrangements in which it is involved

Obligations of the AB

- AB shall give due notice of any changes to its requirements for accreditation
- It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes
- Following a decision on, and publication of, the changed requirements, it shall verify that each accredited body carries out any necessary adjustments

Questions

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ANAB Accreditation Manager
RMP, PT & Medical Programs
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PTPA Data Files & Review

TNI August 2017 Shawn Kassner

PTPA Data Review Role

- Monitor that PTPs are following:
 - Following the FoPTs for the calculation of acceptance criteria and assigned values.
 - TNI Vol 3 for statistics and evaluation of laboratory results.
 - Their company SOPs that were reviewed and approved by their PTPA
 - ISO 17043 and ISO 13528 per their accreditation.



PTP Data Files

- The PTPs upload or provide individual study data to thier PTPA database.
- The data provided for each PTPA is very similar.
- Data is received by study type/ product #/lot
 - No analytes listed by themselves
 - No way to confuse between FoPT sections



What is checked?

- Study open and close dates
- Study acceptance limits
- Assigned values are within the FoPT concentration range.
- Assigned values span the concentration range over time.



What is checked?

- Verification, homogeneity, and stability (VHS) limits correct?
- VHS data are evaluated correctly?
- Are the samples?
 - Homogeneous prior to the study opening?
 - Stable throughout the study time frame?
- Each study must be provided within days of the final reports being issued.



Study Performance Checks

- · Do the following match historical data
 - Study mean
 - Study standard deviation
 - Study failure rates
- With higher fail rates
 - Review study statistics for problems
 N's, study mean and standard deviation
 - Are there indications to a poor sample, poor study performance, or something else?

Study Performance Checks

- Do we need to contact the PTP to answer questions about the data.
- Have we ever contacted the PTPs?
 - Yes! They have always been open to providing further data.
 - Extremely rare that issues lead to problems.



Study Performance Frequency

- Periodic checks of the data are performed
 - Every study is reviewed for basic compliance
 - Each 6 mos the data are pulled for an overall review
 - Prior to each assessment the data are reviewed for each provider.
- Issues are typically handled during the assessments.



What we do not receive...

- The data does not include:
 - Methods or technologies reported
 - Method or technology statistics
 - Number of laboratories using which technology
 - Study performance of each technology/ method
 - Any individual laboratory data



Blinded FoPT Committee Info

- study type;
- study matrix;
- analyte name;
- analyte code;
- technology ID (optional);
- assigned value;

- study mean;
- number of laboratory participants;
- study standard deviation;
- opening date;
- · concentration units;
- number of data points;
- number of laboratories that failed

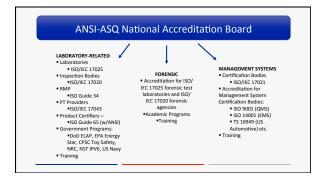






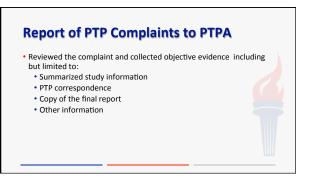


Non-governmental organization that provides accreditation services to public-sector and private-sector organizations Multilateral recognition arrangements signatory of the International Accreditation Forum (IAF) International Laboratory Accreditation Cooperation (ILAC) Jointly owned by ANSI and ASQ





Report of PTP Complaints to PTPA • One Complaint (Deemed Not Valid) • Scoring Issue: • 4,4' DDD • Not spiked in sample by PTP • Lab Reported result above PTRL, not a "< value" • lowest cal std of lab at the PTRL • PTP assigned appropriately < PTRL



Relevant Clauses of EL V3

- EL V3 clause 6.3.5 requires the PTP to set assigned value for unspiked analytes shall to <PTRL.
- EL V3 clause 10.3.2 states; "If the Assigned Value is set to the PTRL with a less than sign (<) or set to "0", any numeric value reported with a less than sign (<), a reported value of "0" or a reported numeric value less than the PTRL shall be scored "Acceptable".
- EL V3 clause 7.1.1 requires, "All unspiked analytes shall be analytically verified to ensure that they are not present at or above one-half the PTRL."

Result of Complaint

- Lab agreed both parties complied with standard requirements
- Lab with EL-V1M1, Section 5.2.1(a),(i) (reporting requirements)
 PTP with those in previous slide
- Lab surmised DDT breakdown contribution > Lowest Cal standard
- TNI standard includes no commentary on organic breakdown components related to column performance while scoring PT studies at low end of FoPT range
- Lab stills feels aggrieved by outcome

Review of Analytes w/ Failure Rates of >10%

- Reviewed all analytes
 - DW. NPW. SCM
- Non-spiked analytes reviewed with no issues

FoPT Tables

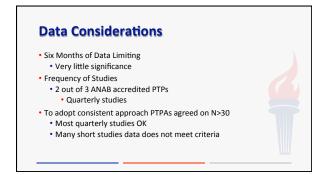
- Effective tables found of TNI Website:
 - DW FOPT (01_03_2012)
 - NPW FoPT (04_01_2016)
 - SCM FoPT (04_01_2016)
- No additional considerations due to FoPT changes

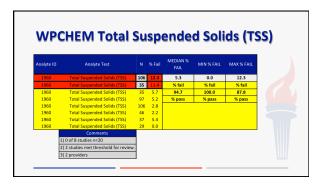
Data Selection Criteria (agreed by PTPAs)

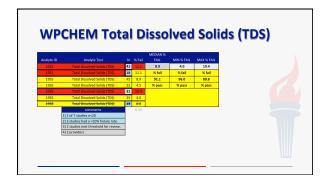
- Analytes had to have more than one failure in 6 month period
 - One or multiple PTPs
 - Number of participants >30
 - N<10 treated as outlier in dataset review

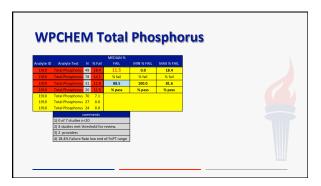
Data Analysis

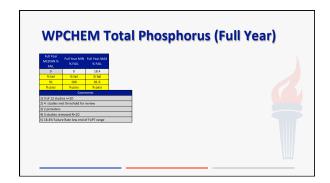
- 4025 datasets reviewed
- 376 (study type/analyte) combos >10% Failure before criteria applied
- 5 (study type/analyte) combos after criteria
- Then Reviewed
 - Median % Failure
 - May give a better idea of a 'typical' value
 - Think median income
 - Not skewed as much by large or small values
 - Range of % Failures

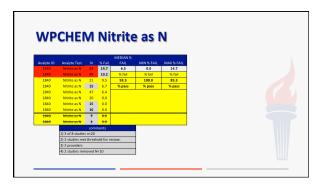


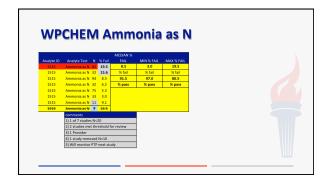
















A2LA PTPA Update Report

TNI August 2017 Shawn Kassner

PT Provider Status

- ERA Renewed 3/29/17, Valid through 9/30/18
- Phenova Renewed 5/30/17, Valid through 9/30/18
- New York State Department of Health Wadsworth Center – Renewed 3/20/17, Valid through 11/30/18
- Advanced Analytical Renewed 8/29/16, Valid through 1/31/18
- No complaints for any provider.





> 10% Fail Analytes

Criteria to Determine

- Data was reviewed for the following criteria
 - N > 30
 - Multiple providers with the same analyte
 10% fail
- Why apply the criteria?
 - Statistically valid
 - Ensures the analyte is not provider specific



Data Challenges

- All PTPs have small data sets across analytes/studies types
- All small data sets with high failure rates due to few laboratory failures
 - Multiple methods reported same data pt
- No issues with
 - Acceptance criteria problems
 - PTP samples



Data Review Steps

- FR >10% Analytes One PTP
 - The analyte history was reviewed across PTPs.
 - Study summary statistics
 - VHS data were examined
 - PTPs were contacted as necessary.
- All instances where studies that had low n's were data related.



