TNI PT Program Executive Committee Meeting Summary

August 6, 2018

1. Roll call, approval of minutes and overview:

Chair, Maria Friedman, called the TNI PT Program Executive Committee (PTPEC) meeting to order in New Orleans, at 1:30pm Central. Attendance is recorded in Attachment A – there were 9 members present.

2. Opening

Maria reviewed the work done by the committee since the last meeting (see Attachment D).

3. PTPA Presentations

ANAB – Presentation – Matt Sica

Matt reviewed the presentation provided in Attachment E.

There were no complaints.

- Failure Rates above 10% see slides
 - o There may have been some studies where participants were at 20.
 - o 390 studies and only 13 met >10% failure.
 - Ammonia was a provider issue. Only one provider had the problem and it has been worked through.
 - o There does seem to be a problem with the Solids limits. This is a repeat.

Shawn Kassner noted that the failure rate calculation and tracking is something being considered in the setting FoPT Limits SOP. It was commented that the Chemistry FoPT Subcommittee can look at problem analytes after finishing up Radiochemistry table updates.

A2LA – Presentation - Shawn Kassner

Shawn reviewed the presentation provided in Attachment E.

Need to be sure nothing is provider specific.

There's always a small data set from a PT Provider. The failure rates are often higher with these data sets.

There are only 5 analytes where a repeated failure issue is seen.

Carl noted that he thinks based on the presentations, the PT Program is functioning well.

It was asked if a Method Update Rule has impact on PT Data? The appropriate data sets should be shared with the PTPAs to watch it.

Instrumentation has changed in the last year especially in Wet Chemistry. IC's are now in most labs.

4. Review of PTP/NEFAP Combined Evaluation SOP (SOP 7-101)

Ilona reviewed the changes made to the combined evaluation SOP (7-101) and to the DRAFT response to the Policy Committee. What started out as a simple process to approve these documents turned into a long discussion once the Committee began to review the dispute procedures in Section 6.11. At the last meeting (7/19/18) it was decided to have the PTP SOP Subcommittee work on updating the PTP SOP for disputes, appeals and complaints (SOP 4-102) so that SOP 7-101 can reference it. Once the subcommittee started working on it, they decided it was better not to include the dispute procedures for the recognition process (between the PTPEC and Recognition Committee (RC)) in the PTPEC 's dispute SOP, but that it should be placed into the combined evaluation SOP. They provided language for the Committee to look at in SOP 7-101.

Matt prefers to see the dispute procedures stay in the program dispute process (SOP 4-102).

A motion was made by Matt to update SOP 4-102 and not include dispute resolution in the combined evaluation SOP (SOP 7-101). The motion was seconded by Michella.

Comments:

- Stacie would like a procedure to be in place that makes sure this dispute process is handled consistently.
- The issue of concern is what happens if the PTPEC disagrees with the RC's recommendation and does not want to endorse it. Matt asked if this is appropriate. The PTPEC and NEFAP EC only get the recommendation letter that summarizes what the RC looked at and what's its conclusion was. This is not enough information to dispute an AB's recognition. The PTPEC and NEFAP EC are supposed to take the recommendation and endorse it as per SOP 7-101. Matt asked why a dispute

procedure is needed beyond what is already in the PTPEC's dispute SOP (SOP 4-102) when the RC is the one making the final decision/recommendation. He also noted that he is concerned about the language in SOP 7-101 that does not make it clear that the RC is making the final decision. The executive committee acts upon the recognition and recognizes the AB and provides the actual certificate. They do not vote to approve the AB. Any vote of endorsement is only confirmation that the RC did its job properly - the RC looked at what they were supposed to look at to vote on recognition of the AB.

- The NELAP AC gets to review the actual evaluation documentation including the Evaluation Team's report. The PTPEC and NEFAP EC do not see the actual evaluation documentation. The executive committees only sees the information summarized in the example recommendation letter in the SOP 7-101 attachments.
 - Matt asked how can the executive committee not accept the recommendation, without access to the reports and all notes. If they have authority to with hold recognition, they would all need access to all documents and records related to the evaluation. He encourages the process to be transparent, where the most important step is the determination and training of the evaluators...the end process should only be a vote to approve the recommendation whatever it may be.
 - O Ilona commented that when NEFAP was formed it was decided that the NGAB's would not vote on each other's recognition. There were some strong statements made by some of the NGABs that it was a competition issue unique to the US. That is why the Recognition Committee (RC) was developed. There are no NGABs on the RC.
- It was noted that the Policy Committee had some concerns about having the Recognition Committee make the final decision on recognition. They felt it was in conflict with the new TNI organization. After much discussion the Policy Committee could accept the concept of an endorsement and this is why the language is written as it is in the SOP. Matt feels the PTPEC should push back on this language and just state that the RC makes the decision and the executive committees implement the decision.
- Matt provided information on what is different with the International recognitions the NGAB's participate in. He noted that the Regional Authorities recognition council typically have access to the evaluation documents. So the council can ask targeted questions of the evaluated AB and evaluation team to clarify points before acting on the recommendation.
- Carl commented that the only way to deal with the NGAB issue is to leave the decision to the Recognition Committee.
- Matt summarized his thoughts on a dispute procedure between the executive committee and the RC: That would bring the entire TNI process into disrepute. If the recognition committee is compromised, then TNI as an organization has failed to vet

or properly train the members of the process. The recognition committee has to have the tools, access to docs and records and experience to thoroughly evaluate the AB and to provide conclusions and recommendation on the status. The process needs to be transparent to ensure it is followed. If the executive committee is not part of the actual evaluation process, what is the for cause situation that they can state the process is not followed. The corrective action process of the evaluation and subsequent appeals process are the two dispute points....those are between the RC and the AB...The executive committee has noting to do with it and should not stop the process without access to the entire file.

- There were a number of committee members and conference attendees that agreed the language in SOP 7-101 should be updated to accurately reflect the process.
- Given time constraints of the meeting, it was decided that a small group of people representing PTPEC, NEFAP EC and the Combined Evaluation SOP Subcommittee should meet with Alfredo and Jerry to discuss their concerns and reach a conclusion on the wording of the SOP. The SOP will then be brought back to each executive committee for review of the updated language and voting. Ilona will reach out to Jerry and Alfredo.
- Matt and Michella withdrew their motion and second until further discussion can happen.

5. Subcommittee Reports

<u>Chemistry FoPT Subcommittee</u> – Bob Shannon and Keith McCroan are working on a new procedure for Radiochemistry FoPT calculations. Current limits are based on the original EPA procedures. The subcommittee will begin meeting again once Bob and Keith have a proposal to present.

 \underline{SOP} Subcommittee – The subcommittee has completed its recommendation on dispute procedures. They are still working on the FoPT SOP – 4-101. This may take a year to complete – at least.

<u>FoPT Table Format Subcommittee</u> – The subcommittee has worked on all the FoPT tables at this point. The IT Committee is reviewing an SOP on how analyte and method codes will be implemented. Once this is done, they will be able to finish up.

<u>Microbiology FoPT Subcommittee</u> – The subcommittee is continuing to work on the ARA.

6. Future Plans

See slides in Attachment D.

- Matt They can look at failure rate and see 100% success rate on most analytes. Is this really helpful? What is the purpose of the PTs? Carl noted that there are regulatory acceptance limits. Is it OK that labs pass their PTs? They all have great quality systems now. Is the challenge adequate?
- Andy asked about experimental PTs. Will they be brought back?
- It was mentioned that labs need to run PTs for each method. They can't report the same PT for multiple methods under the same technology. This could be an SIR. PT providers don't want to see the same number reported twice.
 - Maria thinks this may be a California issue. Regulations that are more stringent trump.
 - o DW does require the lab must run a PT for each method 1x per year.
 - o If you choose to report all methods under on technology if you fail one ... you fail all.

7. New Business.

- None.

8. Action Items

The action items can be found in Attachment B. The action items will be reviewed at the next meeting.

9. Next Meeting

The next meeting will be on 9/20/18 by teleconference at 1pm Eastern. There will not be a call on the third Thursday in August.

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

Maria adjourned the meeting at 4:56 Central. (Motion: Matt Second: Fred Unanimously approved.)

Attachment A

Participants TNI Proficiency Testing Program Executive Committee

Affiliation Members Rep Contact Information Maria Friedman (2020) ΑB California Water Maria.Friedman@waterboards.ca.gov (Chair) Board Present Dixie Marlin (2018*) Other Marlin Quality marlinguality@gmail.com (Vice-Chair) Management, LLC Absent Ilona Taunton, TNI tauntoni@msn.com Program Administrator Present ALS Environmental Eric Smith (2019) Lab eric.smith@alsglobal.com **Absent** Carl Kircher (2021*) AB Florida Department Carl.Kircher@flhealth.gov of Health Present Andy Valkenburg LAB **Energy Laboratories** avalkenburg@energylab.com (2021*) Present Jennifer Duhon (2019*) Other Millipore Sigma jennifer.duhon@sial.com Present Matt Sica (2020) ANAB, ANSI-ASQ AB msica@anab.org National Accreditation Board Present Gil Dichter (2018*) Other **IDEXX** Water gil-dichter@idexx.com Absent Patrick Garrity (2019*) AB Kentucky DEP patrick.garrity@ky.gov Present Michella Karapondo Other USEPA karapondo.michella@epa.gov (2019*)Present Fred Anderson (2020*) Other Advanced Analytical Fred@advancedgc.com Solutions, LLC Present Jennifer Mullins (2020*) Upper Occoquan jennifer.mulllins@uosa.org Lab Service Authority Present Environmental Scott Haas (2020*) FSMO shaas@etilab.com Testing, Inc. Absent

Attachment B

Action Items – TNI PT Executive Committee

| | retion rem | Action Items – INI PT Executive Committee | | | | |
|------|------------------------------|-------------------------------------------|---------|-------------------------|-----------------|--|
| | A 4* T4 | *** | Date | Expected | Actual | |
| 20.5 | Action Item | Who | Added | Completion | Completion | |
| 295 | Moved from Backburner: | Shawn | | New Date: | In Progress | |
| | PTPA Evaluation Checklist | Ilona | | 8/31/18 | (will use 2009 | |
| | needs to be updated prior to | | | | TNI Standards | |
| | next round of evaluations. | | | | and current | |
| | (Originally discussed | | | | SSAS | |
| | 8/6/13) | | | | Standards) | |
| 349 | Review LAMS/FoPT Table | ALL | 4/20/17 | 4/25/17 | In Progress | |
| | Differences document. | | | | WET is still | |
| | Provide comments by email | | | 2/28/18 - For | being | |
| | and next meeting. | | | WET? | reviewed. | |
| | 5 | | | June 2018 for | Update | |
| | | | | all tables. | 1/23/18: | |
| | | | | | Subcommittee | |
| | | | | New target | expects to | |
| | | | | date: 7/15/18 | have updated | |
| | | | | | FoPT tables | |
| | | | | | with CAS #'s | |
| | | | | | and LAMS | |
| | | | | | changes by | |
| | | | | | 3/15/18. | |
| | | | | | 2/22/19: Still | |
| | | | | | in progress. | |
| | | | | | 6/21/18: Still | |
| | | | | | working with | |
| | | | | | Rami. | |
| 352 | Moved from Backburner | All | 2/20/14 | TBD | In Progress – | |
| | (originally discussed | | | (see #350) | Update of SOP | |
| | 2/20/14): | | | | 4-101 | |
| | When new limits are | | | 350: Prepare | | |
| | established for the FoPTs, | | | <i>formal</i> | 6/21/18: Gil | |
| | what is considered to be a | | | request to | noted that this | |
| | statistically significant | | | SOP | SOP will be | |
| | change to the old rates? At | | | Subcommittee | worked on | |
| | what point is it appropriate | | | regarding | again at the | |
| | to question new limits? This | | | updating | next meeting. | |
| | lends to the TSS discussion | | | FoPT tables | An expected | |
| | a few months ago. | | | and | completion | |
| | | | | <i>applicable</i> | date will be | |
| | Patrick commented that it | | | backburner | given at July | |
| | would make sense to look at | | | items just | meeting. | |

| | Action Item | Who | Date Added | Expected Completion | Actual Completion |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------|------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | 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. | | | moved to the Action Items table (#352, 353) | |
| 353 | Discuss possible procedural changes to how limits are updated. Maria talk to SOP Subcommittee. (Need to look at PT database implications.) | All | | TBD | In Progress – Update of SOP 4-101 Maria will send a copy to close this item. |
| 358 | 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 | Maria will resend to Gil and this item will be closed. 3/15/18: Still in progress. |
| 361 | Analyte Code changes needed in LAMS. (TKN) | Maria Dan Hickman | 7/20/17 | 9/30/17 | Still need to look into TKN issue. 2/22/18 – Maria will confirm. |
| 363 | Discuss procedural change in how changes are made to LAMS. Consider notifying PTPEC before relevant changes are made and provide a summary of changes at some frequency. | | | 1/31/17 | Will talk to IT about getting this in an SOP. 12/21/17: Maria will follow-up on this. 3/20/18: Maria will check this week. 6/21/18 – still being worked on. |
| 368 | Forward Jerry's question to Chemistry FoPT Subcommittee. (Analyte | Maria | 8/24/17 | 9/1/17 | Maria will resend to Carl. 6/21/18 – |

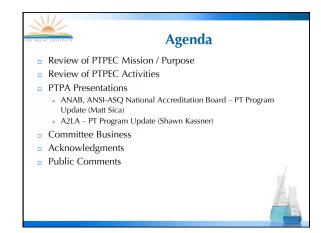
| | Action Item | Who | Date Added | Expected Completion | Actual Completion |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---------------|---------------------|---------------------------|
| | code change for the non-polar extractable materials.) | | 11000 | | Maria will send to Ilona. |
| 373 | Carl will notify the PTPEC when Bob and Keith complete their comparison table to the Radiochemistry FoPT work the Chemistry FoPT Subcommittee has already prepared. | Carl | 12-21-17 | 3-31-18 | |
| 384 | Meet with Dan Hickman to get Analyte Codes and then prepare final DRAFT of Micro DW and WW tables. Send to Jennifer for review. | Maria | 4/19/18 | 5/15/18 | Still in Progress |
| 385 | Send Micro DW and WW tables to PTPEC for review and vote at next meeting. | Maria | 4/19/18 | 5/15/18 | Still in Progress |
| 389 | Present recommended LAMS updates to Dan Hickman. | Maria | 5/17/18 | 5/20/18 | |
| 390 | Update SOP 7-101 with PTPEC and NEFAP EC comments. Send to committees for final review. | Ilona/Stacie | 7/19/18 | 8/6/18 | Complete |
| 391 | Setup meeting with Jerry and Alfredo to discuss combined evaluation process. | Ilona | 8/6/18 | 9/20/18 | |
| | | | | | |
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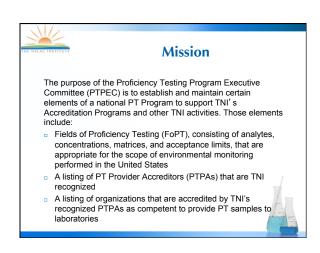
Attachment C

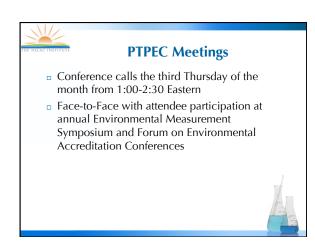
Backburner / Reminders – TNI PT Executive Committee

| | 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 | |
| | | | |
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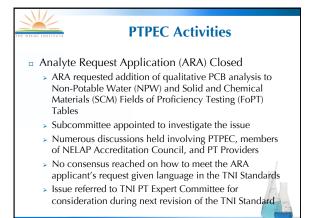


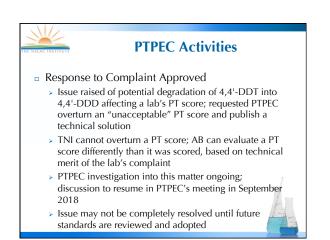


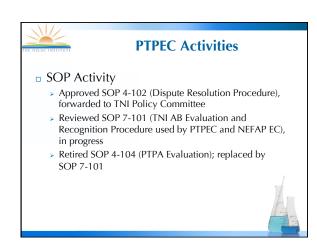


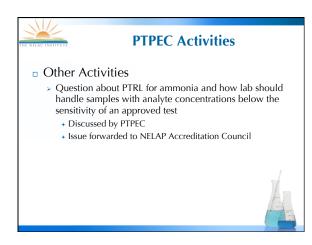


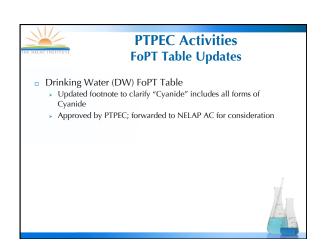


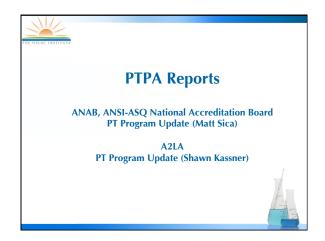






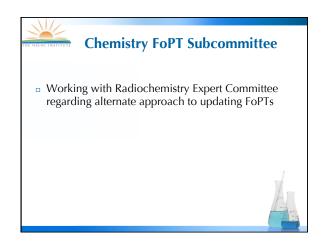


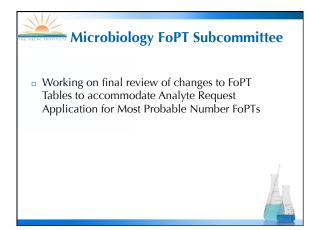


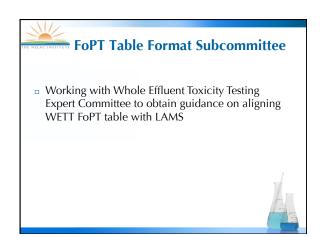


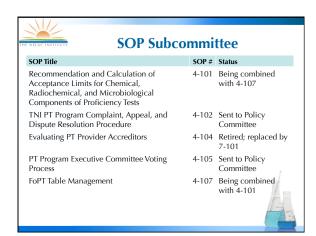




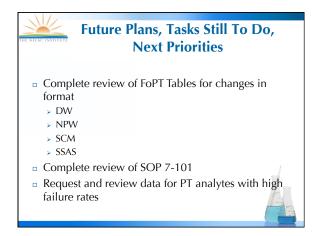


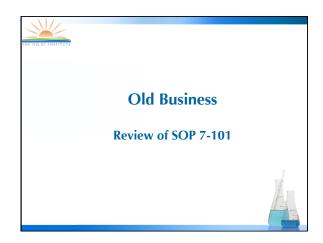


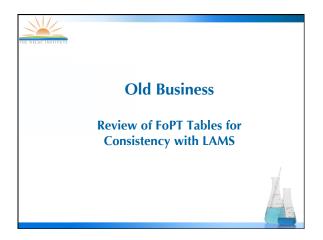






























A2LA PTPA Update Report

TNI August 2018 Shawn Kassner

PT Provider Status

- ERA Renewal Assessment Pending, Valid through 9/30/18
- Phenova Renewal Assessment Completed, Valid through 9/30/18
- New York State Department of Health Wadsworth Center – Renewal Assessment Pending, Valid through 11/30/18
- Advanced Analytical Renewal Assessment Pending, Valid through 1/31/18
- No complaints for any provider.



New PTP Portal

- Updated PTP data upload portal for:
 - First implemented ~15 yrs ago.
 - Modernized website.
 - Improved sustainability.
 - Improved ease of use.
 - More efficient.





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 pts



Data Challenges

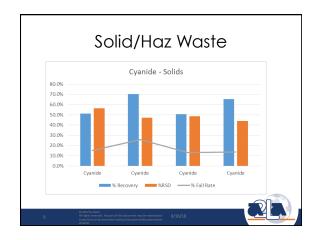
- What do these data sets represent?
 - Initial data is one year's worth of data
 - Each data point is a study summary for an analyte.
 - 17397 data points across 4 PTPs
 - 5285 data points Failure rates > 10% and n > 30
 - 184 data points met criteria across multiple PTPs.
 - 1.06 % of the data produced by PTPs.

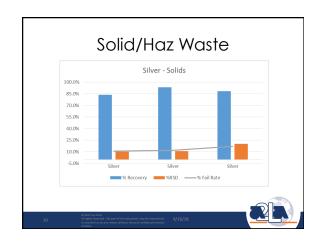


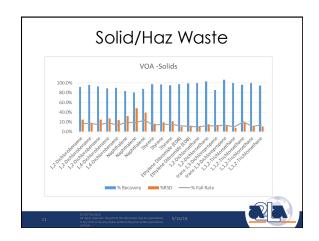
Data Review Steps

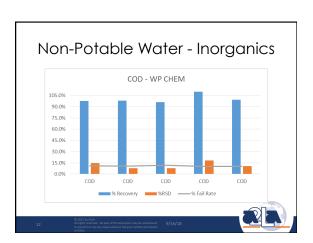
- FR > 10% Analytes for One PTP
 - The analyte history was reviewed across PTPs.
 - Study summary statistics
 - VHS data were examined
 - PTPs were contacted as necessary.
- All instances where studies that had low n's were data related.

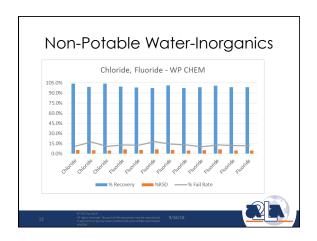


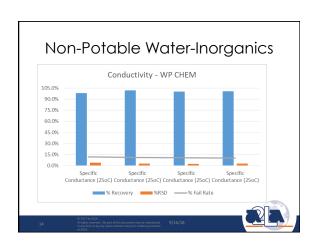


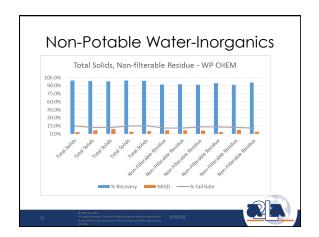


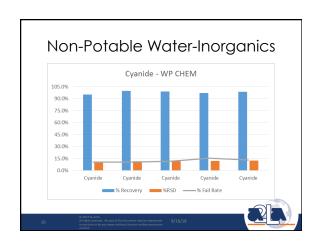


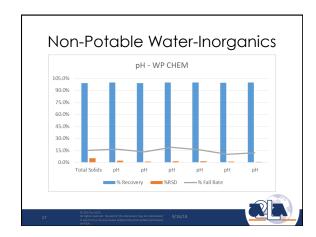


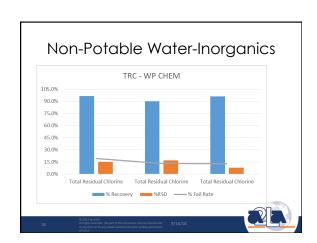


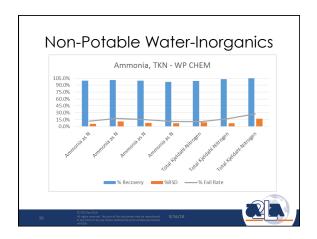


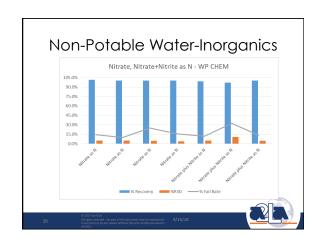


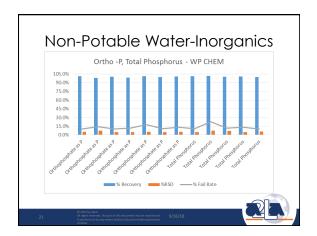


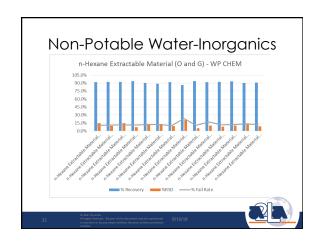


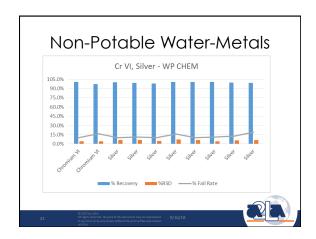


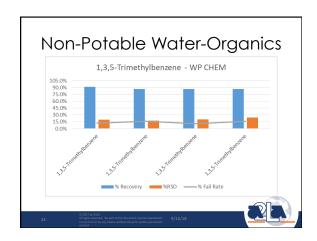


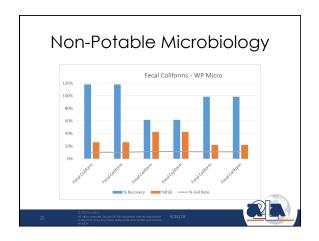


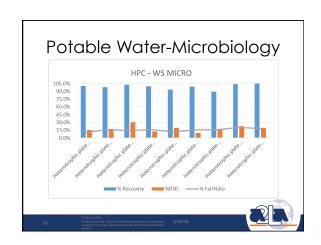


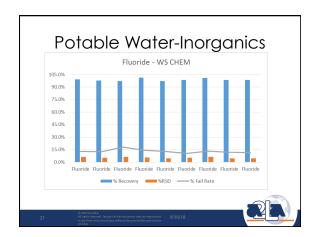


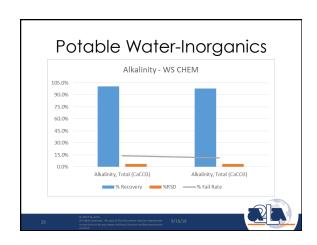


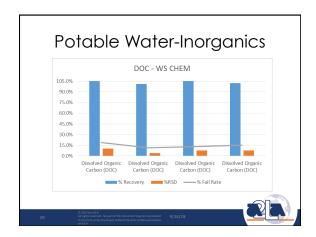


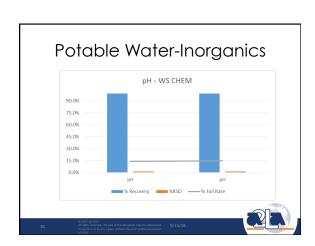


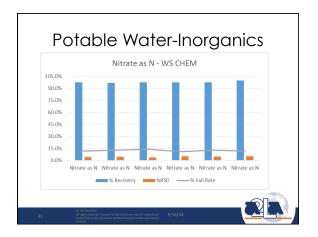


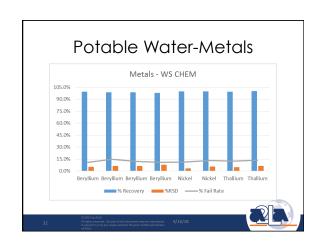


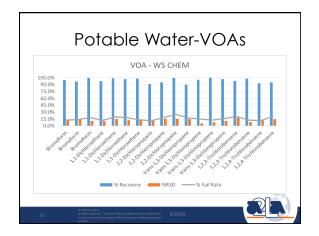












Data Conclusions

- PT acceptance limits are data quality objectives for laboratory performance.
- All analytes have been presented historically multiple times.
- No Issues with:
 - PT samples
 - Verification, homogeneity, stability data
- SOP Subcommittee considering adding this analysis to the FTOP SOP.



Thank You!

- Our customers, the A2LA accredited proficiency testing providers.
- Our staff, assessors, and the PTPEC and PTEC that support us in the continuous improvement of our accreditation program.









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



