

**PT Committee Vote and Response to Comments  
August 2009**

**Comment Number 122**

VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing  
Section 4.2.1

**Comment w/Rationale for Change:** This comment is regarding the number of and frequency that NELAC accredited laboratories are required to analyze PT samples for the aqueous matrices "Potable" and "Non-Potable" water. Labs that are accredited in the two aqueous categories potable and non-potable are performing 4 PT's per year for similar methodologies. Prior to the EPA 40 CFR Monday, March 12, 2007 update, we were at least reporting different methods for the DW and WW PT's, but now, they are the same method references. In order to attract more participating labs and AB's we need to harmonize the TNI PT standard with the EPA DW Manual. The 5th Edition, page IV-5, Section 7.2 states:

" . . .analyze PT samples. . .at least once every 12 months for each analyte and by each method used to analyze compliance samples. . . .A make up PT sample must be successfully analyzed."

One approach would be to change the definition of matrix to combine potable and non-potable water and call them "Aqueous". This would not be easy since Accreditation Bodies have framed their applications and fees by category, and potable rules must also follow the EPA DW Manual. This adjustment to the PT schedule would facilitate a cooperative relationship with EPA Office of Ground Water and Drinking Water concerns as stated in the Director Cynthia C. Dougherty's May 14 2007 Memorandum on Drinking Water Laboratory Program Oversight.

**Proposed Change:** Here is very simple suggested text to change the draft V1, M1: Proficiency Testing language for Continued Accreditation:

- 4.2.1 a) analyze at least one TNI-compliant PT sample per year;
- 4.2.1 b) maintain a history of at least one successful performance, as describe in Section 6.0, out of the most recent two attempts;
- 4.2.1 d) analyze PT samples for the sample FoPT no fewer than 15 days apart and no more than 12 months apart.

The remaining text may be clarified to require a passing corrective action PT within the same year. **With this type of schedule, labs may perform in 2 studies per year, i.e., potable then non-potable.** For soil PT's, there could still be the 2 studies per year requirement if there is too much disagreement from the TNI members.

Please consider this idea for the sake of time and cost to laboratories and AB's.

**Vote Summary**

Option	Classification	Gradients of Agreement	Vote
1	Persuasive	Endorse – Comment is persuasive; no objection to change proposed.	2
2	Persuasive	Agree With Reservation – Comment is persuasive with some objection to change proposed.	2
3	Not Persuasive	Veto – Comment is not persuasive; will not accept change proposed.	5

## Comments:

It is not practical to have a general acceptance for similar analytes in different matrices. The conditions discussed in the comment should be part of the considerations for a comprehensive overhaul of PT requirements.

The commenter indicates that the primary reason to change the current system is to attract more laboratories and accrediting bodies to TNI. There is no indication that the requirement to perform two PTs per year for each FoPT is a major barrier to participation in the program.

The commenter indicates that laboratories are participating in both WP and WS. Many laboratories do not participate in both studies.

The major change proposed by the commenter is to merge the Water Supply (WS) and Water Pollution (WP) studies to one aqueous matrix and require participation in one proficiency test study per year. It is recognized that the Fields of Proficiency Testing include some overlap of analytes and methodology. However, the required concentration ranges, analyte lists and acceptance criteria of the studies are not sufficiently similar to merge the two matrices. The concentration ranges and acceptance criteria of many of the analytes have been set by federal regulation (see 40 CFR Parts 141.23 and 141.24 as well as the "National Standards for Water Proficiency Testing, Criteria Document") and therefore may not be changed.

Also to be considered is that within an analytical method two aqueous matrices may require different processing. For example: EPA Method 200.7 permits direct analysis of potable water samples for trace metals, direct digestion of non-potable water samples is not permitted. In order to meet regulatory requirements to analyze proficiency test samples in the same manner as routine samples a laboratory would be expected to digest non-potable water samples in WP studies but not the potable water samples in WS studies.

This change in the PT program is not a very simple text change as the commenter indicates. To merge the WP and WS programs would require major regulation and implementation changes at the federal and state level.

The matrix for WS and WP samples appears to be the same. There are differences in acceptance criteria and perhaps concentration ranges. The PT Committee should look at this issue and see if an alternate PT model for aqueous samples can be developed.

Persuasive with or without the study that was conducted by Dan Tholen of A2LA. While we are PT providers and would like to keep and expand our market, our collective experience shows there is no significant difference between labs doing 1 PT or 2 PT's per year as laboratory quality is a function of many variables that do not readily lend themselves to a statistical evaluation. The issue should be formally reviewed every few years as a matter of TNI quality policy as all procedures under TNI.

I do want to point out that Micro PT's were not discussed in any of deliberations except what I had brought up on 08/04/2009. Here the risk factor may actually require more than 2 PT's year.

In any event this process did receive significant attention by both sides of the issue. My recommendation is that we canvas all labs in NELAC to see what they would like.

The commenter is requesting that the WP and WS proficiency testing programs be combined into a single aqueous proficiency testing program. A single proficiency testing (PT) sample

being analyzed once per every 12 months while maintaining a history of two successful evaluations out of the last three.

The issues of concern are three fold. The first concern is the combination of the WS and WP programs. The two programs have very different concentration ranges listed in the TNI Fields of Proficiency Testing Tables and in the regulations that are listed in the CFR. The concentration ranges for a majority of the analytes has little and in some cases no overlap. The acceptance criteria between the two programs are also quite different, the WP program has acceptance criteria of  $\pm 3$  expected standard deviations, while the WS program has acceptance criteria based on  $\pm 2$  expected standard deviations.

The commenter states reducing PT frequency will attract additional ABs. The NELAC PT program needs be based on what is meaningful for laboratories and ABs, not on the marketability of the NELAC program to expand the number of participating states. Combining Potable and Non-Potable matrices into an "aqueous" matrix would not be appropriate, as there are differences in data quality objectives for potable and non-potable programs. PT acceptance limits, and the concentrations of interest are very different, making the creation of one PT difficult, and unreasonable as a means to assess a laboratory across multiple matrices.

There are differences in methodologies for potable and non-potable matrices, specifically for organics. There are also differences in sample preparation techniques for these different matrices across many methods.

A. The comment's statement "In order to attract more participating labs and AB's," is not compelling for two reasons.

- 1) Rationale that this would attract more labs is not proven.
- 2) Some current AB's might have to withdraw because of state regulatory restrictions requiring 2 PT's per year.

B. Concentration ranges are different for most analytes in WS versus WP, i.e., successful analysis at a WS concentration would not demonstrate proficiency with lower WP level.

C. With increasing NELAP emphasis on self-monitoring quality systems, 2 annual PT's maintain at least a modicum of external monitoring of technical capability.

D. Without a clear desire for combined WS and WP from both the EPA and AB's, the TNI PT Committee would be wasting its time working on a revision.

### Comment Number 203

Steve Axelrod

VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing

Section 4.2.1

**Comment w/Rationale for Change:** Where the opportunity presents itself, it seems reasonable that a PT standard should be able to be reported for more than one field of accreditation to provide a cost savings to the laboratory. NELAC certification is an extremely costly proposition and it seems that there has been little regard to consider the cost to the labs as part of the development of the standards. Perhaps a new TNI committee can be created for that purpose.

Proposed Change: Allow PT standards to be used for more than one field of accreditation when possible. Promote this concept with the PT providers.

### Vote Summary:

Option	Classification	Gradients of Agreement	Vote
1	Persuasive	Endorse – Comment is persuasive; no objection to change proposed.	1
2	Persuasive	Agree With Reservation – Comment is persuasive with some objection to change proposed.	
3	Not Persuasive	Veto – Comment is not persuasive; will not accept change proposed.	8

### Comments:

It is not clear what is meant by "fields of accreditation", so the comment is not actionable. However, a comprehensive overhaul of PT requirements should consider the allowance of PT on one analyte/matrix to be used as PT on other related analytes.

Laboratories are already permitted to analyze a single PT sample by multiple methods for a single field of proficiency testing (FoPT) when the FoPT are within the same FoPT matrix.

The intent of the commenter seems to be to permit the use of a single proficiency test sample to meet the requirements of both drinking water and non-potable water (i.e. merge the Water Supply and Water Pollution Studies). The required concentration ranges, analyte lists and acceptance criteria of the studies are not sufficiently similar to merge the two matrices. The concentration ranges and acceptance criteria of many of the analytes have been set by federal regulation (see 40 CFR Parts 141.23 and 141.24 as well as the "National Standards for Water Proficiency Testing, Criteria Document") and therefore may not be changed.

Also to be considered is that within an analytical method two aqueous matrices may require different processing. For example: EPA Method 200.7 permits direct analysis of potable water samples for trace metals, direct digestion of non-potable water samples is not permitted. In order to meet regulatory requirements to analyze proficiency test samples in the same manner as routine samples a laboratory would be expected to digest non-potable water samples in WP studies but not the potable water samples in WS studies.

"Laboratories are already permitted to analyze a single PT sample for multiple methods and multiple fields of proficiency testing when the FoPT are within the same field of accreditation matrix."

The commenter appears to be requesting that the fields of proficiency testing (FoPT) are tied to fields of accreditation and where possible the PT results are used to cross between fields of

accreditation. The current FoPT scheme allows for the use of proficiency testing results across methods by technology for multiple fields of accreditation. Section 5.1.1 was revised, as stated in the committee's initial response. The commenter's request to harmonize the fields of accreditation and fields of proficiency is unclear as to what the proposed change they are requesting. With the ability to use PT results for multiple accreditation's, I find the comment is not persuasive.

Laboratories are already permitted to analyze a single PT for multiple fields of accreditation within the same matrix. Allowing analysis of the same PT across different matrices would not be appropriate, as there are differences in data quality objectives for potable and non-potable programs. PT acceptance limits, and the concentrations of interest are very different, making the creation of one PT difficult, and unreasonable as a means to assess a laboratory across multiple matrices.

The comment is unclear. Does the commenter expect one PT annually for a field of accreditation?

**Comment Number 225**

VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing  
Section 4.2.1

**Comment w/Rationale for Change:** With this schedule, labs will be required to perform two (2) aqueous studies per year, i.e., potable then non-potable, instead of four (4).

This comment is regarding the number of and frequency that NELAC accredited laboratories are required to analyze PT samples for the aqueous matrices “Potable” and “Non-Potable” water. Labs that are accredited in the two aqueous categories potable and non-potable are performing 4 PT’s per year for identical methodologies. Prior to the EPA 40 CFR Monday, March 12, 2007 update, labs were at least reporting different methods for the WS (potable) and WP (non-potable) PT’s, but now, the same methods are referenced. In order to attract more participating labs and AB’s, TNI should harmonize the TNI Volume 1, Module 1 PT standard with the EPA Drinking Water Manual for Laboratory Certification. The DW manual 5th Edition, page IV-5, Section 7.2 states:

“. . .analyze PT samples. . .at least once every 12 months for each analyte and by each method used to analyze compliance samples. . . .A make up PT sample must be successfully analyzed.”

It would be complicated to change the definition of matrix to combine potable and non-potable water categories, since Accreditation Bodies have framed their applications and fees by category, and the PT provider products are well known as WS and WP. Adjusting the PT schedule, however, would facilitate a cooperative relationship with EPA Office of Ground Water and Drinking Water concerns as stated in the Director Cynthia C. Dougherty’s May 14 2007 Memorandum on Drinking Water Laboratory Program Oversight.

This idea will cut the time and costs to both labs and AB’s.  
Proposed Change 4.2.1 a) analyze at least one TNI-compliant PT samples per year;  
4.2.1 b) maintain a history of at least one successful performances, as described in Section 6.0, out of the most recent two attempts;  
4.2.1 d) analyze PT samples for the sample FoPT no fewer than 15 days apart and no more than 12 months apart.

OR

As another option, we could define a PT matrix called “Aqueous PT”, considering that the PT Providers use the same materials to prepare WS and WP aqueous PT’s. So the text could stay the same, but add: of “two TNI-compliant Aqueous PT samples per year”. There would still be the 2 studies per year requirement for soil PT’s. Non-NELAP states and participating labs would still be demonstrating their performance on the methods two times per year, which is twice as often as EPA requires for certification.

**Vote Summary:**

Option	Classification	Gradients of Agreement	Vote
1	Persuasive	Endorse – Comment is persuasive; no objection to change proposed.	1
2	Persuasive	Agree With Reservation – Comment is persuasive with some objection to change proposed.	3
3	Not Persuasive	Veto – Comment is not persuasive; will not accept change proposed.	5

## Comments:

It is not practical to have a general acceptance for similar analytes in different matrices. The conditions discussed in the comment should be part of the considerations for a comprehensive overhaul of PT requirements.

The commenter indicates that the primary reason to change the current system is to attract more laboratories and accrediting bodies to TNI. There is no indication that the requirement to perform two PTs per year for each FoPT is a major barrier to participation in the program.

The major change proposed by the commenter is to merge the Water Supply (WS) and Water Pollution (WP) studies to one aqueous matrix and require participation in one proficiency test study per year. It is recognized that the Fields of Proficiency Testing include some overlap of analytes and methodology. However, the required concentration ranges, analyte lists and acceptance criteria of the studies are not sufficiently similar to merge the two matrices. The concentration ranges and acceptance criteria of many of the analytes have been set by federal regulation (see 40 CFR Part 141.23 and 141.24 as well as the "National Standards for Water Proficiency Testing, Criteria Document") and therefore may not be changed.

Also to be considered is that within an analytical method two aqueous matrices may require different processing. For example: EPA Method 200.7 permits direct analysis of potable water samples for trace metals, direct digestion of non-potable water samples is not permitted. In order to meet regulatory requirements to analyze proficiency test samples in the same manner as routine samples a laboratory would be expected to digest non-potable water samples in WP studies but not the potable water samples in WS studies.

The proposed change indicates that acceptable proficiency test performance would be one successful attempt out of the most recent two. Under this scoring system a laboratory would not be considered to be out of compliance until two to three years after the initial PT failure. This is not sufficient to ensure data quality needs of regulators are met.

The matrix for WS and WP samples appears to be the same. There are differences in acceptance criteria and perhaps concentration ranges. The PT Committee should look at this issue and see if an alternate PT model for aqueous samples can be developed.

The commenter is requesting that the WP and WS proficiency testing programs be combined into a single aqueous proficiency testing program. A single proficiency testing (PT) sample being analyzed once per every 12 months while maintaining a history of two successful evaluations out of the last three.

The issues of concern are three fold. The first concern is the combination of the WS and WP programs. The two programs have very different concentration ranges listed in the TNI Fields of Proficiency Testing Tables and in the regulations that are listed in the CFR. The concentration ranges for a majority of the analytes has little and in some cases no overlap. The acceptance criteria between the two programs are also quite different, the WP program has acceptance criteria of  $\pm 3$  expected standard deviations, while the WS program has acceptance criteria based on  $\pm 2$  expected standard deviations.

The second concern is that in harmonizing the differences between the acceptance criteria would mean requiring wastewater treatment facilities to meet drinking water standards nationally. This would place an unnecessary burden on these facilities, while benefiting commercial laboratories that are participating in both programs.

The third concern is the maintaining a history of the two successful attempts out of the last three for PT performance. In states where a single PT is required there is much more stringent levels of compliance for corrective action. Typically, in these states the corrective action requirements are to be completed within the same calendar year or even within weeks of receiving the "Not Acceptable" evaluation from the PT provider. Maintaining this level of corrective action would most likely not be acceptable to the accrediting bodies.

Given the different concentration ranges, different acceptance criteria, differing regulations governing the two programs and the maintaining of the two out of three levels of passing, I find the comment not persuasive.

The commenter states reducing PT frequency will attract additional ABs. The NELAC PT program needs be based on what is meaningful for laboratories and ABs, not on the marketability of the NELAC program to expand the number of participating states. Combining Potable and Non-Potable matrices into an "aqueous" matrix would not be appropriate, as there are differences in data quality objectives for potable and non-potable programs. PT acceptance limits, and the concentrations of interest are very different, making the creation of one PT difficult, and unreasonable as a means to assess a laboratory across multiple matrices.

There are differences in methodologies for potable and non-potable matrices, specifically for organics. There are also differences in sample preparation techniques for these different matrices across many methods.

A. The comment's statement "In order to attract more participating labs and AB's," is not compelling for two reasons. 1) Rationale that this would attract more labs is not proven. 2) Some current AB's might have to withdraw because of state regulatory restrictions requiring 2 PT's per year.

B. Concentration ranges are different for most analytes in WS versus WP, i.e., successful analysis at a WS concentration would not demonstrate proficiency with lower WP level.

C. With increasing NELAP emphasis on self-monitoring quality systems, 2 annual PT's maintain at least a modicum of external monitoring of technical capability.

D. Without a clear desire for combined WS and WP from both the EPA and AB's, the TNI PT Committee would be wasting its time working on a revision.

**Comment Number 312**

VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing  
Section 4.1 and 4.2

**Comment w/Rationale for Change:** Our municipal lab currently pays more >\$10,000 a year in PT samples. We view this as excessive especially in the light of Florida Governments having to make serious cutbacks. We question what the benefit is here, other then providing revenue to the PT providers. Consider the following:

- 1) The majority of the wet chemistry and metals PT samples that many of us are required to analyzed are duplicated for WP and WS samples, resulting in the requirement to analyze 4 PTs sample a year for the same/similar method and technology!
- 2) The EPA DW Manual only requires one sample to be analyzed every 12 months.
- 3) PT samples are in a clean matrix, and if a lab is following the method, they should yield results similar to the calibration verification standards, of which an auditor should be reviewing upon inspection. So why require this extra expense? The value of analyzing PTs has its place, but we question the value of the frequency, which directly equates to cost. The cost of these samples should equal the benefit!

**Proposed Change** 1) For initial accreditation, only require the analysis of one PT sample.  
2) For continued accreditation, require labs to analyze one PT per twelve month period, and when labs utilize the same method/technology for both drinking water and non-potable water certifications; allow labs the opportunity to report one FoPT sample for both WP and WS. If sample concentration is an issue, and labs want to kill two birds with one stone, then require labs to order the lower concentration.

**Vote Summary:**

Option	Classification	Gradients of Agreement	Vote
1	Persuasive	Endorse – Comment is persuasive; no objection to change proposed.	1
2	Persuasive	Agree With Reservation – Comment is persuasive with some objection to change proposed.	3
3	Not Persuasive	Veto – Comment is not persuasive; will not accept change proposed.	5

**Comments:**

It is not practical to have a general acceptance for similar analytes in different matrices. The conditions discussed in the comment should be part of the considerations for a comprehensive overhaul of PT requirements. One successful PT before accreditation is not sufficient.

The first proposed change is to require the analysis of only one proficiency test sample for initial accreditation. Successful participation in one study to obtain initial accreditation is not sufficient to demonstrate that the laboratory has proficiency with a new method or technology. Under this system a laboratory could participate in, and fail, multiple studies then pass a single study and gain accreditation. The current requirement to pass two out of the most recent three attempts demonstrates successful use of the method over time.

The commenter also proposes allowing a laboratory certified in both drinking water and non-potable water to participate in either a Water Supply (WS) or Water Pollution (WP) study per year. It is recognized that the Fields of Proficiency Testing include some overlap of analytes and methodology. However, the required concentration ranges, analyte lists and acceptance criteria of the studies are not sufficiently similar to merge the two matrices. The concentration ranges and acceptance criteria of many of the analytes have been set by federal regulation (see

40 CFR Part 141.23 and 141.24 as well as the “National Standards for Water Proficiency Testing, Criteria Document”) and therefore may not be changed.

Also to be considered is that within an analytical method two aqueous matrices may require different processing. For example: EPA Method 200.7 permits direct analysis of potable water samples for trace metals, direct digestion of non-potable water samples is not permitted. In order to meet regulatory requirements to analyze proficiency test samples in the same manner as routine samples a laboratory would be expected to digest non-potable water samples in WP studies but not the potable water samples in WS studies.

The matrix for WS and WP samples appears to be the same. There are differences in acceptance criteria and perhaps concentration ranges. The PT Committee should look at this issue and see if an alternate PT model for aqueous samples can be developed.

The commenter is requesting that the WP and WS proficiency testing programs be combined into a single aqueous proficiency testing program, with a single proficiency testing (PT) sample being analyzed once per every 12 months. The commenter is also asking to change the initial requirements for accreditation to one PT result.

The combination of the WS and WP programs for proficiency testing is a concern for two reasons. The first reason, as stated by the commenter, the two programs have very different concentration ranges listed in the TNI Fields of Proficiency Testing Tables and in the regulations that are listed in the CFR. The concentration ranges for a majority of the analytes has little and in some cases no overlap. The second reason, is that the acceptance criteria between the two programs are also quite different, the WP program has acceptance criteria of  $\pm 3$  expected standard deviations, while the WS program has acceptance criteria based on  $\pm 2$  expected standard deviations. Though the commenter mentions using the lower concentration ranges, the acceptance criteria between the two programs are very different and would lead to higher failure rates.

Given the different concentration ranges, different acceptance criteria, and differing regulations governing the two programs, I find the comment not persuasive.

There are different regulatory requirements for the determination of PT acceptance limits for potable and non-potable water based program requirements. Allowing a single PT to meet both programs would not be appropriate, as there are differences in data quality objectives for potable and non-potable programs. PT acceptance limits, and the concentrations of interest are very different, making the reporting of PT results to meet both matrices difficult, and unreasonable as a means to assess a laboratory across multiple matrices.

- A. Concentration ranges are different for most analytes in WS versus WP, i.e., successful analysis at a WS concentration would not demonstrate proficiency with lower WP level.
- B. With increasing NELAP emphasis on self-monitoring quality systems, 2 annual PT's maintain at least a modicum of external monitoring of technical capability.
- C. Without a clear desire for combined WS and WP from both the EPA and AB's, the TNI PT Committee would be wasting its time working on a revision.

**Comment Number 331**

VOLUME 1: LABORATORY REQUIREMENTS Module 1 - Proficiency Testing  
Section 4.2 & 5.2.5

**Comment w/Rationale for Change:** What is the purpose of running a WS and a WP study, each, twice a year? Both are in nice clean matrices, therefore, one study for each per year would provide the same information without making the labs buy and perform duplicate analyses. With the ever-increasing costs of PTs, we labs have trouble understanding why more than one study per year isn't sufficient.

Proposed Change 4.2.1.a) analyze one TNI-compliant PT sample per year per FoPT;  
b) maintain a history of at least one successful performance, as described in Section 6.0, out of the most recent two attempts;

4.2.2 "...at least once per year..."

4.2.3 "...shall analyze one PT sample for the experimental..."

5.2.5 "...annual analysis schedule necessary to maintain accreditation..."

**Vote Summary:**

Option	Classification	Gradients of Agreement	Vote
1	Persuasive	Endorse – Comment is persuasive; no objection to change proposed.	2
2	Persuasive	Agree With Reservation – Comment is persuasive with some objection to change proposed.	3
3	Not Persuasive	Veto – Comment is not persuasive; will not accept change proposed.	4

**Comments:**

It is not practical to have a general acceptance for similar analytes in different matrices. The conditions discussed in the comment should be part of the considerations for a comprehensive overhaul of PT requirements.

The analysis of one TNI-compliant proficiency test sample per year, per FoPT may be sufficient. This proposed change deserves further consideration. To date neither the adequacy of one proficiency test study per year, nor the need for two proficiency test studies per year has been clearly demonstrated.

The scoring criteria suggested by the commenter are not sufficiently rigorous to ensure data quality. Under the proposed scoring system of one successful performance of the most recent two attempts, a laboratory would not be considered to be out of compliance until two to three years after the initial PT failure. Any change to the PT participation frequency must also include associated changes to the system used to rate laboratory performance over time.

The matrix for WS and WP samples appears to be the same. There are differences in acceptance criteria and perhaps concentration ranges. The PT Committee should look at this issue and see if an alternate PT model for aqueous samples can be developed.

The commenter is requesting that the WP and WS proficiency testing programs be combined into a single aqueous proficiency testing program. A single proficiency testing (PT) sample being analyzed once per every 12 months while maintaining a history of two successful evaluations out of the last three.

The issues of concern are three fold. The first concern is the combination of the WS and WP programs. The two programs have very different concentration ranges listed in the TNI Fields of Proficiency Testing Tables and in the regulations that are listed in the CFR. The concentration ranges for a majority of the analytes has little and in some cases no overlap. The acceptance criteria between the two programs are also quite different, the WP program has acceptance criteria of  $\pm 3$  expected standard deviations, while the WS program has acceptance criteria based on  $\pm 2$  expected standard deviations.

The second concern is that in harmonizing the differences between the acceptance criteria would mean requiring wastewater treatment facilities to meet drinking water standards nationally. This would place an unnecessary burden on these facilities, while benefiting commercial laboratories that are participating in both programs.

The third concern is the maintaining a history of the two successful attempts out of the last three for PT performance. In states where a single PT is required there is much more stringent levels of compliance for corrective action. Typically, in these states the corrective action requirements are to be completed within the same calendar year or even within weeks of receiving the "Not Acceptable" evaluation from the PT provider. Maintaining this level of corrective action would most likely not be acceptable to the accrediting bodies.

Given the different concentration ranges, different acceptance criteria, differing regulations governing the two programs and the maintaining of the two out of three levels of passing, I find the comment not persuasive.

Combining Potable and Non-Potable matrices into an "aqueous" matrix would not be appropriate, as there are differences in data quality objectives for potable and non-potable programs. PT acceptance limits, and the concentrations of interest are very different, making the creation of one PT difficult, and unreasonable as a means to assess a laboratory across multiple matrices.

There are differences in methodologies for potable and non-potable matrices, specifically for organics. There are also differences in sample preparation techniques for these different matrices across many methods.

Concentration ranges are different for most analytes in WS versus WP, i.e., successful analysis at a WS concentration would not demonstrate proficiency with lower WP level.

B. With increasing NELAP emphasis on self-monitoring quality systems, 2 annual PT's maintain at least a modicum of external monitoring of technical capability.

C. Without a clear desire for combined WS and WP from both the EPA and AB's, the TNI PT Committee would be wasting its time working on a revision.

**Comment Number 227**

VOLUME 2: ACCREDITATION BODY REQUIREMENTS Module 2 Proficiency Testing  
Section 5.2.1

**Comment w/Rationale for Change:** This comment is regarding the number of and frequency that NELAC accredited laboratories are required to analyze PT samples for the aqueous matrices “Potable” and “Non-Potable” water. Labs that are accredited in the two aqueous categories potable and non-potable are performing 4 PTs per year for identical methodologies. Prior to the EPA 40 CFR Monday, March 12, 2007 update, labs were at least reporting different methods for the WS (potable) and WP (non-potable) PTs, but now, the same methods are referenced. In order to attract more participating labs and ABs, TNI should harmonize the TNI Volume 1, Module 1 PT standard with the EPA Drinking Water Manual for Laboratory Certification. The DW manual 5th Edition, page IV-5, Section 7.2 states:

“. . .analyze PT samples. . .at least once every 12 months for each analyte and by each method used to analyze compliance samples. . . .A make up PT sample must be successfully analyzed.”

It would be complicated to change the definition of matrix to combine potable and non-potable water categories, since Accreditation Bodies have framed their applications and fees by category, and the PT provider products are well known as WS and WP. Adjusting the PT schedule, however, would facilitate a cooperative relationship with EPA Office of Ground Water and Drinking Water concerns as stated in the Director Cynthia C. Dougherty’s May 14 2007 Memorandum on Drinking Water Laboratory Program Oversight.

As another option, we could define a PT matrix called “Aqueous PT”, considering that the PT Providers use the same materials to prepare WS and WP aqueous PT’s. So the text could stay the same, but add: of “two TNI-compliant Aqueous PT samples per year”. There would still be the 2 studies per year requirement for soil PT’s. Non-NELAP states and participating labs would still be demonstrating their performance on the methods two times per year, which is twice as often as EPA requires for certification.

This idea will cut the time and costs to both labs and AB’s.

**Proposed Change:** The Primary AB shall have a process that checks that the laboratories analyze one PT sample for the FoPT per year maintaining a history of at least one successful analyses for the FoPT out of the most recent two attempted when a...

**Vote Summary:**

Option	Classification	Gradients of Agreement	Vote
1	Persuasive	Endorse – Comment is persuasive; no objection to change proposed.	1
2	Persuasive	Agree With Reservation – Comment is persuasive with some objection to change proposed.	3
3	Not Persuasive	Veto – Comment is not persuasive; will not accept change proposed.	5

**Comments:**

It is not practical to have a general acceptance for similar analytes in different matrices. The conditions discussed in the comment should be part of the considerations for a comprehensive overhaul of PT requirements.

The commenter indicates that the primary reason to change the current system is to attract more laboratories and accrediting bodies to TNI. There is no indication that the requirement to perform two PTs per year for each FoPT is a major barrier to participation in the program.

The major change proposed by the commenter is to merge the Water Supply (WS) and Water Pollution (WP) studies to one aqueous matrix and require participation in one proficiency test study per year. It is recognized that the Fields of Proficiency Testing may include some overlap of analytes and methodology. However, the required concentration ranges, analyte lists and acceptance criteria of the studies are not sufficiently similar to merge the two matrices. The concentration ranges and acceptance criteria of many of the analytes have been set by federal regulation (see 40 CFR Part 141.23 and 141.24 as well as the “National Standards for Water Proficiency Testing, Criteria Document”) and therefore may not be changed.

Also to be considered is that within an analytical method two aqueous matrices may require different processing. For example: EPA Method 200.7 permits direct analysis of potable water samples for trace metals, direct digestion of non-potable water samples is not permitted. In order to meet regulatory requirements to analyze proficiency test samples in the same manner as routine samples a laboratory would be expected to digest non-potable water samples in WP studies but not the potable water samples in WS studies.

The proposed change indicates that acceptable proficiency test performance would be one successful attempt out of the most recent two. Under this scoring system a laboratory would not be considered to be out of compliance until two to three years after the initial PT failure. This is not sufficient to ensure data quality needs of regulators are met.

The matrix for WS and WP samples appears to be the same. There are differences in acceptance criteria and perhaps concentration ranges. The PT Committee should look at this issue and see if an alternate PT model for aqueous samples can be developed.

The commenter is requesting that the WP and WS proficiency testing programs be combined into a single aqueous proficiency testing program. A single proficiency testing (PT) sample being analyzed once per every 12 months while maintaining a history of two successful evaluations out of the last three.

The issues of concern are three fold. The first concern is the combination of the WS and WP programs. The two programs have very different concentration ranges listed in the TNI Fields of Proficiency Testing Tables and in the regulations that are listed in the CFR. The concentration ranges for a majority of the analytes has little and in some cases no overlap. The acceptance criteria between the two programs are also quite different, the WP program has acceptance criteria of  $\pm 3$  expected standard deviations, while the WS program has acceptance criteria based on  $\pm 2$  expected standard deviations.

The second concern is that in harmonizing the differences between the acceptance criteria would mean requiring wastewater treatment facilities to meet drinking water standards nationally. This would place an unnecessary burden on these facilities, while benefiting commercial laboratories that are participating in both programs.

The third concern is the maintaining a history of the two successful attempts out of the last three for PT performance. In states where a single PT is required there is much more stringent levels of compliance for corrective action. Typically, in these states the corrective action requirements are to be completed within the same calendar year or even within weeks of receiving the “Not

Acceptable” evaluation from the PT provider. Maintaining this level of corrective action would most likely not be acceptable to the accrediting bodies.

Given the different concentration ranges, different acceptance criteria, differing regulations governing the two programs and the maintaining of the two out of three levels of passing, I find the comment not persuasive.

The commenter states reducing PT frequency will attract additional ABs. The NELAC PT program needs be based on what is meaningful for laboratories and ABs, not on the marketability of the NELAC program to expand the number of participating states. Combining Potable and Non-Potable matrices into an “aqueous” matrix would not be appropriate, as there are differences in data quality objectives for potable and non-potable programs. PT acceptance limits, and the concentrations of interest are very different, making the creation of one PT difficult, and unreasonable as a means to assess a laboratory across multiple matrices.

There are differences in methodologies for potable and non-potable matrices, specifically for organics. There are also differences in sample preparation techniques for these different matrices across many methods.

Though PT providers use same materials to produce both potable and non-potable samples, the ranges and acceptance limits differ based on program requirements.

A. The comment’s statement “In order to attract more participating labs and AB’s,” is not compelling for two reasons. 1) Rationale that this would attract more labs is not proven. 2) Some current AB’s might have to withdraw because of state regulatory restrictions requiring 2 PT’s per year.

B. Concentration ranges are different for most analytes in WS versus WP, i.e., successful analysis at a WS concentration would not demonstrate proficiency with lower WP level.

C. With increasing NELAP emphasis on self-monitoring quality systems, 2 annual PT’s maintain at least a modicum of external monitoring of technical capability.

D. Without a clear desire for combined WS and WP from both the EPA and AB’s, the TNI PT Committee would be wasting its time working on a revision.