VOTING DRAFT STANDARD

VOLUME 3

GENERAL REQUIREMENTS FOR ENVIRONMENTAL PROFICIENCY TEST PROVIDERS

Description

This Voting Draft Standard is a proposed revision of the 2009 standard (EL-V3-2009). It has been prepared by the TNI Proficiency Testing Expert Committee.

Note. The tracking shows proposed changes from the 2009 standard (EL-V3-2009)

VOLUME 3

GENERAL REQUIREMENTS FOR ENVIRONMENTAL PROFICIENCY TEST PROVIDERS

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

1.1 Introduction

This Volume specifies the requirements for proficiency testing (PT) providers conducting PT studies for the evaluation of environmental testing laboratories.

1.2 Scope

The PT program includes the following elements:

a) The production and supply of PT samples that challenge the critical components of each analytical procedure, from initial sample preparation to final data analysis;

b) The yielding of PT data that are technically defensible on the basis of the type and quality of the PT samples provided; and

c) The preparation of PT samples which pose equivalent difficulty and challenge regardless of the manner in which the PT samples are designed and manufactured by the PT providers.

1.3 Applicability

This volume is applicable to any person or organization seeking to operate as a TNI-compliant PT provider.

2.0 REFERENCES

2.1 Kafadar, Karen. “A Biweight Approach to the One-Sample Problem,” *Journal of the American Statistical Association*, Vol. 77, No. 378, June, 1982, pp. 416-424

2.2 *ISO/IEC 17025:2005(E) General requirements for the competence of testing and calibration laboratories.*

2.3 *ISO Guide 34:2009(E) General requirements for the competence of reference material producers.*

2.4 *ISO/IEC 17043:2010(E) General requirements for proficiency testing*

2.5 *ASTME178 Standard Practice for Dealing With Outlying Observations*

2.6 *ISO 17011:2004* Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies

3.0 TERMS AND DEFINITIONS

For the purpose of this Standard, the relevant terms and definitions are conformant with *ISO/IEC 17043:2010(E),* ISO*/IEC 17011:2004(E), Clause 3* and *ISO/IEC 17025:2005(E), Clause 3*. Additional relevant terms are defined below.

3.1 **Assigned Value:** Value attributed to a particular property of a proficiency test standard, see Section 5.7 for further discussion of assigned values.

3.2 **Acceptance Limits:** The range of values that constitute acceptable performance for a laboratory participating in PT study.

3.3 **Field of Proficiency Testing (FoPT):** Matrix, technology/method, analyte combinations for which the composition, spike concentration ranges and acceptance criteria have been established by the Proficiency Testing Program Executive Committee.

3.4 **Primary Accreditation Body (Primary AB):** The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

3.5 **Proficiency Testing (PT):** A means to evaluate a laboratory's performance, under controlled conditions, relative to a given set of criteria, through analysis of unknown samples provided by an external source.

3.6 **Proficiency Testing Program (PT Program):** The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of results and the collective demographics and results summary of all participating laboratories.

3.7 **Proficiency Testing Provider (PT Provider):** A person or organization accredited as a Conformity Assessment Body by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.

3.8 **Proficiency Testing Provider Accreditor (PTPA):** An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.

3.9 **Proficiency Testing Reporting Limit (PTRL):** The lowest acceptable results that could be obtained from the lowest spike level for each analyte.

3.10 **Proficiency Testing Sample (PT Sample):** A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.

3.11 **Study (or PT Study)**: This term refers to a scheduled PT Study or a Supplemental PT Study.

a) **Scheduled Proficiency Testing Study (Scheduled PT Study)**: A single complete sequence of circulation and scoring of proficiency testing samples to all participants in a proficiency test program. The study must have the same pre-defined opening and closing dates for all participants.

b) **Supplemental Proficiency Testing Study (Supplemental PT Study)**: A PT sample that may be from a lot previously released by a PT provider that meets the requirements for supplemental PT samples given in this standard but that does not have a pre-determined opening and closing date.

3.12 **PT Study Closing Date:**.

a) **Scheduled PT Study**: The calendar date for which all laboratories must submit analytical results for a PT sample to a PT Provider.

b) **Supplemental PT Study**: The calendar date a laboratory submits the results for a PT sample to the PT Provider

3.13 PT Study Opening Date:

a) **Scheduled PT Study**: The calendar date that a PT sample is first made available to any participants of the study by the PT Provider.

b) **Supplemental PT Study**: The calendar date the PT Provider ships the sample to a laboratory.

3.14 **WETT** – Whole Effluent Toxicity Testing

3.15 **NOEC** – No Observable Effects Concentration

3.16 **Non-NOEC** – analytes that are not No Observable Effects Concentration, such as IC25 or LD50.

3.17 **IC25** – Inhibiting concentration where there is 25% reduction in growth or reproduction.

3.18 **LD50** – Lethal dose concentration where 50% of the organisms do not survive.

3.16 **Lot** – a definite amount of a material produced during a single manufacturing cycle and intended to have uniform character and quality. (per *ISO/IEC 9001:2000)*

3.17 **Reference Material (RM)** – material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process. (per *ISO/IEC 17043:2010(E))*

3.18 **Certified Reference Material (CRM)** – reference material characterized by a metrologically valid procedure for one or more specific properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. (per *ISO/IEC 17043:2010(E))*

4.0 PT PROVIDER ACCREDITATION

4.1 The PT providers shall be accredited to ISO 17043:2010 General Requirements for Proficiency Testing by a TNI-approved PTPA..

4.2 The PT provider shall be accredited by a TNI-approved PTPA for every TNI FoPT which they will offer in their PT programs

4.3 In order to receive and maintain accreditation for any analyte in any FoPT table, the PT provider shall demonstrate compliance with all requirements of this Standard during onsite assessments and ongoing oversight conducted by the PTPA per Volume 4 of this Standard.

4.4 PT providers shall be subject to biennial onsite assessments conducted by their chosen TNI-approved PTPA. They may also be subject to unannounced assessments for cause.

4.5 PT providers shall submit data from each of their PTPA-accredited PT studies to the PTPA for review to determine compliance with this Standard.

4.5.1 The information required in these submittals, including the format and frequency/timing, shall be determined by the PTPA.

4.5.2 The provider shall not identify any participant laboratory to the PTPA without the expressed written consent of the laboratory.

4.6 Upon request by the PTPA, the PT Provider shall supply, at no charge, PT samples as specified by the PTPA, which are included in the PT Provider's scope of accreditation, to the PTPA for submission to a referee laboratory.

4.7 In conflicts with the PTPA, PT providers shall follow the PTPA's appeals process.

4.8 Unresolved conflicts with the PTPA shall be submitted to the PT Program Executive Committee.

5.0 MANAGEMENT REQUIREMENTS

5.1 Quality System Requirements

5.1.1 The PT provider's manufacturing system shall meet the requirements of ISO Guide 34:2009(E) General requirements for the competence of reference material producers

5.1.2 The testing facilities used to support the verification, homogeneity and stability testing required in this Standard shall meet the requirements of ISO 17025:2009(E) General Requirements for the Competency of Testing and Calibration Laboratories.

5.1.3 If the PT provider holds specific accreditations related to any of the requirements in Sections 5.1.1 through 5.1.2, this shall not limit the PTPA's ability to assess and make determinations related to the PT Provider's conformance to these requirements.

5.1.4 Providers shall maintain all records related to each PT study for a minimum of five (5) years after the close of the PT study.

5.2 Provider Conflict of Interest and Confidentiality

PT providers seeking to obtain or maintain accreditation shall:

a) inform all internal and contract personnel who perform work on PT studies of the PT provider's obligation to report personal and organizational conflicts of interest to the PTPA;

b) immediately make a full disclosure to the PTPA of any identified actual or potential organizational conflict of interest. The disclosure shall include a description of any action that the provider has taken or proposes to take after consultation with the PTPA to avoid, mitigate or neutralize the actual or potential conflict of interest;

c) not release the assigned values or acceptance limits of any PT sample prior to the conclusion of the study, except to the PTPA upon request;

NOTE: PT providers may release, at the conclusion of a PT study, without permission of participant laboratories, summaries of participant laboratory results that do not identify individual laboratories.

5.3 Complaints Handling

5.3.1 PT providers shall provide to the PTPA all recorded complaints upon request.

5.3.2 Any complaint received by a PT provider that remains unresolved after ninety (90) days shall be submitted to the PTPA.

5.4 PROVISION OF PT SAMPLES

5.4.1 Study Duration

The study closing date shall be no more than forty-five (45) calendar days after the opening date of the study or as specified by the PT Program Executive Committee.

5.4.2 Scheduled PT Studies

5.4.2.1 Scheduled PT studies shall consist of PT sample lots (or batches) that have not been provided in any form or by any entity, to actual or potential participant laboratories prior to the opening date of the study.

5.4.3 Supplemental PT Studies

5.4.3.1 For supplemental PT samples, the PT Provider shall:

a) Supplemental PT samples may be from lots that have been previously used in a PT study.

b) conduct stability testing at the close of the supplemental PT study or have data showing, to the satisfaction of the PTPA, that the sample was stable during the time period of the supplemental study;

c) have documented procedures and systems in place to track all lots and assigned values of samples received by laboratories that may be used as supplemental PT samples;

d) not supply a supplemental PT sample to a laboratory that has received that sample in a previous PT study, or in any other form, or has had access to the assigned values for that sample;

e) remove the original lot number, study number, and/or tracking ID number of each supplemental PT sample and assign a unique identifier.

5.4.3.2 Quantitative Supplemental PT - The laboratory shall inform the PT provider that a supplemental PT sample is being used for corrective action purposes for a specific quantitative analyte or analytes, the PT provider shall supply a supplemental PT sample that contains the specified analyte(s) spiked into the sample. The sample does not have an assigned value of <PTRL for the laboratory-specified analyte(s).

5.4.3.3 Analyte Identification Supplemental PT - The laboratory shall inform the PT provider that a supplemental PT sample is being used for corrective action purposes for a specific qualitative (analyte identification) test, whether the analyte of interest is spiked into the sample shall be randomly determined by the PT provider so that the laboratory will not automatically know that it is present or not. If the analyte(s) is randomly spiked into the supplemental PT sample, the laboratory shall also be tested on the quantitative portion of the test.

5.4.3.4 Analyte Group Supplement PT - The laboratory shall inform the PT provider that a supplemental PT sample is being used for corrective action purposes for a specific qualitative group (presence/absence and/or identification) test, the full group test shall be designed from the applicable FoPT table.

Note: Microbiology Coliform 10 sample test and Aroclor identification are considered group tests.

5.4.3.5 The closing date of a supplemental PT study shall be the date that the participant(s) has reported study data for the required analytes.

5.4.3.6 The closing date of a supplemental PT study shall be no more than forty-five (45) days after the opening date of the study.

5.5 PT SAMPLE DESIGN AND MANUFACTURE

5.5.1 Design Review

PT providers shall demonstrate to the satisfaction of the PTPA that their PT sample designs and manufacturing processes:

a) Permit participating laboratories to generate results that fall within the PT sample acceptance limits defined in the TNI Fields of Proficiency Testing Tables;

b) provide equivalent challenge to all participant laboratories

5.5.2 Sample Matrices

5.5.2.1 The matrix for soil PT samples shall be well-characterized natural soil and shall not contain greater than 90% sand by mass.

5.5.3 Sample Analytes

5.5.3.1 PT providers shall prepare samples that are compliant with the criteria defined by the PT Program Executive Committee and published in the TNI FoPT Tables on the TNI website.

5.5.3.2 When the PT Program Executive Committee makes changes to the PT sample design criteria, PT providers shall comply with the revised requirements per the PT Program Executive Committee's implementation schedule.

5.5.3.3 For those multi-analyte categories designated in the TNI FoPT tables as not requiring all analytes to be spiked, the PT Provider shall determine the number of analytes based on the following.

a) PT samples that are to be scored for one (1) to ten (10) analytes shall include all of the analytes;

b) PT samples that are to be scored for ten (10) to twenty (20) analytes shall include at least ten (10) analytes or 80% of the total, whichever number is greater;

c) PT samples that are to be scored for more than twenty (20) analytes shall include at least sixteen (16) analytes, or 60% of the total analytes, whichever number is greater;

d) If following 5.5.3.3.b) or 5.5.3.3.c) above and the calculated percentage of the total number of analytes in the PT sample is a fraction, the fraction shall be rounded up to the next whole number.

5.5.3.4 PT providers shall use a random-selection process to determine which analytes will be spiked and unspiked within any given PT sample.

5.5.3.4.1 PT providers may make modifications to randomly-selected analyte lists based on technical (i.e. compatibility, interference) issues.

5.5.3.4.2 Modifications to randomly-determined analyte lists shall be documented.

5.5.3.5 If the provider spikes analytes not on the TNI FoPT Tables in their PT samples, the PT provider shall ensure, to the satisfaction of the PTPA, that these additional analytes do not interfere with laboratory performance for the required analytes. Such additional analytes do not count toward the minimum analyte requirements as specified in the current version of the FoPT tables.

5.6 PT SAMPLE TESTING

5.6.1 Verification of Assigned Value

5.6.1.1 PT providers shall analytically verify the assigned value of all analytes in all PT samples prior to use in a PT study.

5.6.1.2 PT providers shall verify the assigned value using a Certified Reference Material (CRM), where available.

5.6.1.3 If a CRM is not available, then verification shall be performed against a Reference Material (RM). If a CRM and/or a RM are not available, the calibration material shall be manufactured under the requirements of ISO Guide 34.

5.6.1.4 The assigned value verification shall include calibration standard(s), calibration verification standard(s), and proficiency testing materials under test. The calibration and calibration verification standards shall consist of CRM, RM, and/or ISO Guide 34 materials as applicable from different lots.

5.6.1.5 The PT provider shall have documented criteria for the acceptance of the results of the calibration verification material, where applicable.

5.6.1.6 The relative standard deviation of the provider's verification method shall be established by a method validation study for each method and instrument.

5.6.1.7 For aqueous chemistry analytes, the assigned value of an analyte is verified if the mean of the provider's verification analyses is within one-third of the laboratory acceptance limits (C) ,as calculated per Section 5.9.2, not to exceed a maximum of 10%, of either:

a) the assigned value, if an unbiased verification method is used; or

b) the expected mean value for the analyte, if a biased method is used.

For analytes that are based on the study mean and study standard deviation, the PT Provider shall establish criteria approved by the PTPA that demonstrate verification of the assigned value.

5.6.1.8 For solid matrix, microbiology, and protozoan analytes, the assigned value of an analyte is verified if the mean of the provider's verification analyses is within one-half of the laboratory acceptance limits (C), as calculated per Section 5.9.2, of either:

a) the assigned value, if an unbiased verification method is used; or

b) the expected mean value for the analyte, if a biased method is used.

For analytes that are based on the study mean and study standard deviation, the PT Provider shall establish criteria approved by the PTPA that demonstrate verification of the assigned value.

5.6.1.9 All unspiked analytes shall be analytically verified to ensure that they are not present at or above one-half the PTRL.

5.6.1.10 Any PT sample that fails to meet the requirements of this Section shall not be used in a PT study.

5.6.2 Homogeneity Testing

5.6.2.1 PT providers shall analytically verify that all analytes in all PT samples within a packaging event are sufficiently homogenous prior to their use in a PT study.

5.6.2.2 Homogeneity testing shall be performed on a representative selection of samples randomly selected from each final packaged PT sample batch prior to shipment to participant laboratories.

5.6.2.3 PT samples which fail to meet the requirements of this Section shall not be used in a PT study.

5.6.3 Stability Testing

5.6.3.1 PT providers shall verify that all analytes in all PT samples remained stable during the course of the study.

5.6.3.2 PT providers shall retain samples of the original PT study material until the close of the study for use in post-study analytical verification.

5.6.3.3 PT sample stability assessments shall be based on analytical data comparing the mean of a series of random samples analytically tested before the start of a study to the mean of a series of random samples analytically tested after the study close date.

5.6.3.4 The stability of an analyte is verified if either:

a) the difference between the mean of the provider's verification analyses and the mean of the provider's stability analyses is within one-fifth of the laboratory acceptance limits as calculated per Section 5.9.2; or

b) the mean of the provider's stability analyses meet the requirements for verification as defined in Section 5.6.1.7 or 5.6.1.8, depending on the study matrix.

5.6.3.5 Post-study stability verification shall include ensuring that unspiked analytes are still below one-half the PTRL.

5.6.3.6 PT samples or analytes which fail to meet the criteria of this Section shall be invalidated in the PT study and described in the study discussion report.

5.6.4 Verification, Homogeneity and Stability Testing Reporting

5.6.4.1 Upon request, the PT provider shall release the study specific results of the provider's assigned value, verification, homogeneity, and stability testing for any PT sample/analyte to laboratories and/or the laboratories' accreditation bodies after the release of the final study reports.

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5.6.4.2 After the issuance of final evaluation reports, the PT provider shall release to the PTPA the results of the provider's assigned value verification, homogeneity, and stability testing for all PT samples/analytes included in each PT study.

5.6.4.3 The PT provider shall follow the format and schedule for submittal of these data as provided by the PTPA.

5.7 Assigned Values

5.7.1 PT providers shall use a random process to determine the target assigned values for their PT samples within the specified concentration ranges as listed in the most current approved TNI FoPT tables.

5.7.1.1 PT provider may make modifications to randomly-selected assigned values based on technical (i.e., solubility, compatibility, interference) issues.

5.7.1.2 Any modifications to randomly-selected assigned values shall be documented with the justification for the modification(s).

5.7.2 Assigned values for aqueous, non-microbiological analytes that are measured (chemical concentrations, isotope activities, etc.):

a) shall be equal to the made-to values of the analytes based on gravimetric and volumetric measurements of a starting material of known concentration, or if the analyte assigned value is determined by the PT providers measurement, then the assigned value shall be set to the mean of the PT provider's verification analyses

b) shall be presented as three (3) significant figures.

5.7.3 Assigned values for quantitative microbiology and protozoan analytes:

a) shall be equal to the study calculated mean as specified in Sections 5.9.2.5 or 5.9.2.8. as appropriate

b) shall be presented as a whole number with no more than three (3) significant figures for quantitative methods utilizing microbial colony counting techniques; for example membrane filtration methods (MF) and pour plate methods,

c) shall be set to three (3) significant figures for quantitative methods utilizing statistical probability techniques; for example most probable number (MPN) methods.

5.7.4 Assigned values for solid and chemical matrix analytes:

a) shall be equal to the natural (background) concentration as analytically determined by the PT provider, plus the made-to concentrations of any spiked analytes based on gravimetric and volumetric measurements of a starting material of known concentration, and

b) if the analyte assigned value is determined by the PT providers measurement, then the assigned value shall be set to the mean of the PT provider's verification analyses,

b) shall be presented as three (3) significant figures.

5.7.5 Assigned Values for WETT analytes:

a) NOEC Analytes: Assigned Value should be set to the Study Median of the data reported by laboratories; reported values are <6.25%, 6.25%, 12.5%, 25%, 50%, 100%, or >100%. If the Median falls between two of these values, then the Assigned Value is set at the higher value.

b) Non-NOEC Analytes: Assigned Value should be set to the Study Mean, calculated using reported values from 6.25% and 100%, inclusive.

5.7.6 Assigned values for qualitative analytes shall be represented as "Present" or "Absent".

5.7.7 All unspiked analytes shall have their assigned values set to "<" PTRL, as the analytes' PTRLs are listed in the most current approved FoPT tables.

5.8 Operation of Proficiency Testing Program

5.8.1 Study Instructions

The PT Provider shall not directly market or instruct laboratories to use additional quality control samples or quality control samples designed specifically for a given PT sample or PT Study.

5.9 PT Study Data Analysis

5.9.1 Data Review

5.9.1.1 PT providers shall review all PT study data sets for bimodal or multi-modal distributions and/or situations where results from a given method have disproportionately large failure rates or reporting anomalies.

5.9.1.2 If a multi-modal distribution is found related to analytical method and acceptance criteria are calculated using robust statistical analysis of participant data, results shall be evaluated on a method-specific basis.

5.9.1.3 PT providers shall review all PT study data sets for disproportionately high or low failure rates compared to historical norms.

5.9.2 Acceptance Limit Determination

5.9.2.1 PT providers shall calculate acceptance limits per the requirements defined in the TNI FoPT Tables. Use C to denote the acceptance interval (as in +/-C).

5.9.2.2 Analyte- or study-specific evaluation criteria defined in the TNI FoPT Tables shall supersede the criteria in this Section.

5.9.2.3 Acceptance limits shall be represented following the same significant figure rules as defined for assigned values in Section 5.7.

5.9.2.4 For acceptance limits calculated using only the PT provider's assigned value (i.e. a fixed percentage limit around the assigned value, regression equation using the assigned value to determine an estimated mean and estimated standard deviation, etc.), the PT provider shall use their assigned value and calculate the acceptance limits using the criteria defined in the TNI FoPT Tables.

5.9.2.5 For acceptance limits calculated using the actual study mean, the PT provider shall use the mean as calculated by the following procedures:

a) for samples sizes of twenty (20) or more values: the biweight mean (per Section 2.1) using fifteen (15) iterations with c=4 and c_o=6;

b) for samples sizes of seven (7) to twenty (20) values: the arithmetic mean after outlier testing using the T test (see ASTM E178) or other PTPA-accepted outlier testing procedure. No more than 20% of the values in any set shall be treated as outliers;

c) sample sizes of less than seven (7) values shall only be evaluated using a statistical procedure approved by the PTPA.

5.9.2.6 For acceptance limits calculated using the actual study standard deviation, the PT provider shall use the standard deviation as calculated by the following procedures:

a) for samples sizes of twenty (20) or more values: the biweight standard deviation (per section 5.9.2.5, as appropriate)) using fifteen (15) iterations with c=4 and c_o=6;

b) for samples sizes of seven (7) to twenty (20) values: the standard deviation after outlier testing with the T test (see ASTM E178) or other PTPA-accepted outlier testing procedure. No more than 20% of the values in any set may be treated as outliers;

c) sample sizes of less than seven (7) values shall only be evaluated using a statistical procedure approved by the PTPA.

5.9.2.7 For acceptance limits calculated using the actual study median, the PT provider shall use the median calculated from all properly reported data pointsin the data set.

5.9.2.8 For protozoan acceptance limit calculation the acceptance limits are determined by the using the study data reported by the participating laboratories.

5.9.2.8.1 All final reported results of the accredited participating laboratories shall be used to calculate study mean and standard deviation.

5.9.2.9 For acceptance limits calculated for WETT:

a) NOEC Analytes: Lower Acceptance Limit is the test dilution below the Median (or <6.25%, whichever is higher); Upper Acceptance Limit is the test dilution above the Median (or >100%, whichever is lower). If the Median is between two test dilutions, then the Lower Acceptance Limit is the second test dilution below the Median, and the Upper Acceptance Limit is the second test dilution above the Median.

b) Non-NOEC Analytes: Mean +/- 2 Standard Deviations. If the upper limit is greater than 100%, then set the Upper Acceptance Limit at ">100%." If the lower limit is less than 6.25%, then set the Lower Acceptance Limit to "<6.25%."

5.9.2.10 PT Providers shall not use results reported with greater than (>) and less than (<) signs and alpha numeric characters in statistical calculations for chemistry, radiochemical, microbiology, and protozoan analytes.

5.9.3 Evaluation of Individual Participant Results

5.9.3.1 Assigned Value Greater than the PTRL

5.9.3.1.1 The result shall be scored “Acceptable” if:

a) the numeric value reported is within or equal to the established acceptance limits.

5.9.3.1.2 The result shall be evaluated “Not Acceptable” if:

a) the numeric value is reported with a less than (<) sign;

b) the numeric value reported is outside the established acceptance limits;

c) the numeric value is reported with a greater than (>) sign.

5.9.3.2 Assigned Value Less than (<) the PTRL

5.9.3.2.1 The result shall be scored “Acceptable’ if:

a) the numeric value reported is less than the PTRL or

b) the numeric value is reported with a less than (<) sign.

5.9.3.2.2 The result shall be scored “Not Acceptable” if;

a) the numeric value reported is greater than or equal to the PTRL;
b) the numeric value is reported with a greater than (>) sign.

5.9.3.3 No evaluation Scoring

A reported value shall be scored “No Evaluation” if it cannot be evaluated (e.g., alpha characters for a quantitative test).

If an analyte in the PT sample is invalidated the reported value shall be scored “No Evaluation” and the PTP shall provide an explanation of the cause for invalidation in the final evaluation report submitted to participant laboratories and the ABs for which the laboratories designated submission of the report.

5.9.3.4 Not Reported Scoring

Analytes included in a PT sample but not reported by the laboratory shall be scored as “Not Reported”.

5.10 GENERATION OF STUDY REPORTS

5.10.1 Schedule

5.10.1.1 The reports defined in Sections 5.10.1.3 and 5.10.1.4 shall be submitted to the required parties no later than twenty-one days after the close of the study.

5.10.1.2 Reports shall be submitted to all participant laboratories and laboratory-requested accreditation bodies within the same twenty-four (24) hour period. Providers shall supply PT data in formatting acceptable to the laboratory requested accreditation bodies.

5.10.1.3 The following information shall be included in the final evaluation report:

a) PT provider name;

b) PT provider PTPA accreditation number;

c) participant laboratory name;

d) participant laboratory physical address;

e) name, title and telephone number of laboratory point of contact, as provided;

f) participant laboratory’s primary accreditation body ID, as provided;

g) EPA laboratory accreditation number;

h) study number;

i) opening and closing dates of the study;

j) date report was prepared;

k) date report was amended, if applicable;

l) study discussion including any pertinent information which addresses unusual details of the study (e.g., need to change an assigned value or delete an analyte from evaluation);

m) study matrix, per the TNI FoPT Tables.

5.10.1.4 The following information shall be included for each PT sample/analyte in the final evaluation report:

a) lot or PT samples number;

b) analyte name;

c) analyte code defined in the TNI FoPT Tables;

d) identification of those analytes included and not included in the PT provider's PTPA accreditation;

e) assigned value, as described in this is standard;

f) acceptance limits;

g) laboratory value, as reported;

h) method description, as reported;

ij) evaluation per Section 5.9.3;

j) mean calculated from study participant data; and

k) standard deviation calculated from study participant data.

5.10.1.5 Each page of the final evaluation report shall include an indication of the length of the report, presented by either "Page X of Y" or the total number of pages with each page consecutively numbered.

5.11 Study Failure Rate Report

5.11.1 Upon request by either a participant laboratory or a laboratory accreditation body, the PT provider shall make available a report listing the total number of participating laboratories and the number of laboratories scoring "Not Acceptable" for those analytes reported by the laboratory.