

C305 – SPECIFIC CHECKLIST: PROFICIENCY TESTING PROVIDER ACCREDITATION PROGRAM - NELAC CHAPTER 2

The following pages present the Chapter 2 requirements for *the A2LA NELAC Proficiency Testing Provider Accreditation Program*¹. The NELAC PT provider's policies and procedures must meet these requirements, along with the requirements found in *R303 – Specific Requirements: NELAC Proficiency Testing Provider Accreditation Program*. Quality system documentation and supporting records must be available for the assessor's review.

NELAC PT Provider Instructions: PT providers must comply with all applicable requirements stated herein. If the requirements include the need for a **written policy, procedure or arrangement**, that requirement statement in this checklist is shaded. To assist the assessor in determining your compliance, you must complete the document reference identifiers in the checklist's second column (labeled Reference²) for each shaded requirement. The appropriate "reference" can include quality manual, SOPs, records, etc. references. The references provided **must** specify procedure number, page number and section number, if possible. Submit this checklist as part of the application for accreditation. This serves to help both the NELAC PT provider and the assessors prepare for the assessment and may save a significant amount of assessment time and cost. **If the shaded references are not provided as described above, the application will be considered incomplete and will be returned to the NELAC PT provider for the necessary references.** The NELAC PT provider must also be in compliance with all other non-shaded areas but the assessor will most likely verify compliance of those requirements on-site, through review of records, for example, in lieu of through a written policy, procedure or arrangement.

Assessor Instructions: Review the NELAC PT provider's documented quality system to verify compliance with the applicable requirements contained in this checklist. Assess to verify that the documented quality system is indeed implemented as described. **Every checklist should be accompanied by a tick mark in the yes (Y), no (N), or not applicable (NA) space.** Record comments related to any requirement in the space provided and sign on the appropriate line on page 2. Assess the PT provider's technical competence to operate specific PT programs. Record comments related to the PT programs on the draft scope(s). All deficiencies must be identified and explained in the assessor deficiency report.

NELAC PT Provider NAME _____ City: _____ State: _____

Personnel Information (Names, Titles, and Responsibilities):

Technical Manager: _____

Quality Manager: _____

Essential Personnel and Their Unique Capability² _____

¹These requirements are based on those contained in the June 2003 "National Environmental Laboratory Accreditation Conference (NELAC) Constitution, Bylaws and Standards, Chapter 2, Proficiency Testing.

²An "essential person" is anyone whose absence or departure would reduce the PT Provider's competence to operate one or more PT programs, and would necessitate removal from the PT Provider's Scope of Accreditation, any PT program for which that person is contributing unique capabilities.

C305 – Specific Checklist: Proficiency Testing Provider Accreditation Program – NELAC Chapter 2

To the best of my knowledge, all NELAC proficiency testing provider document references noted below as well as actual proficiency testing provider practices have been assessed for compliance with the relevant requirements of *R303 – Specific Requirements: NELAC Proficiency Testing Provider Accreditation Program*, contained in this checklist. Any areas of noncompliance have been fully described in the Assessor Deficiency Report.

Assessor Signature: _____ Date: _____

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			Comments
		Compliance			
		Y	N	NA	
2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS					
<p>2.1. In addition to complying with the requirements of this chapter, any person, private party or government entity seeking to participate as a designated PTOB/PTPA-approved PT Provider shall also comply with the requirements of the applicable Appendices A, B, C, D, E, F, and G. The criteria set forth in these standards shall be used by laboratories and PT Providers, for the purposes of obtaining or maintaining NELAP accreditation or NELAP approval.</p> <p>In addition to complying with the requirements of this chapter and appendices, any entity seeking to participate as a designated PTOB/PTPA-approved PT Provider shall also comply with all applicable requirements of “National Standards for Water Proficiency Testing Studies, Criteria Document”, USEPA or other NELAC Documents that define analyte numbers, concentrations, and acceptance criteria as required by Ch. 2 section C.1.1.2.</p>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
2.2.1 The provider shall produce and distribute PT samples, evaluate study results against published performance criteria, and report the results to laboratories, the respective Primary Accrediting Authorities, and the appropriate PTOB/PTPA. PT Providers will only supply PT samples outside their Fields of Accreditations as determined by the PTOB/PTPA.					
2.3.3 The matrices of all PT samples shall, to the extent possible, resemble the matrices for which the laboratory seeks to obtain or maintain accreditation. Samples may not be reused in any subsequent NELAC PT study except as described in section 2.7.3. The PT Provider shall provide study instructions in such a manner so as to not offer any inappropriate assistance to the laboratories under test or enable or encourage the non-routine analysis of the PT samples.					
2.3.3.1 The PT provider shall prepare each sample lot such that the prepared concentration of each analyte in each lot is unique.					
2.3.3.2 The PT provider shall design and manufacture, and test the samples for homogeneity, stability and verification of assigned values as required by Appendix B (See pages 9-11 of this checklist). This testing shall verify that the quality of all samples is acceptable for use in each field of proficiency testing.					
2.3.4.1 PT Providers shall use the data acceptance criteria in Appendix C to evaluate laboratories' PT data to ensure a laboratory's performance shall be judged fairly and consistently.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
2.3.5 Each PT Provider shall evaluate the data and issue a report to the laboratories within 21 calendar days of the close of each study. The report shall be issued within the same 24 hour period to the participating laboratory and its Primary Accrediting Authorities designated by the laboratory.					
2.3.6 Each PT provider shall certify that it is free of any organizational conflict of interest					
A PT provider shall never split a sample lot and offer these samples for sale as known-value check samples before the unknown samples are used in a PT study.					
Each PT provider shall follow procedures and have systems in place that maintain confidentiality and security of all assigned values through the closing date or each study.					
All records shall be retained for a period of five years					
2.6 PT providers shall evaluate results from all PT studies using NELAC-mandated acceptance criteria described in Appendix C of Chapter 2. Each result shall be scored on an acceptable/not acceptable basis.					
The PT provider shall provide the participating laboratories and the Primary Accrediting a report showing at a minimum:					
Provider information:					
- Provider name and PTOB/PTPA accreditation number in the header					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
Laboratory information:					
- Laboratory name and address (location) of the laboratory, in the header.					
- Primary Accrediting Authority ID or USEPA ID if applicable, in the header. Name, title, and telephone number of the laboratory point of contact, in the header or cover letter.					
Study information:					
-Study number and study type, in the header.					
-Opening date and closing date of the study, in the header.					
-Date of amended report, if applicable, in the header.					
Report information:					
- Analyte name for each analyte included in the standard.					
- Method Description.					
- Laboratory value as reported.					
- Assigned values and acceptance values reported to three significant figures.					
- The acceptable/not acceptable status.					
- A “No evaluation” score for reported values containing alpha characters.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
- An indication of “Not reported” when an analyte within a PT sample is left blank.					
- 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.					
If the report and other PT study information is available in electronic format, it shall be available only to the designated laboratory representatives who participated in the PT study and the primary accrediting authority.					
Upon request by either the Primary Accrediting Authorities or laboratories, the PT Provider shall make available a report listing the total number of participating laboratories and the number of laboratories scoring not acceptable for each analyte.					
The PT Providers shall not disclose specific laboratory results or evaluations to any other parties without the written release of the laboratory.					
2.7.5 The PT provider shall report laboratory PT performance results to the Primary Accrediting Authority within the same 24 hour period that it reports the results to the laboratory.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
2.7.3.1 Corrective action PT samples must meet the following criteria:					
2.7.3.1b) The standard must be from a lot that has been demonstrated to have met all of the design, testing, and verification requirements of Chapter 2 and associated Appendices. PT samples from previously released NELAC compliant PT studies may be used in Corrective Action PT studies so long as they are within the stability period (e.g., an expiration date) for that sample.					
2.7.3.1c) The PT Provider cannot supply the laboratory with a sample that has been previously sent to the laboratory. The original sample tracking ID must be masked and the sample tracking ID shall be unique. (See NELAC Chapter 2, section A.5.2)					
2.7.3.1d) For corrective action supplemental studies, the assigned values for all analytes requested by the laboratory must not be equal to zero with the exception of the qualitative PCB group and qualitative microbiology.					
2.7.3.1 (continued) All other aspects of Supplemental PT studies for Demonstrating Corrective Action including scoring and distribution of final reports must meet all other requirements of the NELAC PT program.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
APPENDIX A – PT PROVIDER APPROVAL CRITERIA					
A.1 Approval Process					
PT providers must submit the results of PT programs operated for NELAC to A2LA for review and evaluation and agrees to accept the findings and decisions of A2LA as final.					
A.2 Quality System Requirements					
The manufacturing quality system used by the PT provider shall meet the requirements of both ISO 9001 and ISO Guide 34.					
The design and operation of the PT provider’s proficiency testing program shall meet the requirements of ISO Guide 43.					
The testing facilities used to support the verification, homogeneity and stability testing required in Appendix B shall meet the requirements of both ISO/IEC 17025 and the relevant NELAC Standards.					
<i>Note: The ability to meet the requirements of ISO 9001, Guide 34, Guide 43, ISO/IEC 17025 and the relevant NELAC Standards can be met by meeting the requirements of A2LA’s NELAC PT Provider Requirements Assessor Checklists.</i>					
A.3 Provider Facilities and Personnel					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
Each provider is required to have systems in place to produce, test, distribute and provide data analysis and reporting functions for any series of samples for which they are requesting approval.					
The provider shall have in place sufficient technical staff, instrumentation and computer capabilities as may be required by A2LA to support the production, distribution, analysis, data collection, data analysis and reporting functions of the samples.					
No portion of the production, testing, distribution, data collection, data analysis, nor data reporting functions may be outside the control of the PT Provider for any particular study, since it is essential that the confidentiality of the samples be maintained throughout the PT study. <i>“Control” can mean ownership or that the subcontracted service is performed under an agreement which specifically ensures the ability of the provider to access and restrict the distribution of information related to these services.</i>					
Subcontracted services shall be assessed by a NELAC PTOB/PTPA and meet the same criteria as the PT provider.					
A.4 Sample Formulation Review					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
The PT provider shall demonstrate to A2LA by submission of appropriate data, that the sample formulation for which the PT provider is seeking approval shall permit participating laboratories to generate results that fall within the sample acceptance ranges established by the NELAC Standing Committee on PT and meet the criteria of the “National Standards for Water Proficiency Testing Studies, Criteria Document (USEPA)					
A.5 Provider Conflict-of-Interest Requirements					
PT providers seeking approval shall document to the satisfaction of A2LA that they do not have a conflict of interest with any laboratory seeking, or having, NELAP accreditation. PT providers shall notify A2LA of any actual or potential organizational conflicts of interest, including but not limited to:.					
a) any financial interest in a laboratory seeking, or having, NELAP accreditation.					
b) the sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, NELAP accreditation.					
The PT provider is required to inform all internal and contract personnel who perform work on NELAC PT samples of their obligation to report personal and organizational conflicts of interest to A2LA.					

Requirement	Reference	RESERVED FOR ASSESSORS ONLY			
		Compliance			Comments
		Y	N	NA	
The provider shall have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of the NELAC PT program. If an actual, or potential organizational conflict of interest is identified during the performance of work in support of the NELAC PT programs, the PT provider shall immediately make a full disclosure to A2LA.					
The disclosure shall include a description of any action which the provider had taken or proposes to take, after consultation with A2LA, to avoid, mitigate or neutralize the actual or potential conflict of interest.					
A.5.1 PT providers shall not sell, distribute, or provide samples used in the NELAC PT program prior to the conclusion of a study for which they were designed. Providers shall not sell, distribute, or provide samples of identical formulation and concentration to those samples which it is currently using in a NELAC study. For supplemental PT studies for Demonstrating Corrective Action, the requirements in section 2.7.3.1 of the standard shall apply.					
A.5.2 PT Providers must have procedures in place to track which laboratories have received which studies if the PT Providers.					
A.6 Confidentiality of PT Study Data					
The PT provider shall demonstrate to A2LA that it has systems in place to ensure that the confidentiality of data associated with NELAC PT samples and programs are not compromised.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
Providers shall not release the assigned values of any sample currently being used in a NELAC PT study prior to the conclusion of the study.					
A.7 Data Review and Evaluation					
The NELAC designated PTPA/PTOB shall review the data from PT Provider's studies to ensure that acceptance limits used to evaluate laboratories are consistent with national standards as established by NELAC.					
The PTOB/PTPA shall also evaluate the performance of the PT Providers by monitoring, and reporting, to both the providers and the PT Board the pass/fail rates of all providers on all samples tested.					
A PTOB/PTPA is required to investigate any PT Provider whose pass/fail rate is statistically different from the national average.					
A.8 Complaints & Corrective Action					
The PT provider shall prepare a written summary of all written complaints regarding technical aspects of the studies and the corrective action taken for every complaint. This report shall be available to the A2LA on demand.					
All PT Provider complaints that remain unresolved after 90 days shall be referred to A2LA.					
A.10 Notification of Sample Integrity					
The provider is responsible for notifying all laboratories, A2LA and the Primary Accrediting Authorities when a particular analyte was determined not to meet the requirements of Appendix B within 21 days of the study closing date.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
APPENDIX B - PT SAMPLE DESIGN & ACCEPTANCE GUIDELINES					
B.1 Sample Formulation Approval					
<p>The PT provider shall demonstrate the adequacy of sample formulation to the satisfaction of A2LA.</p> <p>The criteria for formulation adequacy are that the sample shall provide equivalent challenge to the laboratories under test as similar samples for the same parameters as other providers;</p> <p>and that the sample shall exhibit laboratory acceptance rates, measured as provider percentage pass/fail performance, consistent with other samples used in the program for the same parameters.</p>					
B.1.1 The testing and verification protocol required to establish sample equivalency shall be agreed to by both the PT provider and A2LA on a case-by-case basis.					
B.1.2 One or more specific analyte(s) may not be included in a sample, yet those analyte(s) shall be counted and scored with the analytes that are present in the PT study. The value assigned to these unspiked analytes would be zero. The PT Provider shall prepare samples including a minimum number of analytes according to the following criteria:					
a) PT samples that are to be scored for one to ten analytes must include all of these analytes.					
b) PT samples that are to be scored for ten to twenty analytes must include at least ten of these analytes or 80% of the total, whichever number is greater.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
c) PT samples that are to be scored for more than twenty analytes must include at least sixteen of these analytes, or 60% of the total analytes, whichever number is greater.					
d) If following (b) or (c) above and a percentage of the total number of analytes in the sample is a fraction, the fraction shall be rounded up to the next whole number. For example, 16 analytes x 0.80 = 12.8=13 analytes in the sample.					
e) PT Providers shall use a random selection process to determine which parameters will be assigned zero values within any given PT sample.					
All other PT samples must contain all the analytes of interest within the concentration ranges as required by the standard.					
B.1.4 Soil PT samples shall be well-characterized natural soil and cannot contain 100% sand.					
B.2 Verification of Assigned Values					
All PT samples used for obtaining NELAP accreditation shall be analyzed by the PT provider prior to shipment to the laboratories to ensure suitability for use in the program.					
The assigned values of the sample shall be used to establish acceptance criteria, and it shall be verified by analysis.					
PT providers shall verify the assigned value by direct analysis against NIST SRM, if a suitable NIST SRM is available for use.					

Requirement	Reference	RESERVED FOR ASSESSORS ONLY			
		Compliance			Comments
		Y	N	NA	
<p>If a NIST SRM is not available then verification shall be performed against an independently prepared calibration material.</p> <p><i>(An independent prepared calibrant is one prepared from a separate raw material source, or one prepared and documented by a source external to the provider.)</i></p>					
<p>B.2.1 The method used by the PT provider for verification analysis shall have a relative standard deviation of not more than 50% of the relative standard deviation predicted as the assigned value by the laboratory acceptance criteria being used by NELAC for each parameter.</p>					
<p>The relative standard deviation of the provider's verification method shall be established by a method validation study, and the suitability for use shall be approved by A2LA.</p>					
<p>B.2.2 The assigned value for every parameter in all PT samples shall be verified by analysis.</p> <p>The assigned value of the analyte is verified if the mean of the verification analyses is within 1.5 standard deviations, as calculated as described in Sections C.1.1.1 or C.1.1.2, of either a) the assigned value if an unbiased verification method is used or b) the mean value for the analyte as calculated in Sections C.1.1.1 or C.1.1.2 if a biased method is used.</p>					
<p>The standard deviation of the verification analyses also shall be less than one standard deviation as calculated in Sections C.1.1.1 or C.1.1.2.</p>					

Requirement	Reference	RESERVED FOR ASSESSORS ONLY			
		Compliance			Comments
		Y	N	NA	
For analytes that are evaluated using fixed percentages as defined in Section C1.1.1, standard deviations are calculated by assuming that the fixed percentage is equal to two standard deviations.					
NELAC Proficiency Testing Reporting Limits (PTRLs) are provided as guidance to laboratories analyzing NELAC PT samples. NELAC PTRLs are also provided as guidance to PT Providers. At a minimum for all analytes with an assigned value equal to “0”, the PT Provider should verify that the sample does not contain the analyte at a concentration greater than or equal to the PTRL. (Please note that the source of this requirement is a footnote located on the NELAC Fields of PT Tables.)					
B.3 Homogeneity Testing					
Homogeneity testing is required on all PT samples prior to sample shipment to the laboratories.					
B.3.1 The homogeneity of the samples shall be established using a generally accepted statistical procedure. The procedure selected by the PT provider shall be capable of evaluating the relative consistency of each analyte across the production run, and shall be performed on the final packaged samples. The procedure shall establish at the 95% confidence level that the assigned value is consistent across the production run.					
Samples, or parameters, which fail to pass the homogeneity testing criteria cannot be used in the NELAC PT program to evaluate laboratories.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>B.3.2 A suitable homogeneity testing procedure shall be capable of comparing the between-sample to within-sample standard deviation across the PT provider's packaging run, and shall ensure comparability with 95% confidence.</p> <p><i>Suitable homogeneity testing procedures are available in both ISO Guide 35 and the REMCO/AOAC Harmonized Protocol for PT of Analytical Laboratories.</i></p>					
The homogeneity testing procedure used by the PT provider shall be approved for use by A2LA.					
B.4 Stability Testing					
<p>The samples used in the NELAC PT program shall be verified as stable for the period of each study. Therefore, the stability of all samples and parameters shall be established by the PT provider following the close of data submission from the laboratories.</p> <p>The samples are considered stable for the period of the study if the mean analytical value as determined after the study for each parameter falls within the 95% Confidence Interval calculated for the prior shipment verification testing used to establish the assigned value.</p>					
The testing procedure used for stability testing shall be approved for use by A2LA.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
B.5 Data Reporting by the PT providers					
The results of sample assigned value verification, homogeneity, and stability testing for each PT study shall be available only to the designated laboratory representatives participating in that study.					
All data developed by the provider in support of verification testing, homogeneity testing, and stability analysis shall be provided to any laboratory participating in the program upon request after the close of the study.					
Providers shall supply PT data to the Primary Accrediting Authorities, as per section 2.6, in a format acceptable to the Primary Accrediting Authority.					
B.5.1 The data developed by the PT provider in support of verification and homogeneity testing shall be supplied in summary format to A2LA in an electronic format to be determined by A2LA. Verification and homogeneity data shall be supplied to A2LA prior to sample distribution to the laboratories.					
B5.2 All summary data from the laboratories and the results of stability testing shall be provided to A2LA in an electronic format to be determined by A2LA within 30 calendar days of the close of the study.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
APPENDIX C – PT ACCEPTANCE CRITERIA & PT PASS/FAIL CRITERIA					
C.0 Purpose, Scope and Applicability					
The PT provider shall submit all laboratories’ performance rating(s) to the Primary Accrediting authority, as described in Chapter 2 of the NELAC standards, to be used as a tool for determining a laboratory’s accreditation status.					
C.1.1 Acceptance limits are separated into two categories. Results for analytes with acceptance limits determined as described in Sections C.1.1.1 and C.1.1.2 shall be used in the determination of a laboratory’s PT field of testing pass/fail evaluation.					
Results for analytes with acceptance limits determined as described in Section C.1.1.3 shall not be used as part of the field of proficiency testing acceptable/not acceptable evaluation.					
C.1.1.1 <u>Drinking water, waste water, and ambient water analytes with USEPA established acceptance limits</u> : PT Providers shall utilize the proficiency testing acceptance limits that have been established by USEPA in the “National Standards for Water Proficiency Testing, Criteria Document” where they apply.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>C.1.1.2. For analytes not included in “National Standards for Water Proficiency Testing, Criteria Document” PT Providers shall use acceptance limits established by the NELAC Standing Committee on PT and shall be made available to A2LA by the PT Committee Chair or the Director of NELAP.</p> <p>Data from sources such as the USEPA Proficiency Evaluation (PE) studies, interlaboratory results from professional organizations such as ASTM, other PT Providers, commercial and non-profit organizations, shall be used to establish the evaluation criteria.</p>					
<p>C.1.1.3 Experimental Data: The laboratory shall receive a copy of its own experimental data from the PT provider at the conclusion of the PT study.</p>					
<p>C.2 Acceptable PT Results for Chemical Analysis in Potable Water and Non potable water PT samples</p>					
<p>A laboratory’s PT analyte result is acceptable when it falls within the regulatory promulgated acceptance limits (Section C.1.1.1). For Section C.1.1.2 analytes, PT Providers shall use the PT sample’s verified assigned value and said regression equations to determine the mean and standard deviation.</p>					
<p>Acceptance limits shall be set at the mean \pm two standard deviations for potable water analytes and the mean \pm three standard deviations for non-potable water analytes.</p> <p>A result is acceptable when it falls within these derived acceptance limits.</p>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
C.3 Not Acceptable PT Results for Potable Water and Non-Potable Water PT Samples					
A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:					
a) the result falls outside the acceptance limits;					
b) The laboratory reports a result for an analyte not present in the PT sample (i.e. false positive); or					
c) the laboratory does not withdraw from a study as described in section 2.7.7, and fails to submit its results to the PT Provider on or before the deadline for the PT study.					
C.4 Additional Requirements for PT Providers					
PT providers shall examine all data sets for bimodal distribution and/or situations where results from a given method have disproportionately large failure rates or reporting anomalies to A2LA. <i>If bimodal or multimodal distribution is found and acceptance criteria are calculated using robust statistical analysis, data should be scored by method specific robust statistical analysis.</i>					
All PT test data are to be submitted to A2LA in the format specified by A2LA and shall be reviewed annually by the NELAC Standing Committee for PT for the purpose of revising existing and establishing new evaluation criteria.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
APPENDIX E - MICROBIOLOGY					
E.0 Semi-annual PT is required per the schedule provided in Section 2.4					
E.1 Samples					
PT providers shall present samples either as full volume samples or preparations easily reconstituted to full volume samples.					
For the SDWA, there shall be ten 100+ ml. samples (as presented or after reconstitution) for the qualitative determination (presence/absence) of total coliform and fecal coliform (or E. coli).					
Sample sets which are provided to the laboratories shall contain bacteria that produce the following:					
- Verification as total and fecal coliforms (E. coli)					
- Verification as total coliforms, but not as fecal coliforms					
- Bacterial contaminates which shall not verify as total or fecal coliforms					
Furthermore, each set shall contain the following samples:					
- One to four samples containing an aerogenic strain of Escherichia coli for total and fecal coliform positive results using all USEPA approved methods.					
- One to four samples containing Enterobacter sp. or other microorganisms ensuring a total coliform positive and fecal coliform negative result using all USEPA approved methods.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
- One to four samples containing Pseudomonas sp. or other microorganisms ensuring a total and fecal coliform negative result using all USEPA approved methods.					
- One to four blank samples					
- Optionally, one sample for the quantitative determination of Heterotropic Plate Count					
Sample sets for qualitative analysis shall be randomly composed of samples that are Total coliform absent, Total coliform only present and Fecal coliform (E. coli) present.					
E1.2 For the CWA, one sample shall be provided for the quantitative determination of Total coliform or Fecal coliform.					
Providers <i>may</i> require laboratories to analyze samples during a fixed time period after sample shipment or at any time during the testing period which shall not exceed the time limit set in Chapter Two.					
E.2 Sample Preparation and Quality Control					
PT Providers shall select bacterial strains and holding media that produce the appropriate biochemical reactions for all approved analytical methods. This shall be documented by analyses performed by the provider prior to sample shipment.					
The provider shall also demonstrate that the samples are stable by analysis of a randomly selected set either after the study closing date or in the case of a study with a fixed testing period, on the last working day of the testing period.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
E.3 Scoring					
E3.1 Qualitative Analyses, SDWA Samples: Participating laboratory results shall be considered acceptable or unacceptable when compared to the known presence or absence of total coliform or fecal coliform (E. coli) bacteria. Passing shall be considered as nine out of ten samples having acceptable results, and no false negatives reported.					
E3.2 Quantitative Analyses: Quantitative result data sets shall be evaluated by analytical method using standard statistical analysis with outlier rejection. Most probable number data shall be transformed to logs prior to statistical analysis.					
Acceptable results are those that are within the interval defined by the mean \pm two standards deviations for SDWA analytes or within the 99% confidence limits as set by the mean, stand deviation and set size (n) for their respective data set for all other analytes.					
E3.2.1 Each PT Provider's microbiological data set shall be comprised of at least 20 valid data points for each method evaluated. Sample sets of less that 20 data points may be used only with the approval of A2LA.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
APPENDIX F – ENVIRONMENTAL TOXICOLOGY					
F.1 Rationale					
PT samples shall be comprised of unknown concentrations of EPA’s historical reference toxicant materials. Every effort shall be made by A2LA working together with the providers to reduce the number of variables in each method (i.e. organism age, etc.) while following the routine language of the EPA protocols.					
APPENDIX G – RADIOCHEMISTRY					
G.1 PT Provider Licensing					
Possession, transfer and use of radioactive materials is regulated by the Nuclear Regulatory Commission (NRC) or State radiological departments. The PT provider shall ensure that they are licensed not only for the possession and use of radioactive materials in their facility but also for the explicit distribution of these materials in commerce.					
G.2 SDWA Sample Design					
The PT Provider must ensure that the sample design used for the SDWA radiochemical PT samples meets the applicable criteria contained in the USEPA’s “National Standards for Water Proficiency Testing Studies, Criteria Document”					

Requirement	Reference	RESERVED FOR ASSESSORS ONLY			
		Compliance			Comments
		Y	N	NA	
G.2.1 Assigned values must be within the ranges established by the USEPA in the “National Standards for Water Proficiency Testing Studies, Criteria Document”, where they apply. Assigned values are selected such that the concentration of each analyte will vary over time throughout the concentration range.					
The PT provider must also ensure that the method for selecting an assigned value meets the applicable criteria contained in the EPA’s USEPA’s “National Standards for Water Proficiency Testing Studies, Criteria Document”. The assigned value is determined based on the mass of standard added to the volume of water as follows: Assigned value (pCi/L) = pCi activity added ÷ volume preserved water ÷ dilution factor					
G.3 Scoring					
The results from a participating laboratory testing under the SDWA are classified as “acceptable” or “not acceptable” based upon the criteria in the USEPA’s “National Standards for Water Proficiency Testing Studies, Criteria Document”. The tests in the document include an evaluation of the average of the required three independent determinations for each radionuclide. Acceptance limits are provided in the NELAC PT Acceptance Limits for Radionuclides table which is located on the NELAC website.					
G.4 Study Timetables					
Semi-annual proficiency testing is required per the schedule contained in Section 2.4					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
APPENDIX H – PERFORMANCE TESTING REQUIREMENTS FOR FIELD AIR MEASUREMENT					
H.0 Introduction: Purpose, Scope and Applicability					
This standard is developed only for category 2 performance testing of field measurements where delivery of a standard PT sample is possible. Two distinct sets of scoring criteria are defined:					
1) whether of not an individual analyte result is either “acceptable” or ”not acceptable” and					
2) whether or not a laboratory’s initial PT performance for a group of interdependent analytes can be evaluated as “pass” or “fail”.					
The PT provider will submit all field measurement performance rating(s) to the Primary Accrediting Authority as described in Chapter 2 of the NELAC standards, to be used as a tool for determining a laboratory’s accreditation status. <i>PT acceptance limits and pas/fail criteria are established on a PT field of testing basis.</i>					
H.2 Acceptance Limits					
Acceptance limits are established for each analyte. Whether or not a laboratory has passed or failed a group of interdependent analytes is based on the number or results that are determined to be acceptable.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
H.2.1 Analyte Acceptance Limit Categories: Acceptance limits are separated into two categories. Results for analytes with acceptance limits determined as described in Sections H.2.1.1 and H.2.1.2 shall be used in the determination of a laboratory's PT field of testing pass/fail evaluation.					
H.2.1.1 Analytes with USEPA Established Acceptance Limits (Prepared \pm fixed percentage or Mean \pm 2 standard deviations): PT providers shall utilize the PT acceptance limits that have been established by USEPA in the National Standards for air proficiency testing studies where they apply. <i>The National Standards are incorporated in this Appendix by reference.</i> EPA's established proficiency test acceptance limits for chemical analytes are typically expressed in the following manner:					
- Prepared \pm fixed percentage: Acceptance limits shall be set at \pm the published fixed percentage of the analyte's verified prepared value.					
- Mean \pm 2 standard deviations: The NELAC Standing Committee on PT has a process for establishing linear regression equations relating a PT sample's prepared value to mean and prepared value to standard deviation; acceptance limits shall be set using said equations and the sample's verified prepared value. Linear regression equations may only be used for prepared values that fall with the range of prepared values use to establish said equations.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
- In the event that there are no linear regression equations available for a given analyte, that analyte shall be treated as described in Section H.2.1.3.					
H.2.1.2. Analytes with acceptance limits derived from regression equations established by the NELAC Standing Committee on proficiency testing: When USEPA Program regulations for establishing acceptance criteria are not available providers shall set acceptance limits using regression equations that predict the mean and standard deviation for an analyte in a given range of concentrations.					
All regression equations shall be approved by the NELAC Standing Committee on PT prior to use by and A2LA-approved PT provider. For these analytes, the PT provider shall use the sample's verified prepared value and said equations to determine the men and standard deviation.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			Comments
		Compliance			
		Y	N	NA	
H.2.1.3 Experimental Data: Analytes without promulgated acceptance limits or established regression equations: For those analytes not included in categories H.2.1.1 or H.2.1.2, e.g., newly regulated analytes, or analytes in a matrix that have not been fully evaluated in interlaboratory studies.					
<p>- NELAC acceptance limits shall be established only after interlaboratory data has been collected for a minimum of one year unless the NELAC Standing Committee on PT determines that sufficient data have been collected in less time. The data obtained during the one-year period shall be referred to as “experimental data”.</p> <p><i>The NELAC Standing Committee on PT shall derive regression equations to be used to establish acceptance limits for analytes in the experimental category after sufficient data have been collected.</i></p>					
- The laboratory shall receive a copy of its own experimental data from the PT provider at the conclusion of the PT study.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
H.3 Acceptable PT Results for Chemical Analytes in Field Air PT Measurements					
Criteria for acceptable results will be dependent on the precision and accuracy of the accepted field measurement method. A laboratory's PT analyte result is acceptable when it falls within the regulatory promulgated acceptance limits (Section H.2.1.1).					
For Section H.2.1.2 analytes, PT providers shall use the PT sample's verified prepared value and said regression equations to determine the mean and standard deviation.					
Acceptance limits shall be set at the mean \pm two standard deviations for ambient air or source sample analysis. A result is acceptable if it falls within these derived acceptance limits.					
H.4 Not Acceptable PT Results for Source and Ambient PT Samples					
Criteria for acceptable results will be dependent on the precision and accuracy of the accepted field measurement method. A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:					
a) The results falls outside the USEPA's promulgated acceptance limits (Section H.2.1.1) or outside prediction interval derived from established regression equations;					
b) The lab reports a result for an analyte not present in the PT sample (i.e., a false positive)					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>c) The lab reports a result of “not detected” , (or similar indication of no detection), for an analyte present in the PT sample (i.e., a false negative).</p> <p>If the laboratory reports a result less than the lowest concentration contained in the NELAC-approved PT concentration range for an analyte present in the PT sample at a concentration within the NELAC-approved PT concentration range, the result shall be classified as a false negative and scored as “not acceptable”.</p>					
<p>d) The lab fails to submit its results to the PT provider on or before the deadline for the PT study.</p>					
H.5 NELAC PT Study Pas/Fail Criteria					
<p>Once data acceptability has been determined as described in sections H.1 through H.3 of this appendix, the laboratory’s PT “pass” or “fail” evaluation is determined as described in this section . Pass/fail criteria are used when groups of interdependent analytes are evaluated as a unit for the laboratory’s initial demonstration of proficiency.</p>					
<p>H.5.2 Non-interdependent Analyte PT Samples: <i>Currently not expected to apply to the air matrix.</i></p>					
<p>H.5.3 Promulgated USEPA Pass/fail Criteria: In all cases, promulgated USEPA pass/fail criteria, e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1), shall be used as NELAC PT pass/fail criteria as applicable. The criteria described in Section H.5.4 shall be used in the absence of promulgated USEPA pass/fail guidelines.</p>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
H.5.4 Pass/fail Criteria for Interdependent Analyte PT Samples: PT pass/fail evaluations for interdependent analyte PT samples shall be determined as follows:					
<p>- To receive a score of “Pass”, a laboratory must produce “acceptable” results for XX% of the analytes in an interdependent analytes PT sample. Greater than 100-XX% “not acceptable” results shall result in the laboratory receiving a score of “fail” for that series of analytes.</p> <p><i>For example, a laboratory must report all “acceptable” results for an interdependent analyte PT Sample containing 1-4 analytes; may report no more than one “not acceptable” result for a sample containing 5-9 analytes; two “not acceptable” results for a sample containing 10-14 analytes.</i></p>					
A “not acceptable” result for the same analyte in two consecutive PT studies shall also result in the laboratory receiving a score of “fail” for that analyte.					
H.5.5 Pass/fail Criteria for Non-Interdependent Analyte PT Samples: <i>Currently not expected to apply to the air matrix.</i>					