

C304 – SPECIFIC CHECKLIST: PROFICIENCY TESTING PROVIDER ACCREDITATION PROGRAM – NELAC REQUIREMENTS FOR WATER STUDIES

The following pages present the portion of *R303 – Specific Requirements: NELAC Proficiency Testing Provider Accreditation Program* identified in the National Standards for Water Proficiency Testing Studies Criteria Document (December 30, 1998); herein identified as “this criteria document”¹. The NELAC PT provider’s policies and procedures must meet these requirements, along with the requirements found in A2LA’s *PT Provider Requirements Assessor Checklist, ISO/IEC 17025, Relevant sections of NELAC Chapter 5, and NELAC Chapter 2*. 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 Reference") 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.

Please note: Clause identifiers found in this checklist were added by A2LA to aid in the assessment process and are not present in this criteria document.

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: _____

Master Code: _____

Assmnt ID #: _____

Cert No.: _____

¹The National Standards for Water Proficiency Testing Studies Criteria Document includes tables that the provider shall demonstrate adherence to, as a requirement of this program.

C304 – Specific Checklist: Proficiency Testing Provider Accreditation Program – NELAC Requirements for Water Studies

To the best of my knowledge, all 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 this criteria document, and contained in this checklist. Any areas of noncompliance have been fully described in the Assessor Deficiency Report.

Assessor Signature: _____ Date: _____

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			Comments
		Compliance			
		Y	N	NA	
PART 1 - WATER SUPPLY STUDIES - STUDY CRITERIA DOCUMENT					
1.1 CHEMISTRY STUDIES					
1.1.1 DESCRIPTION					
1.1.1.1 Assigned Value -- The gravimetric true concentration of an analyte in a sample to be analyzed or an appropriate reference value whenever necessary. This value should be reported to three (3) significant digits. A reference value (the study mean) is necessary for asbestos, residual free chlorine, and total filterable residue to develop acceptance limits, and as the assigned value printed on reports distributed to study participants.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>1.1.1.2 Analyte -- PT study providers may vary their sample designs from the present EPA sample designs, for example, in the number of analytes in a particular ampule, in the source of starting materials, solvents, and dilution schemes, etc. The number of samples and the specifics within each sample also remain within the discretion of the PT study providers. The purpose of any PT program is to evaluate the "routine" analytical capacity of the laboratory to reliably analyze environmental test samples. Hence, providers will not encourage non-routine analysis by the laboratories. Excessive volume of sample may encourage multiple analyses which would be non-routine. Sufficient sample volume is needed for proper handling of samples and it is reasonable to have an excess volume available in case of spilling or mishandling by the laboratory in the dilution phase of sample preparation.</p>					
<p>1.1.1.3 Concentration -- PT test samples contain fixed concentrations of the analytes of concern at levels within the concentration ranges given. The specific fixed concentrations are random and the PT study providers will use a random number generator to fix the specific concentrations. Each study is expected to have unique concentrations and are to be used in only one study. However, the provider has the option to adjust the value of individual analytes within a given sample if the value obtained from the random number generator would cause the resulting PT sample to be unacceptable, so long as the concentrations of these related analyte groups vary together randomly within their specified range.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>1.1.1.4 Acceptance Limits -- For most regulated analytes of concern, the acceptance limits are specified in the regulations. These regulatory acceptance limits will be the assigned value (T) of the analytes in the PT sample +/- some percentage of T. These are called the fixed limits. However, for each analyte that does not have fixed limits, the acceptance limits equal the estimated mean recovery +/- 2.0 estimated standard deviations. Tables provide the coefficients and constants for calculating the estimated mean recovery (R) and the estimated standard deviation (s) given T. The acceptance limits should be reported to three (3) significant figures.</p> <p>Limits for asbestos, residual free chlorine and total filterable residue are exceptions to the normal procedure for setting limits because a gravimetric true value is not available. For these three analytes, the study provider first estimates the central tendency of the in control study data. For sample sizes of 20 or more values, calculate the biweight mean using 15 iterations with $c = 4$ and $co = 6$. For sample sizes less than 20, calculate the arithmetic mean after outlier testing with the T test; no more than 20% of the values in any set may be treated as outliers. Then, using the mean estimate and the equation for these analytes, the study provider estimates the standard deviation of the in control data. For these three analytes ONLY, calculate-acceptance limits as the mean estimate +/- 2.0 estimated standard deviations.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>1.1.1.5 Reports -- PT providers are expected to send study samples, data report forms, and PT study instructions to participating laboratories. The PT study providers are expected to enter data report forms returned from laboratories into a computer file for processing. The provider should calculate the acceptance limits and performance evaluations and generate a PT study report for each individual participant. This report should be distributed to each participating laboratory, and to all appropriate certifying officials designated by the laboratory within 21 calendar days of the completion date of the study. The provider is expected to generate a summary report and a study discussion report for the appropriate certifying officials. The study discussion report should also be sent to EPA and NIST within 21 calendar days of the completion date of the study. The study discussion report should address any details of the study which were unusual.</p>					
<p>1.1.2 Data Evaluation</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>1.1.2.1 For Assigned Value Not Equal to Zero -- When the reported value does not have a < or > sign, the value is acceptable if it is inside or equal to the acceptance limits. The reported value is not acceptable if it is either below the lower acceptance limit or above the upper acceptance limit. When the reported value has a < sign, it is only acceptable if the acceptance limits have a lower value of zero and the reported range is entirely within the acceptance limits. Reported values with a < sign are not acceptable if the lower acceptance limit is above zero. Reported values with > signs are always not acceptable. For reported values which are not numbers, a numeric evaluation is not possible; these values should be evaluated as NO EVAL.</p>					
<p>1.1.2.2 For Assigned Value Equal to Zero -- If the reported value is zero or contains a < sign, the reported value is acceptable. If the reported value is any numeric value other than zero or contains a > sign, the reported value is not acceptable. For reported values which are not numbers, a numeric evaluation is not possible; these values should be evaluated as NO EVAL.</p> <p>Note that a reported value with a < or > sign implies a range of values. For example, a reported value of < 8 implies a range from zero to 8; a reported value of >8 implies a range from 8 to infinity.</p> <p>Note that a blank response for an analyte with Assigned Value set to zero should not be evaluated.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>1.1.2.3 Files For each study conducted, each provider should send four electronic data files to the EPA, NERL, EERD, NWQAPB, 26 West M. L. King Drive, Room 525, Cincinnati, OH 45268 for use in the PT database. These files include: the initial assigned values and limits file, the final assigned values and limits file, the study data file, and the summary results file. As part of the quality control actions, the initial assigned values and acceptance limits file should be sent to EPA prior to sample distribution. The other three files should be submitted to EPA within 21 calendar days after the study is completed.</p>					
<p>1.1.2.4 Laboratory Identification Numbers (EPA Lab Code) -- Each PT study participant must have a unique laboratory identification number assigned by EPA. This is a 7-character identifier, in which the first two characters are the postal abbreviation for the state and the remaining 5 characters are numeric. The number of participants in any state does not currently exceed 3000. If the study participant does not already have a laboratory identifier, it must obtain one from EPA, NERL, EERD, NWQAPB, 26 West M. L. King Drive, Room 525, Cincinnati, OH 45268.</p> <p>The participant needs the laboratory identification number and is expected to provide it and the appropriate certifying official (s) name and address to the accredited PT study provider. If this information is incomplete, the PT study provider should not send samples to the laboratory.</p>					
<p>1.1.2.5 Study Mode - The provider has the option to perform the study in one of two modes: quantitative only or qualitative and quantitative.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p><u>Quantitative Mode:</u> In the quantitative only mode the provider prepares samples in which the analytes are known to the laboratory. The laboratory responds with a value for each of the known analytes. Each value per analyte is compared to the acceptance limits. If the value is within the limits, the value is evaluated as acceptable. There is no qualitative evaluation in the quantitative only mode.</p>					
<p><u>Qualitative and Quantitative Mode:</u> In the qualitative and quantitative mode, the provider prepares samples in which the analytes are not known to the laboratory. The laboratory should respond with values for analytes that are present, and < values or zero for analytes that are not present. To have an acceptable evaluation under the qualitative and quantitative mode, the analyte must be correctly identified and the value must be within the acceptance limits. Unacceptable evaluations will be given when the analyte is misidentified or the value is outside the acceptance limits. Blank responses to qualitative analytes will not be evaluated. For analytes that are not present, an evaluation of unacceptable will occur if the laboratory reports a real value or a > value. For qualitative analytes which are not present, the provider will assign a zero as the assigned value.</p>					
<p>1.1.2.6 PT providers have the option to leave certain parameters out of specific PT samples (i.e., assign zero values to individual analytes within a given PT sample). Rules to be followed when producing such samples containing compounds regulated under the SDWA are:</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
a) PT samples that contain from 1 to 10 parameters must comprise all the analytes;					
b) PT samples that purportedly contain between 10 and 20 parameters must comprise at a minimum 10 or 80%* of the parameters, whichever is greater;					
c) PT samples that purportedly contain more than 20 parameters must comprise at a minimum 16 or 60% of the parameters, whichever is greater.					
d) PT providers will use a random number generator to determine which parameters will be assigned zero values within any given PT sample.					
*Fractions must be rounded-up. For example, a PT sample that purportedly contains 16 parameters ($16 \times 0.80 = 12.8$) must contain 13 parameters at a minimum.					
1.1.2.7 Frequency -- EPA has a need for a minimum of two studies per year (proposed--March and October).					
1.1.2.8 Record Retention -- It is the responsibility of the provider to meet the requirements of the Federal and State records disposition schedules.					
1.1.3 Reporting Criteria					
1.1.3.1 Criteria for Data Report Form					
a) Study type and date (date of study evaluation)					
b) Study number					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
c) Provider name and accreditation number					
d) Complete name and address of laboratory					
e) EPA Laboratory identification number					
f) Name, title, telephone number, signature of laboratory official who has approved the data on the report plus the date					
g) Analyte number and name for each analyte					
h) Lot number					
i) Method code					
j) Method description					
k) </> Field					
l) Reported value in standard units, reported to 3 significant digits					
m) Name and complete address of Certifying Authority					
<i>1.1.3.2 Criteria For Individual Laboratory Evaluation Report</i>					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Complete name and address of laboratory					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
e) EPA Laboratory identification number					
f) Name, title, telephone number, signature of laboratory official who has approved the data on the report plus the date					
g) Analyte number and name for each analyte					
h) Lot number					
i) Method code					
j) Method description					
k) </> Field					
l) Reported value in standard units, reported to 3 significant digits					
m) Assigned value, reported to 3 significant digits					
n) Acceptance limits, reported to 3 significant digits					
o) Evaluation					
1.1.3.3 Criteria For Summary Report by Provider					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Analyte number and name for each analyte reported					
e) Lot number for each analyte reported					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
f) Assigned value for each analyte					
g) Total # of Reported Values for each analyte					
h) Total # of Acceptable Reported Values for each analyte					
i) Total # of Unacceptable Reported Values for each analyte					
j) Total # of Reported Values with No Evaluation for each analyte					
1.1.3.4 Criteria For Study Discussion Report					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Any pertinent information which addresses unusual details of the study (e.g. need to change an assigned value or delete an analyte from evaluation).					
1.1.3.5 Criteria For Data Files To Be Submitted To EPA Database For Each Study					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
For each PT study they conduct, providers are expected to submit four data files to the EPA for use in the database. These files are: the initial assigned values and limits file, the final assigned values and limits file, the study data file, and the summary results file. These files should be named: INITIAL.TXT, FINAL.TXT, DATA.TXT, and SLTMNIARY.TXT, respectively. The initial assigned values and limits file should be sent to EPA at the beginning of the study (prior to sample distribution), and the other three files should be sent to EPA within 21 calendar days after the study is completed. The Assigned Value reported in these files should always be the value which was used to calculate limits. For those few analytes (asbestos, residual free chlorine, and total filterable residue) which use the study mean as the Assigned Value, it is understood that this value is not available when Initial Assigned Values and Limits File is submitted; it should be included in the Final Assigned Values and Limits File.					
1.1.3.6 File To Send At Beginning of Study					
1.1.3.6.1 Initial Assigned Values and Limits File					
1.1.3.6.2 Before shipping samples to participants, each provider is expected to submit a standard ASCII, comma-delimited file to EPA. This file should contain the provider's assigned value and acceptance limits for each analyte/ sample used in the study. It must have the fields in the order listed in the first table found on page 6 of this criteria document.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.1.3.7 Three Files To Send At End Of Study					
1.1.3.7.1 Final Assigned Values and Limits File					
At the end of a study, each provider is expected to submit an ASCII, comma-delimited file to EPA. This file should contain the assigned values and evaluation limits which were used for each analyte/ sample used in the study. It must have the fields in the order listed in the table found on page 6 of this criteria document.					
Note that if the final assigned values or limits differ from those reported in the initial file, the provider must explain the reason for this difference in the Study Discussion Report.					
1.1.3.7.2 Study Data File					
At the end of the study, each provider is also expected to send an ASCII, comma delimited file to the EPA with the laboratory data which was evaluated by this provider. For each reported value in the study, this file should contain the fields in the order listed in the first table found on page 7 of the criteria document. The <i>Outlier</i> field in this file should be used by providers to identify reported values which are outliers. An asterisk in this field indicates an outlier; for reported values which are not outliers, this field should be left blank. Values may be outliers when the assigned value is set to study mean for this analyte and the number of reported values (N) for this analyte < 20.					
1.1.3.7.3 Study Summary Results File					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
Finally, at the end of each study, providers are expected to also submit a comma delimited, ASCII file to the EPA which contains the summary results information for the study. For each unique analyte /sample in the study, this file must contain the fields in the order listed in the second table on page 7 of this criteria document. For the <i>Study Date</i> field below, please note that there should only be one study date for each PT study.					
1.2 MICROBIOLOGY STUDIES					
1.2.1 DESCRIPTION					
In past microbiology performance evaluation studies EPA provided laboratories with aqueous samples in ampules for the analysis of total and fecal coliforms and <i>Escherichia coli</i> by the presence-absence concept as required by the Total Coliform Rule, Parts 141 and 142, 54 FR 27544 and 56 FR 636. After promulgation of additional methods for <i>E. coli</i> , EPA included these additional methods in the study.					
To properly evaluate drinking water laboratories for microbiology certification, accredited PT study providers must use appropriate sample set design and sample production. The following criteria for sample sets are necessary to ensure sample integrity so that comparable data is generated by the study participants.					
1.2.2 Criteria					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.2.2.1 Sample set criteria					
The laboratories will analyze samples for total and fecal coliforms by the presence-absence concept as required by the Total Coliform Rule. Each shipment contains ten samples for testing, all shipped at the same time, and contains the same assortment of unknowns. The sample set variously contain non-coliforms, coliforms, fecal conformers, <i>E. coli</i> , and blanks. Samples may be either lyophilized, dehydrated or in an aqueous liquid matrix. If samples are shipped in liquid, shipments are permitted only during months where freezing or excessive heat is not likely to occur (April-May & September-October) and delivery must be guaranteed within 30 hours of preparation. Lyophilized and dehydrated samples need to be shipped within 3 months of preparation. In either case, laboratories are to analyze the samples according to the study instructions.					
1.2.2.2 Sample set composition					
1.2.2.2.1 The sets of ten samples which are provided to the laboratories shall contain bacteria that produce the following results when analyzed:					
1.2.2.2.2 Sheen colonies which will verify as total and fecal coliforms.					
1.2.2.2.3 Sheen colonies which will verify as total coliforms, but not as fecal coliforms.					
1.2.2.2.4 Atypical colonies which will not verify as total or fecal coliforms.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.2.2.2.5 Furthermore, each set shall contain the following samples:					
1.2.2.2.6 Three samples containing an aerogenic strain of <i>Escherichia coli</i> for total and fecal coliform positive results using all EPA approved methods.					
1.2.2.2.7 Three samples containing <i>Enterobacter sp.</i> or other microorganisms ensuring a total coliform positive and fecal coliform negative result using all EPA approved methods.					
1.2.2.2.8 Two samples containing <i>Pseudomonas sp.</i> or other microorganisms ensuring a total and fecal coliform negative result using all EPA approved methods.					
1.2.2.2.9 Two blank samples.					
1.2.2.2.10 Sample sets for qualitative analysis shall be randomly composed of samples that are total coliform absent, total coliform only present, fecal coliform (<i>E. coli</i>) present, and blanks. The study provider will send participants samples for each method, i.e., Membrane Filtration (NE), Multiple Tube Fermentation (MTF), Presence-Absence (P-A), and the Chromogenic/Fluorogenic (Chromo/Fluoro) methods.					
1.2.2.2.11 There are two analytes (Total Coliform and Fecal Coliform (<i>E. coli</i>) for each method. Each of these analytes can have one or more uniquely ordered sets of 10 samples, which is called a "series". Each series, therefore, has a unique set of answers. Providers should assign a letter (A-Z) to uniquely identify each series for an analyte.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.2.2.2.12 Frequency of Study					
A drinking water microbiology laboratory is required to have annual certification for each method used for analysis. Therefore, SDWA certification authorities will require laboratories to participate in a minimum of one performance evaluation study per method per year.					
1.2.2.2.13 Reported Data Evaluation					
Reported values in WSMICRO studies are evaluated on two levels, by sample and by analyte. First, the individual reported value for each sample of an analyte is evaluated as "Acceptable" or "Not Acceptable". Then, the analyte is evaluated, based on the reported values for all samples. "Acceptable" performance for the analyte means correct analysis of a minimum of 9 out of the 10 samples for each analyte, with no false negatives. In other words, one false positive or one blank sample may be missed. Any other reported values will be evaluated as "not acceptable" for the analyte. Results submitted after cut-off dates should not be evaluated.					
1.2.3 Reports					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>1.2.3.1 The accredited provider will send study samples, a data report form, and study instructions to participating laboratories. The provider will enter the laboratories' data report forms into a computer file for processing. The provider will calculate the failure rate and performance evaluations and generate a report for each individual participant. This report will be distributed to each participating laboratory, and to all certifying officials designated by the laboratory within 21 calendar days of the completion date of the study. The provider will also generate a summary report and a study discussion report which will be sent to the certifying officials. The study discussion report will also be sent to EPA and the PTPA within 21 calendar days of the completion date of the study. The study discussion report will address any details of the study which were unusual. The EPA database will be used to generate an overall summary of the studies by combining summary reports from the various accredited providers. The overall summary report will be distributed to the certifying officials.</p>					
<p>1.2.3.2 For each study conducted, each provider should send four data files to EPA, NERL, EERD, NWQAPB, 26 West M. L. King Drive, Room 525, Cincinnati, OH 45268 for use in the PT database. These files include: the initial assigned values file, the final assigned values file, the study data file, and the summary results file. As part of the quality control actions, the initial assigned values file should be sent to EPA prior to sample distribution. The other three files should be submitted to EPA within 21 calendar days after the study is completed.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.2.3.3 Laboratory identification number					
The participant must provide their laboratory identification number and identify their certifying official(s) to the NIST-accredited study provider. If this information is incomplete, the provider will not send samples to the laboratory.					
1.2.3.4 Method description					
The new system will require a description of the source of the method, the method number, and the revision, if applicable. Examples are "SM 9221-18 Ed" and "56 Fed Reg 636". This system replaces the EPA two-digit system, allows the reviewers to know what method was used by the laboratory directly, and helps to eliminate reporting errors when using method codes. The new system will allow 30 characters to handle all potential method description information.					
1.2.3.5 Criteria for Data Report Form					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Complete name and address of laboratory					
e) EPA Laboratory identification number					
f) Name, title, telephone number, signature of laboratory official who has approved the data on the report plus the date					
g) Series Identifier for each analyte reported					
h) Analyte number and name for each analyte					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
i) Sample number					
j) Method code					
k) Method description					
l) Reported value "1" for presence, "0" for absence					
m) Name and complete address of Certifying Authority					
1.2.3.6 Criteria for Individual Laboratory Evaluation					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Complete name and address of laboratory					
e) EPA Laboratory identification number					
f) Name, title, telephone number, signature of laboratory official who has approved the data on the report plus the date					
g) Analyte number and name for each analyte					
h) Sample number					
i) Method code					
j) Method description					
k) Reported Value (" 1 " for presence, "0" for absence)					
l) Assigned value (code for each sample series)					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
m) Evaluation of reported value for each sample					
n) Evaluation for the analyte (based on evaluation of the 10 samples)					
1.2.3.7 Criteria for Summary Report by Provider					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Series Identifier for each analyte					
e) Analyte number and name for each analyte reported					
f) Sample number for each analyte reported					
g) Assigned value for each sample of each analyte					
h) Total reported values for each sample of each analyte					
i) Number acceptable values for each sample of each analyte					
j) Number unacceptable values for each sample of each analyte					
k) Total reported values for each analyte					
l) Number acceptable values for each analyte					
m) Number unacceptable values for each analyte					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.2.3.8 Criteria for Study Discussion Report					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and NIST accreditation number					
d) Any pertinent information which addresses unusual details of the study (e.g. need to change an assigned value or delete an analyte from evaluation).					
e) Describe contents of each sample used in the study					
1.2.3.9 Criteria for Data Files to Be Submitted to National Database for Each Study					
For each Microbiology PT study they conduct, providers are expected to submit four data files to EPA for use in the database. These files are: the initial assigned values file, the final assigned values file, the study data file, and the summary results file. These files should be named: INITIAL.TXT, FINAL.TXT, DATA.TXT, and SUMMARY.TXT, respectively. The initial assigned values file is expected to be sent to EPA at the beginning of the study prior to sample distribution, and the other three files should be sent to EPA within 21 calendar days after the study is completed.					
1.2.3.10 File to Send at Beginning of Study					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>1.2.3.10.1 Initial Assigned Values File</p> <p>Before shipping samples to participants, each provider is expected to submit a standard ASCII, comma-delimited file to EPA. This file should contain the assigned value for each analyte/sample used in the study. It must have the fields in the order listed in the first table found on page 14 of the criteria document.</p>					
<p>1.2.3.11 Three Files To Send At End Of Study:</p>					
<p>1.2.3.11.1 Final Assigned Values and Limits File</p> <p>At the end of a study, each provider is expected to submit an ASCII, comma-delimited file to EPA. This file should contain the assigned values which were used for each analyte/ sample in the study. It must have the fields in the order listed on the table found on pages 14 and 15 of the criteria document.</p>					
<p>If the final assigned values differ from those reported in the initial file, the provider must explain the reason for this difference in the Study Discussion Report.</p>					
<p>1.2.3.11.2 Study Data File</p> <p>At the end of the study, each provider is expected to also send an ASCII, comma-delimited file to EPA with the laboratory data which was evaluated by this provider. For each reported value in the study, this file should contain the fields in the order listed in the table found on page 15 of this criteria document.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>0.1.2.10.2 Study Summary Results File</p> <p>Finally, at the end of each study, providers are expected to also submit a comma-delimited, ASCII file to EPA which contains the summary results information for the study. For each unique analyte /sample in the study, this file must contain the fields in the order listed in the table on page 15 of this criteria document. For the <i>Study Date</i> field, please note that there should only be one study date for each PT study.</p>					
1.3 RADIOCHEMISTRY STUDIES					
1.3 DESCRIPTION					
<p>Simulated environmental samples containing known amounts of one or more radionuclides are prepared and periodically distributed to laboratories. These laboratories perform the required analyses and return their data for statistical analysis and comparison with assigned values as well as with analytical values obtained by other participating laboratories. A report is returned to each participant. The program thus enables each laboratory to document the precision and accuracy of its radiation data, to identify instrumental and procedural problems, and to compare its performance with that of other laboratories.</p>					
1.3.1 Assigned Values					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
Standards are universally supplied with certified concentrations on an activity per mass basis, activity/gram. Proficiency testing OM samples are prepared based on mass of standard added to a known mass of preserved water sufficient for the study. The assigned value is the concentration of the PT sample laboratories are to reproduce.					
1.3.2 Verification Analysis of Performance Evaluation Samples					
From each batch of PT sample three samples representing top, middle, and bottom of the PT sample batch, and of the volume provided participants, are required. Three aliquots from each sample are analyzed and the pooled mean is compared to the assigned value. These values are also reported in the participant report. The assigned value is verified if the measured value is less than or equal to two normalized deviations from the assigned value. If the measured value is outside this limit the batch of PT sample is rejected, or the study is invalidated.					
1.3.3 Study Concentrations					
1.3.3.1 Performance evaluation samples must, to the degree possible, represent samples collected in the field. The techniques and geometries employed for measurement are critical components in radiochemical measurements. Therefore, amputated PT samples are incompatible with this specification.					
1.3.3.2 Assigned values should be at levels consistent with drinking water MCLS.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.3.3.3 Assigned values should be in the ranges listed in the Study Concentrations Table found on Page 18 of the EPA National Standards for Water Proficiency Testing Studies Criteria Document (December 30, 1998).					
1.3.3.4 Initially select a target value around the midpoint of the range.					
1.3.3.5 Determine two additional target values at two and four standard deviations above and below the midpoint.					
1.3.3.6 Select one of these four points as the starting concentration of the PT samples					
1.3.3.7 Subsequent assigned values should differ from the previous PT sample assigned value by three standard deviations or more.					
1.3.4 Types Of Environmental Samples Distributed - Water					
1.3.4.1 Water samples containing several different mixtures of radioactive materials make up the Performance Evaluation Studies Program:					
1.3.4.2 One-liter samples containing cobalt-60, zinc-65, cesium-134, cesium-137, and barium-133 at eight times the assigned value preserved with 0.5M hydrochloric acid, distributed twice a year for analysis of gamma emitters. Requires an eightfold dilution for proficiency testing.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.3.4.3 Four-liter samples containing iodine-131 at the assigned value preserved with sodium thiosulfate and sodium carbonate, distributed twice a year. No dilution required for proficiency testing.					
1.3.4.4 Four-liter samples containing iodine-131 at the assigned value preserved with sodium thiosulfate and sodium carbonate, distributed twice a year. No dilution required for proficiency testing.					
1.3.4.5 Sixty-milliliter samples prepared with distilled water low in background tritium (< 25 pCi/L), distributed twice a year for tritium analysis along with a blank for background correction. No dilution required for proficiency testing.					
1.3.4.6 One-liter samples containing natural uranium, radium-226, and radium-228 at sixteen times the assigned value preserved with 0.5M hydrochloric acid, distributed three times a year. A 16-fold dilution is required for proficiency testing.					
1.3.4.7 One-liter samples containing strontium-89 and strontium-90 at eight times the assigned value preserved with 0.5M hydrochloric acid, distributed twice a year. An eightfold dilution is required for proficiency testing.					
1.3.4.8 One-liter samples containing a mixture of radionuclides at sixteen times the assigned values preserved with 0.5M hydrochloric acid, distributed twice a year. Two one-liter samples are sent per study:					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.3.4.8 a) Sample A: containing radium-226, radium-228, and natural uranium is also analyzed for gross alpha activity; and					
1.3.4.8 b) Sample B: containing strontium-89, strontium-90, cobalt-60, cesium-134, cesium-137 is also analyzed for gross beta activity.					
1.3.5 Analysis of Data					
1.3.5.1 Each participating laboratory is required to perform three independent determinations for the radionuclide(s) included in a study. Samples which require special dilution and/or processing should be accompanied by an instruction sheet attached to the results report form.					
1.3.5.2 After receipt of reports from the participating laboratories, the data are analyzed. This analysis includes determination of the laboratory standard deviation, and calculation of the normalized range, normalized deviation, sample standard deviation, and the grand average of all laboratories. A report is generated containing data reported by participating laboratories which are listed according to their identity code; the results of the analysis are included in the report which is sent to each participant.					
1.3.6 Reports					
1.3.6.1 The NIST accredited PT providers are expected to send study samples, data report forms, and PT study instructions to participating laboratories. The PT study providers are expected to enter data report forms returned from laboratories into a computer file for processing.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.3.6.2 The providers should calculate the acceptance limits and performance evaluations and generate a PT Combined Laboratory Evaluation and Summary Report for each individual participant.					
1.3.6.3 This report should be distributed to each participating laboratory, and to all appropriate certifying officials designated by the laboratory within 21 calendar days of the completion date of the study.					
1.3.6.4 The provider is also expected to generate a study discussion report. The study discussion report should also be sent to EPA and NIST within 21 calendar days of the completion date of the study. The study discussion report should address any details of the study which were unusual. EPA will use the data collected from PT providers in the EPA PT database to generate an overall summary of the studies by combining reports from the various NIST accredited PT study providers. This overall summary report will be distributed to the appropriate certifying officials.					
1.3.7 Evaluation of Radiochemistry Data					
1.3.7.1 Each participant response for an analyte is evaluated according to the following four categories:					
a) Participant response is, or is not an outlier					
b) Non-outlier responses are above, below, or within control limits					
c) Insufficient data (participant did not report three numbers)					
d) No data submitted (i.e. - "non-response')					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.3.7.2 A printed message or symbol should appear in the evaluation reports to identify (i.e. - tag) laboratory data in each of these categories.					
1.3.7.3 Files					
For each study conducted, each provider should send four electronic data files to EPA, NERL, EERD, NWQAPB, 26 West M. L. King Drive, Room 525, Cincinnati, OH 45268 for use in the PT database. These files include: the initial assigned values and limits file, the final assigned values and limits file, the study data file, and the summary results file. As part of the quality control actions, the initial assigned values and acceptance limits file should be sent to EPA prior to sample distribution. The other three files should be submitted to EPA within 21 calendar days after the study is completed.					
1.3.8 Reporting Criteria					
1.3.8.1 Criteria For Data Report Form					
a) Study type (WSRAD)					
b) Study Date (date of study evaluation)					
c) Study number					
d) Provider name and accreditation number					
e) Complete name and address of laboratory					
f) EPA Laboratory identification number					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
g) Name, title, telephone number, signature of laboratory official who has approved the data on the report plus the date					
h) Sample type					
i) Analyte number and name for each analyte					
j) Lot number					
k) Method code					
l) Method description					
m) Reported value #1					
n) Reported value #2					
o) Reported value #3					
p) Significant figures: For numbers 9 or less, 2 significant figures; for 10-999, 3 significant figures; for 1000-9999, 4 significant figures; and for values greater than or equal to 10000, 3 significant figures are carried through the calculations.					
q) Name and complete address of Certifying Authority					
1.3.8.2 Criteria For Combined Laboratory Evaluation and Summary Report by Provider					
a) Study type (WSRAD)					
b) Study Date (date of study evaluation)					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
c) Study number					
d) Provider name and NIST accreditation number					
e) Sample type					
f) Analyte number and name for each analyte					
g) Number of participants in the study					
h) Assigned value					
i) Expected precision limits, including:					
(i) control limits (3 sigma)					
(ii) warning limits (2 sigma)					
j) For all respondents and non-outlier respondents:					
k) mean for a respondents; grand average for non-outlier respondents					
l) standard deviation					
m) variance					
n) coefficient of variation - as a percent					
o) deviation of mean from the assigned value - as a percent					
p) normalized deviation of mean from the assigned value					
q) median					
r) deviation of median from the assigned value - as a percent					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
s) normalized deviation of median from the assigned value					
t) Distribution of data for all data submitted, including the outlier's Results, alphabetical by lab code including:					
(i) three reported values					
(ii) experimental sigma					
(iii) range analyses					
(iv) average (of three reported values)					
(v) normalized deviation from the grand average					
(vi) normalized deviation from the assigned value					
(vii) a printed message or symbol (tag) indicating the evaluation for each participant response - i.e. - whether it is: an outlier, outside control limits, insufficient data, or no data was submitted.					
u) Sorted data by the mean from lowest to highest, including a printed message or symbol (tag) to indicate which values are in the categories in (g) above.					
v) The provider's validation data (and identification of provider's labcode) should also be included in the Combined Laboratory Evaluation and Summary Report.					
1.3.8.3 Criteria For Study Discussion Report					
a) Study type and date (date of study evaluation)					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
b) Study number					
c) Provider name and NIST accreditation number					
d) Any pertinent information which addresses unusual details of the study (e.g. need to change a assigned value or delete an analyte from evaluation).					
e) Added concentration of radionuclide					
f) Comparison of added concentration to validated concentration					
g) Explanation if added concentration is more than +/- 2 Normalized Deviations different than the measured concentration, and action to be taken by the provider to notify participants that the study has been invalidated and canceled.					
1.3.8.4 Criteria For Data Files To Be Submitted To EPA Database For Each Study					
For each PT study they conduct, providers are expected to submit four data files to EPA for use in the database. These files are: the initial assigned values and limits file, the final assigned values and limits file, the study data file, and the summary results file. These files should be named: INITIAL.TXT, FINAL.TXT, DATA.TXT, and SUMMARY.TXT, respectively. The initial assigned values file should be sent to EPA at the beginning of the study (prior to sample distributions, and the other three files should be sent to EPA within 21 calendar days after the study is completed.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
1.3.8.4.1 File To Send At Beginning of Study					
Initial Assigned Values and Limits File Before shipping samples to participants, each provider is expected to submit a standard ASCII, comma-delimited file to EPA. This file should contain the provider's assigned value for each analyte/sample used in the study. It must have the fields in the order listed in the table found on page 22 of the criteria document.					
1.3.8.4.2 Files To Send At End Of Study					
1.3.8.4.2.1 Final Assigned Values and Limits File At the end of a study, each provider is expected to submit an ASCII comma-delimited file to EPA. This file should contain the assigned values and evaluation limits which were used for each analyte/ sample used in the study. It must have the following fields in the order as listed on the first table found on page 23 of the criteria document.					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>1.3.8.4.2.2 Study Data File</p> <p>At the end of the study, each provider is also expected to send an ASCII, comma-delimited file to EPA with the laboratory data which was evaluated by this provider. For each participant response in the study, this file should contain the following fields in the order as listed on the table found on page 23 of the criteria document. Note that <i>Insufficient Data</i> refers to participant responses which do not have three reported values or which have reported values that are not numbers. <i>No Response</i> refers to participants who were sent samples, but did not return data. When there is insufficient data or no response, the statistics listed in the file below (Experimental Sigma, etc.) cannot be computed correctly.</p>					
<p>1.3.8.4.2.3 Study Summary Results File</p> <p>Finally, at the end of each study, providers are expected to also submit a comma-delimited, ASCII file to EPA which contains the summary results information for the study. For each unique analyte /sample in the study, this file must contain the following fields in the order listed on the table found on page 24 and 25 of this criteria document. For the <i>Study Date</i> field please note that there should only be one study date for each PT study.</p>					
PART 2 - WATER POLLUTION STUDIES - CRITERIA DOCUMENT					
2.1 CHEMISTRY STUDIES					
2.1.1 DESCRIPTION					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>2.1.1.1 Analyte -- PT study providers may vary their sample designs from the present EPA sample designs, for example, in the number of analytes in a particular ampule, in the source of starting materials, solvents, and dilution schemes, etc. The number of samples and the specifics within each sample also remain within the discretion of the PT study providers. The purpose of any PT program is to evaluate the "routine" analytical capacity of the laboratory to reliably analyze environmental test samples. Hence, providers will not encourage non-routine analysis by the laboratories. Excessive volume of sample may encourage multiple analyses which would be non-routine. Sufficient sample volume is needed for proper handling of samples and it is reasonable to have an excess volume available in case of spilling or mishandling by the laboratory in the dilution phase of sample preparation.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>2.1.1.2 Concentration -- PT test samples contain fixed concentrations of the analyses of concern at levels within the concentration ranges given. The provider has discretion to determine the solvents and dilution scheme (if used). The specific fixed concentrations are random and the PT study providers would use a random number generator to fix the specific concentrations. Each study is expected to have unique concentrations and are to be used in only one study. However, the provider has the option to adjust the value of individual analytes within a given sample if the value obtained from the random number generator would cause the resulting PT sample to be unacceptable, so long as the concentrations of these related analyte groups vary together randomly within their specified range. Examples of an unacceptable PT sample would be a large difference in concentration of two analytes which would cause major interferences (spectral, chromatographic, etc.).</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>2.1.1.3 Acceptance and Warning Limits -- For ease of computation, acceptance limits will be calculated by the provider as the estimated mean recovery ± 3.0 estimated standard deviations and warning limits will be the estimated mean recovery ± 2.0 estimated standard deviations. Tables provide the coefficients and constants for calculating the estimated mean recovery and the estimated standard deviation given an assigned value based on regression equations from the most recent EPA studies. The acceptance and warning limits should be reported to three (3) significant figures.</p> <p>Limits for specific conductance, total dissolved solids and total residual chlorine are exceptions to the normal procedure for setting limits because gravimetric true values are not available. For these three analytes, the study provider first estimates the central tendency of the in-control study data. For sample sizes of 20 or more values, calculate the biweight mean using 15 iterations with $c = 4$ and $co = 6$. For sample sizes less than 20, calculate the arithmetic mean after outlier testing with the T test; no more than 20% of the values in any set may be treated as outliers. Then, using the mean estimate and the equation for these analytes, the study provider estimates the standard deviation of the in-control data. For these three analytes ONLY, calculate acceptance limits as the mean estimate ± 3.0 estimated standard deviations and warning limits as the mean estimate ± 2.0 estimated standard deviations.</p>					
<p>2.1.1.4 Reports-see report section under Part I “Water Supply” of this checklist.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>2.1.1.5 Data Evaluation -- Below is an explanation of how to evaluate data reported by study participants. The evaluation process is fairly simple for most reported values. It becomes more complicated for values reported with "less than" or "greater than" signs.</p>					
<p>2.1.1.6 For Assigned Value Not Equal to Zero -- When the reported value does not have a < or > sign, the value is acceptable if it is inside or equal to the acceptance limits. If the reported value is inside the acceptance limits but outside the warning limits, the reported value is acceptable but should be flagged as "check for error". The reported value is not acceptable if it is either below the lower acceptance limit or above the upper acceptance limit. When the reported value has a < sign, it is only acceptable if the acceptance limits have a lower value of zero and the reported range is entirely within the acceptance limits. Reported values with a < sign are unacceptable if the lower acceptance limit is above zero. Reported values with > signs are always not acceptable. "Check for error" evaluations are not appropriate for < or > or reported values. For reported values which are not numbers, a numeric evaluation is not possible; these values should be evaluated as NO EVAL.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>2.1.1.7 For Assigned Value Equal to Zero** -- If the reported value is zero or contains a < sign, the reported value is acceptable. If the reported value is any numeric value other than zero or contains a > sign, the reported value is not acceptable. "Check for error" evaluations are not appropriate for < or > reported values. For reported values which are not numbers, a numeric evaluation is not possible; these values should be evaluated as "NO EVAL.</p> <p>Note that a reported value with a < or > sign implies a range of values. For example, a reported value of "< 8" implies a range from zero to 8; a reported value of ">8" implies a range from 8 to infinity.</p> <p>Note that a blank response for an analyte with Assigned Value set to zero should not be evaluated.</p>					
<p>2.1.1.8 Files-see the files section under Part I "Water Supply" of this checklist.</p>					
<p>2.1.1.9 Laboratory Identification Numbers-see the Laboratory Identification numbers sections under Part I "Water Supply" of this checklist.</p>					
<p>2.1.1.10 Study Mode-see the Study Mode section under Part I "Water Supply" of this checklist.</p>					
<p>2.1.2 Reporting Criteria</p>					
<p>2.1.2.1 Criteria for Data Report Form</p>					
<p>a) Study type and date (date of study evaluation)</p>					
<p>b) Study number</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
c) Provider name and accreditation number					
d) Complete name and address of laboratory					
e) EPA Laboratory identification number					
f) Name, title, telephone number, signature of laboratory official who has approved the data on the report plus the date					
g) Analyte number and name for each analyte					
h) Lot number					
i) Method code					
j) Method description					
k) </> Field					
l) Reported value in standard units, reported to 3 significant digits					
m) Name and complete address of WP officials to receive study results					
2.1.2.2 Criteria for Individual Laboratory Evaluation Report					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
d) Complete name and address of laboratory					
e) EPA Laboratory identification number					
f) Name, title, telephone number, signature of laboratory official who has approved the data on the report plus the date					
g) Analyte number and name for each analyte					
h) Lot number					
i) Method code					
j) Method description					
k) </> Field					
l) Reported value in standard units, reported to 3 significant digits					
m) Warning limits, reported to 3 significant digits					
n) Assigned value, reported to 3 significant digits					
o) Acceptance limits, reported to 3 significant digits					
p) Evaluation					
2.1.2.3 Criteria for Summary Report by Provider					
a) Study type and date (date of study evaluation)					
b) study number					
c) Provider name and accreditation number					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
d) Analyte number and name for each analyte reported					
e) Lot number for each analyte reported					
f) Assigned value for each analyte					
g) Total # of Reported Values for each analyte					
h) Total # of Acceptable Reported Values for each analyte					
i) Total # of Check for Error Values for each analyte					
j) Total # of Unacceptable Reported Values for each analyte					
k) Total # of Reported Values with No Evaluation for each analyte					
2.1.2.4 Criteria for Study Discussion Report					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Any pertinent information which addresses unusual details of the study (e.g. need to change a assigned value or delete an analyte from evaluation).					
2.1.2.5 Criteria for Data Files to Be Submitted to the EPA Database for Each Study					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>For each PT study they conduct, providers are expected to submit four data files to the EPA for use in the PT database. These files are: the initial assigned values and limits file, the final assigned values and limits file, the study data file, and the summary results file.</p> <p>These files should be named: INITIAL.TXT, FINAL.TXT, DATA.TXT, and SUMMARY.TXT, respectively. The initial assigned values and limits file should be sent to EPA at the beginning of the study (prior to sample distribution), and the other three files should be sent to EPA within 21 calendar days after the study is completed.</p> <p>The Assigned Value reported in these files should always be the value which was used to calculate limits. For those few analytes (specific conductance, total dissolved solids, and total residual chlorine) which use the study mean as the Assigned Value, it is understood that this value is not available when Initial Assigned Values and Limits File is submitted; it should be included in the Final Assigned Values and Limits File</p>					
<p>2.1.2.5.1 Initial Assigned Values and Limits File</p> <p>Before shipping samples to participants, each provider is expected to submit a standard ASCII, comma-delimited file to EPA. This file should contain the assigned value and evaluation limits for each analyte/ sample used in the study. It must have the fields in the order listed in the table found on page 30 of this criteria document.</p>					
<p>2.1.2.5.2 Three Files to Send at End of Study</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>2.1.2.5.2.1 Final Assigned values and Limits File</p> <p>At the end of a study, each provider is expected to submit an ASCII, comma-delimited file to EPA. This file should contain the assigned values and evaluation limits which were used for each analyte/ sample used in the study. It must have the fields in the order listed in the second table found on pages 30 and 31 of this criteria document.</p>					
<p>2.1.2.5.2.2 Study Data File</p> <p>At the end of the study, each provider is also expected to send an ASCII, comma-delimited file to EPA with the laboratory data which was evaluated by this provider. For each reported value in the study, this file should contain the fields in the order listed in the table found on page 31 of this criteria document. The <i>Outlier</i> field in this file should be used by providers to identify reported values which are outliers. An asterisk in this field indicates an outlier; for reported values which are not outliers, this field should be left blank. Values may be outliers when the assigned value is set to study mean for this analyte and the number of reported values for this analyte < 20.</p>					
<p>2.1.2.5.2.3 Study Summary Results File</p> <p>Finally, at the end of each study, providers are also expected to submit a comma-delimited, ASCII file to EPA which contains the summary results information for the study. For each unique analyte /sample in the study, this file must contain the fields in the order listed in the table on page 31 and 32 of this criteria document. For the Study Date field, please note that there should only be one study date for each PT study.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
PART 3 - DMRQA STUDIES - CRITERIA DOCUMENT					
3.1 CHEMISTRY STUDIES					
3.1.1 DESCRIPTIONS					
3.1.1.1 Analyte -see analyte Part 1 “Water Supply”					
<p>3.1.1.2 Acceptance and Warning Limits -- For ease of computation, acceptance limits will be the estimated mean recovery \pm 3.0 estimated standard deviations and warning limits will be the estimated mean recovery \pm 2.0 estimated standard deviations. The acceptance and warning limits should be reported to three (3) significant figures.</p> <p>Limits for total residual chlorine are an exception to the normal procedure for setting limits because gravimetric true values are not available. For this analyte, the study provider first estimates the central tendency of the in-control study data. For sample sizes of 20 or more values, calculate the biweight mean using 15 iterations with $c = 4$ and $co = 6$. For sample sizes less than 20, calculate the arithmetic mean after outlier testing with the T test; no more than 20% of the values in any set may be treated as outliers. Then, using the mean estimate and the equation for this analyte, the study provider estimates the standard deviation of the in-control data. For this analyte ONLY, calculate acceptance limits as the mean estimate \pm 3.0 estimated standard deviations and warning limits as the mean estimate \pm 2.0 estimated standard deviations.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>3.1.1.3 Reports -- The accredited provider will send study samples, a DMRQA laboratory data report form, and a set of analytical instructions to laboratories who request samples. Laboratories send these report forms with analytical results to the permittees for whom they do analyses.</p> <p>The provider calculates the warning limits, acceptance limits, and performance evaluations and generates a report for each individual permittee. In addition, a disk copy of all of the individual permittee evaluations, sorted by state and NPDES permit shall be sent by all providers to the individual state and regional regulatory authorities. These reports are distributed: to each participating permittee and regulatory authority within 21 calendar days of study completion.</p> <p>The provider will generate a summary report and a study discussion report which will be sent to the appropriate officials. The study discussion report will also be sent to EPA and NIST within 21 calendar days of study completion. The study discussion report will address any details of the study which were unusual. The EPA database will be used to generate an overall summary of the studies by combining summary reports from the various accredited providers. This overall summary report will be distributed to the appropriate officials.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>3.1.1.4 For Assigned Value Not Equal to Zero -- When the reported value does not have a < or > sign, the value is acceptable if it is inside or equal to the acceptance limits. If the reported value is inside the acceptance limits but outside the warning limits, the reported value is acceptable but should be flagged as check for error. The reported value is not acceptable if it is either below the lower acceptance limit or above the upper acceptance limit. When the reported value has a < sign, it is only acceptable if the acceptance limits have a lower value of zero and the reported range is entirely within the acceptance limits. Reported values with a < sign are unacceptable if the lower acceptance Limit is above zero. Reported values with > signs are always not acceptable. Check for error evaluations are not appropriate for < or > reported values. For reported values which are not numbers, a numeric evaluation is not possible; these values should be evaluated as NO EVU.</p> <p>Note that a reported value with. a < or > sign implies a range of values. For example, a reported value of "< 8" implies a range from zero to 8; a reported value of ">8" implies a range from 8 to infinity.</p>					
<p>3.1.1.5 Files-see files section found in Part I “Water Supply” of this checklist.</p>					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
3.1.1.6 NPDES Permit Numbers -- Each permittee must report their NPDES permit number on the DMRQA permittee data report form which they submit to EPA and the laboratory reporting form which they submit to the provider for evaluation. The permittee must provide the permittee identification number and the appropriate official (s) to the accredited PT study provider. If this information is incomplete, the study provider will not evaluate the data and will send the laboratory report back to the provider.					
3.1.1.7 Frequency -- There will be only one DMRQA study per year. EPA will send out an announcement (308 letter) each Spring.					
3.1.1.8 Record Retention -- It is the responsibility of the provider to meet the requirements of the Federal and State records disposition schedules.					
3.1.2 Reporting Criteria					
3.1.2.1 Criteria for DMRQA Laboratory Report Form					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Complete name and address of laboratory					
e) EPA Laboratory identification number					
f) Name, title, telephone number, signature of laboratory official who has approved the data on the report plus the date					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
g) Analyte number and name for each analyte					
h) Lot number					
i) Voluntary analyte flag ('X' or blank)					
j) Method code					
k) Method description					
l) </> Field					
m) Reported value in standard units, reported to 3 significant digits					
n) Complete Name and address of permittee					
o) NPDES Permittee identification number					
p) Name, title, telephone number, signature of permittee official who has approved the data on the report, date					
q) Complete name and address of DMRQA official(s) to receive study results					
3.1.2.2 Criteria for Individual Permittee Evaluation Report					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and accreditation number					
d) Complete name and address of laboratory					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
e) EPA Laboratory identification number					
f) NPDES Permittee identification number					
g) Name, title, telephone number of permittee official who has approved the data on the report plus the date					
h) Analyte number and name for each analyte reported					
i) Lot number					
j) Voluntary analyte flag					
k) Method code					
l) Method description					
m) </> field					
n) Reported value in standard units, reported to 3 significant digits					
o) Assigned value, reported to 3 significant digits					
p) Warning limits, reported to 3 significant digits					
q) Acceptance limits, reported to 3 significant digits					
r) Evaluation					
3.1.3.3 Criteria for Summary Report					
a) Study type and date (date of study evaluation)					
b) Study number					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
c) Provider name and accreditation number					
d) Analyte number and name for each analyte reported					
e) Lot number for each analyte reported					
f) Assigned value for each analyte					
g) Total # of Reported Values for each analyte					
h) Total # of Acceptable Reported Values for each analyte					
i) Total # of Check for Error Values for each analyte					
j) Total # of Unacceptable Reported Values for each analyte					
k) Total # of Reported Values with No Evaluation for each analyte					
3.1.3.4 Criteria for Study Discussion Report					
a) Study type and date (date of study evaluation)					
b) Study number					
c) Provider name and NIST accreditation number					
d) Any pertinent information which addresses unusual details of the study (e.g. need to change a assigned value or delete an analyte from evaluation).					
3.1.3.5 Criteria for Data Files to Be Submitted for Each Study					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>For each PT study, NIST-accredited PT study providers are expected to submit four data files to the USEPA for use in the database. These files are: the initial assigned values and limits file, the final assigned values and limits file, the study data file, and the summary results file. These files should be named: IMTIAL.TXT, FINAL.TXT, DATA.TXT, and SUMMARY.TXT, respectively. The initial assigned values and limits file should be sent to EPA at the beginning of the study prior to sample distribution, and the other three files should be sent to EPA within 21 calendar days after the study is completed.</p> <p>The Assigned Value reported in these files should always be the value which was used to calculate limits. For one analyte (total residual chlorine) which uses the study mean as the Assigned Value, it is understood that this value is not available when Initial Assigned Values and Limits File is submitted; it should be included in the Final Assigned Values and Limits File.</p>					
3.1.3.6 File to Send at Beginning of Study					
<p>3.1.3.6 Initial Assigned Values and Limits File</p> <p>Before shipping samples to participants, each provider is expected to submit a standard ASCII, comma-delimited file to EPA. This file should contain the assigned value and evaluation limits for each analyte/ sample used in the study. It must have the fields in the order listed in the table on page 38 and 39 of this criteria document.</p>					
3.1.3.7 Files to Send at End of Study					

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>3.1.3.7.1 Final Assigned values and Limits File</p> <p>At the end of a study, each provider is expected to submit an ASCII, comma-delimited file to EPA. This file should contain the assigned values and evaluation limits which were used for each analyte/ sample used in the study. It must have the fields in the order listed in the table on page 39 of this criteria document.</p>					
<p>3.1.3.7.2 Study Data File</p> <p>At the end of the study, each study provider is also expected to send an ASCII, comma-delimited file to EPA with the laboratory data which was evaluated by this provider. For each reported value in the study, this file should contain the fields in the order listed in the table found on pages 39 and 40 of this criteria document.</p> <p>The <i>Outlier</i> field in this file should be used by providers to identify reported values which are outliers. An asterisk in this field indicates an outlier; for reported values which are not outliers, this field should be left blank. Values may be outliers when the assigned value is set to study mean for this analyte and the number of reported values (N) for this analyte < 20.</p>					
<p>3.1.3.7.3 Study Summary Results File</p> <p>At the end of each study, providers are also expected to submit a comma-delimited, ASCII file to EPA which contains the summary results information for the study. For each unique analyte /sample in the study, this file must contain the fields in the order listed in the table found on page 40 of this criteria document. For the Study Date field, please note that there should only be one study date for each PT study.</p>					