DEPARTMENT OF ENVIRONMENTAL PROTECTION
Bureau of Laboratories

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Policy:	It is the policy of the Department of Environmental Protection (DEP) to provide laboratory management personnel with the information necessary to either obtain or maintain accreditation to perform and report environmental analyses in Pennsylvania.
Purpose:	The purpose of this document is to assist environmental laboratories in obtaining and maintaining accreditation under the Pennsylvania NELAP program.
Applicability:	The guidance will apply to all laboratories desiring to obtain and maintain accreditation under the Pennsylvania NELAP program as an alternative to accreditation under the Pennsylvania State Laboratory Accreditation Program.
Disclaimer:	The policies and procedures outlined in this guidance document are intended to supplement existing requirements. Nothing in the policies or procedures shall affect regulatory requirements. The policies and procedures herein are not an adjudication or a regulation. There is no intent on the part of DEP to give these rules that weight or deference. This document establishes the framework, within which DEP will exercise its administrative discretion in the future. DEP reserves the discretion to deviate from this policy statement if circumstances warrant.
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Environmental Laboratory Accreditation Manual for Laboratories Seeking Accreditation Utilizing the NELAC Standard

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DISCLAIMER

This document is a preliminary draft for discussion. The requirements stated in this preliminary draft include requirements from both State and Federal regulations. The specific citations of these State and Federal regulations will be identified in the later drafts of this document.

INTRODUCTION

The Environmental Laboratory Accreditation Act (Act 90-2002) ("Act") provides the Department of Environmental Protection ("Department") with the power and duty to offer National Environmental Laboratory Accreditation Program ("NELAP") accreditation to those laboratories seeking this accreditation. The Environmental Laboratory Accreditation Act (Act 90-2002) specifically gives the Department the authority to grant NELAP accreditation, after approval as a NELAP Accrediting Authority ("AA")), incorporating the National Environmental Laboratory Accreditation Conference ("NELAC") Standard by reference, and establishing fees for accreditation.

In order to ensure that Pennsylvania laboratories are continuing to report the most accurate information according to the most reliable standards, the Department is offering a dual system of laboratory accreditation. Current Pennsylvania State Laboratory Accreditation is based upon compliance with Departmental guidelines, including the *Procedures for the Approval and Accreditation of Laboratories in the Commonwealth of Pennsylvania,* the Chapter 252 Regulations, and the current edition of the EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water*. For requirements specific to the analysis of drinking water, see, 25 Pa. Code Chapter 109. The Pennsylvania Oil and Gas Program also contains specific requirements that are located in 25 Pa. Code Chapter 78. The requirements delineated in Chapters 78 and 109 are in addition to the requirements of the NELAC Standard. NELAP accreditation, using the NELAC Standard and this guidance is available as an alternative to accreditation under the Pennsylvania State Laboratory Accreditation Program.

The NELAC adopted standards for the performance of laboratory analyses to support various EPA Programs. These standards are applicable to all environmental laboratories. Under the dual system, accreditation of Pennsylvania environmental laboratories will be based upon the most current aforementioned Departmental guidelines or Departmental guidelines incorporating the most current NELAC Standard. Requirements for the use of specific methodology or quality control practices may be contained in the regulations for a particular program or in a permit issued by the Department. These requirements must also be met.

This document contains the specific requirements that must be met in order for a laboratory to obtain and maintain accreditation as a NELAP Accredited Environmental Laboratory in Pennsylvania. Accreditation to the NELAC Standard or Pennsylvania State accreditation is required for laboratories testing drinking water, non-potable water or solid and chemical materials as required by any of the following statutes:

1. The Oil and Gas Act (58 P.S. §§ 601.101 - 601.605).
2. The Clean Streams Law (35 P.S. §§ 691.1 - 691.1001).
3. The Hazardous Sites Cleanup Act (35 P.S. §§ 6020.101 - 6020.1305).
4. The Land Recycling and Environmental Remediation Standards Act (35 P.S. §§ 6026.101 - 6026.908).
5. The Pennsylvania Safe Drinking Water Act (35 P.S. §§ 721.1 - 721.17).
6. The Solid Waste Management Act (35 P.S. §§ 6018.101 - 3018.1003).
7. The Storage Tank and Spill Prevention Act (35 P.S. §§ 6021.101 - 6021.2104).
8. The Pennsylvania Bituminous Coal Mine Act (52 P.S. §§ 701-101 - 701-706).
9. The Surface Mining Conservation and Reclamation Act (52 P.S. §§ 1396.1 - 1369.31).
10. The Coal Refuse Disposal Control Act (52 P.S. §§ 30.51 - 30.206).
11. The Bituminous Mine Subsidence and Land Conservation Act (52 P.S. §§ 1406.1 - 1406.21).
12. The Noncoal Surface Mining Conservation and Reclamation Act (52 P.S. §§ 3001 – 3326).

1.0 BACKGROUND

EPA sponsors NELAC as a voluntary association of state and federal officials. The purpose of the organization is to foster the generation of environmental laboratory data of known and documented quality through the adoption of national performance standards for environmental laboratories and other entities directly involved in the environmental field measurement and sampling processes.

The Department's Bureau of Laboratories' Laboratory Accreditation Program has been delegated the right, responsibility, and authority to administer the accreditation of environmental laboratories according to the NELAC Standard. This document provides information and guidance to laboratories seeking to obtain and maintain accreditation as an environmental laboratory from Pennsylvania under the NELAC Standard. Accreditation programs are administered in a manner that will ensure the protection of the environment and the health of the citizens of the Commonwealth of Pennsylvania.

All accreditation activities are conducted in an impartial and non-discriminatory manner and are confined to matters specifically related to the fields of accreditation being sought by the laboratory. The Department has no rules, regulations, procedures, or practices that require membership or participation of any laboratory or other professional association. The Department does not impose any financial conditions or restrictions for participation in the accreditation program other than the fees authorized by territorial, state, or federal law. Applications for initial NELAP accreditation will be processed in the order in which a complete application is received. The Department uses the current NELAC Standard as the basis for the evaluation of laboratories seeking NELAP accreditation from the Department. The current NELAC standard is the currently effective revision as defined by NELAC. The section numbers listed in this document refer to the July 2003 version of the NELAC Standard.

2.0 APPLICATION AND APPROVAL PROCEDURE

2.1 Application Materials.

NOTE: Any sub-facilities or remote laboratory sites (including mobile laboratories) are considered separate facilities and must submit a separate application.

Application forms and instructions may be downloaded from www.dep.state.pa.us. Type in keyword "labs".

Upon request, a laboratory will be sent an application packet consisting of:

(a) Application forms.

(b) Instructions.

(c) Any other pertinent information including a copy of this guidance.

Note: Copies of 25 Pa. Code Chapter 252 are available to download from www.PABulletin.com, click "Search", select "Volume ___", select "Volume __, Number __", scroll down to "Environmental Quality Board", and select "Environmental Laboratory Accreditation". Copies may also be requested by mail. The effective version of the NELAC Standard may be obtained from www.epa.gov/nelac.

2.2 Submission of Application.

A complete application package must contain:

(a) Completed application.

(b) Quality Manual (See Section 2.3.2 of this guidance) (The Quality Manual must be submitted with the initial application, thereafter with subsequent renewal applications when changes have been made to the laboratory's quality manual, and upon request by the Department).

(c) Appropriate fees in the form of a check made payable to "Commonwealth of Pennsylvania."

The laboratory shall submit the completed application package by US mail to:

Pennsylvania Department of Environmental Protection
Attn: Laboratory Accreditation Program
P.O. Box 1467
Harrisburg, PA 17105-1467

All modes of delivery other than US mail must be made to:

Laboratory Accreditation Program
Pennsylvania Department of Environmental Protection
Bureau of Laboratories
2575 Interstate Drive
Harrisburg, Pa 17110-9332

2.3 Review of Application.

2.3.1 Completeness.

All appropriate sections of the application must be completed for the requested fields of accreditation. Incomplete applications will be returned to the laboratory or the missing information will be requested before the application can be processed.

2.3.2 Quality Manual.

All laboratories analyzing environmental samples must adhere to the Quality Control ("QC") procedures specified in the methods. The NELAC Standard specifies the general requirements for the competence to carry out environmental tests. It contains all the requirements that environmental testing laboratories are to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. To ensure that routinely generated analytical data are scientifically valid and defensible and are of known and acceptable precision and accuracy, each laboratory must prepare a written description of its Quality Assurance ("QA") activities in the Quality Manual, or include such practices in the Quality Manual by reference to other laboratory documents, such as SOPs. The Quality Manager is responsible for keeping the Quality Manual up to date. All laboratory personnel must be familiar with the contents of the Quality Manual. The Quality Manual must be submitted to the Department for review with an initial application for accreditation and prior to the on-site assessment if changes have been made to the Quality Manual since the laboratory's last submittal.

The laboratory Quality Manual must meet the requirements outlined in Chapter 5 of the NELAC Standard. If a particular item is not relevant, the Quality Manual should state this and provide a brief explanation. A laboratory Quality Manual should be responsive to the requirements in Chapter 5 of the NELAC Standard while remaining brief and easy to follow. Minimizing paperwork, while improving dependability and quality of data, are the intended goals.

2.3.3 Technical Director.

The technical director(s) must meet the qualifications listed in Section 4.1.1 of the NELAC Standard. The technical director(s) is a full-time member of the staff of an environmental laboratory who exercises actual day-to-day supervision of

laboratory procedures and reporting of results. The title of said person may include but is not limited to technical director, laboratory director, laboratory supervisor, or laboratory manager. A laboratory may appoint one or more technical directors for the appropriate fields of testing for which they are seeking accreditation. His/her name must appear in the national database when the database becomes available. This person's duties shall include, but not be limited to, monitoring standards of performance in quality control and quality assurance; monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data; ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and providing educational direction to laboratory staff.

An individual may not be the technical director of more than one accredited environmental laboratory without authorization from the primary Accrediting Authority. Circumstances to be considered in the decision to grant such authorization shall include, but not be limited to, the extent to which operating hours of the laboratories to be directed overlap and adequacy of supervision in each laboratory. In the event that the technical director is absent for a period of time exceeding 15 consecutive calendar days, the environmental laboratory shall designate another staff member meeting the qualifications of the laboratory supervisor to temporarily perform this function. If the technical director's absence exceeds 65 consecutive calendar days, the Department shall be notified in writing.

2.3.4 Quality Manager.

The laboratory shall appoint a member of the staff as a quality manager. The quality manger (however named) has responsibility for the quality system and its implementation. The quality manger shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources, and to the technical director. Where staffing is limited, the quality manager may also be the technical director or deputy technical director.

The quality manager (and/or his/her designees) shall:

a) Serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data.

b) Have functions independent from laboratory operations for which they have quality assurance oversight.

c) Be able to evaluate data objectively and perform assessments without outside (e.g. managerial) influence.

d) Have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC.

e) Have a general knowledge of the analytical test methods for which data review is performed.

f) Arrange for or conduct internal audits on the entire technical operation annually.

g) Notify laboratory management of deficiencies in the quality system and monitor corrective actions.

2.4 Demonstration of Capability.

Prior to the acceptance and institution of any test method, a satisfactory Demonstration of Capability is required. Specific details are contained in Section 5.5.4.2.2 of the NELAC

Standard. For some methods or programs the laboratory must be able to achieve published method detection limits ("MDLs") or Reporting Limits. Data supporting the Demonstration of Capability and any required MDLs or Reporting Limits must be available to the Department on request and/or during the on-site assessment.

2.5 Fee Schedule.

Laboratories applying for accreditation or renewal of accreditation shall submit the appropriate annual fee along with the required application. Fees are in accordance with the Environmental Laboratory Accreditation Regulations, 25 Pa. Code, Chapter 252, Subchapter B, §252.204. Checks must be made payable to "Commonwealth of Pennsylvania". **FEES ARE NONREFUNDABLE.**

	Accreditation Category	Fee (1)
Application Fees	Application Fee – Initial Application	$ 600
	Application Fee - Renewal Application	$ 500
	Application Fee – Ownership Transfer	$ 150
	Application Fee – Addition of Fields of Accreditation	$ 250
Drinking Water Fees	Basic Drinking Water Category – includes 1 method for each of the following: Total Coliform Bacteria, Fecal Coliform Bacteria, *E. coli* Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	$ 600
	Asbestos	$ 350
	Microbiology	$ 450
	Trace Metal Category	$ 450
	Inorganic Non-metal Category	$ 500
	Trace Metal & Inorganic Non-metal Categories	$ 800
	Volatile Organic Chemicals	$ 500
	Extractable and Semi-volatile Organic Chemicals	$ 750
	Dioxin	$ 600
	Radiochemical Category	$ 700
Non-potable Water Fees	Basic Non-potable Water Category – includes 1 method for each of the following: Fecal Coliform Bacteria, BOD, CBOD, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, and 1 method for each type of residue	$ 700
	Asbestos	$ 350
	Microbiology	$ 400
	Trace Metal Category	$ 450
	Inorganic Non-metal Category	$ 550
	Trace Metal and Inorganic Non-metal Categories	$ 900
	Volatile Organic Chemicals	$ 500
	Extractable and Semi-volatile Organic Chemicals	$ 950

	Dioxin	$ 600
	Radiochemical Category	$ 600
	Whole Effluent Toxicity Testing Category	$ 600
Drinking Water & Non-potable Water Fees	Microbiology	$ 750
	Trace Metal Category	$ 800
	Inorganic Non-metal Category	$1,000
	Trace Metal and Inorganic Non-metal Categories	$1,550
	Volatile Organic Chemicals	$ 900
	Extractable and Semi-volatile Organic Chemicals	$1,650
	Dioxin	$1,050
	Radiochemical Category	$1,050
Solid and Chemical Materials	Asbestos	$ 350
	Microbiology	$ 450
	Trace Metal Category	$ 450
	Inorganic Non-metal Category	$ 550
	Volatile Organic Chemicals	$ 550
	Extractable and Semi-volatile Organic Chemicals	$1,200
	Dioxin	$ 600
	Radiochemical Category	$ 600

(1) In addition to the appropriate fee, out-of-State laboratories shall reimburse the Department for out-of-State travel related expenses necessitated by the accreditation.

Accreditation fees should be calculated by adding the appropriate application fee to the appropriate category fee. For example, if a laboratory wishes to apply for initial accreditation for the basic drinking water category, the fee for initial application would be $1,200 ($600 initial application fee + $600 basic drinking water category fee). Upon renewal of their accreditation, this same laboratory would submit a $1,100 fee with their renewal application ($500 renewal application fee + $600 basic drinking water category).

The Department will re-evaluate the fees at least every three years for any disparity between program income generated by the fees and the cost of administering the program.

2.6 Proficiency Test Samples.

To be accredited initially and to maintain accreditation, a laboratory shall successfully complete two single blind, single-concentration proficiency test ("PT") studies, where available, per year for each PT field of testing (matrix, technology/method, and analyte/analyte group) for which it seeks to obtain or maintain accreditation. The laboratory must successfully analyze two PT studies for each requested field of proficiency testing within the most recent three rounds attempted. Laboratories must obtain PT samples from a PTOB/PTPA-approved PT Provider. Each laboratory shall participate in at least two PT studies for each PT field of testing per year unless a different

frequency for a given program is defined in the NELAC Standard. Chapter 2 of the NELAC Standard provides additional detailed information on the PT studies and on the analysis of PT samples.

The PT samples shall be analyzed and the results returned to the PT Provider no later than 45 calendar days from the opening of the study (i.e., first day that samples are shipped or available to laboratories). The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for the routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis.

Laboratories shall comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released:

a) A laboratory may not send any PT sample, or a portion of a PT sample, to another laboratory for any analysis for which it seeks accreditation or is accredited.

b) A laboratory may not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation or is accredited.

c) Laboratory management or staff may not communicate with any individual at another laboratory (including intra-company communication) concerning a PT sample.

d) Laboratory management or staff may not attempt to obtain the assigned value of any PT sample from their PT Provider.

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports resulting from the analysis of any PT sample for five years or for as long as is required by the applicable regulatory program, whichever is greater. These records shall include a copy of the PT study report forms used by the laboratory to record and report PT results. All of these laboratory records shall be made available to the assessors during on-site assessments of the laboratory.

A PT study must be analyzed on a semi-annual basis. The Department will consider closing dates of successive proficiency rounds for a given field of proficiency testing that are less than 7 months apart as meeting the requirement to analyze PTs approximately six months apart. Failure to meet the required semi-annual schedule, as determined by the closing date of the study, shall be considered a failed PT study. Each laboratory shall participate in at least two PT studies for each field of testing per year unless a different frequency for a given program is defined in the NELAC Standard.

2.7 On-site Assessment.

An initial on-site assessment is required of all laboratories seeking accreditation. All accredited laboratories must be reassessed at least once every 2 years. Additional on-site assessments may be performed at the Department's discretion. Procedures for conducting on-site assessments are contained in the NELAC Standard and internal Department procedures.

The assessment may be a general assessment to determine the capability of the laboratory to perform environmental testing or a specific examination of a certain area of testing. The assessment will include both an appraisal of the laboratory's operations and a review of the appropriate records. The assessment will cover all of the tests for which the laboratory seeks accreditation. All on-site assessments will utilize NELAC approved checklists or their equivalent.

Upon completion of the on-site assessment, the on-site assessor(s) will prepare a formal written report. Reports are normally issued within 30 calendar days following completion of the assessment. The assessment report will contain all information pertinent to the assessment and the Department's determination of the accreditation status of the laboratory.

Within 30 calendar days of the receipt of the report, the laboratory shall prepare and submit a corrective action report. The corrective action report shall include the action that the laboratory shall implement to correct each deficiency and the time period required to accomplish the corrective action. The Department will review and respond to the written corrective action report within 30 calendar days after receipt of the corrective action report. If any portion of the corrective action report is not acceptable, the laboratory shall submit within 30 calendar days of the receipt of the Department's response a revised written corrective action report. If the corrective action report is not acceptable after the second submittal, the Department may revoke accreditation in accordance with the NELAC Standard and Department procedures.

If the laboratory fails to implement the corrective actions as stated in their corrective action report, accreditation for fields of testing, specific methods, or analytes within those fields of testing shall be revoked.

2.8 Awarding of Accreditation.

When a participating laboratory has met the requirements specified for obtaining accreditation, including all of the requirements in Chapter 5 of the NELAC Standard, the laboratory will receive a Certificate of Accreditation from the Department. The certificate will provide the following information: the name of the laboratory, address of the laboratory, and the specifications of the accreditation action. The Certificate of Accreditation will contain a Scope of Accreditation as an attachment. A new and revised Scope of Accreditation will be issued with each change in accreditation status. Additional terms and conditions may be specified in an addendum to the Certificate of Accreditation. Addenda or attachments to the Certificate of Accreditation shall be considered to be official documents and a part of the Certificate of Accreditation. The laboratory must have a certificate from each state or Federal Department/Agency through which it is accredited.

Regardless of the accreditation status of the parent laboratory, the sub-facilities (laboratories operating under the same parent organization, analytical procedures, and quality assurance system) are inspected and processed separately and shall obtain their own Certificate of Accreditation. A separate application, including appropriate fees, is required for each sub-facility. Any sub-facilities or remote laboratory sites (including mobile laboratories) are considered separate facilities and subject to separate announced and unannounced assessments.

2.9 Notification and Reporting Requirements.

2.9.1 General Requirements.

2.9.1.1 The accredited laboratory shall notify the Department of any changes in key accreditation criteria within 30 calendar days of the change. This written notification is required for, but is not limited to, changes in the laboratory ownership, location, key personnel, and major instrumentation. All such updates are public record and any or all of the information contained therein may be put into the national database.

2.9.1.2 Laboratories granted secondary accreditation under NELAP must notify the Department in writing, within 48 hours, whenever that laboratory's Primary Accrediting Authority terminates accreditation for any field of accreditation. Failure to provide timely notification to the Department of any termination of

accreditation by the Primary Accrediting Authority may result in revocation of accreditation for all parameters.

2.9.2 Safe Drinking Water Program Requirements.

2.9.2.1 A laboratory accredited by the Department shall submit to the Department, in a manner approved by the Department, the results of all test measurements or analyses performed by the laboratory on behalf of a regulated public water system in accordance with the provisions of 25 Pa. Code Chapter 109. The time limits for routine reporting of those results are located in 25 Pa. Code § 109.810(a).

2.9.2.2 A laboratory accredited by the Department that performs tests and analyses on behalf of a regulated public water system, shall follow the reporting procedures set forth in 25 Pa. Code § 109.810(b) whenever an MCL, MRDL, or a treatment technique performance requirement under 25 Pa. Code § 109.202 (relating to State MCLs, MRDLs and treatment technique requirements) is violated or a sample result requires the collection of check samples under 25 Pa. Code § 109.301 (relating to general monitoring requirements).

2.9.2.3 A laboratory accredited by the Department that performs tests and analyses on behalf of a regulated public water system under 25 Pa. Code Chapter 109 shall notify each public water supplier served by the laboratory within 48 hours of the following:

2.9.2.3.1 A failure to renew or Department denial of renewal of existing accreditation for a category of accreditation.

2.9.2.3.2 Revocation of accreditation by the Department or voluntary withdrawal by the laboratory.

2.10 Change in Ownership or Location.

Accreditation may be transferred when the legal status, ownership, or location of an accredited laboratory changes without affecting its staff, equipment, and organization. The accredited laboratory shall notify the Department in writing of any changes in ownership within 30 calendar days of the change and submit the appropriate application and application fees. The Department may conduct an on-site assessment to verify effects of such changes on laboratory performance. All of the previous terms and conditions in the Certificate of Accreditation apply to the new ownership and/or the new location of a laboratory. All of the conditions in the NELAC Standard apply to the new ownership and/or the new location of a laboratory.

2.11 Record Keeping and Retention.

All laboratory records associated with accredited parameters shall meet the requirements of the NELAC Standard and shall be maintained for a minimum of five years unless otherwise designated for a longer period in another regulation or authority. In the case of data used in litigation, the laboratory is required to store such records for a longer period upon written notification from the Department.

3.0 ACCREDITATION STATUS

3.1 Types of Accreditation.

After review of PT sample results and an on-site assessment, the Department will classify the laboratory for each contaminant or group of contaminants according to the following rating scheme:

3.1.1 Accredited: A laboratory that meets the minimum requirements of this guidance document, the NELAC Standard, and all applicable regulatory requirements. "Accredited" status may not be granted to any laboratory that has not met performance criteria specified in the NELAC Standard or the regulations and policies of the Department.

3.1.2 Not Accredited: A laboratory that possesses major deficiencies and, in the opinion of the Department, cannot produce valid data within the acceptance limits specified in the applicable regulations and within the policies of the Department. A "not-accredited" laboratory may not analyze or report the results of compliance samples.

3.1.3 Suspension: A laboratory that possesses deficiencies and, in the opinion of the Department, cannot produce valid data within the acceptance limits specified in the applicable regulations and within the policies of the Department. "Suspension" is the temporary removal of a laboratory's accreditation for a defined period of time not to exceed 6 months. A suspended laboratory may not analyze or report the results of compliance samples.

3.1.4 Applied: A laboratory that has initially requested accreditation for a field of testing but does not meet the requirements of all applicable regulations and/or policies of the Department. An "applied" laboratory may not analyze or report the results of compliance samples.

3.2 Maintaining Accreditation.

Accreditation shall remain in effect until revoked by the Department, withdrawn at the written request of the accredited laboratory, or until the expiration of the accreditation period. The accreditation period will not exceed 12 months. To maintain accreditation, the accredited laboratory shall complete or comply with all NELAC Standard and Departmental regulations. Failure to complete or comply with these standards or regulations shall be cause for suspending or revoking accreditation as specified in Departmental regulations or in this guidance.

Accredited laboratories shall submit a completed renewal application and the appropriate fee to the Department at least 60 calendar days prior to the expiration of the current accreditation period. Failure of the laboratory to submit a renewal application in a timely manner may result in the loss of accreditation during the processing of the application. Applications are processed in the order in which they are received.

3.3 Denial, Suspension, and Revocation of Accreditation.

3.3.1 Denial.

3.3.1.1 The Department will deny an application for accreditation, transfer of accreditation or application for renewal of accreditation under one or more of the following circumstances:

a) The laboratory is in continuing violation of or demonstrates an inability or lack of intention to comply with Chapter 252 or other laws administered by the Department.

b) The Department revoked the laboratory's Certificate of Accreditation for all fields of accreditation for failure to correct deficiencies identified in an on-site assessment report within the previous 6 months.

3.3.1.2 The Department may deny an application for accreditation, transfer of accreditation or application for renewal of accreditation for one or more of the following reasons:

a) Falsifying analyses.

b) Failure to comply with the reporting and notification requirements as specified in §252.708 (relating to reporting and notification requirements).

c) Making misrepresentations to the Department.

d) Engaging in unethical or fraudulent practices.

e) Analysis of proficiency test studies by personnel other than the analysts associated with the routine analysis of environmental samples in the laboratory.

f) Failure to submit a completed application.

g) Failure to pay required fees.

h) Failure of laboratory staff to meet the personnel qualifications of education, training and experience.

i) Failure to successfully analyze and report proficiency test studies as required by Chapter 252.

j) Failure to respond to an on-site assessment report with a corrective action report within the required timeframes.

k) Failure to implement the corrective actions detailed in the laboratory's corrective action report within a timeframe approved by the Department.

l) Failure to implement a quality assurance program.

m) Denial of entry to the Department during normal business hours for an on-site assessment.

n) Violation of a statute, Chapter 252 or an order by the Department.

o) Failure to meet the requirements of Chapter 252.

3.3.1.3 Upon reapplication, the laboratory again will be responsible for all of the fees applicable as part of the initial application for accreditation.

3.3.2 Suspension.

3.3.2.1 The Department will suspend an environmental laboratory's accreditation for all fields of accreditation when the Department is denied access to the laboratory during normal business hours. Upon notice from the Department, the laboratory must immediately cease analysis of environmental samples.

3.3.2.2 The Department will suspend a laboratory's accreditation in full or in part for one or more of the following reasons:

a) If the Department finds that protection of public health, safety or welfare requires emergency action.

b) If the laboratory fails to successfully complete a PT study within the previous 12 months.

c) The laboratory fails two consecutive PT studies for a particular field of accreditation.

3.3.2.3 The Department may suspend a laboratory's accreditation in total or in part for one or more of the following reasons:

a) Failure to comply with the reporting and notification requirements as specified in § 252.708 (relating to reporting and notification requirements).
b) Failure to implement a quality assurance program.
c) Failure to employ staff that meets the personnel qualifications for education, training and experience.

3.3.2.4 A laboratory may continue to analyze environmental samples for those fields of accreditation not affected by the suspension.

3.3.2.5 Within 72 hours of receiving notice of the suspension of accreditation from the Department, the laboratory must notify each of its customers affected by the suspension in writing on a form approved by the Department.

3.3.3 Revocation.

3.3.3.1 The Department will revoke an environmental laboratory's accreditation for a field of accreditation when, after being suspended due to failure to participate in a required PT, or due to a failure to obtain an acceptable result for a PT study, the laboratory's analysis of the next PT study results in a failed PT for that field of accreditation.

3.3.3.2 The Department may revoke a laboratory's accreditation, in part or in total, for one or more of the following reasons:

a) Failure to respond to an on-site assessment report with a corrective action report within the required timeframes.
b) Failure to correct deficiencies identified during an on-site assessment of the laboratory.
c) Failure to implement corrective action related to violations or deficiencies found during an on-site assessment.
d) Failure of a laboratory that has been suspended to correct all outstanding violations or deficiencies within 6 months of the effective date of the suspension.
e) Violation of a condition of accreditation.
f) Violation of a statute, Chapter 252 or an order by the Department.
g) Falsifying analysis.
h) Making misrepresentations to the Department.
i) Engaging in unethical or fraudulent practices.
j) Analysis of Proficiency Test Studies by personnel other than the analysts associated with the routine analysis of environmental samples in the laboratory.
k) Failure to implement a quality assurance program.

l) Failure to participate in the proficiency test study program as required by Chapter 252.

m) Denial of entry to the Department during normal business hours for an on-site assessment.

n) Failure to comply with the reporting and notification requirements as specified in §252.708 (relating to reporting and notification requirements).

o) Failure to employ staff that meets the personnel qualifications for education, training and experience.

p) Failure to meet the requirements of Chapter 252.

3.3.3.3 An environmental laboratory may continue to analyze environmental samples for those fields of accreditation not revoked.

3.3.3.4 Within 72 hours of receiving notice of the revocation of accreditation from the Department, the laboratory must notify each of its customers affected by the revocation in writing on a form approved by the Department.

3.3.4 Upgrading of Status.

Laboratories are only considered for upgrade to Accredited status after identified deviation(s) or other cause(s) for denial, revocation, or suspension have been eliminated or rectified.

3.3.4.1 A laboratory which lost accreditation for failure to correctly analyze PT studies is eligible for upgrade of status after meeting the PT study requirements.

3.3.4.2 The Department will deny an application for accreditation if the laboratory is in continuing violation of or demonstrates an inability or lack of intention to comply with the Department's regulations and laws.

3.3.4.3 The Department will deny an application for accreditation if the laboratory if the Department revoked accreditation for all fields of accreditation for failure to correct deficiencies identified in an ousite assessment report within the previous six (6) months.

3.3.5 Voluntary Relinquishment.

3.3.5.1 An environmental laboratory wishing to voluntarily relinquish its certificate of accreditation must notify the Department in writing.

3.3.5.2 A laboratory that relinquishes its certificate of accreditation must insure that records are maintained in accordance with §252.706 (relating to record keeping).

3.3.5.3 Within 72 hours of voluntarily relinquishing its certificate of accreditation, the laboratory must notify each of its customers affected by the voluntary relinquishment in writing on a form approved by the Department.

3.4 Subcontracting Analyses.

If a laboratory subcontracts one or more analyses, it must subcontract to a laboratory accredited by the Department for the requested analyte(s). A laboratory acting as an agent of a Public Water System ("PWS") that takes a sample and subcontracts that sample to a certified laboratory must insure that the PWS receives all information required by 25 PA. Code Chapter 109. The agent laboratory must notify the subcontracting laboratory that the sample is from a PWS so the subcontracting laboratory uses appropriate methodology and quality control and is aware of the reporting and notification requirements of 25 Pa. Code § 109.810 (b). The laboratory that is seeking to subcontract analyses must follow all required reporting procedures. Identification of the laboratory that performs the subcontracted analyses must appear on all report forms.

4.0 OUT-OF-STATE LABORATORIES

Pennsylvania offers Primary NELAP accreditation for drinking water, non-potable water and solid and chemical material matrices to out-of-State laboratories, where NELAP accreditation for those matrices is unavailable in their State of residence. Secondary NELAP accreditation is available to any out-of-State laboratory with primary accreditation from any NELAP approved Accrediting Authority.

Primary and Secondary NELAP accreditation is available for any for any of the following, or any combination(s) of the following, to out-of-State laboratories:

- Drinking Water.
- Wastewater.
- Solid and Chemical Materials.

To be accredited in Pennsylvania, out-of-State laboratories must meet the same requirements as laboratories located within Pennsylvania. In addition to the appropriate fee, out-of-State laboratories shall reimburse the Department for out-of-State travel related expenses necessitated by primary accreditation. Separate on-site inspections may be performed for Microbiology, Chemistry, and Radiochemistry accreditation.

The Department will grant accreditation to out-of-State laboratories accredited by other NELAP recognized Accrediting Authorities in accordance with the NELAC Standard (Section 6.2.1) and NELAC and NELAP policies. The Department will only consider the current Certificate of Accreditation issued by the NELAP recognized Primary Accrediting Authority. To apply for secondary NELAC accreditation, the laboratory shall:

- Submit a properly completed application.
- Submit a quality manual with initial application and upon request thereafter.
- Pay the appropriate annual fee.
- Submit a copy of a valid accreditation certificate from a NELAP recognized Accrediting Authority.
- Submit a copy of all on-site assessments conducted by the primary NELAP recognized Accrediting Authority in the last two years and as they are conducted thereafter.
- Submit copies of all PT sample results reported within the past 12 months and as they are performed thereafter.
- Agree to obey all program requirements regarding accredited environmental laboratories.

Upon receipt of a completed application for secondary accreditation, the Department will issue the laboratory a Certificate of Accreditation accompanied by the laboratory's Scope of Accreditation as an attachment. The certificate and scope are usually issued within 30 days of receipt of the completed application for accreditation.

If the Department notes any potential nonconformance with the NELAC Standard by a laboratory applying for secondary accreditation through Pennsylvania, the Department shall:

1) Notify the applicable NELAP recognized Primary Accrediting Authority and the laboratory in writing of the nonconformance. The laboratory will not be notified in situations where administrative or judicial prosecution is contemplated.
2) Not take final action on the application for secondary NELAC accreditation until the alleged nonconformance issue has been resolved, if noted during the initial application process.
3) Not change the accreditation status of the laboratory until the alleged nonconformance issue has been resolved, if noted after secondary NELAC accreditation has been awarded to the laboratory.
4) If the Primary Accrediting Authority does not take timely or appropriate actions regarding the nonconformance, the NELAP Director will be notified of the dispute between the Accrediting Authorities regarding dispositions of the nonconformance.

5.0 USE OF ACCREDITATION BY NELAP ACCREDITED LABORATORIES

Laboratories accredited by the Department shall:

1) Post or display their most recent accreditation certificate including their accredited fields of testing in a prominent place in the laboratory facility.
2) Make accurate statements concerning their accredited fields of testing and accreditation status.
3) Accompany the Department's name and/or the NELAC/NELAP logo with at least the phrase "NELAP accredited" and the laboratory's accreditation number or other identifier when the Department's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports, or other materials.
4) Not use their certificate of accreditation, Department accreditation status, and/or NELAC/NELAP logo to imply endorsement by the Department.

Laboratories choosing to use the Department's name, making reference to its NELAP accreditation status, and/or using the NELAC/NELAP logo in any catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports, or other materials shall:

1) Distinguish between proposed testing for which the accredited laboratory is accredited and the proposed testing for which the accredited laboratory is not accredited.
2) Include the accredited laboratory's accreditation number or other identifier.

Accredited laboratories upon suspension, revocation, or withdrawal of their accreditation shall:

1) Discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results, or other materials that contain reference to their past accreditation status and/or display the NELAC/NELAP logo.
2) Return any certificates of accreditation to the Department within 48 hours.