

Instructions for Environmental Laboratories Seeking Accreditation from the PA-DEP

Disclaimer: The information in this document does not supplant the provisions of the Environmental Laboratory Accreditation Regulations, 25 Pa Code, Chapter 252 or the TNI Standard. This document is a tool to help laboratories comply with Chapter 252 and the TNI Standard. If there is any disagreement between the contents of this document and Chapter 252 and the TNI Standard, the regulations or standard shall prevail. The examples given in this document are for illustrative purposes only, meant to aid individuals in visualizing applications of the regulatory requirements. These examples do not represent all method or regulatory requirements.

1.0 INTRODUCTION

In the Commonwealth of Pennsylvania, numerous decisions are made daily by the public, the regulated community and the government that are based upon data generated by environmental laboratories, and valid and accurate data is essential to determine compliance with State and Federal laws. In order to protect the health, safety and welfare of the citizens of the Commonwealth, the Commonwealth of Pennsylvania has been directed to establish, administer and enforce an environmental laboratory accreditation program under the Environmental Laboratory Accreditation Act, 27 Pa. C.S. §§ 4101 – 4113. The Department of Environmental Protection (“Department”), therefore, developed the accreditation requirements set forth in 25 Pa Code Chapter 252 (“Chapter 252”), which enables the Department to assure the quality of data used to make environmental decisions. Chapter 252 was originally promulgated in January 2006 and updated twice, April 2010 and July 2017.

In order to ensure that Pennsylvania laboratories are able to meet their customer’s needs, the Department’s regulations and laws, and other non-DEP regulatory requirements, the Department offers a dual system of laboratory accreditation: Pennsylvania State Laboratory Accreditation and voluntary NELAP Accreditation. Laboratories seeking NELAP accreditation are required to meet the applicable requirements of Chapter 252 and the currently approved, adopted, and implemented TNI Standard.

The Chapter 252 regulation and/or the TNI Standard do not encompass every requirement that an accredited environmental laboratory must meet. Laboratories are responsible for knowing and adhering to all State, Federal, Program, and permit requirements applicable to the specific compliance purpose. For requirements specific to the analysis of drinking water, see 25 Pa. Code Chapter 109. The Pennsylvania Oil and Gas Program also mandates specific requirements that are located in 25 Pa. Code Chapter 78. The requirements delineated in Chapters 78 and 109 are in addition to those requirements of Chapter 252.

Requirements for the use of specific methodology or quality control practices may be contained in the Drinking Water Regulations (25 Pa. Code Chapter 109), Oil and Gas Program Regulations (25 Pa. Code Chapter 78), the most recent revision of the Code of Federal Regulations (40 CFR), or in a permit issued by the Department. These requirements must also be met.

This document contains specific requirements that must be met in order for a laboratory to obtain and maintain accreditation as an Environmental Laboratory performing testing or analysis of drinking water, non-potable water or solid & 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).

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12. The Noncoal Surface Mining Conservation and Reclamation Act (52 P.S. §§ 3001 – 3326).

The Department's Bureau of Laboratories' Laboratory Accreditation Program ("LAP") administers its accreditation programs in a manner that will ensure the protection of the environment and the health of the citizens of the Commonwealth of Pennsylvania.

2.0 APPLICATION PROCEDURE

2.1 Application Materials.

Chapter 252, Subchapter B outlines the regulatory authority granted to the LAP as it relates to Applications, Fees, and Supporting Documents. Application forms and instructions may be found at the Laboratory Accreditation Program's ("LAP") website. Laboratories are required to submit a full and complete application that includes all required attachments. In addition to the accreditation requirements, laboratories seeking accreditation with the LAP must meet the requirements of the Part 1 – Initial/Renewal Application Instructions relating to payment of fees and submission of an application for accreditation.

The Department requires accreditation for any analytical testing of drinking water, non-potable water, and solid & chemical materials conducted for compliance with any of the 12 statutes listed in 252.3, relating to Scope. The methods and analytes for which the LAP offers accreditation are complex and regularly amended. As such, the LAP does not maintain a master list of matrix/method/analyte accreditation offerings. Each laboratory must determine based on the matrix, regulatory program, or permit requirements what accreditation is necessary for the testing to be conducted. Laboratories are expected to complete the Part 2 – Methodology Requests application indicating for which matrices – methods – analytes accreditation is sought.

Laboratories may choose to request changes to their Scope of Accreditation at any time. Requests to add fields of accreditation must be submitted in accordance with the instructions for submission of a Part 4 – Add Fields of Accreditation application. Requests to withdraw accreditation can be submitted via letter with a signature of a responsible laboratory official.

NOTE: Even though a parent laboratory might be accredited, the sub-facilities or mobile laboratories (laboratories operating under the same parent organization, analytical procedures, and quality assurance system) are inspected or processed separately and each shall obtain its own Certificate of Accreditation. A separate application, including appropriate fees, is required for each sub-facility (i.e.: physical location). Any sub-facilities or remote laboratory sites, including mobile laboratories, are considered separate sites and are subject to separate announced and unannounced assessments. A mobile laboratory is a portable, enclosed structure within which testing or analysis of environmental samples occurs. Vehicles that do not house laboratory equipment or analytical testing but are used for transporting field measurement equipment are not considered to be mobile laboratories or separate facilities.

2.2 Laboratory Supervisor

Each laboratory seeking accreditation from the LAP is required to have a DEP-approved and qualified laboratory supervisor. The responsibilities of the laboratory supervisor are specifically outlined in § 252.301 and more generally, the laboratory supervisors are responsible for the laboratory's compliance with the accreditation requirements. The laboratory supervisor must meet the educational and experience requirements of § 252.302. Laboratories may choose to name one or more individuals to perform the functions and have responsibilities of a laboratory supervisor.

The laboratory must complete the Part 3 – Add/Change Laboratory Supervisor application in accordance with the Part 3 – Add/Change Supervisor Application Instructions.

The LAP will not approve an individual who does not meet BOTH the educational and experience requirements of the applicable standard. (NOTE: Both Chapter 252 and the TNI Standard include requirements for education and experience.) Experience must be hands-on analytical experience with the preparation, calibration, analysis, testing, etc. of samples using the same or similar instrumentation for which the laboratory seeks accreditation. Data review, management, or non-analytical experience will not be considered as applicable experience to meet the requirements.

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Chapter 252 outlines the specific requirements for which the laboratory supervisor is responsible in § 252.304. These requirements include, but are not limited to establishing and meeting the education and experience requirements for laboratory personnel, training of analytical testing personnel, maintaining documentation of training (including ethics training, and initial and continuing demonstration of capability), maintenance, review and approval, and retention of Standard Operating Procedures, ensuring compliance with required quality control, oversight of laboratory personnel, reporting of analytical results, etc.

Chapter 252 also outlines the amount of time a laboratory supervisor may be absent from the laboratory (maximum 21 days) before the laboratory must ensure that an alternate laboratory supervisor is performing the supervisory duties. If a laboratory is without a DEP-approved and qualified laboratory supervisor for more than 21 consecutive days, the laboratory must cease testing. The laboratory may choose to subcontract compliance testing to another accredited laboratory. Alternatively, the laboratory may choose to designate an individual to serve as an alternate or deputy laboratory supervisor. An alternate or deputy laboratory supervisor would need be approved by the DEP's LAP before he or she can be considered qualified to serve as a laboratory supervisor.

Laboratories seeking NELAP accreditation must have one or more laboratory supervisors (or technical directors, however named) that meet the requirements of the TNI Standard. In addition to one or more technical directors, the TNI Standard requires NELAP accredited laboratories to name a Quality Manager.

2.3 Quality Manual

Laboratories are required to develop and maintain a Quality Manual ("QM") (however named), that meets the requirements of 25 Pa. Code, § 252.401(a). The laboratory's QM must state the environmental laboratory's policies, operational procedures, protocols, and practices established to meet the requirements for accreditation. The policies and procedures that must be included or referenced in the laboratory's QM are:

- Ethics Policy Statement (§ 252.401(d))
- Document Control System (§ 252.401(c))
- Recordkeeping Procedures (§ 252.706)
- Procedures for termination of operations and transfer of records (§ 252.706(c))
- Procedures for detecting and permitting departures from established procedures (§ 252.401(i) and (h))
- Procedures for detecting and preventing improper practices (§ 252.304(b)(7))
- Sample Handling and acceptance procedures (§ 252.401(f) and (g))
- Reporting of analytical results (§ 252.401(j))
- The monitoring of quality of results (§ 252.401(l))

Laboratories that seek NELAP accreditation must also meet the requirements of Volume 1 of the TNI Standard.

2.3 Fees

Laboratories applying for Accreditation or Accreditation Renewal 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 the "Commonwealth of Pennsylvania". Fees are nonrefundable. The appropriate fee will include the Application Fee (Initial or Renewal for State or NELAP accreditation) and the applicable Category fee(s) for the specific fields of accreditation requested.

2.4 Submission and Review of Application

The LAP's website includes the necessary applications and instructions their completion. Laboratories must submit the completed applications and the required attachments directly to the LAP. The laboratory must

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follow the instructions provided in the document "Part 1 – Initial/Renewal Application for Accreditation Instructions."

All appropriate sections of the application must be completed for the requested fields of accreditation. The LAP will review the application and make a determination on the completeness, including evaluation of the laboratory supervisor qualifications. Missing or incomplete information will be requested before the application can be processed.

The LAP will review the laboratory's complete application, including the Quality Manual and other supporting documentation and SOPs to determine the laboratory's preliminary competency. If the laboratory demonstrates an ability to meet the accreditation requirements, the LAP will schedule an on-site assessment to determine compliance. NOTE: The LAP generally does not require on-site assessments of laboratories applying for Secondary NELAP accreditation.

3.0 OTHER ACCREDITATION REQUIREMENTS

3.1 Physical Facilities, Equipment, Supplies, Reference Materials

The laboratory must be furnished with all items of equipment, both testing and support, that are required to generate valid analytical results. The laboratory must also purchase equipment, supplies and reference materials that meet the requirements of § 252.306. In addition to maintenance of the equipment, the laboratory must maintain documentation and records that demonstrate compliance with all storage, preparation, and use requirements.

NOTE: For the purposes of this section, the references and requirements of § 252.306 are applicable to laboratories seeking State Accreditation. Laboratories seeking NELAP accreditation can use these references for guidance but must adhere to the requirements of the TNI Standard.

3.2 Methodology

Section 252.307 outlines the requirements for method selection and validation. This section of Chapter 252 also summarizes the sample collection, preservation, handling, transport, and acceptance requirements for accredited laboratories. The LAP has developed guidance to assist laboratory compliance with the sample handling requirements. This guidance is available on the Department's website.

3.3 Quality Assurance and Quality Control Requirements

Subchapter D of Chapter 252 outlines the specific requirements for quality control and quality assurance to which the laboratory must adhere. All laboratories are required to meet the Basic Requirements of § 252.401, which include requirements for:

- Quality Manual
- Document Control
- Recordkeeping
- Procedures for Detecting and Permitting Departures from Established Procedures
- Procedures for Detecting and Preventing Improper Practices
- Sample Handling and Acceptance
- Reporting Analytical Results
- Monitoring the Quality of Results

Laboratories seeking accreditation for chemistry, toxicity, microbiology, and radiochemistry must adhere to the requirements of the appropriate sections 252.402 through 252.405.

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NOTE: For the purposes of this section, the references and requirements of §§ 252.402 – 405 are for laboratories seeking State Accreditation. Laboratories seeking NELAP accreditation can use these references for guidance but must adhere to the requirements of the TNI Standard.

3.4 Proficiency Testing Studies

The Pennsylvania Environmental Laboratory Accreditation Regulations (25 Pa. Code, § 252.501) require that laboratories successfully complete at least one set of proficiency test ("PT") studies for each of the parameters for which accreditation is sought. The LAP has also developed a PT Guidance Document for Laboratories that more clearly explains the PT rules and how the Department interprets those rules. This guidance document is located at the LAP's website under "Compliance Assistance."

PT studies are required to be performed in the same manner as unknown/real environmental compliance samples. This means PT samples cannot be analyzed with extra quality control, additional replicates, or with multiple individuals performing the test. PT samples that are not handled in the same manner as real environmental samples will not be considered valid for compliance purposes.

Laboratories must pass the PT studies for each Field of Proficiency Testing ("FoPT") as required by the PA Bulletin before the LAP will consider granting accreditation. Once accredited, laboratories are required to analyze and obtain acceptable scores for each requested FoPT at least annually. PT studies are scored based on the closing dates of the studies and laboratories must maintain a history of at least one passing PT per FoPT every year; closing dates of successive PT studies for an FoPT cannot be more than 13 months apart.

Information on available PTs and approved PT providers may be obtained from the Laboratory Accreditation Program's *List of Available Fields of Proficiency Testing* and *List of Approved Proficiency Test Providers*.

Laboratories seeking NELAP accreditation are also subject to the requirements of Volume 1, Module 1 of the TNI Standard relating to Proficiency Testing studies. Laboratories seeking NELAP accreditation are required to perform PT studies more frequently than the Chapter 252 regulation requires of State accredited laboratories. NELAP laboratories must maintain successful PT performance in 2 out of the most recent 3 attempts for a FoPT and these attempts must occur no more than every 7 months.

3.5 Recordkeeping

Laboratories must maintain complete and accurate records of all laboratory activities. The Chapter 252 regulation includes numerous requirements for the generation and maintenance of records. These records may be electronic or hard-copy. In addition to the requirements within each of the other sections of Chapter 252, laboratories must maintain records in accordance with the requirements of § 252.706. Specifically, laboratories must ensure that the documentation maintained in the laboratory allows for historical reconstruction of all activities. The laboratory's records must also demonstrate compliance with the analytical and method requirements. This section also outlines the requirements for electronic records and changes to records.

3.6 Safe Drinking Water Act ("SDWA") Requirements

Laboratories that seek to obtain or maintain accreditation in the drinking water matrix must also meet the requirements of 25 Pa. Code, Chapter 109. Laboratories are required to review, validate, and report SDWA compliance samples in accordance with the requirements of § 252.708(a). The SDWA analysis, review, and reporting requirements are more fully described in guidance documents and other memoranda listed under "Compliance Assistance" on the LAP's website.

The Department has developed a process by which laboratories may seek approval to report qualified SDWA results to the Drinking Water Electronic Reporting system ("DWELR"). This process is outlined in the "Request to Report Qualified DW Sample Results Instructions" available on the LAP's website. NOTE: The Department will only consider sample results that can be considered valid for compliance purposes and the request to report qualified DW results is to be used as a last resort.

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3.7 Subcontracting Analyses

A laboratory must subcontract analyses covered under Chapter 252 to an appropriately accredited environmental laboratory. Laboratories may not subcontract testing to a laboratory that is not accredited and in compliance with Chapter 252. This would include laboratories with NELAP accreditation from another NELAP-recognized Accreditation Body. Secondary NELAP accreditation is not automatic. Laboratories must apply for and obtain accreditation from the LAP (i.e.: hold a valid Certificate of Accreditation from the PA-DEP).

A laboratory acting as an agent of a Public Water System ("PWS") that subcontracts samples to an accredited laboratory must ensure that the PWS receives all information required by 25 Pa. Code Chapter 109. The agent laboratory must notify the subcontracted laboratory that the sample is from a PWS so the subcontracted 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 subcontracts analyses must follow all required reporting procedures. The testing laboratory is responsible for reporting the results to the DWELR unless the testing laboratory authorizes another accredited laboratory to report results. This authorization must be made in writing.

In all cases, the subcontracted laboratory must be indicated on the final report, the subcontract laboratory's DEP Lab ID# must be noted on the report, and all subcontracted test results must be identified on the final report. Alternatively, the agent/originating laboratory may choose to provide the subcontract/testing laboratory's test report directly to the customer/client.

3.8 NELAP Accreditation Requirements

Laboratories seeking NELAP accreditation, whether Primary accreditation or Secondary accreditation, are required to meet the requirements of the current approved, adopted, and implemented version of the TNI Standard. Volume 1, Module 2 of the TNI Standard outlines the specific requirements for Management Requirements and Technical Requirements. Volume 1, Modules 3 through 7 outline the specific technical requirements for Asbestos, Chemistry, Microbiology, Radiochemistry, and Toxicity. Laboratories seeking NELAP accreditation are required to meet the requirements of the TNI Standard. Laboratories seeking NELAP accreditation from the Department are also required to meet the provisions of § 252.5 relating to NELAP Equivalency. Specifically, laboratories seeking NELAP (either primary or secondary) accreditation must meet several of the 25 Pa. Code Chapter 252 provisions:

- Comply with Subchapter B relating to applications, fees, and supporting documents
- Comply with Subchapter E relating to PT study requirements
- Comply with Subchapter F relating to assessment requirements
- Comply with Subchapter G relating to miscellaneous provisions
- Comply with § 252.307 relating to methodology
- Comply with § 252.401 relating to basic requirements

The LAP has developed a guidance document titled "NELAP Accreditation FAQ" that all NELAP laboratories should use to assist with compliance with the Chapter 252 provisions. This FAQ is available on the LAP website.

4.0 ON-SITE ASSESSMENT

Prior to granting Primary NELAP or State accreditation to an environmental laboratory, the Department will perform an on-site assessment of the laboratory in accordance with § 252.601. In addition, prior to granting accreditation for an additional field of accreditation, the Department may perform an on-site assessment. The Department may conduct announced or unannounced on-site assessments to ensure compliance with the conditions of accreditation, Chapter 252 and all other orders issued by the Department. All accredited laboratories will be reassessed approximately once every 2-3 years. Additional on-site assessments may be performed at the Department's discretion. The LAP has developed an On-Site Assessment guidance document for laboratories that more clearly explains the on-site assessment and corrective action process. The Department has also

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prepared a FAQ document relating to Corrective Actions. These guidance documents are available at the LAP's website under "Compliance Assistance."

The assessment may be general 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, analytical equipment, laboratory supervision and personnel, and a review of the appropriate records. The assessment will cover all of the fields of testing for which the laboratory seeks accreditation.

5.0 ACCREDITATION DECISION

5.1 Awarding Accreditation

The Department grants accreditation to laboratories that meet the requirements of Chapter 252. The LAP will issue an Accreditation Certificate valid for one year. Accompanying the Certificate is a Scope of Accreditation that outlines the specific Matrix – Method – Analyte combinations for which the laboratory is accredited and may perform DEP compliance testing. The LAP issues Scopes of Accreditation on an "as needed" basis, which would include times when a laboratory seeks to add or withdraw fields of testing from their Scope of Accreditation or when the LAP finds that the laboratory is out of compliance and accreditation should be suspended or revoked for one or more fields of accreditation.

Accredited laboratories are required to meet the requirements of § 252.704 (related to voluntary relinquishment), § 252.705 (related to use of accreditation), § 252.707 (related to subcontracting), and § 252.708 (related to reporting and notification). Each of these sections mandates additional requirements accredited laboratories must understand and comply with upon receiving accreditation from the LAP. Failure to meet the requirements of Chapter 252 are cause for denial, suspension, and even revocation of accreditation.

5.2 Denial, Suspension, Revocation of Accreditation

Laboratories that fail to meet the accreditation requirements are subject to denial, suspension, or revocation of accreditation. The causes for action against laboratories for non-compliance are listed in §§ 252.701, 702, and 703.

5.3 Expiration of Application

In accordance with § 252.207, applications for accreditation are valid for one year from the date of receipt. Applications open for more than one year automatically expire. If a laboratory fails to meet the accreditation requirements within one year and intends to continue with the accreditation process, the laboratory must pay the appropriate application fee to keep the application active.

6.0 ACCREDITATION STATUS

6.1 Accredited – Fields of Testing for which a laboratory meets the minimum requirements for accreditation are deemed "Accredited" and listed on the laboratory's Scope of Accreditation.

6.2 Not Accredited – Not Accredited is equivalent to an inactive accreditation status for which a laboratory must submit an application for accreditation in order to be considered for an upgrade to Accredited. Laboratories may not perform testing on DEP compliance samples when the accreditation status of an analyte is "Not Accredited."

6.3 Suspended – Suspended is an active accreditation status used to designate when a laboratory has not met or does not meet one or more of the requirements for accreditation but is not required to submit an application for accreditation in order to be considered for an upgrade to Accredited. Laboratories may not perform testing on DEP compliance samples when the accreditation status of an analyte is "Suspended."

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- 6.4 **Denied** – Denied is an inactive accreditation status used to designate when a laboratory has not demonstrated compliance with the accreditation requirements after submission of an application. Laboratories may not perform testing on DEP compliance samples when the accreditation status of an analyte is “Denied.”
- 6.5 **Applied** – Applied is an active accreditation status used to designate when a laboratory has submitted an application for accreditation but has not yet met all requirements for accreditation. Laboratories may not perform testing on DEP compliance samples when the accreditation status of an analyte is “Applied.” The LAP often will notify laboratories of a minimum amount of time to meet the accreditation requirements. Failure to meet the accreditation requirements within that timeframe would result in a denial of accreditation.

7.0 REQUIREMENTS FOR MAINTAINING ACCREDITATION

7.1 Continued Compliance

Laboratories are required to be in continual compliance with the accreditation requirements. At no time is a laboratory permitted, nor is it acceptable for a laboratory to be out of compliance. The Department performs regular on-site and off-site assessment activities to check the laboratory's compliance. Failure to meet the requirements for accreditation is cause for denial, suspension, or revocation of accreditation.

7.2 Applications for Renewal of Accreditation

Accredited laboratories shall submit a renewal application and the appropriate fee to the Department at least 60 calendar days prior to the expiration of the current accreditation certificate. Failure of the laboratory to submit a renewal application in a timely manner may result in the lapse of accreditation if the renewal application is not processed and a valid Certificate of Accreditation issued prior to the expiration of the laboratory's accreditation certificate.

7.3 Notifications of Changes

Laboratories are required to notify the LAP when changes occur to the laboratory's analytical capability, personnel, ownership, administrative information, etc. The requirements for notification and the timelines for the notification are outlined in:

- § 252.202 (transfer of laboratory accreditation and ownership changes);
- § 252.301(h) (temporary absences of laboratory supervisors);
- § 252.708(b) (permanent changes to laboratory supervisor)
- § 252.708(c) (change in legal name of laboratory)
- § 252.708(d) (change in any item contained in the application for accreditation)
- § 252.708(e) (change in analytical capability)
- § 252.708(f) (an out-of-State laboratory's change in accreditation from any other primary Accreditation Body)

The LAP has several application forms for use by laboratories when submitting notifications of changes. These applications include: Part 3 – Add/Change Laboratory Supervisor and Part 4 – Addition of Field of Accreditation, and Part 5 – Changes to Laboratory Information. The Part 5 application includes appendices for notices of changes in Ownership, Quality Assurance Officer, and Administrative Information. These applications, and their instructions for completion and submission, are available on the LAP's website.

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4.0 OUT-OF-STATE LABORATORIES

Out-of-State laboratories may apply for primary or secondary accreditation from the Department. The Department may recognize the accreditation of an environmental laboratory by another state accrediting authority if the standards for accreditation are substantially equivalent to those established under Chapter 252, and the laboratory is physically located within the state granting accreditation. Except as required by the Department's participation in the National Environmental Laboratory Accreditation Program ("NELAP"), the only other state accrediting authority recognized as having standards for accreditation that are substantially equivalent to those of the Department is the New York Department of Health's ("NY-DOH") accreditation for Asbestos. Out-of-State laboratories seeking primary or secondary accreditation from the Department must meet the same requirements as those within the borders of the Commonwealth of PA.

Out-of-State laboratories are also subject to the provisions of § 252.205. Both NELAP and non-NELAP accredited laboratories outside the borders of the Commonwealth are subject to these provisions. In addition to the previously described requirements, the out-of-State laboratory's PA accreditation is directly tied to the laboratory's primary accreditation from another accreditation body. If the laboratory's accreditation is denied, revoked, or suspended by a primary AB, the laboratory's authorization to perform testing or analysis in PA is automatically revoked for the same fields of accreditation as further explained in § 252.205(c).

The Department also reserves the right to conduct on-site assessments of laboratories seeking secondary accreditation with the LAP. The situations that might precipitate the Department's decision to conduct and on-site assessment are described in § 252.205(b).

In addition to the application fees of § 252.204, out-of-State laboratories are responsible for out-of-State reimbursement as outlined in § 252.206.