

PA-DEP Laboratory Accreditation Program	Secondary NELAP Accreditation FAQ
Laboratory Compliance Assistance	Revision 1
	Date: 06/13/2013

Secondary NELAP Accreditation FAQ

Disclaimer: The information in this FAQ does not supplant the provisions of the Environmental Laboratory Accreditation Regulations, 25 Pa Code, Chapter 109, 25 Pa Code, Chapter 252, or the 2009 TNI Standard. This document is a tool to help laboratories understand and comply with the requirements for secondary NELAP accreditation in the Pennsylvania Department of Environmental Protection's Laboratory Accreditation Program. If there is any disagreement between the contents of this document and any of the above regulations, the regulations shall prevail. The examples given in this document are for illustrative purposes only, meant to aide individuals in visualizing applications of the regulatory requirements. These examples do not represent all regulatory requirements, nor do the excerpts from the Environmental Laboratory Accreditation Regulation (25 Pa Code, Chapter 252) represent the whole of the accreditation requirements.

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REGULATORY REQUIREMENTS:

NOTE—Not all requirements are listed here. Applicant laboratories must review 25 Pa Code, Chapter 252 in its entirety to ensure compliance with the PA-DEP's accreditation requirements.

§ 252.3—Scope.

§ 252.3(a) "*Environmental Statutes*. This chapter applies to facilities that test or analyze environmental samples in the matrices listed in subsection (b) for the purpose of complying with the following environmental 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 – 6018.1003).
- (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 and Conservation and Reclamation Act (52 P.S. §§ 1396.1 – 1396.31).
- (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)."

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§ 252.3(b) “Matrix: The following matrices are included:

- (1) Drinking Water (DW)
- (2) Non-Potable Water (NPW)
- (3) Solid and Chemical Materials (SCM)”

§ 252.4—General Requirements.

§ 252.4(a) “Testing or analysis of environmental samples within a matrix identified in § 252.3 and to comply with a statutes listed in § 252.3 shall be performed by an environmental laboratory accredited under this chapter.”

§ 252.4(b) “An environmental laboratory testing or analyzing environmental samples in a matrix identified in § 252.3 and required by a statute identified in § 252.3 shall be accredited and in compliance with this chapter to generate data and perform analysis used to comply with an environmental statute listed in § 252.3.”

§ 252.5—NELAP/TNI Equivalency.

§ 252.5(b) “An environmental laboratory seeking NELAP accreditation shall:

- (1) Submit a complete application as provided in Subchapter B (relating to application, fees and supporting documents).
- (2) Comply with Subchapter E (relating to proficiency test study requirements).
- (3) Comply with Subchapter F (relating to onsite assessment requirements).
- (4) Comply with Subchapter G (relating to miscellaneous provisions).
- (5) Comply with the current edition of the NELAC Standard or TNI Standard.”

§ 252.5(d) “An environmental laboratory receiving NELAP accreditation from the Department may only test or analyze environmental samples within the Fields of Accreditation (FOAs) authorized by the accreditation received from the Department.”

§ 252.201—Application and Supporting Documents.

§ 252.201(a) “An environmental laboratory seeking accreditation for one or more FOAs within a matrix described in § 252.3 or that seeks to add an FOA, shall apply to the Department for accreditation in writing on forms provided by the Department. The applicant shall provide other relevant material requested by the Department.”

§ 252.201(b) “An application for accreditation must include the appropriate application fee in accordance with § 252.204.”

§ 252.203—Accreditation Renewal.

§ 252.203(a) “Applications for accreditation renewal shall be submitted annually to the Department at least 60 calendar days prior to expiration date of the current certificate of accreditation on forms provided by the Department.”

§ 252.203(b) “An application for accreditation renewal must include the appropriate application fee in accordance with § 252.204.”

§ 252.203(c) “Failure to submit an application for renewal in accordance with this section will result in a lapse in accreditation if the Department has not approved the renewal application prior to the expiration of the current certificate of accreditation. If a lapse in accreditation occurs, the

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environmental laboratory shall cease all testing or analysis of environmental samples for the affected FOAs.”

§ 252.205—Out-of-State Laboratories.

§ 252.205(a)(2)(iii) “*Secondary Accreditation.* An environmental laboratory seeking secondary accreditation from the Department shall:

- (A) Submit a properly completed application on forms provided by the Department.
- (B) Pay the appropriate fee.
- (C) Submit a copy of a valid accreditation certificate from the primary AB.
- (D) Submit a copy of all onsite assessment reports conducted by the primary AB within the last 3 years.
- (E) Submit any other material relevant to accreditation, upon request of the Department.”

§ 252.205(c) “If any portion of the secondary NELAP environmental laboratory’s accreditation is denied, revoked, or suspended by the Primary AB, the laboratory’s authorization to perform testing or analysis is automatically revoked for the same fields of accreditation.”

§ 252.501—PT Study Requirements.

§ 252.501(n) “An environmental laboratory seeking to obtain or maintain accreditation in the drinking water matrix shall participate in PT studies that meet the requirements of 40 CFR Part 141 (relating to primary drinking water regulations).”

§ 252.702—Revocation.

§ 252.702(d) “Within 72 hours of receiving notice of the revocation of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the revocation in writing of the revocation on a form approved by the Department.”

§ 252.703—Suspension.

§ 252.703(e) “Within 72 hours of receiving notice of the suspension of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the suspension in writing of the revocation on a form approved by the Department.”

§ 252.705—Use of Accreditation.

§ 252.705(a)(2) “Environmental laboratories accredited by the Department shall make accurate statements concerning their accreditation status.”

§ 252.705(b) “Environmental laboratories using the Department’s name, making reference to its accreditation status or using the Department’s logo in catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials, shall:

- (1) Distinguish between testing for which the laboratory is accredited and testing for which the laboratory is not accredited.
- (2) Include the environmental laboratory’s accreditation number.”

252.707—Subcontracting.

§ 252.707(a) “An environmental laboratory may not subcontract testing or analysis covered under this chapter to an environmental laboratory that is not accredited and in compliance with this chapter.”

§ 252.707(b) “The accreditation number of the subcontracted environmental laboratory shall be indicated on the final report.”

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§ 252.708—Reporting and Notification Requirements.

§ 252.708(a) “An environmental laboratory conducting testing or analysis of drinking water under Chapter 109 (relating to safe drinking water) shall:

- Meet the reporting and notification requirements of that chapter;
- Review all sample analysis data within 24 hours of acquisition of the initial sample results for microbiological, inorganic nonmetals, and trace metals analyses. The 24-hour deadline may be extended to a maximum of 72 hours to accommodate a holiday or weekend when the laboratory is closed for business;
- Review all sample analysis data within 7 days of acquisition of the initial sample results for organics.”

§ 252.708(b) “An environmental laboratory shall notify the Department, in writing, within 20 calendar days of a permanent change in laboratory supervisor.”

§ 252.708(c) “An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in the legal name of the laboratory.”

§ 252.708(d) “An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in any item contained on the application for accreditation.”

§ 252.708(e) “An environmental laboratory shall notify the Department, in writing, if a change in the laboratory’s capability to produce valid analytical results persists for more than 90 calendar days for any FOA listed on the laboratory’s Scope of Accreditation.”

§ 252.708(f) “An out-of-State environmental laboratory with secondary accreditation from the Department shall notify, in writing, the Department within 48 hours of any changes in the laboratory’s accreditation status from any other Primary AB.”

Questions Relating to Terminology:

Question: What does the Department mean by “accreditation number”?

Answer: The term “accreditation number” refers to the PA-DEP Laboratory ID # assigned to the laboratory. Each laboratory is assigned a unique ID # that must be included on all analytical test reports.

Question: What does the Department mean by a notification “in writing”?

Answer: Notification “in writing” consists of notification accompanied with a signature of a responsible laboratory official. This notification must be made in hard-copy form submitted via USPS, Fed-Ex, UPS, facsimile, etc. Notification via e-mail is not acceptable.

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Question: Why is notification via e-mail unacceptable?

Answer: The LAP does not consider e-mail an acceptable form of notification because it does not include an officially recognized form of signature. Additionally, e-mail does not guarantee that the LAP will receive the notification.

Questions Relating to Applications, Fees, and Supporting Documentation:

Question: I have Primary NELAP accreditation from another NELAP AB. Do I automatically have Secondary NELAP accreditation in PA?

Answer: No. All laboratories, both Primary and Secondary, are required to apply for and obtain accreditation from the PA-DEP prior to analysis of compliance samples. An Accreditation Certificate and Scope of Accreditation are not issued until all application requirements are fulfilled. A laboratory will never automatically have secondary NELAP accreditation. Laboratories are not accredited, nor may they claim accreditation without first obtaining a valid Accreditation Certificate and Scope of Accreditation.

Question: What materials do I need to submit with my application for Secondary NELAP accreditation?

Answer: You must submit the items listed in § 252.205(a)(2)(iii), which include a properly completed application, the appropriate fee, a valid copy of an accreditation certificate (and Scope of Accreditation, ACPL, etc.) from the Primary NELAP AB, copies of all on-site assessment reports conducted in the last 3 years, and any additional materials requested by the Department.

Question: What does “additional materials requested by the Department” mean?

Answer: Specific items are listed in the Department’s “Application Instructions” document that is available from the Laboratory Accreditation Program’s website or by request to eplabaccredit@pa.gov. Examples of additional documentation include a quality manual and confirmation from your Primary NELAP AB of approval of your laboratory’s Technical Director. The Department may also request other items it deems necessary.

Question: Is there any way to make the application process easier?

Answer: Yes. All applications must include “Application Part 1—Administrative Information”. Secondary NELAP applicants are not required to complete “Application Part 2—Methodology Requests.”

Initial Applications: Applicants may choose to mark accreditation requests directly on its Primary Certificate or Scope of Accreditation.

Renewal Applications: Applicants should list the location (page # and line #) of the particular FOA from its Primary Certificate, Scope, ACPL, etc. along with its accreditation requests to PA-DEP. This can be accomplished by noting the page # and line # of the Primary Scope directly on a copy of the PA-DEP’s Scope of Accreditation.

Question: What are some common mistakes that laboratories make during the renewal application process?

Answer: Common mistakes made during the renewal application process include:

1. Selecting “No changes to Scope of Accreditation Requested” on Part 1 of the application, but not fully reviewing their current PA-DEP Scope of Accreditation and realizing later that additional FOAs should have been requested.

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2. *Miscalculation of the Accreditation Fees. Remember that you must submit the “Application Fee—Renewal Application for NELAP Accreditation” **and** all appropriate category fees based on the number of matrices requested for a particular category.*
3. *After receipt of your updated renewal Certificate and Scope, laboratories frequently forget to review their new accreditation status. Many times Secondary NELAP applicants think that they have accreditation from their Primary when they submit their application to PA-DEP, when they actually do not and thus, they are not granted accreditation from PA-DEP.*
4. *Forgetting to submit all of the necessary documentation as outlined in the “Application Instructions.” Failure to submit all the necessary information will delay the processing of your application.*

Question: What happens if I forget to request a specific FOA on my renewal application, but I have accreditation from my Primary AB?

*Answer: The Department will only grant secondary NELAP Accreditation for those FOAs for which the laboratory has been granted Primary NELAP accreditation from a recognized NELAP AB **AND** for which the laboratory has applied for accreditation. The Department will not assume that a Secondary NELAP applicant automatically wishes to apply for accreditation for any FOA not specifically requested on its initial or renewal application for accreditation to the PA-DEP. **DO NOT ASSUME** that since you hold accreditation from your Primary AB that you have been granted accreditation from PA-DEP.*

Question: If I apply for Secondary NELAP accreditation in PA for an FOA that I have not yet been granted Primary Accreditation for, how is this application handled?

*Answer: The Department will only grant accreditation for those FOAs listed as “Accredited” on your Primary Scope of Accreditation. Your laboratory would not be permitted to analyze PA-DEP compliance samples without first receiving accreditation and an updated Scope of Accreditation from PA-DEP that lists these FOAs. It is the laboratory’s responsibility to provide the PA-DEP with an updated Scope of Accreditation from the Primary AB when the laboratory obtains accreditation for these FOAs. The laboratory **SHALL NOT** assume that because accreditation is granted by the Primary AB that it may analyze compliance samples from PA-DEP or claim accreditation from PA-DEP.*

Question: Does PA-DEP require accreditation for sample preparation methods?

Answer: Yes. Certain methods do not include the necessary sample preparation procedures; these preparation procedures are listed in separate methods. The PA-DEP requires that laboratories have accreditation for an appropriate preparation method if requesting accreditation for a method that does not include the sample preparation procedure. For example, EPA 8260 does not include the purge and trap preparation procedure. In order for a laboratory to be granted accreditation for EPA 8260 in NPW, the laboratory must apply for and be granted accreditation for EPA 5030.

Question: My Primary NELAP AB does not accredit for separate sample preparation methods, what does that mean for me?

Answer: The PA-DEP will not grant accreditation for a determinative method without first granting accreditation for the preparation method. So, you should obtain confirmation from your Primary NELAP AB that it reviewed and approved the specific preparation methods for which you are applying for accreditation from the PA-DEP. Once your Primary NELAP AB confirms that it reviewed and approved these preparation methods, the PA-DEP will grant your accreditation.

Question: Does PA-DEP require accreditation for Air testing?

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Answer: No. The PA-DEP does not require accreditation for Air. In fact, the PA-DEP does not offer accreditation for Air. The PA-DEP requires accreditation for DW, NPW, and SCM.

Questions Relating to Scope of Accreditation:

Question: What FOAs am I permitted to perform compliance testing for in PA-DEP?

*Answer: PA-DEP requires that all laboratories performing testing or analysis for compliance samples actually have a valid PA-DEP Certificate and Scope of Accreditation. Secondary NELAP accredited laboratories are ONLY accredited for those FOAs that are listed on their PA-DEP Scope of Accreditation **AND** are also included on a valid Certificate and Scope from their Primary AB.*

Question: What happens if I lose accreditation from my Primary AB for an FOA that is listed on my PA-DEP Scope of Accreditation?

*Answer: In accordance with § 252.205(c) "If any portion of the secondary NELAP environmental laboratory's accreditation is denied, revoked, or suspended by the Primary AB, the laboratory's authorization to perform testing or analysis is **AUTOMATICALLY REVOKED** for the same fields of accreditation." This means that you, as a Secondary NELAP laboratory **SHALL NOT** analyze samples for which you are suspended, revoked, or denied from your Primary AB regardless of the accreditation status listed on your PA-DEP Scope of Accreditation.*

Question: What happens if my PA-DEP certificate of accreditation expires before I am able to renew it?

*Answer: Laboratories that perform compliance testing in PA-DEP must hold a valid Accreditation Certificate and Scope of Accreditation. Regardless of whether or not a laboratory holds accreditation with another State, it **shall not** perform compliance testing or claim accreditation without holding a valid Accreditation Certificate from PA-DEP.*

Question: What happens if I analyze PA-DEP samples when I do not have a valid PA-DEP Certificate and Scope of Accreditation?

Answer: You would be in violation of 25 Pa Code, Chapter 252 (Environmental Laboratory Accreditation Regulation) and the Environmental Laboratory Accreditation Act of 2002 (27 Pa C.S. §§ 4101 – 4113). The samples analyzed and results obtained while in violation of the accreditation requirements are invalid for compliance purposes

Questions Relating to Subcontracting and Client Needs:

Question: What are my responsibilities relating to finding a subcontract laboratory?

Answer: As a Secondary NELAP accredited laboratory, it is your responsibility to ensure that you meet your client's needs. You must contact your client and inform him/her that testing will be subcontracted. You should get confirmation/approval from your client in writing.

You are also responsible for ensuring that the subcontract laboratory actually holds accreditation for the testing to be subcontracted. Laboratories are not permitted to subcontract testing to a laboratory that is not a PA-DEP accredited laboratory. The Department recommends that you obtain written confirmation from the subcontract laboratory prior to making the subcontract agreement and/or sending the samples.

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Question: What are my responsibilities if I am the laboratory receiving subcontracted samples for analysis?

Answer: As a laboratory that is receiving samples from another laboratory (meaning you are the subcontract laboratory), it is your responsibility to ensure that you meet the client's needs. The laboratory contracting with you is also your client. You must ensure that you are accredited for the particular FOA (matrix, method, and analyte) before accepting the samples for analysis. You must also ensure that samples are received, handled, prepared, and analyzed properly and with all mandated procedures including adherence to method requirements, holding times, sample preservation, and quality control. These results must be reported accurately and unambiguously.

Question: As a Secondary NELAP accredited laboratory, can I subcontract to a non-NELAP accredited laboratory?

Answer: Maybe. You must find out what accreditation requirements must be met. Specifically, find out if the client needs and/or wants their testing to be conducted by a NELAP accredited laboratory, or if the laboratory needs a laboratory accredited in accordance with the PA-DEP's 25 Pa Code, Chapter 252. If the client needs a PA-DEP accredited laboratory, then the samples may be subcontracted to a non-NELAP laboratory that is accredited in the PA-DEP's State accreditation program.

Question: What information do I need to provide to the subcontract laboratory?

Answer: You must provide all necessary information to ensure that the subcontract laboratory can properly and completely report analysis results and ensure adherence to holding time requirements. Additionally, if the sample is an SDWA compliance sample, the subcontract laboratory must be provided with all necessary information to provide appropriate notification as required by 25 Pa Code, Chapter 109 including, but not limited to, Client Name, PWS ID#, sample type, date, time, and location.

Remember, whether you are the laboratory doing the subcontracting or the laboratory receiving the subcontracted samples, and regardless of whether a laboratory falls within the same corporate structure (i.e.: "sister laboratories"), the requirements for meeting client needs and ensuring accreditation must be met.

Questions Relating to Reporting of Test Results:

Question: Are there any special PA-DEP test report requirements that I must meet as a Secondary NELAP accredited laboratory in the PA accreditation program?

Answer: Yes. As a laboratory accredited by the PA-DEP, you must include your PA-DEP Laboratory ID # on your test reports when you report results that require and/or request PA-DEP accreditation. You must also clearly identify any results that do not meet all applicable accreditation requirements. For example, if the sample was received out-of-hold, the instrumentation is not functioning properly (e.g.: an oven temperature was out of control), the required QC was out of control limits or not analyzed at all, these results must be flagged and appropriately reported to the client on the test report.

Question: How must I report subcontracted results?

Answer: In accordance with § 252.707(b) "The accreditation number of the subcontracted environmental laboratory shall be indicated on the final report." Even though the 2003 NELAC Standard states that the name or accreditation number of the subcontract laboratory must be included

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on the analytical report, 25 Pa Code, Chapter 252 supersedes this option. As a Secondary NELAP accredited laboratory in PA, you must include the accreditation number of the subcontract laboratory. Additionally, the subcontracted results must be **clearly** identified as subcontracted. For example, including the accreditation number of the subcontract laboratory in an “analyst” column **does not** designate results as being subcontracted.

Also, both the 2003 NELAC Standard and the 2009 TNI Standard include the requirement to include the “name and address of the laboratory, and the location where the tests were carried out, if different from the address of the laboratory” issuing the test report. This would apply to all subcontracted test results.

Question: Do I have to designate or flag test results that are not covered under my PA-DEP NELAP Scope of Accreditation? If so, how?

Answer: Yes. You must clearly identify any reported result for which you do not hold PA-DEP accreditation. You may do this by using a qualifier flag stating something to the effect that the results of this testing are not covered by our PA-DEP NELAP Scope of Accreditation. It is **not** acceptable to include statement to the effect that PA-DEP does not offer accreditation or that accreditation is not required.

Questions Relating to Notification Requirements:

Question: Do I have to notify the PA-DEP if I lose accreditation from my Primary AB?

Answer: Yes. In accordance with § 252.708(f) “An out-of-State environmental laboratory with secondary accreditation from the Department shall notify, in writing, the Department within 48 hours of **any** changes in the laboratory’s accreditation status from any other Primary AB.”

Question: The NELAC Standard and TNI Standard have specific notification requirement timelines; does PA-DEP have any special notification timelines?

Answer: Yes. The following 25 Pa Code Chapter 252 notification timelines supersede those listed in either the 2003 NELAC Standard or the 2009 TNI Standard:

- § 252.202(a) “The new owner of an accredited environmental laboratory shall notify the Department in writing within 10 calendar days following a change in laboratory ownership. Within 30 calendar days following the change in laboratory ownership, an accredited laboratory shall do the following:
 - (1) Submit an ownership transfer application, indicating any changes in the equipment, methodology and staffing.
 - (2) Pay the application fee for ownership transfer.
 - (3) Agree to correct any violations that exist at the time of the sale or transfer in accordance with a schedule that is acceptable to the Department.”
- § 252.708(b) “An environmental laboratory shall notify the Department, in writing, within 20 calendar days of a permanent change in laboratory supervisor.”
- § 252.708(c) “An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in the legal name of the laboratory.”
- § 252.708(d) “An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in any item contained on the application for accreditation.” This includes change in address.
- § 252.708(e) “An environmental laboratory shall notify the Department, in writing, if a change in the laboratory’s capability to produce valid analytical results persists for more than 90

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calendar days for any FOA listed on the laboratory's Scope of Accreditation." This would include loss of trained analyst and equipment malfunction/breakdown.

Question: Are there any special drinking water notification requirements that I must meet?

Answer: Yes. In addition to meeting the reporting and notification requirements of 25 Pa. Code, Chapter 109, accredited laboratories must also meet the following notification requirements relating to drinking water sample results:

- Review all sample analysis data within 24 hours of acquisition of the initial sample results for microbiological, inorganic nonmetals, and trace metals analyses. The 24-hour deadline may be extended to a maximum of 72 hours to accommodate a holiday or weekend when the laboratory is closed for business;
- Review all sample analysis data within 7 days of acquisition of the initial sample results for organic analysis.