

PA-DEP Laboratory Accreditation Program	NELAP Accreditation FAQ
Laboratory Compliance Assistance	Revision 2.1
	Date: August 26, 2020

## 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 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 – 1369.31).

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(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).”

§ 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 statute 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.
- (6) Comply with § 252.307 (relating to methodology).
- (7) Comply with § 252.401 (relating to basic requirements).”

§ 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 in writing on forms provided by the Department and in the format specified by the Department.”

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

§ 252.203(d) “Within 48 hours of expiration of the certificate of accreditation, the laboratory shall notify each of its customers affected by the expiration of the certificate of accreditation in writing of the lapse in accreditation. The Department may choose to require the laboratory to use specific language in the written notice or to require Department approval of the notice before issuance.”

**§ 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(b) “The Department may conduct an onsite assessment or require analysis of a proficiency test study by an out-of-State environmental laboratory seeking secondary accreditation for reasons which may include addressing complaints from the public or Department personnel, discrepancies with environmental sample results, onsite assessment deficiencies, frequent errors in reporting data to the Department and suspicions of fraud regarding data quality. If the Department determines that an onsite assessment is required, the environmental laboratory shall pay the Department’s travel costs associated with the onsite assessment in accordance with § 252.206 (relating to out-of-State onsite reimbursement).”

§ 252.205(c) “If any portion of the secondary 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.”

**§ 252.307—Methodology.**

§ 252.307(a) “An environmental laboratory shall follow the requirements for testing or analysis, sample collection, sample preservation and holding times specified in this section.”

§ 252.307(b) “An environmental laboratory shall select an analytical method for a specific test or analysis that meets the following criteria:

- (1) The method is appropriate for the analyte and sample matrix.
- (2) The method is required by, or considered appropriate for use under, applicable State or Federal regulations, a permit, an order, or is an approved alternate method under subsection (c).
- (3) The method enables the laboratory to quantitate at required levels.”

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§ 252.307(f) “When an environmental laboratory collects a sample to be analyzed, the sample collection method required by applicable State and Federal laws, regulations or permit conditions shall be followed.”

§ 252.307(g) “An environmental laboratory shall follow the sample container, preservation procedures and holding times required by State and Federal regulations. If the sample container, preservation procedures and holding times are not required by State or Federal regulations, an environmental laboratory shall follow the sample container, sample preservation procedures and holding time established in the method.”

§ 252.307(j) “An environmental laboratory shall maintain instructions for sample collection and preservation that meet the requirements of subsections (f) and (g).

- (1) The environmental laboratory’s instructions must accurately reflect all aspects of the sample collection and preservation requirements for the particular analyses, including the following:
  - (i) Container type, size and number of containers or bottles.
  - (ii) Sample collection method, amount of sample required and explanation of other specific requirements for sample collection such as “zero headspace” and “first draw.”
  - (iii) Chemical preservation, including type of preservation and the procedure used to preserve the sample.
  - (iv) Thermal preservation, including the temperature requirements and procedure used to preserve the sample.
  - (v) Field blank requirements.
  - (vi) Holding time.
- (2) The environmental laboratory shall make the sample collection and preservation instructions available to all laboratory sample collection personnel and to customers and clients that collect samples.”

**§ 252.401—Basic Requirements.**

§ 252.401(f) “An environmental laboratory shall establish procedures for handling environmental samples.

- (1) The environmental laboratory shall implement procedures for checking and verifying the condition of the sample. The results of these checks shall be recorded. The environmental laboratory shall check:
  - (i) The sample container and the sample preservation, both thermal and chemical, of each sample.
  - (ii) The sample pH for all samples to be analyzed for whole effluent toxicity and safe drinking water chemistry fields of accreditation, unless the sample is collected by the environmental laboratory performing the analysis.
  - (iii) The sample for the presence of residual chlorine when the presence of residual chlorine will compromise the validity of the test.
- (2) The laboratory shall utilize a recordkeeping system that meets the requirements of § 252.706 to document receipt of all sample containers. The recordkeeping system must include the following:
  - (i) The client/project name.
  - (ii) The date, time and location of sample collection, name of sample collector and field identification code.
  - (iii) The date and time of laboratory receipt and identification of the individual receiving the sample at the laboratory.

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- (iv) Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.
- (v) A unique laboratory ID code that corresponds to the information required by this paragraph.
- (vi) An identification of the person making the entries.”

§ 252.401(g) “An environmental laboratory shall have a sample acceptance policy that clearly outlines the circumstances under which environmental samples will be accepted or rejected. The environmental sample acceptance policy must include the following areas:

- (1) Sample identification, location, date and time of collection, collector’s name, preservation type and sample type.
- (2) Sample labeling.
- (3) Use of appropriate containers and sample preservation method.
- (4) Adherence to holding times specified in the regulation and when not specified by the regulation, adherence to the holding times specified by the method.
- (5) Sufficient sample volume shall be available to perform the necessary testing and analysis, including any required quality control testing or analysis.
- (6) Procedures to be used when samples show signs of damage, contamination or inadequate preservation.”

§ 252.401(j) “An environmental laboratory shall develop procedures for reporting results of testing or analysis of environmental samples. Each test report must include at least the following information, except as specified in subsection (k).

- (1) The name and address of the laboratory.
- (2) The total number of pages in the report, including any addendums, in the format of Page x of y.
- (3) The name and address of the client.
- (4) An identification of the test method used.
- (5) An identification of the samples including the client identification code.
- (6) The date and time of sample collection.
- (7) The date of sample analysis.
- (8) The date and time of sample preparation or analysis, or both, if the holding time requirement for either activity is less than or equal to 72 hours.
- (9) The test results and units of measurement.
- (10) The quantitation limit.
- (11) The names, functions and signatures of the persons authorizing the test report.
- (12) An identification of results reported on a basis other than as received (for example, dry weight).
- (13) An identification of testing or analysis results not covered by the laboratory’s scope of accreditation.
- (14) An identification of results that do not meet the requirements of this chapter.
- (15) An identification of subcontracted results.
- (16) A unique test report identifier code, such as a serial number or other unique code.
- (17) An identification of amendments to the test report. The laboratory shall uniquely identify all amendments to a test report. The amended report shall be issued in the form of a further document, data transfer or completely new test report, which includes the statement “Amended” or “Revised” and the identification of the unique laboratory code that meets the requirements of paragraph (16).”

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§ 252.401(m) “To the extent possible, results of testing or analysis of environmental samples shall be reported only if all quality control, analytical testing and sample acceptance measures are acceptable. If a quality control, analytical testing or sample acceptance measure is found to be out of control and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the failed quality control measure shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers.”

§ 252.401(n) “Policies, procedures, protocols and practices specified in this section must be in writing and be followed.”

§ 252.401(o) “The environmental laboratory shall clearly identify opinions and interpretations as opinions and interpretations on test reports. When test reports include opinions and interpretations, the laboratory shall include an explanation for the basis upon which the opinions and interpretations have been made.”

**§ 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. The Department may require the laboratory to use specific language in the written notice or require Department approval of the notice before issuance.”

**§ 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 suspension. The Department may require the laboratory to use specific language in the written notice or require Department approval of the notice before issuance.”

**§ 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.”

§ 252.705(d) “NELAP accredited laboratories shall accompany the Department’s name or the NELAP logo with the phrase “NELAP accredited” and the laboratory’s accreditation number when using the Department’s name or the NELAP logo on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials.”

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**§ 252.706—Recordkeeping.**

§ 252.706(b) “An environmental laboratory shall maintain records, including original handwritten data, that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples, proficiency test studies, initial demonstration of capability or demonstration of continued proficiency.

These records include the following:

- (1) Start and end dates and times of incubations, drying cycles, digestion, distillations, and the like, when a minimum or maximum time is specified by method, regulation or permit.
- (2) Unequivocal link between the laboratory’s sample identification number to the results of all associated quality control.
- (3) Instrument identification.
- (4) Identification of, or reference to, the standards, reagents, media, supplies, and the like, used during sample preparation or analysis, or both.
- (5) The results of chemical or thermal preservation verifications or adjustments, or both.
- (6) Date of sample preparation or analysis, or both.
- (7) Time of sample preparation or analysis, or both, if the holding time for either activity is less than or equal to 72 hours.
- (8) Manual calculations.
- (9) Test results.”

**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.”

**§ 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:

- (1) Meet the reporting and notification requirements of that chapter;
- (2) Review all sample analysis data within 24 hours of acquisition of the initial sample results for 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;
- (3) For organic and radiochemical analyses, review all sample analysis data within 7 days of acquisition of the initial sample results for organic analysis.”
- (4) For microbiological results, read all sample results within 30 minutes of the end of the incubation period.
- (5) Analyze the laboratory control sample at a concentration at or below the maximum contaminant level.
- (6) Report to the Drinking Water Environmental Lab Reporting system only those analytical test results that meet the method, regulatory and permit requirements for sample collection, preservation, holding time, sample analysis and quality control performance, unless the Department has specifically approved that the result may be reported.”

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

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§ 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.”

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**Questions Relating to Terminology:**

**Question: What is the difference between Primary and Secondary accreditation?**

*Answer: Primary accreditation is granted when the PA-DEP directly performs all activities related to the evaluation of the laboratory’s compliance with the accreditation requirements for which the laboratory is subject, including but not limited to: on-site assessment, evaluation and approval of the laboratory supervisor qualifications, evaluation of PT study performance and acceptability, etc. Secondary accreditation is granted when the PA-DEP accepts the evaluation and accreditation decision related to the compliance of a laboratory made by another Accreditation Body.*

*There is no practical difference, as it relates to validity or acceptability of data, between Primary and Secondary accredited laboratories. The practical difference is the agency making the primary decision for the laboratory’s accreditation.*

*The Department offers Secondary accreditation to laboratories with Primary NELAP accreditation from another NELAP-Recognized Accreditation Body and from the NY-DOH ELAP for Asbestos.*

**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.*

**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.*

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## **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. Secondary NELAP applicants are also required to provide confirmation (via email, letter, etc.) from their Primary NELAP AB of the laboratory's Technical Director approval.

**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](mailto:eplabaccredit@pa.gov). Examples of additional documentation include a quality manual. Laboratories seeking DW accreditation are required to submit an SDWA Reporting SOP that meets the requirements of 25 Pa. Code § 109.810 and § 252.708 (See Memo to DW Accredited Labs RE: SDWA Reporting and Notification Requirements available on the LAP's website). The Department may also request other items it deems necessary.

**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

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*Primary AB that it may analyze compliance samples from PA-DEP or claim accreditation from PA-DEP.*

**Question: Is there any way to make the application process for Secondary NELAP accreditation 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. 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.*
- 2. 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.*

*Some common mistakes made by Secondary NELAP laboratories 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.*
- 2. 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.*

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

*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: 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.*

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**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 an appropriate 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.*

*NOTE: As a Secondary NELAP applicant, you are responsible for applying to PA-DEP, and obtaining accreditation, for any preparation method(s) that will be used for PA-DEP compliance purposes. If your Primary NELAP AB does not list preparation methods on its Scope, Certificate, ACPL, etc., the PA-DEP will require confirmation from your Primary NELAP AB that the preparation methods for which you are apply for accreditation in PA have been reviewed and deemed acceptable/approved/however named by the Primary NELAP AB for use. If your Primary AB does not confirm the approval of a particular preparation method, then the PA-DEP will not grant accreditation for the preparation method. You are not permitted to use preparation methods that are not listed on your PA-DEP 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 have a valid PA-DEP Certificate and Scope of Accreditation. Laboratories are only accredited for those matrix – method – analyte combinations listed on the laboratory’s PA-DEP 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. Additionally, in accordance with § 252.708(f), Secondary NELAP accredited laboratories must notify the Department in writing within 48 hours of any changes to its Primary 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 for 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 PA-DEP compliance testing or claim PA-DEP accreditation without holding a valid Accreditation Certificate from PA-DEP.*

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**Question: What happens if I analyze PA-DEP compliance 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. You are also required to note that the testing was not performed by an appropriately accredited laboratory. The TNI Standard, V1M2: 5.10.1 and 5.10.3.1.b require that laboratories:*

- Include all the information requested by the customer and necessary for the interpretation of the test results, and*
- Where relevant, include a statement of compliance/non-compliance with requirements and/or specifications.*

*25 Pa. Code § 252.401(j) also mandates that the laboratory identify test or analysis results that are not covered by the laboratory’s Scope of Accreditation.*

**Questions Relating to Subcontracting, Client Needs, and Contract Review:**

**Question: What if a client or other AB expects, needs, or wants something different than what the TNI Standard or Chapter 252 requires.**

*Answer: As a NELAP AB, the PA-DEP enforces the compliance requirements of the TNI Standard for its applicant laboratories. In addition, all laboratories accredited by the PA-DEP must meet the other regulatory, method, and permit requirements established by the laws and regulations of the Federal Government and the Commonwealth of PA. If a client, customer, other Accreditation Body, etc. determines that a different level of compliance or expectation for performance is warranted, necessary, or required, then the laboratory should meet those expectations of compliance. Note that when a compliance requirement is different from one agency/client to another, the laboratory must adequately meet, through procedure, process, and supporting documentation that it met the “Review of Requests, Tenders, and Contracts” and “Service to Client” sections of the TNI Standard. NELAP accredited laboratories must establish and maintain procedures for the review of requests, tenders, and contracts and be willing to cooperate with customers. In general terms, this means that the laboratory must know and attempt to meet the needs of the clients and regulatory authorities. Where the laboratory cannot meet the needs or expectations, then the laboratory must resolve any differences and document these decisions.*

*When a difference in client needs/demands results in a conflict with the laboratory’s accreditation requirements, then these differences would need to be noted on the final test report, as required by V1M2: 5.10. Specifically, section 5.10.3.1.b states, “in addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of test results, include the following: where relevant, a statement of compliance/non-compliance with the requirements and/or specifications.” The laboratory cannot agree to a client/customer instruction to deviate from the accreditation requirements without noting these non-conformances on the test report, even if such an agreement is documented between the client and the laboratory. Also note, in many cases the client is not the end data user, it is a regulatory agency or even the Accreditation Body itself. The laboratory must ensure that meeting a client request does not violate a regulatory compliance requirement.*

*When in doubt, maintain thorough documentation of client or contract requests and then include a description of any non-conformance to these agreements AND any non-conformance to the*

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*accreditation requirements on the final test report. Documentation could include written and agreed upon contracts, email communications, qualifiers on test reports, descriptions in case narratives, etc.*

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

*Answer: As a 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 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.*

**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. In this case you have multiple clients; the permittee, laboratory contracting with you for the testing, and the DEP. 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 in accordance with any Federal, State, or method requirements.*

**Question: As a 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 the testing to be conducted by a NELAP accredited laboratory, or if the client/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.*

*NOTE: A laboratory that holds NELAP accreditation from another NELAP-Recognized AB is not necessarily accredited to analyze PA-DEP compliance samples. Laboratories performing PA-DEP compliance testing must have a valid Certificate and Scope of Accreditation from the PA-DEP's LAP.*

**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. See Memo to DW Accredited Labs RE: SDWA Reporting and Notification Requirements available on the LAP's website.*

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*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 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 include all elements of § 252.401(j) in addition to the test report requirements of the TNI Standard. Some key elements that are specific to PA-DEP include, but are not necessarily limited to:*

- *Page numbering in an “x of y” format.*
- *The laboratory must include the quantitation limit for each result. Even if the laboratory is reporting results to a different limit, such as the MDL, the quantitation limit for each analyte must be included on the report.*
- *Data qualifier flags relating to any non-conformance (whether it be sample collection, analytical testing, quality control, client-specific requirement, program requirement, etc.) must be included directly with the sample results. 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.*
- *Amendments to test reports must include the statement “Amended” or “Revised” and must include the identification of the unique test report identifier code, such as serial number or other unique ID code from the original 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 TNI Standard makes no reference to an accreditation number of the laboratory, the TNI Standard states that the laboratory performing the subcontracted work shall be indicated on the final report. The TNI Standard also requires that the name, address of the laboratory, and the location where the testing were carried out be included on the test report. As a NELAP accredited laboratory in PA, in addition to the name and address of the subcontract laboratory, you must also 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.*

*NOTE: The TNI Standard includes 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.*

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**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. Nor is it acceptable to include a statement referring the client or any other individual to a website, the laboratory's Scope of Accreditation, etc. Any non-accredited test results must be flagged as such directly on the test report.*

**Questions Relating to Notification Requirements:**

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

*Answer: Yes. The following 25 Pa Code Chapter 252 notification timelines supplement or even supersede those listed in the 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 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 data review and notification requirements of 25 Pa Code, § 252.708(a), relating to drinking water samples:*

- *Review all sample analysis data within 24 hours of acquisition of the initial sample results for 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**;*
- *For organic and radiochemical analyses, review all sample analysis data within 7 days of acquisition of the initial sample results for organic analysis."*

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- *For microbiological results, read all sample results within 30 minutes of the end of the incubation period.*
- *Analyze the laboratory control sample at a concentration at or below the maximum contaminant level.*
- *Report to the Drinking Water Environmental Lab Reporting system only those analytical test results that meet the method, regulatory and permit requirements for sample collection, preservation, holding time, sample analysis and quality control performance, unless the Department has specifically approved that the result may be reported.*

**Question: What is the process for reporting results of SDWA compliance samples when the results do not meet every single requirement, such as sample temperature, sample preservation, or quality control failures (e.g.: matrix spike, surrogate failures, initial calibration, continuing calibration, internal standard)?**

*Answer: The Department’s Drinking Water Electronic Reporting (“DWELR”) system does not have a mechanism to accept data qualifiers. Therefore, reporting results associated with any non-conformance (even ones that do not impact the data results) is a violation of the conditions of accreditation to include appropriate data qualifier flags for any sample results that do not meet the quality control, analytical testing, or sample acceptance measures (§ 252.401(m)). The Department has developed a system whereby an accredited laboratory may request to report qualified DW results. Only results that have specifically been approved to be reported through this “qualified results” system may be reported. The instructions and request form for this process can be found on the PA-DEP LAP website.*

**Question: What does “closed for business” mean as it relates to how quickly SDWA results must be reviewed and validated?**

*Answer: For the purposes of meeting the requirements of § 252.708(a), “closed for business” means that the laboratory is closed, and no one is working. A certain section of the laboratory may be closed for business and another area may not be. For example, the microbiology analysts may be required to come to work on a weekend or holiday to read total and fecal coliform results that come out of the incubator. The microbiology section would be “open for business” while the rest of the laboratory, organics, wet chemistry, etc. is closed.*

*The extension of time for a “close of business” only applies to inorganic non-metals and trace metals analyses. And, the timeline for determining when the results must be reviewed is established by the date and time of ACQUISITION of the result, not when the laboratory re-opens for business. This means, if the result is obtained at 2:00am on Friday, December 23, and the laboratory is closed for a week between Christmas and New Year’s (Saturday, December 24 – Sunday, January 1), the laboratory must make arrangements for the data to be reviewed within the appropriate timelines as established by § 252.708(a), i.e.: within 72 hours of the acquisition of the result, or for the purposes of this example, by 2:00am December 26<sup>th</sup>.*

**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.”*

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## **Questions Relating to Sample Collection, Handling, Acceptance, & Rejection:**

**Question:** There are a lot of new requirements related to the Department's expectations of an accredited laboratory for sample collection and transport instructions, sample acceptance, and sample rejection. Are there any tools available to help labs understand these requirements?

**Answer:** *The Pennsylvania Department of Environmental Protection Bureau of Laboratories has finalized a technical guidance document providing guidelines for the collection, receipt and handling of samples. The document is available on the PA DEP Laboratory Accreditation Program website:*

<http://www.depgreenport.state.pa.us/elibrary/GetDocument?docId=1660439&DocName=01%20-%20GUIDELINES%20FOR%20SAMPLE%20COLLECTION%2C%20RECEIPT%2C%20AND%20HANDLING.PDF%20%20%3Cspan%20style%3D%22color%3Agreen%3B%22%3E%3C%2Fspan%3E%20%3Cspan%20style%3D%22color%3Ablue%3B%22%3E%3C%2Fspan%3E>

*Laboratories are encouraged to regularly review the Department's website and all available resources to ensure compliance with all PA-DEP-specific requirements.*