

CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION

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Subchapter A. GENERAL PROVISIONS

Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

§ 252.204. Fees.

(a) The appropriate fee in accordance with the following schedule must accompany an application for accreditation, renewal of accreditation, change of ownership, change in administrative information, or addition of fields of accreditation, or supplemental onsite assessment. A check must be payable to “Commonwealth of Pennsylvania.” The fees are as follows:

<i>Category</i>	<i>Fee</i>	
Application Fee – Initial Application for State Accreditation	\$750	<u>\$1,000</u>
Application Fee – Renewal Application for State Accreditation	\$500	<u>\$550</u>
Application Fee – Ownership Transfer or Change in Administrative Information	\$150	
Application Fee – Initial Application for NELAP/TNI Accreditation	\$2,500	<u>\$2,750</u>
Application Fee – Renewal Application for NELAP/TNI Accreditation	\$2,000	<u>\$2,200</u>
Application Fee – Addition of Field of Accreditation	\$250	
Application Fee – Supplemental On-Site Assessment	\$500	
Basic Drinking Water Category – includes 1 method for each of the following: Total Coliform Bacteria, Fecal Coliform Bacteria, <i>E. coli</i> Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	\$650	<u>\$700</u>
Basic Non-potable Water Category – includes 1 method for each of the following: Fecal Coliform Bacteria, BOD, CBOD, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, and 1 method for each type of residue including % Solids for land-applied biosolids	\$750	<u>\$800</u>
Whole Effluent Toxicity Testing—first matrix	\$700	<u>\$900</u>
Asbestos—first matrix	\$400	<u>\$500</u>
Asbestos—second matrix	\$350	<u>\$400</u>
Asbestos—third matrix	\$300	<u>\$350</u>
<u>Simple Microbiology (limited to heterotrophic plate count, total coliform, fecal coliform, and <i>E.coli</i>)—first matrix</u>	\$500	<u>\$550</u>
<u>Simple Microbiology (limited to heterotrophic plate count, total coliform, fecal coliform, and <i>E.coli</i>)—second matrix</u>	\$450	<u>\$500</u>
<u>Simple Microbiology (limited to heterotrophic plate count, total coliform, fecal coliform, and <i>E.coli</i>)—third matrix</u>	\$400	<u>\$450</u>

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<u>Complex Microbiology—first matrix</u>		<u>\$1,000</u>
<u>Complex Microbiology—second matrix</u>		<u>\$900</u>
<u>Complex Microbiology—third matrix</u>		<u>\$800</u>
Trace Metal Category—first matrix	\$550	<u>\$650</u>
Trace Metal Category—second matrix	\$500	<u>\$550</u>
Trace Metal Category—third matrix	\$450	<u>\$500</u>
Inorganic Non-metal Category—first matrix	\$600	<u>\$700</u>
Inorganic Non-metal Category—second matrix	\$550	<u>\$600</u>
Inorganic Non-metal Category—third matrix	\$500	<u>\$550</u>
<u>Purgeable</u> Volatile Organic Chemicals —first matrix	\$650	<u>\$750</u>
<u>Purgeable</u> Volatile Organic Chemicals—second matrix	\$600	<u>\$650</u>
<u>Purgeable</u> Volatile Organic Chemicals—third matrix	\$550	<u>\$600</u>
Extractable and Semi-volatile Organic Chemicals—first matrix	\$1,500	<u>\$1,650</u>
Extractable and Semi-volatile Organic Chemicals—second matrix	\$1,400	<u>\$1,500</u>
Extractable and Semi-volatile Organic Chemicals—third matrix	\$1,300	<u>\$1,400</u>
Dioxin—first matrix	\$650	<u>\$750</u>
Dioxin—second matrix	\$600	<u>\$650</u>
Dioxin—third matrix	\$550	<u>\$600</u>
Radiochemical Category—first matrix	\$750	<u>\$900</u>
Radiochemical Category—second matrix	\$700	<u>\$750</u>
Radiochemical Category—third matrix	\$650	<u>\$700</u>

(b) At least every 3 years, the Department will recommend regulatory changes to the fees in this section to the EQB to address any disparity between the program income generated by the fees and program costs. The regulatory amendment will be based upon an evaluation of the accreditation program fees income and the Department's costs of administering the accreditation program.

(c) An environmental laboratory owned or operated by a Commonwealth agency is exempt from this fee requirement, but shall apply for accreditation under this chapter.

(d) Fees are nonrefundable.

(e) In addition to the nonrefundable application fee, an out-of-State environmental laboratory shall reimburse the Department for the costs associated with onsite assessments necessitated by accreditation as specified in § 252.206 (relating to out-of-State onsite reimbursement).

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

§ 252.302. Qualifications of the laboratory supervisor.

(a) A laboratory supervisor of an environmental laboratory engaged in chemical analysis of organics and metals shall have the following qualifications:

- (1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.
- (2) At least 24-college semester credit hours in chemistry.
- (3) At least 2 years of experience in the testing or analysis of environmental samples in representative inorganic and organic fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation. An earned master's or doctoral

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degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering may be substituted for 1 year of experience.

(b) A laboratory supervisor of an environmental laboratory ~~limited to~~ **engaged in** inorganic **non-metals** chemical analysis, ~~other than metals analysis~~, shall have the following qualifications:

- (1) At least an earned associate's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering, or 2 years of equivalent and successful college education.
- (2) At least 16-college semester credit hours in chemistry.
- (3) At least ~~2 years~~ **1 year** of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

(c) A laboratory supervisor of an environmental laboratory engaged in microbiological or biological analysis shall have the following qualifications:

- (1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.
- (2) At least 16-college semester credit hours in general microbiology ~~or~~ **and** biology, **and at least 4 of the 16-college semester credit hours must be in microbiology.**
- (3) At least 2 years of experience in the testing or analysis of environmental samples in representative microbiological or biological fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation. A master's or doctoral degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering may be substituted for 1 year of experience.

(d) A laboratory supervisor of an environmental laboratory engaged in microbiological analysis limited to fecal coliform, total coliform and heterotrophic bacteria shall have the following qualifications:

- (1) At least an associate's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.
- (2) A minimum of 4-college semester credit hours in **biology microbiology.**
- (3) At least 2 years of equivalent and successful college education, including a minimum of 4-college semester credit hours in **biology microbiology**, may be substituted for the associate's degree.
- (4) At least ~~2 years~~ **1 year** of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

(e) A laboratory supervisor of an environmental laboratory engaged in radiological analysis shall have the following qualifications:

- (1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.
- (2) At least 24-college semester credit hours in chemistry.
- (3) At least 2 years of experience in the testing or analysis of environmental samples in representative radiological fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation. An earned master's or doctoral degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering may be substituted for 1 year of experience.

(f) A laboratory supervisor of an environmental laboratory engaged in microscopic examination of asbestos or airborne fibers shall have the following qualifications:

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- (1) For procedures requiring the use of a transmission electron microscope, a bachelor's degree, successful completion of formal course work in the use of the instrument, and 1 year of experience, under supervision, in the use of the instrument. The experience must include the identification of minerals.
- (2) For procedures requiring the use of a polarized light microscope, an associate's degree or 2 years of college study, successful completion of formal coursework in polarized light microscopy, and 1 year of experience, under supervision, in the use of the instrument. The experience must include the identification of minerals.
- (3) For procedures requiring the use of a phase contrast microscope, an associate's degree or 1 year of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and 1 year of experience, under supervision, in the use of the instrument.

(g) Notwithstanding any other provision of this section, a laboratory supervisor of an environmental laboratory limited to the basic nonpotable water category or the basic drinking water category, shall have the following qualifications:

- (1) At least 16-college semester credit hours in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.
- (2) At least 2 years of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

(h) Notwithstanding any other provision of this section, an employee of a drinking water, wastewater or industrial waste treatment facility meeting the following requirements will be deemed qualified as a laboratory supervisor of an environmental laboratory:

- (1) The employee holds a valid treatment plant operator's certificate under the Water and Wastewater Systems Operators' Certification Act (63 P. S. §§ 1001—1015.1) in the appropriate water or wastewater subclassification for the facility.
- (2) The employee holds a valid certificate under the Water and Wastewater Systems Operators' Certification Act for laboratory supervisor in the appropriate water or wastewater subclassification.
- (3) Until 12 months after a certificate under the Water and Wastewater Systems Operators' Certification Act for laboratory supervisor in the appropriate water or wastewater subclassification becomes available from the Department, 2 years of experience performing testing or analysis of environmental samples using the methods and procedures currently in use by the environmental laboratory may be substituted for a laboratory supervisory certificate.

(i) Approval as a laboratory supervisor under subsection (h) will be limited to the fields of accreditation required by the scope of that facility's regulatory permit.

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

§ 252.401. Basic requirements.

(a) An environmental laboratory shall develop and maintain a quality manual appropriate to the type, range and volume of testing and analysis of environmental samples. The quality manual shall be available to and used by environmental laboratory personnel. The quality manual must contain:

- (1) The full name and physical address of the laboratory.
- (2) The name, address (if different from paragraph (1)), and telephone number of laboratory supervisors.
- (3) A revision number and effective date.

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(4) A table of contents, and applicable lists of references, glossaries and appendices.

(b) The quality manual must state the environmental laboratory's policies, operational procedures, protocols and practices established to meet the requirements of this chapter. These policies and procedures must include:

- (1) An ethics policy statement as specified in subsection (d).
- (2) A document control system as specified in subsection (c).
- (3) Recordkeeping as specified in § 252.706 (relating to recordkeeping).
- (4) The procedures for termination of operations and transfer of records as specified in § 252.706 (relating to recordkeeping).
- (5) The procedures for detecting and permitting departures from established procedures as specified in subsections (i) and (h).
- (6) The procedures for detecting and preventing improper practices as specified in § 252.304 (relating to personnel requirements).
- (7) The sample handling and acceptance procedures as specified in subsections (f) and (g).
- (8) The reporting analytical results as specified in subsection (j).
- (9) The monitoring the quality of analysis as specified in subsection (l).

(c) An environmental laboratory shall have a document control system that provides procedures for control and maintenance of all documents. The document control system must ensure that standard operating procedures, methods, manuals or documents clearly indicate the time period during which the procedure or document was in force.

(d) An environmental laboratory shall develop and maintain an ethics policy statement relevant to the employee's duties and responsibilities under the act.

- (1) The laboratory shall implement procedures for educating and training personnel in their ethical and legal responsibilities under the act.
- (2) The laboratory shall provide training in ethical and legal responsibilities within two months of employment to the laboratory and at least every 14 months thereafter for all employees.

(e) An environmental laboratory shall maintain records of the technical personnel, which include dates of employment, signatures, initials and a list of persons authorized to approve or release reports of testing or analysis of environmental samples.

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

- (1) The environmental laboratory shall implement procedures for checking **and documenting the condition of each sample upon receipt at the laboratory** ~~thermal and/or chemical preservation and sample container. Results of these checks shall be recorded.~~ **The documentation maintained by the laboratory shall include:**

- (i) Sample container type and size, such as plastic 1L, amber 40mL vial, etc.**
- (ii) pH of the sample, as measured to meet the specific tolerance for the analysis method for which the sample is to be tested.**
- (iii) Results of the measurement for residual chlorine for SDWA compliance samples**
- (iv) Temperature of the sample with the most recent collection time for each sample set from a particular collection site.**

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

(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.

(h) An environmental laboratory shall document the laboratory management's processes and procedures for permitting departures from the method, quality manual, established policies and procedures or standard operating procedures.

(i) An environmental laboratory shall establish procedures for detecting when departures from the method or quality manual have occurred. These procedures must include the following:

- (1) Identify the individuals responsible for assessing each quality control type.
- (2) Identify the individuals responsible for initiating or recommending, or both, corrective actions.
- (3) Define how the analyst shall treat the results of testing or analysis of environmental samples if the associated quality control measures fail to meet the requirements of the method.
- (4) Specify how out-of-control situations and subsequent corrective actions are to be documented.
- (5) Specify procedures for the laboratory supervisor to review corrective action reports.

(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.

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- (5) An identification of the sample(s) including the client identification code.
- (6) The date and time of sample collection.
- (7) The date of sample analysis.
- (8) The 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 (e.g., 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.

(k) Tests performed by an environmental laboratory operated by a facility that provides results to the facility management for compliance purposes do not need to be reported under subsection (j) regarding procedures for reporting results, provided the information required by subsection (j) is maintained according to § 252.706

(l) An environmental laboratory shall implement procedures or practices to monitor the quality of the laboratory's analytical activities. Examples of the procedures or practices are:

- (1) Internal quality control procedures using statistical techniques.
- (2) Participation in proficiency testing, other interlaboratory comparisons, or round robin testing.
- (3) Analysis of split samples by different laboratories.
- (4) Use of certified reference materials or in-house quality control using secondary reference materials, or both.
- (5) Replicate testing using the same or different test methods.
- (6) Retesting of retained samples.
- (7) Correlation of results for different but related analysis of a sample (for example, total phosphorus should be greater than or equal to orthophosphate).

(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.

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

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

Subchapter F. ONSITE ASSESSMENT REQUIREMENTS

Subchapter G. MISCELLANEOUS PROVISIONS

§ 252.706. Recordkeeping.

(a) An environmental laboratory shall maintain records in an organized manner accessible by the Department.

(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.

(c) All generated ~~data records~~, except ~~data records~~ generated by automated data-collection systems, shall be recorded promptly and legibly in permanent ink or in an electronic format. ~~Changes to records shall be made so that the original entry remains visible. The individual making the change shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.~~

(1) The individual generating the record shall be identified by initials or signature and the individual making the observation shall be identified by initials or signature, if different from the individual generating the record.

(ii) Changes to records shall be made so that the original entry remains visible. The individual making the change shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.

(d) Records required under this chapter shall be maintained for a minimum of 5 years unless otherwise specified.

(e) An environmental laboratory shall have a written plan that specifies how records will be maintained or transferred if the laboratory transfers ownership or terminates operations.

§ 252.707. Subcontracting.

(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.

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

§ 252.708. Reporting and notification requirements.

(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) For ~~microbiological~~, trace metals, and inorganic non-metals, review all sample analysis data within 24 hours of acquisition of the initial sample results. 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 seven days of acquisition of the initial sample results.

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- (b) An environmental laboratory shall notify the Department, in writing, within ~~30~~ 20 calendar days of a permanent change in laboratory supervisor.
- (c) An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in the legal name of the laboratory.
- (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.
- (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 field of accreditation listed on the laboratory's scope of accreditation.
- (f) An out-of-State environmental laboratory with either primary or 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 accreditation body.
- (g) The Department may require additional information or proof of continued capability to perform the testing or analysis for affected fields of accreditation upon receipt of notification under this subsection.
- (h) The Department may require an onsite assessment under § 252.601 (relating to onsite assessment requirements) upon receipt of notification under this subsection.