CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION
Subchapter
A. GENERAL PROVISIONS
B. APPLICATION, FEES AND SUPPORTING DOCUMENTS
C. GENERAL STANDARDS FOR ACCREDITATION
D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS
E. PROFICIENCY TEST STUDY REQUIREMENTS
F. ONSITE ASSESSMENT REQUIREMENTS
G. MISCELLANEOUS PROVISIONS

Subchapter A. GENERAL PROVISIONS

Sec.
252.1. Definitions.
252.2. Purpose.
252.3. Scope.
252.4. General requirements.
252.5. NELAP equivalency.
252.6. Accreditation-by-rule.

§ 252.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Acceptance criteria—Specified limits placed on a measurement, quality control sample or process.

Accreditation—A determination by the Department that an environmental laboratory is capable of performing one or more classes of testing or analysis of environmental samples in accordance with the act and this chapter.

Accreditation-by-rule—Accreditation which an environmental laboratory is deemed to have for the fields of accreditation identified in § 252.6 (relating to accreditation-by-rule) upon compliance with that section.

[Accrediting authority]Accreditation Body—A territorial, state or Federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

Act—27 Pa.C.S. §§ 4101—4113 (relating to environmental laboratory accreditation).

***Action Level*—The concentration of a contaminant which, if exceeded, triggers a treatment or other requirement which a water system must follow.**

Analysis day—A continuous 24-hour period during which testing or analysis of environmental samples is performed.

Analyst—An individual who performs the analytical methods and associated techniques and who is responsible for applying the required laboratory practices and quality controls to meet the required level of quality.

Analyte—The component, compound, element or isotope to be identified or quantified using a test or analysis.

Batch—Environmental samples that are prepared or analyzed together using the same procedures, personnel, lots of reagents and standards.

Batch, analytical—A batch composed of prepared environmental samples that are analyzed together as a group. An analytical batch may contain samples originating from various environmental matrices and can exceed 20 samples.

Batch, preparation—A batch composed of 1 to 20 environmental samples of the same matrix with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours.

Calibration verification standard—A standard used to confirm the validity of a previously performed initial calibration of a measurement process.

Certificate of accreditation—A document issued by the Department certifying that an environmental laboratory has met standards for accreditation.

Commonwealth agency—An agency that is a Commonwealth agency as that term is defined under 62 Pa.C.S. § 103 (relating to definitions.)

Deficiency—A deviation from acceptable procedures or practices.

Detection limit—The lowest concentration or amount of the target analyte that can be identified, measured and reported with confidence that the analyte concentration is not zero.

Drinking water—Any aqueous sample that has been collected for the purposes of demonstrating compliance with the Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1—721.17) or is from a potable or potential potable water source.

ECp—Effective concentration percent—The concentration that affects the test variable at p percent from the control value.

Environmental laboratory—A facility engaged in the testing or analysis of environmental samples.

Environmental sample—A solid, liquid, gas or other specimen taken for the purpose of testing or analysis as required by an environmental statute.

Environmental statute—A statute administered by the Department relating to the protection of the environment or of public health, safety and welfare.

Facility—A sole proprietor, partnership, corporation, association, institution, cooperative enterprise, municipal authority, political subdivision, Federal government or agency, state institution or agency or other legal entity which is recognized by law as the subject of rights and duties.

Field of accreditation—A combination of matrix; method or technology, or both; and analyte or analyte group for which an environmental laboratory may be accredited. Examples are:

(i) Nonpotable water; GC/MS, US EPA Method 625; benzo(a)pyrene.
(ii) Drinking water; ICP, US EPA Method 200.7; magnesium.
(iii) Drinking water; GC/MS, US EPA Method 524.2; total trihalomethanes.

Holding time—The maximum elapsed time from sample collection to initiation of testing or analysis.

ICp—Inhibition concentration percent—The concentration that inhibits the test variable at p percent from the control value.

Industrial wastewater treatment facility—Any facility that treats industrial waste or pollution, but not sewage, as those terms are defined in The Clean Streams Law (35 P. S. §§ 691.1—691.1001).

Initial calibration—Determination by measurement or comparison with a standard of known concentration the correct value or response of each scale reading on a meter, instrument or other device. Comparison of a measurement standard or instrument with another standard or instrument to report or eliminate by adjustment any variation in the accuracy of the item being compared.

Initial demonstration of capability—A procedure to establish the ability of an analyst, technical staff member or work cell to generate data of acceptable accuracy and precision.

LCp—Lethal concentration percent—The concentration that is lethal to p percent of the test organisms from the control organisms.

Laboratory control sample—A sample of a controlled matrix known to be free of the analyte of interest, to which a known and verified concentration of analyte has been added and that is taken through all preparation and analytical steps in the method.

Laboratory management—

(i) The individuals responsible for the overall operation, all personnel and the physical plant of an environmental laboratory.

(ii) The term includes the laboratory supervisor.

***[Laboratory notebook*—A chronological record of observations, results of testing or analysis, equipment maintenance or calibration or other environmental laboratory data. A laboratory notebook may be maintained in an electronic format.]**

Laboratory supervisor—A technical supervisor of an environmental laboratory who supervises laboratory procedures and reporting of analytical data.

Linear range—The range of concentrations over which the instrument response is directly proportional to the analyte concentration.

MCL—Maximum Contaminant Level—The maximum permissible level of a contaminant in water which is delivered to a user of a public water system, and includes the primary and secondary MCLs established under the Safe Drinking Water Act (42 U.S.C.A. §§ 300f—300j—10) and MCLs adopted under the Pennsylvania Safe Drinking Water Act and the regulations promulgated thereunder.

Matrix or *matrices*—The media of an environmental sample that includes drinking water, nonpotable water, and solid and chemical materials.

Matrix spike—A sample prepared by adding a known mass of target analyte to a specified amount of environmental sample and that is taken through all preparation and analytical steps in the method.

Method—The scientific technique used to perform testing or analysis on an environmental sample.

Method blank—A sample of a known matrix, similar to the associated samples, and known to be free of the analyte of interest and that is taken through all preparation and analytical steps in the method.

Mobile laboratory—

(i) A portable enclosed structure within which testing or analysis of environmental samples occurs.

(ii) Examples include trailers, vans and skid—mounted structures configured to house environmental testing equipment and personnel.

NELAC—National Environmental Laboratory Accreditation Conference.

NELAP—National Environmental Laboratory Accreditation Program.

NELAP ***[accrediting authority]accreditation body***—An **accreditation body[accrediting authority]** that has been recognized as meeting the requirements of the NELAC **S[s]**tandard **or the TNI Standard[s]** and has the authority to grant NELAP **or TNI** accreditation.

NIST—The National Institute of Standards and Technology of the United States Department of Commerce's Technology Administration.

NOAEC—No observed adverse effect concentration.

NOEC—No observed effect concentration.

Negative culture control—An organism selected to demonstrate that the medium does not support the growth of nontarget organisms or does not demonstrate the typical positive reaction of the target organisms.

Nonpotable water—

(i) Any aqueous sample excluded from the definition of drinking water matrix.

(ii) The term includes wastewater, ambient water, surface water, groundwater, effluents, water treatment chemicals and **leachates[toxicity characteristic leaching procedure or other extracts].**

Positive culture control—An organism selected to demonstrate that the medium can support the growth of the target organisms and that the medium produces the specified or expected reaction to the target organism.

Primary accreditation—Accreditation received from the Department that is not based upon accreditation from another accrediting authority.

Proficiency test study—A sample or group of samples, the composition of which is unknown to the environmental laboratory and the analyst.

Promulgated method—A protocol for testing or analysis of a specific analyte that is approved for use by a State or Federal regulation.

Quality manual—A document stating, or making reference to, the policies, objectives, principles, responsibilities, accountability, implementation plans, methods, operating procedures or other documents of an environmental laboratory for ensuring the quality of its testing and analysis.

Quantitation limit—The minimum concentration or activity of the component, compound, element or isotope that can be reported with a specified degree of confidence. Typically it is the concentration that produces a signal ten standard deviations above the reagent water blank signal.

Range of quantitation—The concentration range between which an environmental laboratory reports results quantitatively which is defined by a low concentration standard and a high concentration standard.

Reagent water—Water with no detectable concentration of the component, compound, element or isotope to be analyzed and that is free of substances that interfere with the method. Reagent water may be prepared by distillation, ion exchange, adsorption, reverse osmosis or a combination thereof.

Revocation—Removal by the Department of one or more fields of accreditation from an environmental laboratory.

Sample duplicate—Replicate aliquots of the same sample taken through the entire analytical procedure.

Secondary accreditation—Accreditation received from the Department based upon the accreditation status granted by another **[accrediting authority]**<u>**accreditation body**</u>**.**

Solid and chemical materials—Soils, sediments, sludges, solid waste, drill cuttings, overburden, minerals, coal ash, and products and by-products of an industrial process that result in a matrix that is not otherwise defined.

Solid waste—Any waste, including, but not limited to, municipal, residual or hazardous wastes, including solid, liquid, semisolid or contained gaseous materials as that term is defined in the Solid Waste Management Act (35 P. S. §§ 6018.101—6018.1003).

Spike—A known and verified mass or activity of the target analyte of interest added to reagent water or environmental sample to determine recovery efficiency or for other quality control purposes.

Standard operating procedure—A written document that provides detailed instructions for the performance of all aspects of test, analysis, operation or action.

Surrogate—A substance with properties similar to the analyte of interest. A surrogate is unlikely to be found in an environmental sample. A surrogate is added to an environmental sample prior to all preparation and analytical steps in the method for quality control purposes.

Suspension—The temporary removal by the Department of one or more fields of accreditation from an environmental laboratory for a period not to exceed 6 months.

Technical staff—Employees of an environmental laboratory that perform any portion of testing or analysis of environmental samples, including the analysts of the environmental laboratory.

Test—A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

<u>***TNI*—The NELAC Institute or its successor organization/Standard.**</u>

Wastewater—A substance that contains the waste products or excrement or other discharge from the bodies of human beings or animals and noxious or deleterious substances being harmful or inimical to the public health, or to animal or aquatic life, or to the use of water for
domestic water supply or for recreation, or which constitutes pollution under The Clean Streams Law.

Wastewater facility—A facility that operates a system designed to collect, convey or treat wastewater and from which effluent is discharged into waters of this Commonwealth.

Work area—The areas in an environmental laboratory necessary for testing and analysis and related activities. These areas include sample receipt area, sample storage area, chemical and waste storage area, data handling area and analytical areas.

Work cell—A defined group of analysts that together perform testing or analysis of environmental samples.

§ 252.2. Purpose.

The purpose of this chapter is to protect public health, safety, welfare and the environment by ensuring the accuracy, precision and reliability of data generated by environmental laboratories by establishing an accreditation program for environmental laboratories.

§ 252.3. Scope.

(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 Conservation and Reclamation Act (52 P. S. §§ 1396.1—1369.31).
(10) The Coal Refuse Disposal Control Act (52 P. S. §§ 30.51—30.206).
(11) The Bituminous Mine Subsidence and Land Conservation Act (52 P. S. §§ 1406.1—1406.21).
(12) The Noncoal Surface Mining Conservation and Reclamation Act (52 P. S. §§ 3001—3326).

(b) *Matrix*. The following matrices are included:

(1) Drinking water.
(2) Nonpotable water.
(3) Solid and chemical materials.

(c) *Exclusions*. The following testing and analysis is specifically excluded from the requirements of this chapter:

(1) Corrosion protection system testing or testing of a storage tank system for tightness or structural soundness under Chapter 245 (relating to the Administration of the Storage Tank and Spill Prevention Program).
(2) Routine release detection monitoring under §§ 245.442—245.445, 245.543 and 245.613.
(3) Analyses to determine the acceptability of soils for protective, daily, intermediate and final cover material, subbase, clay liner, clay cap, attenuating soil base and liner system construction material under Chapters 260a, 261a, 262a, 263a, 264a, 265a, 266a, 266b, 268a, 269a and 270a (relating to hazardous waste), Chapters 271—273, 275, 277, 279, 281 and 283—285 (relating to municipal waste) and Chapters 287—289, 291, 293, 295 and 297— 299 (relating to residual waste).
(4) Testing or analysis of the physical, chemical, mechanical and thermal properties of liners, liner systems, leachate detection zones and barriers under Chapters 260a, 261a, 262a, 263a, 264a, 265a, 266a, 266b, 268a, 269a, 270a, 271—273, 275, 277, 279, 281, 283—285, 287—289, 291, 293, 295 and 297—299.

§ 252.4. General requirements.

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

(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.

[(c) By July 28, 2006, an environmental laboratory testing or analyzing environmental samples within a matrix identified in § 252.3 and to comply with a statute listed in § 252.3 shall apply to the Department for accreditation in accordance with Subchapter B (relating to application, fees and supporting documents). An environmental laboratory that files an application within that time period shall have interim accreditation to continue operations until the Department takes final action on the application.][(d) After July 28, 2006, an environmental laboratory that seeks accreditation under this chapter shall apply in accordance with Subchapter B. Interim accreditation will not be granted to an environmental laboratory which submits an application for accreditation after July 28, 2006.]

§ 252.5. NELAP/TNI equivalency.

(a) An environmental laboratory may apply to the Department for NELAP accreditation for the fields of accreditation for which the Department offers accreditation.

(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 F (relating to onsite assessment requirements)

(3[2]) Comply with Subchapter G (relating to miscellaneous provisions).

(4[3]) Comply with the current edition of the NELAC Standard or TNI Standard.

(c) An environmental laboratory receiving NELAP accreditation from the Department may apply for accreditation under the remainder of this chapter for the fields of accreditation that are not included in NELAP accreditation and for which the Department offers accreditation.

(d) An environmental laboratory receiving NELAP accreditation from the Department may only test or analyze environmental samples within the fields of accreditation authorized by the accreditation received from the Department.

§ 252.6. Accreditation-by-rule.

(a) *Purpose*. Environmental laboratories performing testing or analysis described in this section will be deemed to have accreditation-by-rule if the following general requirements are met:

(1) The environmental laboratory registers with the Department in accordance with 27 Pa. C.S. § 4107(a).

([1]2) The environmental laboratory performs the testing or analysis in conformance with applicable State or Federal laws, regulations, promulgated methods, orders and permit conditions.

([2]3) The environmental laboratory assures that samples for testing or analysis are properly preserved, are in proper containers, do not exceed maximum holding times between collection and analysis and are handled in accordance with applicable State or Federal Laws, regulations, promulgated methods, orders and permit conditions.

([3]4) The environmental laboratory has the other necessary permits under the applicable environmental protection acts and is operating under the acts and regulations promulgated thereunder and the terms and conditions of permits.

([4]5) Records pertaining to the testing or analysis of environmental samples are retained onsite and in accordance with § 252.706 (relating to recordkeeping). Records shall be made available to the Department upon request.

([5]6) The environmental laboratory is reporting the results of the testing or analysis of environmental samples in conformance with the applicable State or Federal laws, regulations, orders or permit conditions.

(b) *Inappropriate activity*. The Department may require an environmental laboratory deemed to have accreditation-by-rule to apply for, and obtain, environmental laboratory accreditation under Subchapter B (relating to application, fees and supporting documents), or take other appropriate action, when the environmental laboratory is not in compliance with the conditions of accreditation-by-rule or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment of this Commonwealth.

(c) *Testing and analysis of samples from public water suppliers*. An environmental laboratory using an individual meeting the requirements specified in § 109.704 (relating to operator certification) and in compliance with subsections (a) and (b) will be deemed to be accredited under this chapter to perform only those measurements identified in § 109.304(c) (relating to analytical requirements) as measurements that may be performed by a person meeting the requirements of § 109.704.

(d) *Industrial wastewater treatment facility laboratory*. An environmental laboratory operated by an industrial wastewater treatment facility in compliance with subsections (a) and (b) will be deemed to be accredited under this chapter to perform testing or analysis not mandated by the Department and those tests identified in subsection (f).

(e) *Wastewater facility laboratory*. An environmental laboratory operated by a wastewater facility in compliance with subsections (a) and (b) will be deemed to be accredited under this chapter to perform testing or analysis not mandated by the Department and those tests identified in subsection (f).

(f) *Other testing and analysis*. With the exception of environmental laboratories testing or analyzing environmental samples to comply with the Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1—721.17), an environmental laboratory in compliance with subsections (a) and (b) will be deemed accredited under this chapter for the following tests or analyses:

(1) Alkalinity.
(2) Carbon dioxide (CO2).
(3) Color.
(4) Conductivity.
(5) Dissolved oxygen.
(6) Field radioactivity using hand held survey instruments.
(7) Flash point and total halogen determination on waste oil by a waste oil transporter or waste oil transfer facility as required by § 298.44 (relating to rebuttable presumption for waste oil and flash point screening).
(8) Flow.
(9) Foam.
(10) Hardness.
(11) Odor.
(12) Oxidation reduction potential.
(13) Paint filter test.
(14) pH.
(15) Residual disinfectant concentration.

(16) Settleable solids.
(17) Sheen.
(18) Sludge volume index.
(19) Specific gravity.
(20) Sulfite.
(21) Taste.
(22) Temperature.
(23) Turbidity.
(24) Vapor analysis using hand held survey instruments.
(25) Volatile acids in wastewater and sludge.

(g) *Exclusion from requirements*. An environmental laboratory deemed to be accredited under this section is not required to meet any other requirements in this chapter.

Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

Sec.
252.201. Application and supporting documents.
252.202. Application for transfer of laboratory accreditation.
252.203. Accreditation renewal.
252.204. Fees.
252.205. Out-of-State laboratories.
252.206. Out-of-State onsite reimbursement.
252.207. Expiration of application.

§ 252.201. Application and supporting documents.

(a) An environmental laboratory seeking accreditation for one or more fields of accreditation within a matrix described in § 252.3 (relating to scope) or that seeks to add a field of accreditation, 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.

(b) An application for accreditation must include the appropriate application fee in accordance with § 252.204 (relating to fees.)

(c) Environmental laboratories maintained on separate premises shall maintain distinct accreditation. Separate accreditation is not required for environmental laboratories in different buildings on the same or adjoining grounds, provided the laboratories are operated under the same management.

(d) Separate accreditation is required for a mobile laboratory.

§ 252.202. Application for transfer of laboratory accreditation.

(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 environmental 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.

(b) **[Open or pending e]E**nforcement actions will be transferred with the accreditation.

(c) Failure to comply with this section will cause the previous accreditation to expire.

(d) An environmental laboratory may operate under the previous accreditation until the Department makes a final decision on the transfer application. If the Department denies the transfer application, the environmental laboratory is no longer accredited and the new owner shall submit an application under § 252.201 (relating to application and supporting documents).

§ 252.203. Accreditation renewal.

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

(b) An application for accreditation renewal must include the appropriate application fee in accordance with § 252.204 (relating to fees.)

(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 fields of accreditation.

§ 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:

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

Extractable and Semi-volatile Organic Chemicals—nonpotable water	**$ 950**
Dioxin—nonpotable water	**$ 600**
Radiochemical Category—nonpotable water	**$ 600**
Whole Effluent Toxicity Testing Category—nonpotable water	**$ 600**
Microbiology—drinking water and nonpotable water	**$ 750**
Trace Metal Category—drinking water and nonpotable water	**$ 800**
Inorganic Non-metal Category—drinking water and nonpotable water	**$1,000**
Trace Metal and Inorganic Non-metal Categories—drinking water and nonpotable wa	**$1,550**
Volatile Organic Chemicals—drinking water and nonpotable water	**$ 900**
Extractable and Semi-volatile Organic Chemicals—drinking water and nonpota	**$1,650**
Dioxin—drinking water and nonpotable water	**$1,050**
Radiochemical Category—drinking water and nonpotable water	**$1,050**
Asbestos—solid and chemical materials	**$ 350**
Microbiology—solid and chemical materials	**$ 450**
Trace Metal Category—solid and chemical materials	**$ 450**
Inorganic Non-metal Category—solid and chemical materials	**$ 550**
Volatile Organic Chemicals—solid and chemical materials	**$ 550**
Extractable and Semi-volatile Organic Chemicals—solid and chemical materials	**$1,200**
Dioxin—solid and chemical materials	**$ 600**
Radiochemical Category—solid and chemical materials	**$ 600]**

Application Fee – Initial Application for State Accreditation	**$750**
Application Fee – Renewal Application for State Accreditation	**$500**
Application Fee – Ownership Transfer or Change in Administrative Information	**$150**
Application Fee – Initial Application for NELAP/TNI Accreditation	**$2,500**
Application Fee – Renewal Application for NELAP/TNI Accreditation	**$2,000**
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, *E. coli* Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	**$650**
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**
Asbestos—first matrix	**$400**
Microbiology—first matrix	**$500**
Trace Metal Category—first matrix	**$550**
Inorganic Non-metal Category—first matrix	**$600**
Volatile Organic Chemicals —first matrix	**$650**
Extractable and Semi-volatile Organic Chemicals—first matrix	**$1,500**
Dioxin—first matrix	**$650**
Radiochemical Category—first matrix	**$750**
Whole Effluent Toxicity Testing—first matrix	**$700**
Asbestos—second matrix	**$350**
Microbiology—second matrix	**$450**
Trace Metal Category—second matrix	**$500**
Inorganic Non-metal Category—second matrix	**$550**
Volatile Organic Chemicals—second matrix	**$600**
Extractable and Semi-volatile Organic Chemicals—second matrix	**$1,400**
Dioxin—second matrix	**$600**

Radiochemical Category—second matrix	**$700**
Asbestos—third matrix	**$300**
Microbiology—third matrix	**$400**
Trace Metal Category—third matrix	**$450**
Inorganic Non-metal Category—third matrix	**$500**
Volatile Organic Chemicals—third matrix	**$550**
Extractable and Semi-volatile Organic Chemicals—third matrix	**$1,300**
Dioxin—third matrix	**$550**
Radiochemical Category—third matrix	**$650**

(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).

§ 252.205. Out-of-State laboratories.

(a) Out-of-State environmental laboratories may apply for primary accreditation or secondary accreditation from the Department.

(1) *Primary accreditation*. Out-of-State environmental laboratories may apply to the Department for primary accreditation under this chapter.

(2) *Secondary accreditation*.

(i) The Department will recognize accreditation granted by a primary NELAP**/TNI accreditation body[accrediting authority]** for the same fields of accreditation for which the Department is a primary NELAP**/TNI accreditation body[accrediting authority]**.

(ii) The Department may recognize the accreditation of an environmental laboratory by another state accrediting authority if the standards for accreditation are substantially equivalent to those established under this chapter and the laboratory is physically located within the state granting accreditation.

(iii) 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 **accreditation body[accrediting authority].**

(D) Submit a copy of all onsite assessment reports conducted by the primary accrediting authority within the last 3 years.

[(E) Submit copies of all proficiency test sample results reported to the primary accrediting authority within the past 12 months.]

(E[F]) Submit any other material relevant to accreditation, upon request of the Department.

(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).

(c) If any portion of the out-of-State environmental laboratory's accreditation is denied, revoked or suspended by the primary accrediting authority, the laboratory's authorization to perform testing or analysis is automatically revoked for the same fields of accreditation.

§ 252.206. Out-of-State onsite reimbursement.

In addition to the nonrefundable application fee, an out-of-State environmental laboratory shall reimburse the Department for the following costs associated with onsite assessments necessitated by accreditation:

(1) Transportation costs, including airfare, mileage, tolls, car rental, public transportation and parking.
(2) Meals and lodging.
(3) Travel time for each assessor at a rate of $50/hour.

§ 252.207. Expiration of application.

An environmental laboratory that fails to meet the requirements for accreditation within 1 year from the date the Department receives the application shall submit a new application and pay the appropriate fee to become accredited under this chapter.

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

§ 252.301. Laboratory supervisor.

(a) The Department will consider the laboratory supervisor of an environmental laboratory as the individual(s) listed on the laboratory's application for accreditation for which the Department has reviewed and approved his/her qualifications.

(b[a]) Testing, analysis and reporting of data by an environmental laboratory shall be under the direct supervision of a laboratory supervisor.

(c[b]) The laboratory supervisor shall certify that each test or analysis is accurate and valid and the test or analysis was performed in accordance with all conditions of accreditation. A laboratory supervisor may certify a test or analysis by signing the final laboratory report. A laboratory may use other mechanisms to certify a test or analysis, provided the mechanism is documented in the laboratory quality manual.

(d[c]) The laboratory supervisor shall ensure that the records required by this chapter are maintained.

(e[d]) The Department may disqualify a laboratory supervisor who is responsible for the submission of inaccurate test or analysis results.

(f[e]) The Department will disqualify a laboratory supervisor convicted of any crime or offense related to violations of State or Federal laws or regulations related to the provision of environmental laboratory services or reimbursement for the services.

(g[f]) An environmental laboratory may appoint one or more laboratory supervisors for the appropriate fields of accreditation for which they are seeking accreditation.

(h[g]) An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor to temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding 16 consecutive calendar days. If this absence exceeds 30 consecutive calendar days, the environmental laboratory shall notify the Department in writing under § 252.708 (relating to reporting and notification requirements).

(i[h]) An individual may not be the laboratory supervisor of more than one environmental laboratory without authorization from the Department. Circumstances to be considered in the decision to grant the authorization will include at least the following:

(1) The extent to which operating hours of the laboratories to be supervised overlap.

(2) The adequacy of supervision in each laboratory.

§ 252.302. Qualifications of the laboratory supervisor.

(a) A laboratory supervisor of an environmental laboratory engaged in chemical 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 inorganic and organic 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.

(b) A laboratory supervisor of an environmental laboratory limited to inorganic 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 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 **[and]**or biology.

(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 heterotroph**h**ic 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 **[general microbiology]**biology**.**

(3) At least 2 years of equivalent and successful college education, including a minimum of 4-college semester credit hours in **[general microbiology]**__**biology**__, may be substituted for the associate's degree.
(4) 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.

(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:
(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.

§ 252.303. Grandfathering provisions for laboratory supervisors.

(a) A person who does not meet the education credential requirements for a laboratory supervisor but possesses the requisite years of experience required by § 252.302 (relating to qualifications of the laboratory supervisor) shall qualify as laboratory supervisor subject to the following conditions:

(1) The person shall be a laboratory supervisor of the environmental laboratory on January 28, 2006.

(2) The person shall have been a laboratory supervisor of the environmental laboratory for at least 12 months for the fields of accreditation for which the environmental laboratory is applying.

(b) A person will be approved as a laboratory supervisor only for those fields of accreditation for which the person has been laboratory supervisor of the environmental laboratory for at least 12 months.

(c) The Department may approve a person, qualified as a laboratory supervisor under this section, for additional fields of accreditation if the person has the appropriate knowledge, skills and abilities to perform and supervise the testing or analyses on environmental samples for the requested fields of accreditation.

(d) Qualification as a laboratory supervisor under this subsection may not be transferred to another laboratory.

§ 252.304. Personnel requirements.

(a) General requirements for technical staff.

(1) An environmental laboratory shall have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.

(2) Each member of the environmental laboratory technical staff shall be responsible for complying with quality assurance and quality control requirements that pertain to their organizational or technical function.

(3) Each environmental laboratory technical staff member shall have a combination of experience and education to adequately demonstrate a specific knowledge of the member's particular function and a general knowledge of laboratory operations, test methods, quality assurance and quality control procedures and records management.

(b) Laboratory management responsibilities. The environmental laboratory management shall be responsible for:

(1) Defining the minimal level of qualification, experience and skills necessary for all positions or work cells in the environmental laboratory.

(2) Ensuring and documenting that the environmental laboratory technical staff members or work cells have demonstrated capability in the activities for which they are responsible.

(3) Ensuring and documenting that the training and competency of each member of the environmental laboratory technical staff is kept up to date by maintaining records demonstrating the following:

(i) That each employee has read, understood and is using the latest version of the environmental laboratory's quality manual that relates to each employee's job responsibilities.

(ii) That each employee has read, understood and is using the latest versions of the environmental laboratory's standard operating procedures that relate to each employee's job responsibilities.
(iii) Participation in training courses or workshops on specific equipment, analytical techniques or laboratory procedures that relate to each employee's job responsibilities.
(iv) Participation in training courses in ethical and legal responsibilities including the potential liabilities for improper, unethical or illegal actions.
(v) That each employee has read, understood and acknowledged his personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.
(vi) An initial demonstration of capability for each method that relates to the employee's job responsibilities **has been performed. The initial demonstration of capability requirements are as follows:**

(A) Prior to the use of any method, an initial demonstration of capability is required.

(B) An initial demonstration of capability shall be completed each time there is a change in instrument type, personnel, or method.

(C) An initial demonstration of capability must include all sample preparation and analytical steps contained in the method.

(D) If the method or State or Federal regulations specify a procedure for the initial demonstration of capability, that procedure shall be followed, otherwise, an initial demonstration of capability shall be performed as follows:

(I) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not specify a concentration, the concentration must be approximately ten times the detection limit.

(II) At least four aliquots of the quality control sample must be prepared and analyzed according to the method.

(III) Using all of the results, calculate the mean recovery and the standard deviation of the mean recovery for the population sample in the same units used to report environmental samples. When it is not possible to determine mean and standard deviation, such as for presence-absence and logarithmic values, the environmental laboratory shall assess method performance using criteria from the method or other established and documented criteria.

(IV) Compare the information from subparagraph (iii) to the corresponding acceptance criteria for precision and accuracy in the method. To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

(E) When a method has been in use by an environmental laboratory prior to January 1, 2005, and there have been no changes in instrument type, personnel or method, the environmental laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.

(F) The laboratory shall retain all data necessary to reproduce the initial demonstration of capability.

(G) The work cell as a unit shall meet the requirements of this paragraph.

(I) When a member of a work cell changes, the new employee shall work with an experienced analyst in the work cell.

(II) When a member of a work cell changes, the new work cell shall demonstrate capability by means of acceptable quality control performance checks on four consecutive batches. The acceptable performance shall be documented. If any quality control performance check within the four consecutive batches following the change in personnel fails to meet acceptance criteria, an initial demonstration of capability shall be completed.

(III) If the entire work cell is changed, an initial demonstration of capability shall be completed.

(vii) A demonstration of continued proficiency by at least one of the following every 12 months for each method that relates to the employee's job responsibilities:

(A) Another initial demonstration of capability.

(B) Acceptable performance of blind performance samples (single blind to the analyst).

(C) Successful analysis of blind proficiency test samples on a similar test method using the same technology (for example—GC/MS volatiles by purge and trap for EPA Methods 524.2, 624 or 5030/8260 would require documentation for only one of the test methods.)

(D) At least four consecutive laboratory control samples with acceptable levels of precision and accuracy.

(E) Analysis of at least ten authentic samples with results statistically indistinguishable from those obtained by another trained analyst. The samples must include samples free of the analyte of interest and samples containing the analyte of interest at measurable concentrations.

(4) Supervising personnel employed by the laboratory.

(5) Establishing and implementing procedures and processes for permitting departures from documented policies and procedures.

(6) Ensuring that sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored.

(7) Developing a proactive program for prevention and detection of improper, unethical, or illegal actions. Components of this program may include the following:

(i) Internal proficiency testing (single and double blind).

(ii) Postanalysis electronic data and magnetic tape audits or reviews.

(iii) Separate standard operating procedures identifying appropriate and inappropriate laboratory and instrument manipulation practices.

(c) An environmental laboratory shall maintain records on initial demonstrations of capability, demonstrations of continued proficiency, proficiency test samples for each laboratory method and the qualifications, training, skills and experience of the laboratory technical staff members.

§ 252.305. Physical facilities.

(a) An environmental laboratory shall have accommodations, work areas, energy sources, lighting, heating and ventilation necessary to assure proper performance of tests and analyses.

(b) The environment in which testing or analysis of environmental samples is undertaken may not adversely affect the results of the testing or analysis or the required accuracy of measurement.

(c) An environmental laboratory shall document its monitoring and control of environmental conditions where monitoring or control of environmental conditions is specified in a method or by regulation.

(d) There must be effective separation between neighboring work areas and between work areas and nonwork areas when the activities performed in the different areas are incompatible.

(e) Adequate measures shall be taken to ensure that contamination does not adversely affect data quality.

§ 252.306. Equipment, supplies and reference materials.

(a) An environmental laboratory shall be furnished with all items of equipment, including reference materials, required for the correct performance of tests or analyses for which accreditation is sought.

(b) An environmental laboratory shall maintain records of each item of equipment significant to the testing or analysis performed. These records must include documentation on the following:

(1) The name of the item of equipment.
(2) The manufacturer's name, type identification, and serial number or other unique identification.
(3) The date received and date placed in service (if available).
(4) The current location, when appropriate.
(5) If available, condition when received (for example, new, used or reconditioned).
(6) A copy of the manufacturer's instructions, where available.
(7) The dates and results of calibrations or verifications.
(8) The manufacturer's instructions, if available, or reference their location.
(9) The details of maintenance performed.
(10) A history of damage, malfunction, modification or repair.

(c) An environmental laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

(d) Equipment shall be properly maintained, inspected and cleaned.

(e) Any item of equipment that has been subjected to overloading, mishandling, gives suspect results or has otherwise been shown to be defective, shall be taken out of service and clearly identified until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous testing or analysis.

(f) The following pieces of equipment shall be maintained according to this subsection.

(1) *Certified NIST-reference thermometer.*
  (i) A certified NIST-reference thermometer must have appropriate graduations and a range that spans the requirements of the method.
  (ii) The certified NIST-reference thermometer shall be recalibrated at least once every 5 years at the temperatures of use.
  (iii) An environmental laboratory shall retain a certificate documenting traceability of the calibration to NIST standards.
(2) *Working thermometers.*
  (i) Working thermometers must have appropriate graduations and a range that spans the requirements of the method.
  (ii) Working thermometers may be glass, dial or electronic and shall be calibrated against a certified NIST-reference thermometer as follows:
    (A) Glass**,[and]** **liquid filled[electronic thermometers and continuous recording devices]thermometers** shall be calibrated every 12 months at the temperature used.
    (B) Dial **and electronic** thermometers shall be calibrated every 3 months at the temperature used. **Electronic thermometers accompanied by a valid NIST traceable certificate of acceptance may be used for 12 months from the date of receipt before re-calibration. [Dial thermometers that cannot be calibrated may not be used.]**

(C) An environmental laboratory shall maintain records **[in a laboratory notebook]**for each working thermometer that documents the date of calibration, NIST reference thermometer identification, working thermometer identification, reference thermometer temperature reading, working thermometer temperature reading, correction factor and the initials of the individual conducting the calibration.

(D) Working thermometers shall be uniquely identified and labeled with the date of calibration and correction factor.

(iii) The fluid column in glass thermometers may not be separated.

(iv) A working thermometer that differs by more than **2[1]**.0°C from the reference thermometer may not be used.

(3) *ASTM **[type]class** 1, 2 or 3 (Class S or S-1)**, or better** certified reference weights.*

(i) The mass of ASTM **[type]class** 1, 2 or 3 (Class S or S-1)**, or better** certified reference weights shall be recertified at least once every 5 years.

(ii) An environmental laboratory shall retain a certificate documenting traceability of the calibration to ASTM standards.

(4) *Analytical or pan balances.*

(i) Analytical or pan balances must provide sufficient accuracy and sensitivity for the weighing needs of the method.

(ii) An environmental laboratory shall verify the calibration of a balance daily or before each use, whichever is less frequent.

(iii) A reference weight that is damaged or corroded may not be used for calibration of balances.

(iv) Balance calibration shall be verified using a minimum of three ASTM **[type]class** 1, 2 or 3 (Class S or S-1) certified reference weights that bracket the effective range of the balance's use.

(v) An environmental laboratory shall maintain records **[in a laboratory notebook]**of balance calibrations that document the balance identification, date of calibration verification, reference weights used and initials of the individual performing the calibration. **[Correction factors shall be documented and used.]**

(vi) A qualified person shall service and calibrate analytical balances at least once per year.

(vii) Records of annual service shall be maintained and the service date shall be recorded on the balance.

(5) *pH meter.*

(i) A pH meter must be equipped with an appropriate electrode and have scale graduations and accuracy appropriate to the method.

(ii) An environmental laboratory shall utilize either a thermometer or a temperature sensor for automatic compensation to make corrections for pH measurements.

(iii) The pH meter shall be **[standardized]calibrated** daily or before each use, whichever is less frequent, by one of the following:

(A) With at least three standard buffers which are at least three pH units apart and which bracket the expected pH range of the samples.

(B) Use a pH 7.0 and either a pH 4.0 or 10.0 standard buffer; whichever range covers the desired pH range of use.

(iv) Aliquots of standard buffers may not be used for longer than 1 analysis day.

(v) Records of pH meter standardization shall be maintained **[in a laboratory notebook]**that documents the date of standardization, calibration buffers used and initials of the individual conducting the standardization.

(6) *Conductivity meter.*

(i) A conductivity meter must have a probe of sufficient sensitivity for the method. The scale must have readability in appropriate units, for example micromhos or microsiemens per centimeter.

(ii) An in-line conductivity meter that cannot be calibrated may not be used.

(iii) An environmental laboratory shall calibrate the conductivity meter daily or before each use whichever is less frequent, by one of the following:

(a) With certified and traceable standard solutions within the range of interest.

(b) By determining the cell constant utilizing the method described in currently approved editions of Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005.)

(iv) Records of conductivity meter calibrations shall be maintained **[in a laboratory notebook]**that documents the date of calibration, standards used, results of calibration or cell constant determined and the initials of the individual conducting the calibration.

(7) *Refrigeration equipment and freezers.*

(i) An environmental laboratory shall maintain one thermometer immersed in liquid (except electronic thermometers) to the appropriate immersion line for each refrigerator or freezer. The thermometer must be graduated in increments no larger than 1°C.

(ii) Calibration-corrected temperatures for each refrigerator and freezer shall be recorded once a day for each day in use for all laboratory activities. The date, refrigerator or freezer identification, calibration corrected temperature and initial of responsible individual shall be recorded.

(iii) Samples and standards shall be stored in separate refrigerators where the potential for cross-contamination exists.

(iv) Samples which require thermal preservation shall be stored at a temperature which is ± 2°C of the specified preservation temperature unless method specific criteria exist. For samples with a storage temperature of 4°C, storage at a temperature of 0.5°C to 6°C is acceptable.

(v) Freezer temperatures must be less than 0°C.

(8) *Incubators, water baths**, [and]**heating blocks**[.], and ovens*

(i) An environmental laboratory shall control and monitor the temperature of incubators, water baths**, [and]**heating blocks**, and ovens** in accordance with the method or as specified by regulations.

(ii) An environmental laboratory shall maintain a minimum of one thermometer per incubator, water bath**[or]** heating block **or oven** immersed in liquid **or sand for ovens** (except electronic thermometers) to the appropriate immersion line. When used as an incubation unit for microbiology, a minimum of one working thermometer shall be on the top and bottom shelf of the use area in each incubator.

(iii) When used as an incubation unit for microbiology, a water bath must be equipped with a gable cover and a pump or paddles to circulate the water.

(iv) Calibration-corrected temperatures for each incubator, water bath**, [or]**heating block **or oven** shall be recorded once a day for each day in use for all laboratory activities. When used as an incubation unit for microbiology, the calibration-corrected temperature shall be recorded at least twice per day in use with the readings separated by at least 4 hours. The incubator, water bath or heating block identification, date, time, calibration corrected temperature and the initials of the responsible individual shall be recorded.

(9) *Volumetric dispensing devices.*

(i) Except for Class A glassware, mechanical volumetric dispensing devices including burettes, autopipetors and dilutors, must be of sufficient sensitivity for the application. Delivery volumes of mechanical volumetric dispensing devices shall be checked using a**n appropriate[gravimetric]** method at least once every 3 months.

(ii) Verification shall be considered acceptable if the accuracy of the volumetric dispensing device is within 2.5% of expected values. Volumetric dispensing devices that do not meet this criterion shall not be used.

(10) *Graduated sample containers.*

(i) Except for Class A glassware, w[W]hen graduation marks on **[clear glass or plastic]filter** funnels**, [or]**sample bottles **or labware** are used to measure sample volume, an environmental laboratory shall verify and document the accuracy of the volume **of use for[of]** each lot or at least once per year, whichever is more frequent.

(ii) Verification shall be considered acceptable if the accuracy of the graduated sample container is within 2.5% of expected values. Graduated sample containers that do not meet this criterion shall not be used to measure sample volumes.

[(11) *Spectrophotometer or colorimeter*. A spectrophotometer or colorimeter must be calibrated according to the manufacturer's specifications or test methods. An environmental laboratory shall maintain records of the calibrations.]

(g) An environmental laboratory shall maintain records for all reference materials, reagents and support services utilized by the laboratory for testing or analysis.

[(h) Reference materials and reagents used for environmental testing must meet the following minimum requirements:

(1) Analytical reagent grade chemicals or equivalent are acceptable, unless a method specifies other reagent purity grade requirements.

(2) Reagent and standard solutions shall be checked regularly for signs of decomposition, evaporation, and expiration. An environmental laboratory shall maintain standard and reagent preparation. Standards and reagent preparation logs must contain identification of the compound, concentration, date prepared, initials of the individual preparing the solution and expiration date.

(3) Reagent and standard solution containers shall be labeled with identification of the compound, concentration, date prepared, initials of the individual who prepared the solution and expiration date.

(4) Purchased chemicals, solutions and standards shall be labeled with date of receipt and the date when the container is opened. Purchased chemicals, solutions and standards without an expiration date on the original container shall be discarded after 10 years from the date of receipt.

(5) When reagents are removed from a container, the amount removed shall be used entirely or the unused portion discarded.

(6) Compressed gases must be of commercial grade, unless a method specifies other requirements.]

(h) Reference materials, reagents, media and laboratory supplies that are essential to obtain analytical results (such as filters, solid-phase extraction disks/cartridges, pre-sterilized filtration units, certified pre-cleaned laboratory supplies, disposable volumetric equipment, pre-preserved sample containers) must meet the following minimum requirements:

(1) Analytical reagent grade chemicals or equivalent are acceptable, unless a method specifies other reagent purity grade requirements.

(2) Standard, reagent, and laboratory supply receipt records shall be maintained. These records shall include vendor, lot number, amount received, date of receipt, expiration date and certificates of analysis or purity, if available.

(3) Purchased chemicals, solutions, standards, media and laboratory supplies shall be labeled with date of receipt, expiration date and the date when the container is

opened. Purchased chemicals, solutions and standards without an expiration date on the original container shall be discarded after 10 years from the date of receipt.

(4) An environmental laboratory shall maintain records of standard, reagent and media preparation. Standard and reagent preparation records must contain identification of the compound, manufacturer, lot number, concentration, amount prepared, date prepared, final pH if used for microbiology testing, initials of the individual preparing the solution and expiration date.

(5) Reagent and standard solution containers shall be labeled with identification of the compound, traceability to the preparation record, such as unique identifier, and expiration date

(6) Standards, reagents and media shall not be used past the date of expiration unless re-evaluated and validated by a Department approved procedure.

(7) Reagent and standard solutions shall be checked regularly for signs of decomposition and evaporation. Reagent and standard solutions exhibiting signs of decomposition or evaporation shall be discarded.

(8) When reagents are removed from a container, the amount removed shall be used entirely or the unused portion discarded.

(9) Compressed gases must be of commercial grade, unless a method specifies other requirements.

(i) Plastic and glassware shall be cleaned to meet the sensitivity of the test method. Any cleaning and storage procedures that are not specified by the method shall be documented in a laboratory standard operating procedure.

§ 252.307. Methodology.

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

(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.

(c) When a method meeting the requirements of subsection (b) is not available, an environmental laboratory may apply to the Department to use alternate or experimental procedures.

(1) The Department will approve the use of alternate methodologies if the EPA has approved their use. An environmental laboratory shall submit a copy of the EPA's written approval for the use of the alternate method to the Department.

(2) The Department may allow alternate methods that use new or innovative technologies on a case-by-case basis.

(3) An environmental laboratory shall submit a request for use of new or innovative technology in writing to the Department. The request must include the reasons for proposing the method and the potential scope of use for the method.

(4) The Department will establish criteria for validating the method that are based upon the analyte to be tested.

(5) Upon receipt of the method validation data that meets the established criteria, the Department will approve or deny the request within 90 days and inform the laboratory of the basis of its decision in writing. The evaluation for approval will include consideration of the demonstrated need for the new or innovative technology, reasons for using the

method, performance of the method, method validation data and applicability of the method to the matrix.

(d) An environmental laboratory shall develop and maintain written standard operating procedures for all fields of accreditation.

(1) The environmental laboratory's standard operating procedures must accurately reflect all aspects of the testing or analysis for the fields of accreditation, including the following:

(i) Identification of the method.

(ii) Effective date.

(iii) Scope, including applicable matrix or matrices**, quantitation range, and for drinking water testing MCL(s) or action levels as appropriate.**

(iv) Equipment and supplies.

(v) Reagents and standards.

(vi) Quality control.

(vii) Calibration and standardization.

(viii) Analytical procedure.

(ix) Calculations.

(x) Corrective actions or contingencies for handling out-of-control or unacceptable quality control data.

(xi) Reporting of results.

(2) The standard operating procedures may consist of copies of published or referenced test methods or standard operating procedures that have been written by the environmental laboratory. When modifications to the published or referenced method have been made by the laboratory or when the published or referenced method is ambiguous or provides insufficient detail, the changes or clarifications shall be clearly described.

(e) An environmental laboratory shall make copies of the standard operating procedures, the promulgated method, Department regulations and Department guidance pertaining to testing or analysis of environmental samples available to the technical staff.

(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.

(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.

(h) The range of quantitation and detection limit shall be determined for each analyte reported by an environmental laboratory in accordance with a method specified by the Department.

(i) When a method specifies a validation procedure, the validation procedure shall be completed before environmental samples may be analyzed and reported. The results of this validation procedure shall be documented and kept on file for the duration of use of the method and for at least 5 years after the method is no longer in use.

[(j) The initial demonstration of capability requirements are as follows:

(1) Prior to the use of any method, an initial demonstration of capability is required.

(2) An initial demonstration of capability shall be completed each time there is a change in instrument type, personnel, or method.

(3) An initial demonstration of capability must include all sample preparation and analytical steps contained in the method.

(4) If the method or State or Federal regulations specify a procedure for the initial demonstration of capability, that procedure shall be followed, otherwise, an initial demonstration of capability shall be performed as follows:

(i) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not specify a concentration, the concentration must be approximately ten times the detection limit.

(ii) At least four aliquots of the quality control sample must be prepared and analyzed according to the method.

(iii) Using all of the results, calculate the mean recovery and the standard deviation of the mean recovery for the population sample in the same units used to report environmental samples. When it is not possible to determine mean and standard deviation, such as for presence-absence and logarithmic values, the environmental laboratory shall assess method performance using criteria from the method or other established and documented criteria.

(iv) Compare the information from subparagraph (iii) to the corresponding acceptance criteria for precision and accuracy in the method. To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

(5) When a method has been in use by an environmental laboratory prior to January 1, 2005, and there have been no changes in instrument type, personnel or method, the environmental laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.

(6) The laboratory shall retain all data necessary to reproduce the initial demonstration of capability.

(7) The work cell as a unit shall meet the requirements of this paragraph.

(i) When a member of a work cell changes, the new employee shall work with an experienced analyst in the work cell.

(ii) When a member of a work cell changes, the new work cell shall demonstrate capability by means of acceptable quality control performance checks on four consecutive batches. The acceptable performance shall be documented. If any quality control performance check within the four consecutive batches following the change in personnel fails to meet acceptance criteria, an initial demonstration of capability shall be completed.

(iii) If the entire work cell is changed, an initial demonstration of capability shall be completed.]

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 shall contain:**

(1) Laboratory's full name and physical address.

(2) Name, address (if different from above), and telephone number of laboratory supervisor(s).

(3) Revision number and effective date.

(4) 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 shall include:**

(1) Ethics policy statement as specified in subsection (d).

(2) Document control system as specified in subsection (c).
(3) Recordkeeping as specified in § 252.706 (relating to recordkeeping).
(4) Procedures for termination of operations and transfer of records as specified in § 252.706 (relating to recordkeeping).
(5) Procedures for detecting and permitting departures from established procedures as specified in subsections (i) and (h).
(6) Procedures for detecting and preventing improper practices as specified in § 252.304 (relating to personnel requirements).
(7) Sample handling and acceptance procedures as specified in subsections (f) and (g).
(8) Reporting analytical results as specified in subsection (j).
(9) 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 **[have]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 thermal and/or chemical preservation and sample container. Results of these checks shall be recorded.

(2) The laboratory shall utilize a recordkeeping system that meets the requirements of Section 706 (related to recordkeeping) to document receipt of all sample containers. The recordkeeping system shall include

(i) Client/project name.
(ii) The date, time and location of sample collection, name of sample collector and field identification code.
(ii) Date and time of laboratory receipt.
(iii) Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code
(iv) Unique laboratory ID code that corresponds to the information required by this paragraph.
(v) 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 shall 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) Identification of the test method used.
(5) 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) Time of sample preparation and/or analysis 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) Quanitation Limit
(11) The name(s), function(s), and signature(s) of the person(s) authorizing the test report.
(12) Results reported on a basis other than as received (e.g., dry weight).
(13) Identification of testing or analysis results not covered by the laboratory's scope of accreditation.
(14) Identification of results that do not meet the requirements of this Chapter.
(15) 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 pursuant to subsection (j) (relating to laboratory sample handling procedures) provided the information required by subsection (j) is maintained according to § 252.706

(l[k]) 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[l]) 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 and 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.

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

§ 252.402. Essential quality control requirements— chemistry.
(a) In addition to the requirements of § 252.401 (relating to basic requirements), laboratories performing testing or analysis of environmental samples in the area of chemistry shall comply with this section.

(b) When the method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

(c) Initial calibration requirements are as follows:
(1) An environmental laboratory shall follow the initial calibration requirements of the method.
(2) The results of testing or analysis of environmental samples shall be determined from an initial calibration and may not be determined from any continuing calibration verification, unless otherwise required by regulation, method or program.
(3) The details of the initial calibration procedures including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the laboratory's standard operating procedure.
(4) Raw data records shall be retained to permit reconstruction of the initial calibration.
(5) Initial calibrations shall be verified with a standard obtained from a second manufacturer or with a standard from the same manufacturer if the verification standard is documented by the manufacturer as prepared independently of the standard used during initial calibration.
[(6) Results not bracketed by the initial calibration standards shall be reported with appropriate qualifiers.]
(6[7]) The lowest standard used for initial calibration may not be below the detection limit. The lowest standard must be at or below the lower limit of the range of quantitation.

(d) Except for methods that explicitly allow initial calibration using a single concentration of standard, initial calibration shall be done using multiple concentrations of standards according to the requirements of this subsection.
(1) Unless otherwise specified in the method, the initial calibration must meet one of the following criteria:
(i) A relative standard deviation of less than 20% for the calculated response factors.

(ii) A **coefficient of determination[correlation coefficient]** (r^2) of 0.99 for a linear calibration curve.

(iii) A **coefficient of determination[correlation coefficient]** (r^2) of 0.999 for a nonlinear calibration curve **determined with the use of at least 6 calibration standards** or as otherwise specified by the Department.

(2) If the initial calibration fails to meet established acceptance criteria, corrective action shall be performed and all associated environmental samples shall be reanalyzed after an acceptable initial calibration is obtained. If reanalysis of the environmental samples is not possible, a new environmental sample shall be collected.

(3) If the results of testing or analysis of environmental samples that are below the initial calibration range are reported, the results shall be reported with appropriate data qualifiers.

(4) If the results of testing or analysis of environmental samples are above the initial calibration range, the environmental sample shall be diluted and reanalyzed or the results reported with appropriate data qualifiers. Sample results within the established calibration range will not require data qualifiers.

(5) The lowest calibration standard may not be below the detection limit and may not be above the MCL.

(6) If the method does not specify the number of calibration standards, the minimum number of calibration standards **for a response factor or linear calibration**, not including blanks or a zero standard, shall be determined as follows:

(i) For an initial calibration covering a range up to 20 times the lowest quantitation level, a minimum of three calibration standards shall be used.

(ii) For an initial calibration covering a range from greater than 20 times and up to 50 times the lowest quantitation level, a minimum of four calibration standards shall be used.

(iii) For an initial calibration covering a range greater than 50 times and up to 100 times the lowest quantitation level, a minimum of five calibration standards shall be used.

(e) For a method that explicitly allows calibration using a single concentration of a standard, not including a blank or zero concentration standard, the initial calibration shall meet the requirements of this subsection.

(1) Prior to the testing or analysis of environmental samples, the linear range of the instrument shall be established by analyzing a series of standards, one of which shall be at the lowest quantitation level.

(2) An initial calibration using a single calibration standard and a zero point shall be performed at the beginning of each analysis day.

(3) A standard corresponding to the lowest quantitation level must be analyzed with each analytical batch and must meet the acceptance criteria established by the method. When there are no established criteria in the method, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

(4) If the results of testing or analysis of environmental samples that are below the lowest quantitation level verification standard, specified in paragraph (3), are to be reported, the results shall be reported with appropriate data qualifiers.

(5) If the results of testing or analysis of environmental samples produce a result above the associated single point standard, the environmental laboratory shall do one of the following:

(i) Analyze a standard at or above the sample concentration that meets established acceptance criteria to validate linearity.

(ii) Dilute the sample so that the result falls below the single point calibration concentration.

(iii) Report the data with an appropriate data qualifier.

(f) Calibration verification requirements are as follows:

(1) A calibration verification standard shall be analyzed at the beginning and end of each analysis day. For methods that use an internal standard, a calibration verification standard is not required at the end of the analysis day unless specified in the method, or State or Federal law or regulation.

(2) A calibration verification standard shall be analyzed after every ten samples, unless a different frequency is specified in the method.

(3) At a minimum, the **laboratory shall verify the calibration curve of each analytical batch[day] with [concentration of the]**calibration verification standard**s [shall be alternated between]at** a low and a high level.

(i) The concentration of the low calibration verification standard shall be within the lower 20% of the calibration curve and not more than five times the lowest quantitation level.

(ii) The concentration of the high calibration verification standard shall be within the upper 20% of the calibration curve.

(4) Details of the calibration verification procedure including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the laboratory's standard operating procedure.

(5) Raw data records shall be retained to permit reconstruction of the calibration verification.

(6) Acceptance criteria for calibration verification standards in the method shall be followed. When there are no established criteria in the method, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

(7) If a calibration verification standard fails the established acceptance criteria, an environmental laboratory shall initiate corrective actions. If the corrective actions fail to produce an immediate consecutive calibration verification standard within the acceptance criteria, a new calibration verification standard shall be prepared. If the freshly prepared calibration verification standard fails to produce a result within the established acceptance criteria, the environmental laboratory shall recalibrate the test or analysis according to the method or as set forth in subsection (c) and as set forth in either subsection (d) or (e).

(8) To the extent possible, and as provided by paragraph (1), environmental samples not bracketed by acceptable calibration verification standards shall be reanalyzed. If the calibration verification standard 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 calibration verification standard shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers. Sample results associated with an unacceptable calibration verification may be useable under the following conditions:

(i) When the acceptance criteria for the calibration verification are exceeded high and associated sample results are below the lowest level of quantitation for the analyte of interest.

(ii) When the acceptance criteria for the calibration verification are exceeded low and associated sample results are above the maximum regulatory limit for the analyte of interest.

(g) Method blank requirements are as follows:

(1) A method blank must be processed along with and under the same conditions as the associated environmental samples including all steps of the analytical procedure.

(2) A method blank must be analyzed at a minimum of one per preparation batch. When no separate preparation method is used (example: volatiles in water), the batch shall be defined as no more than 20 environmental samples that are analyzed together using the same method, personnel and lots of reagents.

(3) A method blank must consist of a matrix that is similar to the associated environmental samples and is free of the analytes of interest. When a matrix that is similar to the associated environmental samples that is free of the analytes of interest is not available, reagent water or an artificial or simulated matrix may be used.

(4) A method blank is considered contaminated if one of the following applies:

(i) The concentration of a target analyte in the method blank is at or above the reporting limit established by the method, by the laboratory or by regulation.

(ii) The contamination in the method blank otherwise affects the environmental sample results as described in the method or in individual project data quality objectives.

(5) If a contaminant is detected in the method blank, the source of contamination shall be investigated and measures shall be taken to minimize or eliminate the problem.

(6) To the extent possible, any environmental samples associated with a contaminated method blank shall be reprocessed for analysis. If a contaminated method blank 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 contaminated method blank shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers.

(h) Laboratory control sample requirements are as follows:

(1) A laboratory control sample must be processed along with and under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure.

(2) **A laboratory control sample must consist of a matrix that is similar to the associated environmental samples and is free of the analytes of interest. When a matrix that is similar to the associated environmental samples that is free of the analytes of interest is not available, reagent water or an artificial or simulated matrix may be used. [The laboratory control sample must consist of a defined matrix containing known and verified concentrations of analytes. The Department will allow the use of an artificial or simulated matrix when a defined matrix is not commercially available.]**

(3) An environmental laboratory shall analyze a laboratory control sample at a minimum of one per preparation batch. When no separate preparation method is used, for example volatiles in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together with the same method, personnel and lots of reagents.

(4) All analyte concentrations in the laboratory control sample must be within the calibration range of the method and at or below the maximum contaminant level.

(5) The components to be spiked into the laboratory control sample must be as specified by the method or other regulatory requirement. In the absence of specified components, the environmental laboratory shall use the following:

(i) For those components that interfere with an accurate assessment, such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the laboratory control sample must represent the chemistries and elution patterns of the components to be reported.

(ii) For methods with more than ten analytes, a representative number may be chosen. The analytes selected shall be representative of all chemistries and analytes reported and shall be chosen using the following criteria:

(A) Targeted components shall be included in the laboratory control sample over a 2-year period.

(B) For methods that include 1—10 components, the laboratory control sample must contain all components.

(C) For methods that include 11—20 components, the laboratory control sample must contain at least ten components or 80%, whichever is greater.

(D) For methods with more than 20 components, the laboratory control samples must contain at least 16 components.

(6) Each individual laboratory control sample must be compared to the acceptance criteria in the method. When there are no established criteria in the method, an environmental laboratory shall determine internal criteria and document the procedure used to establish the limits.

(7) Environmental samples associated with an out of control laboratory control sample must be reprocessed and reanalyzed from the beginning of the method or the results reported with the appropriate data qualifiers.

(i) Sample duplicate requirements are as follows:

(1) A sample duplicate or matrix spike duplicate must be processed along with and under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure.

(2[1]) A sample duplicate or matrix spike duplicate shall be analyzed at a minimum of one per preparation batch. When no separate preparation method is used, for example volatiles in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together using the same method, personnel and lots of reagents.

(3[2]) An environmental laboratory shall document the calculations used for determining the relative percent difference or other statistical method for evaluation of the duplicate pairs.

(4[3]) Each duplicate relative percent difference shall be compared to the acceptance criteria in the method. When there are no established criteria in the method, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

(5[4]) For duplicate results outside established criteria, corrective action shall be documented and the data reported with appropriate data qualifiers.

(j) Surrogate spike requirements are as follows:

(1) Surrogate compounds, when commercially available, shall be added to all samples, standards and blanks for all organic chromatography test methods.

(2) Surrogate compounds shall be chosen to represent the various chemistries of the target analytes in the method.

(3) The results of the surrogate spike shall be compared to the acceptance criteria published in the method. When there are no established acceptance criteria for surrogate recovery in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(4) For surrogate spike results outside established criteria, corrective action shall be documented and the data reported with appropriate data qualifiers.

(k) Detection limit requirements are as follows:

(1) A detection limit shall be determined by the protocol in the method or regulation. If the protocol for determining detection limits is not specified in the method or regulation, the environmental laboratory shall select a procedure that reflects instrument limitations and the intended application of the method.

(2) A detection limit study is not required for any component for which spiking solutions or quality control samples are not available, such as temperature. A detection limit study is not required for testing or analysis where the results are logarithmic, such as pH, or when the results are expressed as presence or absence.

(3) A detection limit shall be initially determined for the compounds of interest in each method in a matrix in which neither the target analyte nor interferences are at a concentration that would impact the results. The detection limit shall be determined in the matrix of interest.

(4) A detection limit shall be determined each time there is a change in the method that affects how the test is performed or that affects the sensitivity of the analysis.

(5) The sample processing steps of the method shall be included in the determination of the detection limit.
(6) Supporting data shall be retained to permit reconstruction of the detection limit study.
(7) An environmental laboratory shall have an established procedure to relate detection limits with quantitation limits.
(8) The method's lower limit of quantitation shall be established and shall be above the detection limit.

(l) When retention times are used for the identification of an analyte, an environmental laboratory shall develop and document acceptance criteria for retention time windows. The laboratory shall document acceptance criteria for mass spectral tuning.

(m) When manual integrations are performed for chromatography methods, the laboratory shall have written procedures for manual integrations and instrument manipulations.
(1) The manual integration procedures shall detail the steps taken to perform the integrations and shall define proper and improper integrations.
(2) The laboratory shall document manual integrations with the reason for the integration and the initials of the individual performing the integration.
(3) The laboratory shall retain a copy of the data before and after manual integration.

(n) The laboratory shall employ confirmation techniques to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory or for a sample location that has not previously yielded detectable results for a particular compound.
(1) Such confirmations shall be performed when analysis involves the use of an organic chromatography method not utilizing a mass spectrometer.
(2) All confirmations shall be documented.

(o) Records of all equipment, reference materials, reagents, and supplies shall be maintained in accordance with the requirements of § 252.306.

§ 252.403. Essential quality control requirements—toxicity testing.
(a) In addition to the requirements of § 252.401 (relating to basic requirements), an environmental laboratory that measures the toxicity or bioaccumulation of contaminants, including testing of effluents, receiving waters, sediments, elutriates, leachates and soils shall comply with this section.

(b) When the method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

(c) An environmental laboratory that measures toxicity or bioaccumulation of contaminants shall comply with Chapter 16 (relating to water quality toxics management strategy—statement of policy) regarding counting of neonates, algae cells and weighing of fish for selected endpoints.

(d) Negative control requirements are as follows:
(1) In addition to the negative controls specified by the method, permit or regulation, additional negative controls shall be included when sample adjustments (for example, pH adjustments or dechlorination) or solvent carriers are used in the test.
(2) The results of the negative controls shall be compared to the acceptance criteria published in the method. When there are no established acceptance criteria for the negative control in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(3) The test acceptability criteria for negative controls as specified in the method must be achieved for both the reference toxicant and the environmental sample toxicity test.

(e) The requirements for reference toxicants are as follows:

(1) The environmental laboratory shall demonstrate the ability to obtain consistent results with reference toxicants before performing toxicity tests on environmental samples.

(i) Intralaboratory precision shall be determined by performing a minimum of five acceptable reference toxicant tests for each method and species using different batches of organisms and negative controls (water, sediment or soil) before performing testing or analysis on environmental samples.

(ii) An environmental laboratory shall maintain control charts for the control performance and reference toxicant statistical endpoint (such as NOEC or ECp) and evaluate the intralaboratory variability with a specific reference toxicant for each method.

(iii) The results of the toxicant test shall be compared to the acceptance criteria published in the method. When there are no established acceptance criteria for the toxicant test in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(2) The following minimum frequency of reference toxicant testing shall be met:

(i) Each batch of test organisms obtained from an outside source, field collection or from laboratory spawning of field-collected species not amenable to routine laboratory culture shall be evaluated with a reference toxicant test of the same type as the environmental toxicity test within 7 days preceding the test or concurrently with the test.

(ii) Test organisms obtained from in-house laboratory cultures shall be tested with reference toxicant tests at least once each month for each method.

(iii) If a species produced by in-house laboratory cultures is used less than once per month, a reference toxicant test of the same type shall be performed with each environmental toxicity test.

(iv) When methods and species commonly used in the laboratory are only tested on a seasonal basis, reference toxicant tests shall be conducted each month the method is in use.

(3) Ongoing environmental laboratory performance shall be documented by maintaining laboratory quality control charts that meet the following requirements:

(i) For endpoints that are point estimates (ICp, ECp), control charts shall be constructed by plotting the cumulative geometric mean and the limits that consist of the upper and lower 95% confidence limits (+2 standard deviations).

(ii) For endpoints from hypothesis tests (NOEC, NOAEC), control charts shall be constructed by plotting the values directly and the control limits shall consist of one concentration interval above and below the concentration representing central tendency or the mode.

(iii) After 20 data points are collected for a method and species, the control charts shall be maintained by using only the most recent 20 data points.

(iv) Test results that fall outside of control chart limits at a frequency of 5% or less shall be retested and confirmed before reporting and all results shall be documented in the report of the testing and analysis.

(v) The endpoint shall be compared to the acceptance criteria published in the method.

(vi) When there are no established acceptance criteria for the endpoint in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(vii) If the reference toxicant fails to meet acceptance criteria, the results of environmental toxicity tests conducted during the affected period shall be examined

for defects and the test repeated using a different batch of organisms or the results shall be reported with appropriate data qualifiers.

(4) Reference toxicant tests conducted for a method and species must use the same reference toxicant, test concentrations, dilution water and data analysis method as the environmental toxicity tests for which the precision is being evaluated unless otherwise specified in the method.

(5) The test duration, dilution or control water, feeding, organism age, age range and density, test volumes, renewal frequency, water quality measurements, number of test concentrations, replicates and organisms per replicate must be the same as the environmental toxicity test. A dilution factor of greater than 0.5 shall be used for both acute and chronic tests.

(f) Sensitivity requirements are as follows:

(1) If the Dunnett's procedure or hypothesis test (NOEC, NOAEC) is used, the statistical minimum significant difference (SMSD) by species shall be calculated according to the formula specified by the method and reported with the test results. The SMSD must be estimated for nonnormal distribution or heterogeneous variances, or both.

(2) Confidence intervals for point estimates (LCp, ICp or ECp) shall be reported as a measure of the precision around the point estimate value.

(g) When required, the data shall be plotted in the form of a curve relating the dose of the chemical or concentration of sample to cumulative percentage of test organisms demonstrating a response, such as death.

(h) At least once every 30 days, an environmental laboratory shall verify and document that the reagent grade water meets the following criteria:

(1) Conductivity must be less than 0.1 µmhos/cm or resistance greater than 17 megohms at 25°C.

(2) pH must be between 5.5 to 7.5.

(3) Total residual chlorine must be nondetectable.

(i) Reagent water used for culturing and testing shall be analyzed for toxic metals and organics whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause can be identified.

(j) An environmental laboratory shall demonstrate that any analyte at a measured concentration or the reported detection limit does not exceed 1/10 the expected chronic value for the most sensitive species tested or cultured.

(k) Air used for aeration of test solutions, dilution waters and cultures must be free of oil and fumes.

(l) The requirements for test organisms are as follows:

(1) An environmental laboratory shall positively identify test organisms to species on an annual basis. The taxonomic reference (citation and pages) and the names of the taxonomic experts shall be documented. When organisms are obtained from an outside source, an environmental laboratory shall obtain the information from the supplier.

(i) Organisms used for a test must be from the same source. When available, certified seeds shall be used for soil tests.

(ii) Organisms used in tests or as brood stock to produce neonate test organisms must appear healthy, show no signs of stress or disease and exhibit survival of greater than 90% during the 24-hour period immediately preceding use in tests.

(iii) An environmental laboratory shall document the health and culturing conditions of all organisms used for testing. The documentation must include culture conditions and observations of any stress, disease or mortality.
(iv) When organisms are obtained from an outside source, the laboratory shall obtain written documentation of the water quality parameters and biological observations for each lot of organisms received.
(v) An environmental laboratory shall record the water quality parameters and the biological observations when the organisms arrive at the environmental laboratory.
(vi) Supporting information such as hatch dates and times, times of brood releases and metrics (for example, chironomid head capsule width) shall be documented.
(vii) Organisms obtained from an outside source may not be from different batches.
(viii) The control population of *Ceriodaphnia* in chronic effluent or receiving water tests may not contain more than 10% males.
(ix) Test soils and sediments must be within the geochemical tolerance range of the test organism.

(2) The requirements for feeding of test organisms are as follows:
(i) For each new batch of laboratory-prepared food or lot of commercial food used by the environmental laboratory, the performance of organisms fed with the new food shall be compared with the performance of organisms fed with a food of known quality. The suitability of food used for culturing shall be determined using a measure that evaluates the effect of food quality on survival and growth or reproduction of each of the relevant test species.
(ii) Foods used only in chronic toxicity tests shall be evaluated using the reference toxicant employed in the environmental laboratory quality assurance program, and shall be compared with results of previous tests using a food of known quality.
(iii) In the case of algae, rotifers or other cultured foods, which are collected as a continuous batch, the quality of the food shall be assessed as described in subparagraphs (i) and (ii) each time new nutrient stocks are prepared, a new starter culture is employed or when a significant change in culture conditions occurs.
(iv) The environmental laboratory shall have written procedures for the statistical evaluation of food acceptability.
(v) Food used to culture organisms used in bioaccumulation tests shall be analyzed for the compounds to be measured in the bioaccumulation tests.

(m) Equipment requirements are as follows:
(1) If closed incubators are used, culturing and testing of organisms shall be separated to avoid loss of cultures due to cross-contamination.
(2) Temperature control equipment must be adequate to maintain the required test temperature. The average daily temperature of the test solutions shall be maintained within 1°C of the selected test temperature for the duration of the test. Temperature measurements shall beamed at least once per 24-hour period. The test temperature for continuous-flow toxicity tests shall be monitored and recorded continuously.
(3) The test chambers used in a test must be identical.
(4) Materials used for test chambers and any material coming in contact with test samples, solutions, control water, sediment, soil or food must be nontoxic and cleaned according to the method. Materials may not add to nor reduce sample toxicity.
(5) Light intensity shall be maintained as specified in the method. Measurements shall be made and recorded at least once per 12 months.
(6) The photoperiod shall be maintained as specified in the method and be documented at least once every 90days.
(7) For algal and plant tests, the light intensity shall be measured and recorded at the start of each test.(n) The requirements for sample holding times and conditions are as follows:
(1) The sample holding time may not exceed 36 hours.

(2) The last use of the sample in renewal tests may not exceed 72 hours unless specifically approved by the Department.
(3) Samples shall be chilled to 4°C during or immediately after collection and held at that temperature until time of analysis.

(n[o]) Chronic tests must have a minimum of four replicates per treatment.

(o[p]) The requirements for testing conditions are as follows:
(1) Dissolved oxygen and pH in aquatic tests must be within acceptable ranges published in the method. When there are no established acceptance criteria in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.
(2) During aquatic chronic testing, dissolved oxygen and pH shall be measured daily in at least one replicate of each concentration.
(3) In static-renewal tests, dissolved oxygen shall be measured at both the beginning and end of each 24-hourexposure period.
(4) The pH shall be measured at the end of each exposure period after organism transfer.
(5) Minimal aeration may be provided to tests only if acceptable dissolved oxygen concentrations cannot be otherwise maintained or if specified by the method.

(p) Records of all equipment, reference materials, reagents, and supplies shall be maintained in accordance with the requirements of § 252.306.

§ 252.404. Essential quality control requirement—microbiology.
(a) In addition to the requirements of § 252.401 (relating to basic requirements), environmental laboratories performing testing or analysis in the area of microbiology shall comply with this section.

(b) When the method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

(c) The following pieces of equipment shall be maintained according to this subsection:
(1) *Autoclave.*
(i) An environmental laboratory shall use autoclaves that meet specified temperature tolerances of the method. **[Pressure cookers may not be used.]Because of safety concerns and difficulties with operational control, pressure cookers should not be used. Pressure cookers may not be used for sterilization of media.**
[(ii) Prior to first use, an environmental laboratory shall evaluate and document the performance of an autoclave by establishing its functional properties and performance (for example, heat distribution characteristics with respect to typical uses).]
(ii[i]) A continuous temperature-recording device or a maximum-temperature-registering thermometer shall be used during each autoclave cycle.
(iii[v]) An environmental laboratory shall verify the sterilization capability of each autoclave by utilizing appropriate biological indicators (for example, spore strips or ampoules) once a month. Records of biological indicator tests shall be maintained **[in a laboratory notebook]**and include the autoclave identification, date, incubation time and temperature, results and initials of the responsible individual.
(iv) An environmental laboratory shall verify the mechanical timing device, if used, for each autoclave every 3 months. Records of mechanical timer verification shall be maintained **[in a laboratory notebook]**and include the autoclave identification, date, mechanical timing device time, actual time and initials of the responsible individual. Correction factors shall be documented and used.

(v[i]) Autoclaves shall be properly cleaned and maintained. **[A qualified person shall service autoclaves at least once per year. Servicing must include a pressure check and calibration of temperature devices. Records of annual service shall be maintained and the service date shall be recorded on the autoclave.]** **Copies of service contracts or internal maintenance protocols and maintenance records must be kept.**

(vi[i]) Required times for autoclaving items at 121°C are set forth in this subparagraph. The following items must be at temperature for the required amount of time. Except for membrane filters and pads and carbohydrate-containing media, indicated times are minimum times and may necessitate adjustment depending upon volumes, containers and loads. For autoclave runs that include membrane filters and pads and media, the total cycle time may not exceed 45 minutes. Autoclaved membrane filters and pads and media shall be removed immediately after completion of the autoclave cycle.

(A) Membrane filters and pads 10 minutes
(B) Carbohydrate-containing media 12-15 minutes
(C) Contaminated test materials 30 minutes
(D) Membrane filtration units 15 minutes
(E) Sample containers 15 minutes
(F) Individual glassware 15 minutes
(G) Dilution water 15 minutes
(H) Rinse water 15-30 minutes

(vii[i]) Records of each autoclave run shall be maintained **[in a laboratory notebook]**and include the date, contents, sterilization time and temperature, total cycle time (recorded as time in and time out) and initials of the responsible individual.

([ix]viii) If an autoclave cycle fails to meet any requirement, corrective action shall be documented. Media may not be reautoclaved.

(2) *Hot air oven.*

[(i) Prior to first use, an environmental laboratory shall evaluate the performance of each hot air oven by establishing its functional properties and performance (for example, heat distribution characteristics with respect to typical uses).]

(i[i]) An environmental laboratory shall maintain a thermometer, graduated in 10°C increments or less with the bulb placed in sand, in each hot air oven.

(ii[i]) An environmental laboratory shall verify the sterilization capability of each hot air oven by utilizing appropriate biological indicators (for example, spore strips) once a month. Records of biological indicator tests shall be maintained **[in a laboratory notebook]**and include the hot air oven identification, date, incubation time and temperature, results and initials of the responsible individual.

(iii[v]) An environmental laboratory shall sterilize items in a hot air oven maintaining a temperature of 170°—180°C for a minimum of 2 hours. Only dry items may be sterilized in a hot air oven.

(iv) Records of each hot air oven operation shall be maintained and include the date, contents, sterilization time and temperature, and initials of the responsible individual.

[(3) *Optical counting equipment.*

(i) An environmental laboratory shall use appropriate optical counting equipment to view and enumerate colonies.

(ii) A dark field colony counter shall be used to count heterotrophic plate count colonies.

(iii) A 10X to 15X stereomicroscope with a fluorescent light source shall be used to count sheen colonies.]

(3[4]) *Inoculating equipment.*

(i) An environmental laboratory shall use appropriate sterile inoculating equipment.

(ii) Metal loops and needles must be made of nickel alloy or platinum.

(iii) Wooden applicator sticks must be sterilized using dry heat.

(iv) For oxidase tests, nickel alloy loops may not be used.

(4[5]) *Membrane filtration equipment.*

(i) Membrane filtration funnels must be stainless steel, glass**, porcelain** or autoclaveable **or presterilized** plastic. Membrane filtration funnels may not be scratched or corroded and may not leak.

(ii) Membrane filtration units shall be **sterilized[autoclaved]** before the beginning of a filtration series. A filtration series ends when 30 minutes or longer elapses after a sample is filtered.

(iii) Forceps must be blunt and smooth-tipped without corrugations on the inner sides of tips.

(iv) Membrane filters must meet the following requirements:

(a) Membrane filters must be made of cellulose ester, white, grid marked, 47 mm diameter and 0.45-µm pore size unless otherwise specified by the method.

(b) Membrane filters must be either purchased presterilized or autoclaved for 10 minutes at 121°C before use. Membrane filters may not be brittle or distorted.

(c) Membrane filters must be approved (based upon manufacturer data from tests for toxicity, recovery, retention and absence of growth-promoting substances) for the specified analysis for which they are to be used.

[(v) Records of membrane filters shall be maintained and include the type, lot number, date received and date opened. The manufacturer's specification/certification sheet shall be retained for each lot of membrane filters.]

(v[i]) An environmental laboratory using an ultraviolet sanitation lamp to sanitize filtration funnels between successive filtrations shall test the ultraviolet sanitation lamp every 3 months for effectiveness with an appropriate UV light meter or by plate count agar spread plates. Records of ultraviolet lamp tests shall be maintained and bulbs shall be replaced if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.

(5[6]) *Culture dishes.*

(i) Culture dishes must be presterilized plastic or sterilizable glass and of appropriate size for the method.

(ii) Stainless steel canisters, aluminum canisters or a wrap of heavy aluminum foil or char-resistant paper, shall be used for autoclave sterilization of glass culture dishes.

(iii) Loose-lid culture dishes shall be incubated in a tight fitting container containing a moistened paper towel.

(iv) Opened packs of disposable culture dishes shall be resealed between use periods.

(6[7]) *Culture tubes and closures.*

Culture tubes and containers must be of sufficient size to contain medium and sample without being more than three quarters full. Tube closures must be stainless steel, aluminum, plastic or a screw cap with a nontoxic liner.

(7[8]) *Pipettes.*

(i) Pipettes must have legible markings and may not be chipped or etched **and must be accurate to within 2.5% tolerance.**

(ii) Stainless steel canisters, aluminum canisters or a wrap of heavy aluminum foil or char-resistant paper shall be used for autoclave sterilization of pipettes.

(iii) Opened packs of disposable sterile pipettes shall be resealed between use periods.

(8[9]) *Sample containers.*

(i) Sample containers must be sterile plastic bags or wide-mouth plastic or noncorrosive glass bottles with nonleaking ground glass stoppers or caps with nontoxic liners that can withstand repeated sterilization. Sample containers must be capable of holding sufficient volume of sample for all required tests while maintaining adequate air space for mixing.

(ii) Glass stoppers must be covered with aluminum foil or char-resistant paper for sterilization.

(iii) Glass and plastic bottles that have not been presterilized shall be sterilized by autoclaving. Glass bottles may be sterilized by dry heat. Empty containers shall be moistened with several drops of water prior to autoclaving.

(9[10]) *Plastic and glassware washing procedure.*

(i) Prior to the initial use of a lot of detergent or washing procedure, an environmental laboratory shall perform an inhibitory residue test utilizing the method described in the currently approved editions of Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005). Records of inhibitory residue tests shall be maintained and include the detergent identification, date, calculations, results

(ii) Washed plastic and glassware shall be tested at least once each month for possible acid or alkaline residue by testing at least one piece of plastic and glassware with a suitable pH indicator such as 0.04% bromothymol blue. Records of pH tests shall be maintained.

(10[1]) *Ultraviolet lamp.*

An environmental laboratory shall use a 365-nm, 6-watt ultraviolet lamp in a darkened room to view sample fluorescence.

(11[2]) *Quanti-TrayTM Sealer.*

(i) An environmental laboratory shall perform a sealer check on each Quanti-Tray Sealer once a month by adding a dye to a water sample and performing the sealing procedure.

(ii) Records of the sealer check shall be maintained and include the sealer identification, date, results and initials of responsible individual. If dye is observed outside the wells, the Quanti-Tray Sealer may not be used.

(d) The requirements for reagent water are as follows:

(1) An environmental laboratory shall use reagent water in the preparation of media, solutions and buffers.

(2) An environmental laboratory shall demonstrate that reagent water meets the following criteria on a monthly basis or whenever maintenance is performed on the water treatment system or at startup after a period of nonuse longer than 1 month:

(i) Total chlorine residual must be less than 0.1 mg/L.

(ii) Conductivity must be less than 2.0 µmhos/cm or resistance greater than 0.5 megohms at 25°C.

(iii) Heterotrophic plate count must be less than 500 CFU/mL.

(3) An environmental laboratory shall demonstrate that reagent water meets the following criteria every 12 months:

(i) The individual concentration of lead, cadmium, chromium, copper, nickel and zinc must be less than 0.05 mg/L.

(ii) The total concentration of lead, cadmium, chromium, copper, nickel and zinc must be less than 0.1 mg/L.

(iii) Except as provided in subsection (d)(6), the bacteriological water quality test ratio must be between 0.8 and 3.0. The bacteriological water quality test shall be

performed according to the currently approved editions of Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005).

(4) The **[monthly and annual reagent water]**__metals__ analyses may only be performed by an environmental laboratory accredited under this chapter for**[the]** __those__ field__s__ of accreditation**[that includes the analyte].**

(5) Results of the monthly and annual reagent water analysis shall be maintained and include the date, type of test, results and initials of responsible individual. Reagent water that does not meet the required criteria may not be used.

(6) The bacteriological water quality test need not be performed if the environmental laboratory can supply documentation to show that their laboratory pure water or reagent water meets the criteria, as specified in __section 1080 of__ the currently approved editions of Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005), for Type I __(high-quality)__ or Type II __(medium-quality)__ reagent water.

(e) The requirements for dilution/rinse water are as follows:

(1) Stock buffer solution or peptone water shall be prepared as specified in the currently approved editions of Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005).

(2) Stock buffers shall be autoclaved or filter-sterilized. **[Stock buffer containers shall be labeled and dated.]**Stock buffers shall be refrigerated**[.]** __and__**[Stored stock buffers]** must be free from turbidity.

(3) Dilution/rinse water solutions shall be prepared as specified in the currently approved editions of Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005).

[(4) Records of stock buffers and dilution/rinse water preparation shall be maintained and include the date prepared, lot number or laboratory identification of solutions used, amounts measured, final pH and initials of the responsible individual.]

(f) The requirements for media are as follows:

(1) An environmental laboratory shall use dehydrated or commercially manufactured prepared media. Dehydrated media shall be stored in a cool, dry location. Caked or discolored dehydrated media shall be discarded.

[(2) An environmental laboratory that uses commercially prepared media shall maintain records on each lot received that includes the date received, type of media, lot number and pH verification. Media may not be used after the manufacturer's expiration date.]

(__2__**[3])** An environmental laboratory that prepares media from dehydrated stock shall follow method specifications**[and maintain records of each batch that includes the date of preparation, type of media, lot number, amounts measured, sterilization time and temperature, final pH and initials of the responsible individual].**

(__3__**[4])** Media may not be reautoclaved.

(__4__**[5])** After **[sterilization, prepared]**__preparation__, media shall be stored and maintained as follows:

(i) Stored away from sources of direct light.

(ii) Prepared plates shall be stored in sealed plastic bags or containers.

(iii) Each bag, container or rack of broth or agar media shall be labeled with the date prepared or expiration date.

(iv) **[Liquid]Fermentation** media stored in a refrigerator shall be incubated overnight at room temperature before use. Media that shows growth or bubbles may not be used.

(v) Prepared liquid media shall be discarded if evaporation exceeds 10% of the original volume.

(vi) Poured agar plates and broth in tubes, bottles or flasks with loose-fitting closures shall be discarded if not used within 2 weeks of sterilization unless otherwise specified by the method.

(vii) Broth in tightly closed screw-cap tubes, bottles or flasks shall be discarded if not used within 3 months of sterilization unless otherwise specified by the method.

(g) An environmental laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization or environmental exposure as follows:

(1) A sterility blank shall be analyzed for each lot of preprepared, ready-to-use medium and for each batch of medium prepared in the laboratory prior to first use of the medium. Records shall be maintained and include media identification, date, results and initials of responsible individual. If sterility blank indicates contamination, the media may not be used.

(2) For each **re-useable** membrane filtration unit used during a filtration series, the laboratory shall prepare at least one sterility blank at the beginning, after every ten samples, and at the end of the series**. A series is considered ended when more than 30 minutes elapses between filtrations. The laboratory must insert a sterility blank after every 10 samples or sanitize filtration units by UV light after each sample filtration in addition to the regular rinsing procedure. Records of sterility blank results must be maintained. If sterility blanks indicate contamination, the laboratory must treat affected sample according to program requirements.[and record the results. If the membrane filtration unit sterility blank indicates contamination, the data from affected samples shall be invalidated and an immediate resampling requested. When a filtration series is interrupted for more than 30 minutes, the filtration funnels shall be resterilized]**

(3) **For pre-sterilized single use filtration funnel units, a sterility check shall be performed on one funnel unit per lot. [For pour plate technique, sterility blanks of the medium shall be made by pouring at least one uninoculated plate for each lot of preprepared, ready-to use media and for each batch of medium prepared in the laboratory. Results shall be recorded. If the sterility check indicates contamination, the data from affected samples shall be invalidated.]**

(4) Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, presterilized containers with an appropriate nonselective growth media. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with an appropriate nonselective growth media. Results shall be maintained and include sample container identification, date, results and initials of responsible individual. If sample container sterility check indicates contamination, the affected sample container may not be used.

(5) A sterility blank shall be performed on each batch of dilution/rinse water prepared in the laboratory and on each batch of preprepared, ready-to-use dilution water with an appropriate non-selective growth media. The concentration of media shall be single strength after addition of dilution water. Results shall be maintained and include dilution/rinse water identification, date, results, and initials of the responsible individual. If dilution/rinse water sterility check indicates contamination, the affected dilution water may not be used.

(6) At least one filter from each new lot of membrane filters shall be checked for sterility with an appropriate nonselective growth media. Results shall be maintained and include

membrane filter identification, date, results and initials of the responsible individual. If the membrane filter sterility check indicates contamination, the affected membrane filters may not be used.

(h) The requirements for positive and negative culture control checks are as follows:

(1) Each preprepared, ready-to-use lot of medium and each batch of medium prepared in the laboratory shall be tested with at least one pure culture of a known positive reaction prior to first use of the medium **by the laboratory.** Records shall be maintained and include the date, media lot or batch number, type of media, positive culture control organism identification, results and initials of responsible individual. If positive culture control checks do not meet expected results, the affected media may not be used.

(2) Each preprepared, ready-to-use lot of selective medium and each batch of selective medium prepared in the laboratory shall be tested with at least one pure culture of a known negative reaction prior to first use of the medium **by the laboratory**. Records shall be maintained and include the date, media lot or batch number, type of media, negative culture control organism identification, results and initials of the responsible individual. If negative culture control checks do not meet expected results, the affected media may not be used.

(3) An environmental laboratory shall use stock positive and negative culture controls that are known and traceable to a recognized National collection. Documentation of traceability shall be maintained.

(4) Stock positive and negative culture controls shall be discarded upon the manufacturer's expiration date unless it is shown through appropriate biochemical and purity tests that the stock culture control has not been contaminated or altered.

(5) Culture controls may be single use or cultures maintained by the laboratory using a documented procedure that maintains the purity and viability of the organisms.

(6) Cultures maintained by the laboratory the following criteria must be met:

(i) Reference control cultures may be revived and sub-cultured once to provide reference stocks.

(ii) Reference stocks shall be preserved using a method which maintains the characteristics of the organism strains. If reference stocks are thawed they may not be re-frozen and re-used.

(iii) Working stocks shall be prepared from reference stocks for routine laboratory work.

(iv) If the laboratory sequentially cultures working stocks, the laboratory must prepare a second working stock. Sequential culturing may not be performed from a working stock that has been used for routine laboratory work

(v) Working stocks may not be used for more than 30 days.

(vi) Working stocks shall not be sequentially cultured more than five times and shall not be sub-cultured to replace reference stocks.

(vii) Secondary working stocks shall be used to prepare sequential working stocks.

(i) **[The requirements for test variability/reproducibility are as follows: (1)]**For test methods that specify colony counts, duplicate counts shall be performed monthly analysts, each analyst shall count typical colonies on the same plate. Counts may not differ by more on one positive sample for each month that the test is performed. If the laboratory has two or more analysts, each analyst shall count typical colonies on the same plate. Counts may not differ by more than 10% In an environmental laboratory with only one analyst, the analyst shall count the same plate twice. Counts may not differ by more than 5%.

[(2) If the protocol for a method does not require a positive culture control during sample analysis, the environmental laboratory shall analyze a positive culture control organism through the entire method on a monthly basis.

(3) If the method determines organism density, a control sample shall be prepared from stock culture to contain 20 to 80 viable organisms per the usual volume analyzed. The positive control shall then be processed through all steps of the method and the density of the positive control determined and recorded.

(4) If the environmental laboratory is using a method for detecting as opposed to counting organisms, a control sample may be inoculated by transferring a portion of the sample from a positive stock culture to 100-mL of reagent or dilution water.]

(j) Records of all equipment, reference materials, reagents, media and supplies shall be maintained in accordance with the requirements of § 252.306.

§ 252.405. Essential quality control requirement—radiochemistry.

(a) In addition to the requirements of § 252.401 (relating to basic requirements), laboratories performing testing or analysis of environmental samples in the area of radiochemistry shall comply with this section.

(b) When the method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

(c) The requirements for initial calibration are as follows:

(1) An environmental laboratory shall follow the initial calibration requirements of the method or regulation.

(2) Initial calibrations shall be performed using calibration standards that have the same general characteristics as the associated environmental samples, for example geometry, homogeneity and density.

(3) The initial calibration must include, when applicable, determination of instrument background, efficiency, mass attenuation and energy calibration.

(4) The results of testing or analysis of environmental samples shall be determined from an initial calibration that is not more than 12 months old and may not be determined from any continuing calibration verification, unless otherwise required by regulation, method or program.

(5) The details of the initial calibration procedures including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the laboratory's standard operating procedures.

(6) Raw data records shall be retained to permit reconstruction of the initial calibration.

(d) The requirements for an instrument suitability verification are as follows:

(1) An instrument suitability verification standard shall be analyzed at the beginning of each analysis day, unless a higher frequency is required in the method or regulation.

(2) The instrument suitability verification standard shall be a check source that provides adequate counting statistics for a relatively short count time and is sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel.

(3) For alpha and gamma spectroscopy systems, the instrument suitability verification standard must include determination of instrument counting efficiency, energy calibration and peak resolution.

(4) For gas-proportional and liquid scintillation counters, the instrument suitability verification standard must include determination of instrument counting efficiency.

(5) For scintillation counters, the instrument suitability verification standard must include determination of instrument counting efficiency.

(6) Details of the instrument suitability verification procedure including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the laboratory's standard operating procedures.

(7) Raw data records shall be retained to permit reconstruction of the instrument suitability verification.
(8) Acceptance criteria for instrument suitability verification standards in the method or regulation shall be followed. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the criteria.
(9) If an instrument suitability verification standard fails the acceptance criteria, an environmental laboratory shall initiate corrective actions.
(10) Environmental samples not bracketed by acceptable instrument suitability verification standards shall be reanalyzed.

(e) The requirements for an instrument background measurement are as follows:
(1) An instrument background check shall be analyzed every analysis day.
(2) Instrument background values shall be subtracted from the total measured activity in the determination of the sample activity.
(3) Each individual background check shall be compared to the acceptance criteria in the method or regulation. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the limits.
(4) Environmental samples associated with an out of control instrument background check shall be reprocessed and reanalyzed from the beginning of the method or the results reported with the appropriate data qualifiers.

(f) The requirements for a method blank are as follows:
(1) A method blank shall be processed along with and under the same conditions as the associated samples including all steps of the preparation and analytical procedure.
(2) A method blank shall be analyzed at a minimum ozone per preparation batch. When no separate preparation method is used, such as gamma analysis in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together using the same method, personnel and lots of reagents.
(3) A method blank must consist of a matrix that is similar to the associated environmental samples and is free of the isotopes of interest. When a matrix that is similar to the associated environmental samples that is free of the analytes of interest does not exist and cannot be prepared, reagent water or an artificial or simulated matrix may be used.
(4) When an environmental sample is analyzed by gamma spectrometry by placing the sample matrix into a calibrated counting geometry, the method blank must consist of a similar counting geometry that is filled to a similar volume with reagent water to partially simulate gamma attenuation due to a sample matrix.
(5) The method blank result may not be subtracted from the sample results in the associated preparation or analytical batch unless permitted by the method or regulation.
(6) The method blank shall be prepared with similar aliquot size to that of the routine samples for analysis. The method blank result and acceptance criteria shall be calculated in a manner that compensates for sample results based upon differing aliquot size.
(7) If a contaminant is detected in the method blank, the source of contamination shall be investigated and measures shall be taken to minimize or eliminate the contamination. A method blank is considered contaminated if one of the following applies:
(i) The activity of a target isotope in the method blank is at or above the reporting limit established by the method or by regulation.
(ii) The contamination in the method blank otherwise affects the environmental sample results as described in the method, regulation or in individual project data quality objectives.
(8) Environmental samples associated with a contaminated method blank shall be reprocessed for analysis or the results reported with the appropriate data qualifiers.

(g) The requirements for a laboratory control sample are as follows:

(1) A laboratory control sample must be processed along with and under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure.

(2) The laboratory control sample must consist of a defined matrix containing known and verified activities of isotopes. When a matrix that is similar to the associated environmental samples that is free of the analytes of interest is not available, reagent water or an artificial or simulated matrix may be used.

(3) A laboratory control sample must be analyzed at a minimum of one per preparation batch. When no separate preparation method is used, such as gamma analysis in water, the batch shall be defined as no more than 20environmental samples that are analyzed together with the same method, personnel and lots of reagents.

(4) The activity of the laboratory control sample must be within the calibration range of the method and one of the following:

(i) Two to ten times the detection limit.

(ii) At an activity level comparable to that of the environmental samples being tested or analyzed, if the sample activities are expected to exceed ten times the detection limit.

(5) The standard used to prepare the laboratory control sample must be from a source independent of the standards used for initial calibration.

(6) When a radiochemical method, other than gamma spectroscopy, has more than one reportable isotope, for example, plutonium, Pu 238 and Pu 239, using alpha spectrometry, only one of the isotopes shall be included in the laboratory control sample. When more than one isotope is present above the specified detection limit, each isotope shall be assessed against the acceptance criteria.

(7) When gamma spectrometry is used to identify and quantitate more than one isotope, the laboratory control sample must contain isotopes that represent the low, for example americium-241, medium, for example cesium-137, and high, for example cobalt-60, energy range of the analyzed gamma spectra. The isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.

(8) Each individual laboratory control sample must be compared to the acceptance criteria in the method or regulation. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the limits.

(9) Environmental samples associated with an out of control laboratory control sample shall be reprocessed and reanalyzed from the beginning of the method or the results reported with the appropriate data qualifiers.

(h) The requirements for sample duplicates are as follows:

(1) A sample duplicate shall be analyzed at a minimum of one per preparation batch. When no separate preparation method is used, for example gamma analysis in water, the batch shall be defined as no more than 20environmental samples that are analyzed together using the same method, personnel and lots of reagents.

(2) An environmental laboratory shall document the calculations used for determining the relative percent difference or other statistical method for evaluation of the sample duplicate pairs.

(3) Each sample duplicate relative percent difference shall be compared to the acceptance criteria in the method or regulation. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

(4) For sample duplicate results outside established criteria, corrective action shall be documented and the affected data reported with appropriate data qualifiers.

(i) Tracer requirements are as follows:

(1) For those methods that utilize a tracer or internal standard, each sample result must have an associated tracer or internal standard recovery calculated and reported.

(2) The tracer or internal standard recovery shall be assessed against the acceptance criteria specified in the method or regulation. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

(3) For tracer or internal standard recovery outside established criteria, corrective action shall be documented and the data reported with appropriate data qualifiers.

(j) Carrier requirements are as follows:

(1) For those methods that utilize a carrier, each sample must have an associated carrier recovery calculated and reported.

(2) The carrier recovery for each sample shall be assessed against the acceptance criteria specified in the method or regulation. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

(3) For carrier recovery outside established criteria, corrective action shall be documented and the data reported with appropriate data qualifiers.

(k) The requirements for detection limits are as follows:

(1) A detection limit shall be determined by the protocol in the method or regulation. If the protocol for determining detection limits is not specified in the method or regulation, the environmental laboratory shall select a procedure that reflects instrument limitations and the intended application of the method.

(2) A detection limit shall be initially determined forth isotopes of interest in each method in a matrix in which neither the target isotope nor interferences are at a concentration that would impact the results. The detection limit shall be determined in the matrix of interest.

(3) A detection limit shall be determined each time there is a change in the method that affects how the testis performed or that affects the sensitivity of the analysis.

(4) The sample processing steps of the method shall be included in the determination of the detection limit.

(5) Supporting data shall be retained to permit reconstruction of the detection limit determination.

(6) An environmental laboratory shall have a written procedure to relate detection limits with quantitation limits.

(7) The method’s lower limit of quantitation shall be established and must be above the detection limit.

(l) Each result shall be reported with the associated measurement uncertainty. The procedures for determining the measurement uncertainty shall be documented and be consistent with the method and regulation.

(m) Records of all equipment, reference materials, reagents, and supplies shall be maintained in accordance with the requirements of § 252.306.

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

§ 252.501. Proficiency test study requirements.

(a) By February 27, 2006, the Department will publish a list in the Pennsylvania Bulletin of fields of accreditation for which proficiency test studies are available. The Department may update the list of available fields of accreditation by publishing a revised list of available proficiency test studies.

(b) An environmental laboratory shall participate in proficiency test studies, when available, as specified in subsection (a), for each field of accreditation for which the laboratory seeks to obtain or maintain accreditation.

(c) Within the 12 months prior to applying for initial accreditation under this chapter or during the approval process, an environmental laboratory shall successfully analyze at least one single blind, single concentration proficiency test study, when available, as specified in subsection (a), for each field of accreditation for which it seeks accreditation.

(d) An environmental laboratory accredited under this chapter shall successfully analyze at least one single blind, single concentration proficiency test study for each field of accreditation, when available, as specified in subsection (a), for which the laboratory is accredited at least once every 12 months.

(e) Proficiency test studies shall be purchased at the environmental laboratory's expense directly from suppliers approved by the Department as a proficiency test provider.

(f) An environmental laboratory shall ensure that all proficiency test study samples are managed, analyzed and reported in the same manner as real environmental samples and utilize the same staff, procedures, equipment, facilities, number of replicates and methods for the routine analysis of the analyte.

(g) An environmental laboratory may not send a proficiency test study, or a portion of a proficiency test study, to another laboratory for analysis for a field of accreditation for which it seeks accreditation or is accredited prior to the time the results of the study are released by the proficiency test study provider.

(h) An environmental laboratory may not knowingly analyze a proficiency test study, or a portion of a proficiency test study, for another environmental laboratory for which the sending environmental laboratory seeks accreditation or is accredited prior to the time the results of the study are released by the proficiency test study provider.

(i) An environmental laboratory may not communicate with another environmental laboratory, including other laboratories under common ownership, concerning the proficiency test study prior to the time the results of the study are released by the proficiency test study provider.

(j) An environmental laboratory may not attempt to obtain the prepared value of a proficiency test study from the proficiency test study provider prior to the time the results of the study are released by the proficiency test study provider.

(k) If an environmental laboratory fails to successfully analyze a proficiency test study for an individual field of accreditation, it shall determine the cause for the failure and take any necessary corrective action. The laboratory shall document the investigation and corrective action.

(l) An environmental laboratory shall direct the proficiency test study provider to report the proficiency test study performance results directly to the Department**'s Laboratory Accreditation Program** at the same time that the provider reports the results to the environmental laboratory.

(m) An environmental laboratory shall maintain copies of all raw data associated with proficiency test studies for at least 5 years.

Subchapter F. ONSITE ASSESSMENT REQUIREMENTS

§ 252.601. Onsite assessment requirements.
(a) Prior to **granting primary accreditation to[accrediting]** an environmental laboratory, the Department will perform an onsite assessment of the laboratory.

(b) Prior to granting accreditation for an additional field of accreditation to an environmental laboratory, the Department may perform an onsite assessment of the laboratory.

(c) The Department may conduct announced or unannounced onsite assessments of an environmental laboratory to ensure compliance with the conditions of accreditation, this chapter or orders issued by the Department.

(d) The Department will provide the environmental laboratory with an onsite assessment report documenting any deficiencies found by the Department.

(e) An environmental laboratory shall submit a corrective action report to the Department within 60 calendar days from receipt of an onsite assessment report from the Department where the Department has found deficiencies. The corrective action report shall document the corrective action taken by the laboratory to correct each deficiency.

(f) An environmental laboratory seeking NELAP accreditation shall submit a corrective action report to the Department within 30 calendar days from receipt of the onsite assessment report from the Department where the Department has found deficiencies. If TNI establishes a different time for submitting corrective action reports, the laboratory shall follow the time established by TNI. The corrective action report shall document the corrective action taken by the laboratory to correct each deficiency.

(g[f]) If any portion of the corrective action report is not acceptable, an environmental laboratory shall submit a revised written corrective action report within 30 calendar days from receipt of the Department's response. If the second corrective action report is not acceptable, the Department may revoke accreditation.

(h[g]) Unless otherwise approved by the Department, deficiencies shall be corrected within 120 calendar days of receipt of the onsite assessment report.

(i[h]) The Department may extend the period of implementing corrective actions, for specific deficiencies, for a maximum of 30 calendar days upon receipt of the laboratory's written petition and corrective action report, when the laboratory must take one or more of the following actions:

(1) Purchase new equipment.
(2) Revise the quality manual.
(3) Replace significant laboratory personnel.

Subchapter G. MISCELLANEOUS PROVISIONS

§ 252.701. Denial of application.
(a) The Department will deny an application for accreditation, transfer of accreditation or application for renewal of accreditation under one or more of the following circumstances:

(1) The environmental laboratory is in continuing violation of or demonstrates an inability or lack of intention to comply with this chapter or other laws administered by the Department.
(2) The Department revoked the environmental laboratory's certificate of accreditation for all fields of accreditation for failure to correct deficiencies identified in an onsite assessment report within the previous 6 months.

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

(1) Falsifying analyses.
(2) Failure to comply with the reporting and notification requirements as specified in § 252.708 (relating to reporting and notification requirements).
(3) Making misrepresentations to the Department.
(4) Engaging in unethical or fraudulent practices.
(5) Analysis of proficiency test studies by personnel other than the analysts associated with the routine analysis of environmental samples in the laboratory.
(6) Failure to submit a complete application.
(7) Failure to pay required fees.
(8) Failure of laboratory staff to meet the personnel qualifications of education, training and experience.
(9) Failure to successfully analyze and report proficiency test studies as required by this chapter.
(10) Failure to respond to an onsite assessment report with a corrective action report within the required timeframes.
(11) Failure to submit an acceptable corrective action report in response to an onsite assessment within the required time frames.
(12) Failure to implement the corrective actions detailed in the environmental laboratory's corrective action report within a time frame approved by the Department.
(13) Failure to implement a quality assurance program.
(14) Denial of entry to the Department during normal business hours for an onsite assessment.
(15) Violation of a statute, this chapter or an order of the Department.
(16) Failure to meet the requirements of this chapter.

§ 252.702. Revocation.

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

(b) The Department may revoke an environmental laboratory's accreditation, in part or in total, for one or more of the following reasons:

(1) Failure to respond to an onsite assessment report with a corrective action report within the required time frames.
(2) Failure to correct deficiencies identified during an onsite assessment of the environmental laboratory.
(3) Failure to implement corrective action related to violations or deficiencies found during an onsite assessment.
(4) Failure of an environmental laboratory that has been suspended to correct all outstanding violations or deficiencies within 6 months of the effective date of the suspension.
(5) Failure to submit an acceptable corrective action report in response to an onsite assessment report within the required timeframes.
(6) Violation of a condition of accreditation.
(7) Violation of a statute, this chapter or an order of the Department.
(8) Falsifying analyses.
(9) Making misrepresentations to the Department.
(10) Engaging in unethical or fraudulent practices.
(11) Analysis of proficiency test studies by personnel other than the analysts associated with the routine analysis of environmental samples in the laboratory.
(12) Failure to implement a quality assurance program.
(13) Failure to participate in the proficiency test study program as required by this chapter.

(14) Denial of entry to the Department during normal business hours for an onsite assessment.
(15) Failure to comply with the reporting and notification requirements as specified in § 252.708 (relating to reporting and notification requirements).
(16) Failure to employ staff that meets the personnel qualifications for education, training and experience.
(17) Failure to meet the requirements of this chapter.

(c) The environmental laboratory may continue to test or analyze environmental samples for those fields of accreditation not revoked.

(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.
(a) Denial of access to the Department during normal business hours will result in immediate suspension of accreditation for all fields of accreditation. Upon notice from the Department, the laboratory shall immediately cease testing or analysis of environmental samples.

(b) The Department will suspend an environmental laboratory's accreditation in total or in part for one or more of the following reasons:
(1) The Department finds that protection of the environment or the public health, safety or welfare requires emergency action.
(2) The environmental laboratory fails to successfully complete a proficiency test study within the previous 12 months.
(3) The environmental laboratory fails two consecutive proficiency test studies for a field of accreditation.

(c) The Department may suspend a laboratory's accreditation in total or in part for one or more of the following reasons:
(1) Failure to comply with the reporting and notification requirements as specified in § 252.708 (relating to reporting and notification requirements).
(2) Failure to implement a quality assurance program.
(3) Failure to employ staff that meets the personnel qualifications for education, training and experience.

(d) A laboratory may continue to test or analyze environmental samples for those fields of accreditation not affected by the suspension.

(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 on a form approved by the Department.

§ 252.704. Voluntary relinquishment.
(a) An environmental laboratory wishing to voluntarily relinquish its certificate of accreditation shall notify the Department in writing.

(b) An environmental laboratory that voluntarily relinquishes its certificate of accreditation shall insure records are maintained in accordance with § 252.706 (relating to recordkeeping).

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

§ 252.705. Use of accreditation.

(a) Environmental laboratories accredited by the Department shall:

(1) Post or display their most recent certificate of accreditation for all fields of accreditation in a prominent place in the laboratory.

(2) Make accurate statements concerning their accreditation status.

(3) Not use their certificate of accreditation, accreditation status or the Department's logo to imply endorsement by the Department.

(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.

(c) Upon suspension, revocation or voluntary relinquishment of accreditation, a laboratory shall:

(1) Discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials that contain reference to the laboratory's past accreditation status.

(2) Discontinue use or display of the Department's logo.

(3) Return certificates of accreditation to the Department within 48 hours.

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

(e) NELAP accredited laboratories may not use their NELAP certificate, NELAP accreditation status or NELAC/NELAP logo to imply endorsement by the Department or NELAC.

§ 252.706. Recordkeeping.

(a) An environmental laboratory shall maintain records in a**n 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.

(c) All generated data, except data 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.

(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**[meet the reporting and notification requirements of that chapter]:**

(1) Meet the reporting and notification requirements of that chapter.

(2) For microbiological, inorganic and wet chemistry analyses, 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 analyses, review all sample analysis data within seven days of acquisition of the initial sample results.

(b) An environmental laboratory shall notify the Department, in writing, within **[30]20** calendar days of a 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[e]) 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 accrediting authority.

(g[f]) 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[g]) The Department may require an onsite assessment under § 252.601 (relating to onsite assessment requirements) upon receipt of notification under this subsection.