

**CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION**

**Subchapter**

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**Subchapter A. GENERAL PROVISIONS**

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**Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS**

**§ 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 the format specified by the Department, in writing** on forms provided by the Department. The applicant shall provide other relevant material requested by the Department **in the format specified 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.

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**§ 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 **in the format specified by the Department,** 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.

**(d) Within 48 hours of expiration of the certificate of accreditation, the laboratory shall notify each of its customers affected by the expiration of the certificate of accreditation in writing of the lapse in accreditation on a form approved by the Department.**

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**§ 252.204. Fees.**

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

<i>Category</i>	<i>Fee</i>	
Application Fee – Initial Application for State Accreditation	<b>\$750</b>	<b><u>\$1,000</u></b>
Application Fee – Renewal Application for State Accreditation	<b>\$500</b>	<b><u>\$600</u></b>
Application Fee – Ownership Transfer or Change in Administrative Information	\$150	
Application Fee – Initial Application for NELAP/TNI Accreditation	<b>\$2,500</b>	<b><u>\$3,000</u></b>
Application Fee – Renewal Application for NELAP/TNI Accreditation	<b>\$2,000</b>	<b><u>\$2,500</u></b>
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– <del>Bacteria</del> , Fecal Coliform– <del>Bacteria</del> , <i>E. coli</i> <del>Bacteria</del> , Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	<b>\$650</b>	<b><u>\$700</u></b>
Basic Non-potable Water Category – includes 1 method for each of the following: Fecal Coliform– <del>Bacteria</del> , 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	<b>\$750</b>	<b><u>\$800</u></b>
Whole Effluent Toxicity Testing—first matrix	<b>\$700</b>	<b><u>\$900</u></b>
Asbestos—first matrix	<b>\$400</b>	<b><u>\$500</u></b>
Asbestos—second matrix	<b>\$350</b>	<b><u>\$400</u></b>
Asbestos—third matrix	<b>\$300</b>	<b><u>\$350</u></b>
<u>Basic Microbiology – includes membrane filtration, pour plate, multiple-tube/multi-well, and chromogenic/fluorogenic techniques</u> —first matrix	<b>\$500</b>	<b><u>\$650</u></b>
<u>Basic Microbiology includes membrane filtration, pour plate, multiple-tube/multi-well, and chromogenic/fluorogenic techniques</u> —second matrix	<b>\$450</b>	<b><u>\$600</u></b>
<u>Basic Microbiology includes membrane filtration, pour plate, multiple-tube/multi-well, and chromogenic/fluorogenic techniques</u> —third matrix	<b>\$400</b>	<b><u>\$500</u></b>
<u>Complex Microbiology—first matrix</u>		<b><u>\$1,000</u></b>
<u>Complex Microbiology—second matrix</u>		<b><u>\$900</u></b>
<u>Complex Microbiology—third matrix</u>		<b><u>\$800</u></b>
Trace Metal Category—first matrix	<b>\$550</b>	<b><u>\$650</u></b>
Trace Metal Category—second matrix	<b>\$500</b>	<b><u>\$550</u></b>
Trace Metal Category—third matrix	<b>\$450</b>	<b><u>\$500</u></b>
Inorganic Non-metal Category—first matrix	<b>\$600</b>	<b><u>\$700</u></b>
Inorganic Non-metal Category—second matrix	<b>\$550</b>	<b><u>\$600</u></b>
Inorganic Non-metal Category—third matrix	<b>\$500</b>	<b><u>\$550</u></b>
<u>Purgeable</u> Volatile Organic Chemicals—first matrix	<b>\$650</b>	<b><u>\$750</u></b>
<u>Purgeable</u> Volatile Organic Chemicals—second matrix	<b>\$600</b>	<b><u>\$650</u></b>
<u>Purgeable</u> Volatile Organic Chemicals—third matrix	<b>\$550</b>	<b><u>\$600</u></b>
Extractable and Semi-volatile Organic Chemicals—first matrix	<b>\$1,500</b>	<b><u>\$1,650</u></b>
Extractable and Semi-volatile Organic Chemicals—second matrix	<b>\$1,400</b>	<b><u>\$1,500</u></b>
Extractable and Semi-volatile Organic Chemicals—third matrix	<b>\$1,300</b>	<b><u>\$1,400</u></b>
Dioxin—first matrix	<b>\$650</b>	<b><u>\$750</u></b>
Dioxin—second matrix	<b>\$600</b>	<b><u>\$650</u></b>
Dioxin—third matrix	<b>\$550</b>	<b><u>\$600</u></b>
Radiochemical Category—first matrix	<b>\$750</b>	<b><u>\$900</u></b>

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Radiochemical Category—second matrix	<b>\$700</b>	<b><u>\$800</u></b>
Radiochemical Category—third matrix	<b>\$650</b>	<b><u>\$700</u></b>

(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 for the same fields of accreditation for which the Department is a primary NELAP/~~TNI~~ accreditation body.

(ii) The Department may recognize the accreditation of an environmental laboratory by another state accreditation body 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.

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

(E) 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 accreditation body, the laboratory's authorization to perform testing or analysis is automatically revoked for the same fields of accreditation.

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

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

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

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

(h) An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor **and who is approved by the Department as described in subsection (a) to** temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding 16 consecutive calendar days. If this temporary 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) 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 of **organics and metals** shall have the following qualifications:

- (1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.
- (2) At least 24-college semester credit hours in chemistry.

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(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~~ **engaged in** inorganic **non-metals** chemical analysis, ~~other than metals analysis,~~ shall have the following qualifications:

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

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

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

**(4) If a method, regulation, or program requires more stringent qualifications for education or experience, or both, the laboratory supervisor shall meet the more stringent requirement.**

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

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

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

- (1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.
- (2) At least 24-college semester credit hours in chemistry **or health physics.**

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- (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.~~ **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.**

(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.

**(j) All college semester credit hours must be obtained from an accredited college or university recognized by the United States Department of Education.**

**(k) All foreign transcripts must be transcribed into English and evaluated for U.S. semester credit hour equivalency by a credential evaluation agency accredited by the National Association of Credential Evaluation Services (NACES) or a Pennsylvania Department of Education approved agency.**

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**§ 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. This documentation shall include:
  - (i) An identification of the analysts involved in the preparation or analysis, or both.
  - (ii) The sample matrix.
  - (iii) The analyte, class of analyte, or measured parameter.
  - (iv) An identification of the test method performed.
  - (v) An identification of the laboratory-specific standard operating procedure used for analysis, including revision number and effective date.
  - (vi) The dates of preparation or analysis, or both.
  - (vii) The summary of analyses, including results.
- (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.

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- (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 **in the lower half of the calibration range or at or below the maximum contaminant level for SDWA compliance testing, whichever is lower.** ~~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 clause (III) to the corresponding acceptance criteria for precision and accuracy in the method. **If the method or regulation does not specify acceptance limits, the %RSD must be less than 20%.** 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 clause.
    - (I) 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.



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- (II) 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 **as required by the initial demonstration described in clause (b)(3)(vi).**
  - (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.

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**§ 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.

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(10) A history of damage, malfunction, modification or repair.

(c) An environmental laboratory shall assure that the test instruments consistently operate within **and all equipment, supplies, and reference materials meet** the specifications required of the application for which ~~the equipment~~ **it** 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, liquid filled 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. -
  - (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 2.0°C from the reference thermometer may not be used.

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

- (i) The mass of ASTM 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.

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- (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 **verification of the** calibration of balances.
  - (iv) Balance calibration shall be verified using a minimum of three ASTM 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 **and verifications** that document the balance identification, date of calibration verification, reference weights used, **observed measurement,** and initials of the individual performing the calibration **verification.**
  - (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 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 calibration shall be maintained in a laboratory notebook that documents the date of calibration, calibration buffers used, **results of the calibration, results of the calibration verification,** and initials of the individual conducting the calibration.
- (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

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- 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 **working** 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  $\pm 2^{\circ}\text{C}$  of the specified preservation temperature unless method specific criteria exist. For samples with a storage temperature of  $4^{\circ}\text{C}$ , storage at a temperature of  $0.5^{\circ}\text{C}$  to  $6^{\circ}\text{C}$  is acceptable.
  - (v) Freezer temperatures must be less than  $0^{\circ}\text{C}$ .
- (8) *Incubators, water baths, heating blocks, and ovens*
- (i) An environmental laboratory shall control and monitor the temperature of incubators, water baths, 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 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, heating block or oven shall be recorded once a day for each **working** 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, **each day the incubator is** in use, with the readings separated by at least 4 hours. The incubator, water bath, heating block or oven 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 **and glass microliter syringes, mechanical** volumetric dispensing devices including, **but not limited to, graduated cylinders, pipettes**, burettes, autopipetors and dilutors, must be of sufficient sensitivity for the application, **and the environmental laboratory shall verify and document the accuracy of the volume of use for each lot or at least once per year, whichever is more frequent.** Delivery volumes of mechanical volumetric dispensing devices shall be checked 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, when graduation marks on funnels, sample bottles or labware are used to measure sample volume **or prepare standards or reagents**, an environmental laboratory shall verify and document the accuracy of the volume of use for 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.

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

(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, **media**, 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, **media**, 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, **media**, 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 may not be used past the date of expiration unless re-evaluated and validated by a procedure approved by the Department prior to use.
- (7) Reagents, **standards, and media and standard solutions** shall be checked regularly for signs of decomposition and evaporation. Reagents, **standards, and media and standard solutions** exhibiting signs of decomposition or evaporation shall be discarded.
- (8) When reagents, **standards, and media** 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.

**(j) The laboratory shall perform temperature distribution studies and temperature recovery studies for incubators that are used as incubation units for microbiology.**

**(1) The laboratory shall perform a temperature distribution study for each incubator, prior to first use, after repair or service, and every 3 years by the following procedure:**

- (i) The laboratory shall develop a procedure to determine the temperature distribution and fluctuations within its incubator(s). The laboratory shall take into account the size of the incubator (height, width, and depth), number of shelves, and type of incubator when developing the procedure to perform the temperature distribution study.**
- (ii) At a minimum, the laboratory shall monitor and record the temperature of each shelf.**

- (iii) Incubators that do not maintain constant temperatures within the acceptable temperature range for the application may not be used. The laboratory may establish procedures to limit incubator use to specific shelves or areas of the incubator that can be verified to maintain acceptable temperature fluctuations.
- (2) The laboratory shall perform a temperature recovery study to determine the amount of time it takes for the incubator to return to the required temperature range, after introduction of samples, for each incubator prior to first use, after repair or service, and every three years by the following procedure:
  - (i) Estimate the maximum number of samples to be placed into the incubator at one time.
  - (ii) Introduce the maximum number of samples established in subpart (A) into the incubator.
  - (iii) Measure and record the temperature every 30 minutes after sample introduction until the temperature readings demonstrate 2 consecutive measurements within the required temperature range for the test temperature.
  - (iv) The laboratory may need to perform multiple temperature recovery studies to determine the maximum number of samples that can be introduced into the incubator until the laboratory establishes a recovery time of less than or equal to 2 hours.
  - (v) Incubators that cannot recover to the required temperature range within 2 hours of sample introduction may not be used.
  - (vi) The laboratory shall limit the number of real environmental samples, including quality control samples, introduced into the incubator at one time to the number determined in subsection (iv).

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#### **Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS**

##### **§ 252.401. Basic requirements.**

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

- (1) The full name and physical address of the laboratory.
- (2) The name, address (if different from paragraph (1)), and telephone number of laboratory supervisors.
- (3) A revision number and effective date.
- (4) A table of contents, and applicable lists of references, glossaries and appendices.

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

- (1) An ethics policy statement as specified in subsection (d).
- (2) A document control system as specified in subsection (c).
- (3) Recordkeeping as specified in § 252.706 (relating to recordkeeping).
- (4) The procedures for termination of operations and transfer of records as specified in § 252.706 (relating to recordkeeping).
- (5) The procedures for detecting and permitting departures from established procedures as specified in subsections (i) and (h).

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- (6) The procedures for detecting and preventing improper practices as specified in § 252.304 (relating to personnel requirements).
- (7) The sample handling and acceptance procedures as specified in subsections (f) and (g).
- (8) The reporting analytical results as specified in subsection (j).
- (9) The monitoring the quality of analysis as specified in subsection (l).

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

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

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

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

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

- (1) The environmental laboratory shall implement procedures for checking **and documenting the condition of each sample after receipt at the laboratory thermal and/or chemical preservation and sample container. Results of these checks shall be recorded. The documentation maintained by the laboratory shall include:**
  - (i) Sample container type and size, such as plastic 1L, amber 40mL vial, etc.**
  - (ii) pH of the sample, as measured to meet the specific tolerance for the analysis method for which the sample is to be tested.**
  - (iii) Results of the measurement for residual chlorine for all SDWA compliance samples and any non-SDWA samples when the presence of residual chlorine will compromise the validity of the test.**
  - (iv) Temperature of the sample.**
- (2) The laboratory shall utilize a recordkeeping system that meets the requirements of § 252.706 to document receipt of all sample containers. The recordkeeping system must include the following:
  - (i) The client/project name.
  - (ii) The date, time and location of sample collection, name of sample collector and field identification code.
  - (ii) The date and time of laboratory receipt **and identification of the individual receiving the sample(s) at the laboratory.**
  - (iii) Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code
  - (iv) A unique laboratory ID code that corresponds to the information required by this paragraph.
  - (v) An identification of the person making the entries.

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

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

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

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

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

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

- (1) The name and address of the laboratory.
- (2) The total number of pages in the report, including any addendums, in the format of Page x of y.
- (3) The name and address of the client.
- (4) An identification of the test method used.
- (5) An identification of the sample(s) including the client identification code.
- (6) The date and time of sample collection.
- (7) The date of sample analysis.
- (8) The **date and** time of sample preparation or analysis, or both, if the holding time requirement for either activity is less than or equal to 72 hours.
- (9) The test results and units of measurement.
- (10) The quantitation limit
- (11) The names, functions, and signatures of the persons authorizing the test report.
- (12) An identification of results reported on a basis other than as received (e.g., dry weight).
- (13) An identification of testing or analysis results not covered by the laboratory's scope of accreditation.
- (14) An identification of results that do not meet the requirements of this Chapter.
- (15) An identification of subcontracted results.



- (16) A unique test report identifier code, such as a serial number or other unique code.**
- (17) An identification of amendments to the test report. The laboratory shall uniquely identify all amendments to a test report, and the amended report shall be issued in the form of a further document, data transfer, or completely new test report, which includes the statement, “Amended Test Report [laboratory code that meets the requirements of subsection (16)]”.**

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

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

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

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

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

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

**§ 252.402. 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.

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- (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 **including, but not limited to, identification or reference to the reagents, standards, and supplies used, date(s) of analysis, instrument identification, results of the initial calibration, calibration criteria, and analyst's initials.**
- (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) 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 ( $r^2$ ) of 0.99 for a linear calibration curve.
  - (iii) A coefficient of determination ( $r^2$ ) 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.

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- (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 with calibration verification standards 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 **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005) to** determine internal criteria and document the procedure used to establish the acceptance limits.

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- (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) **Raw data records shall be retained to permit reconstruction of the method blank.**
- (67) 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:

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- (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.
  - (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 **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005) to determine internal criteria and document the procedure used to establish the limits.**
  - (7) **Raw data records shall be retained to permit reconstruction of the laboratory control sample.**
  - ~~(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) 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

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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) 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) 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 **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005) to** determine internal criteria and document the procedure used to establish the acceptance limits.
- (5) 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 **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005) to** 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.

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(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.

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**§ 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. ~~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) A continuous temperature-recording device or a maximum-temperature-registering thermometer shall be used during each autoclave cycle.
- (iii) 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,

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mechanical timing device time, actual time and initials of the responsible individual. Correction factors shall be documented and used.

- (v) 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) 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) 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.
  - (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) 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) 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) 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) *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) *Membrane filtration equipment.*



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- (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 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- $\mu$ m 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) 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) *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) *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) *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) *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.

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- (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) *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 **and include the date, results, and identification of the responsible individual.**
- (10) *Ultraviolet lamp.* An environmental laboratory shall use a 365-nm, 6-watt ultraviolet lamp in a darkened room to view sample fluorescence.
- (11) *Quanti-Tray™ 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 metals analyses may only be performed by an environmental laboratory accredited under this chapter for those fields of accreditation.

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- (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.
- (7) The heterotrophic plate count and bacteriological water quality test ratio analyses described in subsections (2) and (3) must be performed by an environmental laboratory accredited under this chapter for the appropriate field(s) of accreditation.**

(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 buffers shall be refrigerated and 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).

(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 prepares media from dehydrated stock shall follow method specifications.
- (3) Media may not be reautoclaved.
- (4) After 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) Fermentation media stored in a refrigerator shall be **incubated overnight at brought to** room temperature before use. Media that shows growth **or false positive results 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:

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- (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 **and time of the start and end of incubation**, results and initials of responsible individual. If sterility blank indicates contamination, the media may not be used.
  - (i) **For chromogenic/fluorogenic media, add single-strength media to sterile DI water and incubate at the appropriate temperature and time.**
  - (ii) **For all other media, incubate uninoculated, single-strength at the appropriate temperature and time.**
- (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 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 filtered through each membrane filtration unit 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 **in the same manner as the associated samples and include the date and time of the start and end of the incubation, results, and initials of the responsible individual**. If sterility blanks indicate contamination, the laboratory must treat each affected sample according to program requirements.
- (3) For pre-sterilized single use filtration funnel units, a sterility check shall be performed on one funnel unit per lot.
- (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 **and time of the start and end of incubation**, 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 **and time of the start and end of incubation**, 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.
- (7) Sterility checks on *Quanti-Tray*<sup>TM</sup> sample trays shall be performed on at least one sample tray for each lot of purchased, presterilized sample tray with an appropriate nonselective growth media. Results shall be maintained and include sample tray identification, date and time of the start and end of incubation, results and initials of responsible individual. If sample tray sterility check indicates contamination, the affected sample tray 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 by the laboratory with at least one pure culture of a known

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positive reaction prior to first use of the medium. Records shall be maintained and include the date **and time of the start and end of incubation**, 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 by the laboratory with at least one pure culture of a known negative reaction prior to first use of the medium. Records shall be maintained and include the date **and time of the start and end of incubation**, 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 **reevaluated and validated by a procedure approved by the Department** ~~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 **Department approved and** 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) For test methods that specify colony counts, duplicate counts shall be performed monthly 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%.

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

**(k) All quality control checks, including but not limited to, sterility checks and positive and negative controls shall be conducted after the laboratory receives the material or supply and must be performed by an environmental laboratory accredited under this chapter and utilizing the same supplies, reagents, and media to be used during laboratory analysis of**

**environmental samples. Certificates of Analysis from a manufacturer may not be used to demonstrate compliance with the requirements of this subsection.**

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### **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.

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- (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.
- (n) An environmental laboratory seeking to obtain or maintain accreditation in the drinking water matrix shall participate in proficiency test studies that meet the requirements of 40 CFR, Part 141.
- (o) An environmental laboratory shall evaluate and report the analytical result of each proficiency test study sample to the proficiency test reporting limit for each field of accreditation, when available, as outlined in subsection (a).

**(p) The Department will invalidate any proficiency test study results that are not handled, managed, analyzed, or reported in accordance with this section.**

#### **Subchapter F. ONSITE ASSESSMENT REQUIREMENTS**

##### **§ 252.601. Onsite assessment requirements.**

- (a) Prior to granting primary accreditation to 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. **The Department may deny, suspend, or revoke a laboratory's accreditation in accordance with subchapter G (relating to miscellaneous provisions) before issuing the onsite assessment report or during the corrective action process.**
- (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) 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) Unless otherwise required or approved by the Department, deficiencies shall be corrected within 120 calendar days of receipt of the onsite assessment report.

~~(i) 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.



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- (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 **and maintain correction of** 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.

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(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 ~~as specified in § 252.302 (relating to qualifications of the laboratory supervisor).~~
- (4) Failure to submit an acceptable corrective action report in response to an onsite assessment report within the required timeframes.**
- (5) Failure to correct and maintain correction of deficiencies identified during an onsite assessment of the environmental laboratory.**
- (6) Failure to implement corrective action related to violations or deficiencies found during an onsite assessment.**

(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 or accreditation for fields of accreditation shall notify the Department in writing.

(b) An environmental laboratory that voluntarily relinquishes its certificate of accreditation shall ensure 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 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.

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(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 **expiration**, 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 **unexpired** 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 an organized manner accessible by the Department.

(b) An environmental laboratory shall maintain records, including original handwritten data, that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples, proficiency test studies, initial demonstration of capability, or demonstration of continued proficiency. **These records include, but are not limited to, the following:**

- (1) Start and ending dates and times of incubations, drying cycles, digestions, distillations, sonications, extractions, etc.**
- (2) Start and ending temperatures of ovens, incubators, hot-blocks, water baths, etc.**
- (3) Unequivocal link between the laboratory's sample identification number to the results of all associated quality control**
- (4) Instrument identification**
- (5) Identification of, or reference to, the standards, reagents, media, supplies, etc. used during sample preparation and analysis**
- (6) The results of chemical and thermal preservation verifications or adjustments**
- (7) Date of preparation or analysis, or both**
- (8) Time of preparation or analysis, or both, if the holding time of either activity is  $\leq$  72 hours.**
- (9) Manual calculations**
- (10) Test results**

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

- (1) The individual generating the record shall be identified by initials or signature and the individual making the observation shall be identified by initials or signature, if different from the individual generating the record.**
- (ii) Changes to records shall be made so that the original entry remains visible. The individual making the change shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.**

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

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

#### **§ 252.707. Subcontracting.**

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

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

#### **§ 252.708. Reporting and notification requirements.**

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

- (1) Meet the reporting and notification requirements of that chapter.
- (2) For **microbiological**, trace metals, and inorganic non-metals, review all sample analysis data within 24 hours of acquisition of the initial sample results. The 24-hour deadline may be extended to a maximum of 72 hours to accommodate a holiday or weekend when the laboratory is closed for business.
- (3) For organic **and radiochemical** analyses, review all sample analysis data within seven days of acquisition of the initial sample results.
- (4) For microbiological results, review all sample analysis data within 15 minutes of acquisition of the sample results.**
- (5) Analyze the laboratory control sample(s) with a concentration at or below the maximum contaminant level.**
- (6) Report only those analytical test results that are not associated with data qualifier flags, unless the Department has specifically approved that the result may be reported.**

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

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

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

(e) An environmental laboratory shall notify the Department, in writing, if a change in the laboratory's capability to produce valid analytical results persists for more than 90 calendar days for any field of accreditation listed on the laboratory's scope of accreditation.

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- (f) An out-of-State environmental laboratory with either primary or secondary accreditation from the Department shall notify, in writing, the Department within 48 hours of any changes in the laboratory's accreditation status from any other primary accreditation body.
- (g) The Department may require additional information or proof of continued capability to perform the testing or analysis for affected fields of accreditation upon receipt of notification under this subsection.
- (h) The Department may require an onsite assessment under § 252.601 (relating to onsite assessment requirements) upon receipt of notification under this subsection.