CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION

Subchapter A. GENERAL PROVISIONS

Sec.

§ 252.1. Definitions.

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

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§ 252.4. General requirements.

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(b) An environmental laboratory testing**,** **[or]** analyzing **or reporting results for** environmental samples in a matrix identified in § 252.3 and required by a statute identified in § 252.3 shall be accredited and in compliance with this chapter to generate data and perform analysis used to comply with an environmental statute listed in § 252.3.

§ 252.5. NELAP[/TNI] equivalency.

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(b) An environmental laboratory seeking NELAP accreditation shall:

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(3) Comply with Subchapter F (relating to **[onsite]** assessment requirements).

(4) Comply with Subchapter G (relating to miscellaneous provisions).

(5) Comply with the current edition of the NELAC standard or TNI standard.

(6) Comply with § 252.307 (relating to methodology).

(7) Comply with § 252.401 (relating to basic requirements).

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

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§ 252.6. Accreditation-by-rule.

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

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(6) The environmental laboratory is reporting **only** the results of the testing or analysis of environmental samples **specified in subsections (c) and (f)** in conformance with the applicable State or Federal laws, regulations, orders or permit conditions.

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Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

Sec.

§ 252.201. Application and supporting documents.

(a) An environmental laboratory seeking accreditation for one or more fields of accreditation within a matrix described in § 252.3 (relating to scope) or that seeks to add a field of accreditation, shall apply to the Department for accreditation **[in writing on forms provided by the Department] in the format specified by the Department**. The applicant shall provide other relevant material requested by the Department.

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§ 252.203. Accreditation renewal.

Applications for accreditation renewal shall be submitted annually to the Department at least 60 calendar days prior to the expiration date of the current certificate of accreditation **[on forms provided by the Department] in the format specified by the Department**.

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(c) Failure to submit an application for renewal in accordance with this section will result in a lapse of 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 in a manner approved by the Department.

§ 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, addition of fields of accreditation, or supplemental onsite assessment. A check must be payable to ''Commonwealth of Pennsylvania.'' **When the Department is able to accept credit card payments, an environmental laboratory may make payment via credit card and shall pay to the Commonwealth all service charges or other administrative fees in addition to the accreditation fees.** The fees are as follows:

Category	*Fee*	
Application fee—Initial Application for State Accreditation	**[$750]**	**$1,500**
Application fee—Renewal Application for State Accreditation	**[$500]**	**$700**
Application fee—Ownership Transfer or Change in Administrative Information	$150	
Application fee—Initial Application for NELAP**[/TNI]** Accreditation	**[$2,500]**	**$3,500**

Application fee—Renewal Application for NELAP**[/TNI]** Accreditation	**[$2,000]**	**$2,750**
Application fee—Addition of Field of Accreditation	**[$250]**	**$350**
Application fee—Supplemental Onsite Assessment	$500	
Basic Drinking Water Category—Includes one method for each of the following: Total Coliform Bacteria, Fecal Coliform Bacteria, *E-coli* Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	**[$650]**	**$750**
Basic Nonpotable Water Category—Includes one method for each of the following: Fecal Coliform Bacteria, BOD, CBOD, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, and one method for each type of residue including % Solids for land applied biosolids	**[$750]**	**$850**
Asbestos—first matrix	**[$400]**	**$600**
Basic Microbiology **– includes fecal coliform, total coliform, *E. coli*, and heterotrophic bacteria** —first matrix	**[$500]**	**$700**
Complex Microbiology—first matrix		**$1,000**
Trace Metal Category—first matrix	**[$550]**	**$750**
Inorganic Nonmetal Category—first matrix	**[$600]**	**$850**
Purgeable Volatile Organic Chemicals—first matrix	**[$650]**	**$850**
Extractable and Semivolatile Organic Chemicals—first matrix	**[$1,500]**	**$1,750**
Dioxin—first matrix	**[$650]**	**$850**
Radiochemical Category—first matrix	**[$750]**	**$950**
Whole Effluent Toxicity Testing—first matrix	**[$700]**	**$950**
Asbestos—second matrix	**[$350]**	**$450**
Basic Microbiology **– includes fecal coliform, total coliform, *E. coli*, and heterotrophic bacteria**—second matrix	**[$450]**	**$600**
Complex Microbiology—second matrix		**$900**
Trace Metal Category—second matrix	**[$500]**	**$600**
Inorganic Nonmetal Category—second matrix	**[$550]**	**$700**
Purgeable Volatile Organic Chemicals—second matrix	**[$600]**	**$700**
Extractable and Semivolatile Organic Chemicals—second matrix	**[$1,400]**	**$1,600**
Dioxin—second matrix	**[$600]**	**$700**
Radiochemical Category—second matrix	**[$700]**	**$850**
Asbestos—third matrix	**[$300]**	**$400**
Basic Microbiology **– includes fecal coliform, total coliform, *E. coli*, and heterotrophic bacteria** —third matrix	**$[400]**	**$500**
Complex Microbiology—third matrix		**$800**
Trace Metal Category—third matrix	**[$450]**	**$550**
Inorganic Nonmetal Category—third matrix	**[$500]**	**$650**
Purgeable Volatile Organic Chemicals—third matrix	**[$550]**	**$600**
Extractable and Semivolatile Organic Chemicals—third matrix	**[$1,300]**	**$1,450**
Dioxin—third matrix	**[$550]**	**$650**

Radiochemical Category—third matrix **[$650]** **$750**

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§ 252.205. Out-of-State laboratories.

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

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(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 **provided the environmental laboratory meets the requirements of § 252.5 (relating to NELAP equivalency)**.

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§ 252.206. Out-of-State onsite reimbursement.

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

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(3) Travel time for each assessor at a rate of $ **[50]** **75**/hour.

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

Sec.

§ 252.301. Laboratory supervisor.

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(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] 21** 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).

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§ 252.302. Qualifications of the laboratory supervisor.

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

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(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:

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(3) At least **[2 years] 1 year** of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

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

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(2) At least 16-college semester credit hours in **[general microbiology or]** biology**, and at least 4 of the 16-college semester credit hours must be in microbiology**.

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(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:

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(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:

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(2) At least 24-college semester credit hours in chemistry **or health physics**.

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(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:

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(2) 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 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:

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(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 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.**

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

(j) A laboratory supervisor of an environmental laboratory engaged in whole effluent toxicity analysis 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.

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

(4) At least 2 years of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

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

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

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

§ 252.304. Personnel requirements.

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

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(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:

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(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:

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

(I) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not specify a concentration, the concentration must be **[approximately ten times the detection limit] in the lower half of the calibration range or at or below the maximum contaminant level for Safe Drinking Water Act ("SDWA") compliance testing, whichever is lower**.

(II) At least four aliquots of the quality control sample shall be prepared and analyzed **consecutively** according to the method. **The preparation or analysis, or both, may occur on a single day or over the course of multiple days.**

(III) Using all of the results, calculate **the individual recovery,** 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 subclause (III) to the corresponding acceptance criteria for precision and accuracy in the method. **If the method or regulation does not specify acceptance limits, the % Relative Standard Deviation ("RSD") must be less than 20%.** To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

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(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:

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(D) At least four consecutive laboratory control samples with acceptable levels of precision and accuracy **as required by the initial demonstration of capability described in subparagraph (b)(3)(vi)**.

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§ 252.306. Equipment, supplies and reference materials.

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(c) An environmental laboratory shall assure that the test instruments **and all equipment, supplies and reference materials** consistently operate within **and meet** the specifications required of the application for which **[the equipment] it** is used.

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

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(4) *Analytical or pan balances.*

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(v) An environmental laboratory shall maintain records in a laboratory notebook of balance calibrations **and verifications** that document the balance identification, date of calibration**, date of** verification, reference weights used**, observed measurement** and initials of the individual performing the calibration **verification**.

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(5) *pH meter*.

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(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**].

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(v) Records of pH meter calibration shall be maintained in a laboratory notebook that document the date of calibration, calibration buffers used**, results of the calibration, results of the calibration verification,** and initials of the individual conducting the calibration.

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(7) *Refrigeration equipment and freezers*.

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(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.

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

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(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, and** 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 **such as mechanical pipettes, autopipetors, and dilutors** shall be checked at least once every 3 months.

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(10) *Graduated sample containers*.

(i) Except for Class A glassware, when graduation marks on filter 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.

*****

(g) An environmental laboratory shall maintain records for all reference materials, reagents**, laboratory supplies that are essential to obtain analytical results** 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, presterilized filtration units, certified precleaned laboratory supplies, disposable volumetric equipment, prepreserved sample containers) must meet the following minimum requirements:

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

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(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 reevaluated and validated by a procedure approved by the Department prior to use. **Expired reagents, standards and media shall be segregated from unexpired laboratory materials in a manner that ensures they are not used for the testing of environmental samples.**

(7) Reagent**s, standards and media [and standard solutions]** shall be checked regularly for signs of decomposition and evaporation. Reagent**s, 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.

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

(j) The laboratory shall perform temperature distribution 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 and every three (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.

§ 252.307. Methodology

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

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

(1) The environmental laboratory's instructions must accurately reflect all aspects of the sample collection and preservation requirements for the particular analyses, including the following:

(i) Container type, size, and number of containers or bottles.

(ii) Sample collection method, amount of sample required, and explanation of other specific requirements for sample collection such as "zero headspace" or "first draw".

(iii) Chemical preservation, including type of preservation and the procedure used to preserve the sample.

(iv) Thermal preservation, including the temperature requirements and procedure used to preserve the sample.

(v) Field blank requirements.

(vi) Holding time.

(2) The environmental laboratory shall make the sample collection and preservation instructions available to all laboratory sample collection personnel and to all customers and clients that collect samples.

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

Sec.

252.404. Essential quality control requirement—microbiology.
252.405. Essential quality control requirement—radiochemistry.

§ 252.401. Basic requirements.

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

(1) The environmental laboratory shall implement procedures for checking **[the thermal or chemical, or both, preservation and the sample container] and verifying the condition of the sample**. The results of these checks shall be recorded. **The environmental laboratory shall check:**

(i) The sample container and the sample preservation, both thermal and chemical, of each sample.

(ii) The sample pH for all samples to be analyzed for chemistry, whole effluent toxicity and radiochemistry fields of accreditation.

(iii) The sample for the presence of residual chlorine when the presence of residual chlorine will compromise the validity of the test.

(2) The laboratory shall utilize a recordkeeping system that meets the requirements of § 252.706 to document receipt of all sample containers. The recordkeeping system must include the following:

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(iii) The date and time of laboratory receipt **and identification of the individual receiving the sample(s) at the laboratory**.

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(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).

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(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.

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(15) An identification of subcontracted units.

(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" or "Revised" and includes the identification of the unique laboratory code that meets the requirements of paragraph (16).

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(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.

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(c) Initial calibration requirements are as follows:

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(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 identification**.

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(f) Calibration verification requirements are as follows:

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(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 Stree NW, Washington, D.C. 20005) to** determine internal criteria and document the procedure used to establish the acceptance limits.

*****

(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:

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(5) If a contaminant is detected in the method bank, 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.

(**[6]**7) 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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(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]8**) 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:

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(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.

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(j) Surrogate spike requirements are as follows:

*****

(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.

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§ 252.404. Essential quality control requirement—microbiology.

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(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]**.

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(9) *Plastic and glassware washing procedure.*

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(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**.

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

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(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 paragraphs (2) and (3) must be performed by an environmental laboratory accredited under this chapter for the appropriate field(s) of accreditation.

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(f) The requirements for media are as follows:

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(4) After preparation, media shall be stored and maintained as follows:

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

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

(1) A sterility blank shall be analyzed for each lot of preprepared, ready-to-use medium and for each batch of medium prepared in the laboratory prior to first use of the medium. Records shall be maintained and include media identification, date **and time of the start and end of incubation**, results and initials of responsible **[individual] individual(s)**. 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 reusable 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 shall insert a sterility blank after every 10 samples filtered through each membrane [**filration] 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 sample and include the date and time of the start and end of the incubation, results, and initials of the responsible individual(s)**. If sterility blanks indicate contamination, the laboratory must treat each affected sample according to program requirements.

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(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] individual(s)**. 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 responsible **[individual] individual(s),** 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 **and time of the start and end of incubation**, results and initials of the responsible **[individual] individual(s)**. If the membrane filter sterility check indicates contamination, the affected membrane filters may not be used.

(7) Sterility checks on *Quanti-Tray*™ sample trays shall be performed on at least one sample tray for each lot of purchased, presterilized sample tray with an appropriate non-selective 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 the responsible individual(s). If the sample tray sterility check indicates contamination, the affected lot of sample trays 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 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 **the** responsible **[individual] individual(s)**. 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**] **individual(s)**. If negative culture control checks do not meet expected results, the affected media may not be used.

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(4) Stock positive and negative culture controls shall be discarded upon the manufacturer's expiration date unless **[it is shown through appropriate biochemical and purity tests]reevaluated and validated by a procedure approved by the Department** that **demonstrates 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.

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(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) 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 before or during first use. These checks 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.

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

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

§ 252.501. Proficiency test study requirements.

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(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 result that is not handled, managed, analyzed, or reported in accordance with this section.

Subchapter F. [ONSITE] ASSESSMENT REQUIREMENTS

§ 252.601. [Onsite assessment] Assessment requirements.

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(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 an environmental laboratory's accreditation in accordance with subchapter G (relating to miscellaneous provisions) before issuing the 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.]:**

(1) Document the corrective action taken by the laboratory to correct each deficiency and the timeframe for completion.

(2) Include documentation demonstrating correction of the deficiencies, as requested by the Department.

(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.

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(h) Unless otherwise **required or** approved by the Department, **[deficiencies shall be corrected within 120 calendar days of receipt of the onsite assessment report.]the environmental laboratory shall:**

(1) Correct all deficiencies within 120 calendar days of receipt of the assessment report.

(2) Implement and maintain the corrective actions within the timeframes specified in the corrective action report(s) or as mandated by the Department.

(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:

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Subchapter G. MISCELLANEOUS PROVISIONS

Sec.

§ 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:

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(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:

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(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 **report** within the required time frames.

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(16) Failure to meet the requirements of this chapter.

(17) Failure to maintain test instruments, equipment, supplies, and reference materials that meet the specifications required to produce valid analytical results.

§ 252.702. Revocation.

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

(1) Failure to respond to an **[onsite]** assessment report with a corrective action report within the required time frames.

(2) Failure to correct deficiencies identified during an **[onsite]** assessment of the environmental laboratory.

(3) Failure to implement corrective action **[related to] to correct** 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.

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(11) Analysis of proficiency test studies by personnel**, procedures, equipment, facilities, number of replicates, and methods** other than **[the analysts]those** associated with the routine analysis of environmental samples in the laboratory.

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(17) Failure to meet the requirements of this chapter.

(18) Failure to maintain test instruments, equipment, supplies and reference materials that meet the specifications required to produce valid analytical results.

(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] in a manner** approved by the Department.

§ 252.703. Suspension

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(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 assessment report within the required timeframes.

(5) Failure to correct deficiencies identified during an assessment of the environmental laboratory.

(6) Failure to implement corrective action related to violations or deficiencies found during an assessment.

(7) Failure to maintain test instruments, equipment, supplies and reference materials that meet the specifications required to produce results that meet the specifications required to produce valid analytical results.

(8) Failure to analyze and report proficiency testing study results in accordance with § 252.501 (relating to proficiency testing study results).

(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] in a manner** approved by the Department.

§ 252.704. Voluntary relinquishment.

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(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] in a manner** approved by the Department.

§ 252.705. Use of accreditation.

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

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(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**] **NELAP** logo with the phrase ''NELAP accredited'' and the laboratory's accreditation number when using the Department's name or the **[NELAC/NELAP] 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] NELAP** logo to imply endorsement by the Department or **[NELAC/NELAP] NELAP**.

§ 252.706. Recordkeeping.

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(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 end dates and times of incubations, drying cycles, digestion, distillations, etc. when a minimum or maximum time is specified by method, regulation, or permit.

(2) Unequivocal link between the laboratory's sample identification number to the results of all associated quality control.

(3) Instrument identification.

(4) Identification of, or reference to, the standards, reagents, media, supplies, etc. used during sample preparation and analysis, or both.

(5) The results of chemical and thermal preservation verifications or adjustments, or both.

(6) Date of sample preparation or analysis, or both.

(7) Time of sample preparation or analysis, or both, if the holding time for either activity is less than or equal to 72 hours.

(8) Manual calculations.

(9) Test results.

(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.

(2) 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.

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§ 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:

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

(3) For organic **and radiochemical** analyses, review all sample analysis data within 7 days of acquisition of the initial sample results for organic analysis.

(4) For microbiological results, read all sample results within 30 minutes of the end of the incubation period.

(5) Analyze the laboratory control sample(s) at a concentration at or below the maximum contaminant level.

(6) Report to the Drinking Water Environmental Lab Reporting ("DWELR") system only those analytical test results that meet all method, regulatory, and permit requirements for sample collection, preservation, holding time, sample analysis, and quality control performance, unless the Department has specifically approved that the result may be reported.

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

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