Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE VI. GENERAL HEALTH AND SAFETY

CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION

Subchapter A. GENERAL PROVISIONS

§ 252.1. Definitions.

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

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

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

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

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

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Primary accreditation--Accreditation received from the Department that is not based upon accreditation from another **[~~accrediting authority~~]**__**ACCREDITATION BODY**__.

__***PROFICIENCY TEST REPORTING LIMIT*--THE VALUE THAT CORRESPONDS TO THE LOWEST ACCEPTABLE RESULT THAT COULD BE OBTAINED FROM THE LOWEST SPIKE LEVEL FOR EACH ANALYTE IN A PT SAMPLE.**__

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Nonpotable water--

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

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

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Secondary accreditation--Accreditation received from the Department based upon the accreditation status granted by another **[accrediting authority]** __**accreditation body**__.

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__***TNI*--The NELAC Institute or its successor organization/Standard.**__

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§ 252.4. General requirements.

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[(c) By July 28, 2006, an environmental laboratory testing or analyzing environmental samples within a matrix identified in § 252.3 and to comply with a statute listed in § 252.3 shall apply to the Department for accreditation in accordance with Subchapter B (relating to application, fees and supporting documents). An environmental laboratory that files an application within that time period shall have interim accreditation to continue operations until the Department takes final action on the application.

(d) After July 28, 2006, an environmental laboratory that seeks accreditation under this chapter shall apply in accordance with Subchapter B. Interim

accreditation will not be granted to an environmental laboratory which submits an application for accreditation after July 28, 2006.]

§ 252.5. NELAP/TNI equivalency.

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(b) An environmental laboratory seeking NELAP accreditation shall:

(1) Submit a complete application as provided in Subchapter B (relating to application, fees and supporting documents).

(2) **COMPLY WITH SUBCHAPTER E (RELATING TO PROFICIENCY TEST STUDY REQUIREMENTS).**

[~~(2)~~] (3) Comply with Subchapter F (relating to onsite assessment requirements).

[~~(3)~~] (4) Comply with Subchapter G (relating to miscellaneous provisions).

[~~(4)~~] (5) Comply with the current edition of the NELAC Standard or TNI Standard.

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§ 252.6. Accreditation-by-rule.

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

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

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

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

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

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

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

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Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

§ 252.202. Application for transfer of laboratory accreditation.

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(b) **[Open or pending enforcement] Enforcement** actions will be transferred with the accreditation.

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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, **[or] change in administrative information,** addition of fields of accreditation**, or supplemental onsite assessment**. A check must be payable to "Commonwealth of Pennsylvania." The fees are as follows:

Category	*Fee*
[Application fee--initial application	**$600**
Application fee--renewal application	**$500**
Application fee--ownership transfer	**$150**
Application fee--addition of fields of accreditation	**$250**
Basic drinking water category (one method for each of the following: total coliform bacteria, fecal coliform bacteria, E-coli bacteria, heterotropic bacteria, nitrate, nitrite, fluoride, cyanide)	**$600**
Asbestos--drinking water	**$350**
Microbiology--drinking water	**$450**
Trace metal category--drinking water	**$450**

Inorganic nonmetal category--drinking water	**$500**
Trace metal and inorganic nonmetal category--drinking water	**$800**
Volatile organic chemicals--drinking water	**$500**
Extractable and semivolatile organic chemicals--drinking water	**$750**
Dioxin--drinking water	**$600**
Radiochemical category--drinking water	**$700**
Basic nonpotable water category (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)	**$700**
Asbestos--nonpotable water	**$350**
Microbiology--nonpotable water	**$400**
Trace metal category--nonpotable water	**$450**
Inorganic nonmetal category--nonpotable water	**$550**
Trace metal and inorganic nonmetal category--nonpotable water	**$900**
Volatile organic chemicals--nonpotable water	**$500**
Extractable and semivolatile organic chemicals--nonpotable water	**$950**
Dioxin--nonpotable water	**$600**
Radiochemical category--nonpotable water	**$600**
Whole effluent toxicity testing category	**$600**
Microbiology--drinking water and nonpotable water	**$750**
Trace metal category--drinking water and nonpotable water	**$800**
Inorganic nonmetal category--drinking water and nonpotable water	**$1,000**
Trace metal and inorganic nonmetal category--drinking water and nonpotable water	**$1,550**
Volatile organic chemicals--drinking water and nonpotable water	**$900**
Extractable and semivolatile organic chemicals--drinking water and nonpotable water	**$1,650**
Dioxin--drinking water and nonpotable water	**$1,050**
Radiochemical category--drinking water and nonpotable water	**$1,050**
Asbestos--solid and chemical materials	**$350**
Microbiology--solid and chemical materials	**$450**
Trace metal category--solid and chemical materials	**$450**
Inorganic nonmetal category--solid and chemical materials	**$550**
Volatile organic chemicals--solid and chemical materials	**$550**
Extractable and semivolatile organic chemicals--solid and chemical materials	**$1,200**

Dioxin--solid and chemical materials	**$600**
Radiochemical category--solid and chemical materials	**$600]**
Application fee--Initial Application for State Accreditation	**$750**
Application fee--Renewal Application for State Accreditation	**$500**
Application fee--Ownership Transfer or Change in Administrative Information	**$150**
Application fee--Initial Application for NELAP/TNI Accreditation	**$2,500**
Application fee--Renewal Application for NELAP/TNI Accreditation	**$2,000**
Application fee--Addition of Field of Accreditation	**$250**
Application fee--Supplemental 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**
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**
Asbestos--first matrix	**$400**
Microbiology--first matrix	**$500**
Trace Metal Category--first matrix	**$550**
Inorganic Nonmetal Category--first matrix	**$600**
Volatile Organic Chemicals--first matrix	**$650**
Extractable and Semivolatile Organic Chemicals--first matrix	**$1,500**
Dioxin--first matrix	**$650**
Radiochemical Category--first matrix	**$750**
Whole Effluent Toxicity Testing--first matrix	**$700**
Asbestos--second matrix	**$350**
Microbiology--second matrix	**$450**
Trace Metal Category--second matrix	**$500**
Inorganic Nonmetal Category--second matrix	**$550**
Volatile Organic Chemicals--second matrix	**$600**
Extractable and Semivolatile Organic Chemicals--second matrix	**$1,400**
Dioxin--second matrix	**$600**
Radiochemical Category--second matrix	**$700**
Asbestos--third matrix	**$300**

Microbiology--third matrix	**$400**
Trace Metal Category--third matrix	**$450**
Inorganic Nonmetal Category--third matrix	**$500**
Volatile Organic Chemicals--third matrix	**$550**
Extractable and Semivolatile Organic Chemicals--third matrix	**$1,300**
Dioxin--third matrix	**$550**
Radiochemical Category--third matrix	**$650**

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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 **[accrediting authority] /TNI accreditation body** for the same fields of accreditation for which the Department is a primary NELAP **[accrediting authority] /TNI accreditation body**.

(ii) The Department may recognize the accreditation of an environmental laboratory by another state **[~~accrediting authority~~] 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.

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(iii) An environmental laboratory seeking secondary accreditation from the Department shall:

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(C) Submit a copy of a valid accreditation certificate from the primary **[accrediting authority] accreditation body**.

(D) Submit a copy of all onsite assessment reports conducted by the primary **[~~accrediting authority~~] ACCREDITATION BODY** within the last 3 years.

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(E) [Submit copies of all proficiency test sample results reported to the primary accrediting authority within the past 12 months. (F)] Submit any other material relevant to accreditation, upon request of the Department.

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(c) If any portion of the out-of-State environmental laboratory's accreditation is denied, revoked or suspended by the primary **[~~accrediting authority~~]** **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 individuals listed on the laboratory's application for accreditation for which the Department has reviewed and approved the individual's qualifications.**

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

[(b)] (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.

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

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

[(e)] (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.

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

[(g)] **(h)** An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor to temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding 16 consecutive calendar days. If this **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).

[(h)] **(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.

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(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.

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

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(2) A minimum of 4-college semester credit hours in **[general microbiology]** **biology**.

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

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§ 252.304. Personnel requirements.

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

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(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 MUST INCLUDE:**

(i) AN IDENTIFICATION OF THE ANALYSTS INVOLVED IN THE REPARATION 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:

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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:**

(A) An initial demonstration of capability is required prior to the use of any method.

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

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

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

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

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

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

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

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

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

(G) The work cell as a unit shall meet the following requirements:

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

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

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

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§ 252.306. Equipment, supplies and reference materials.

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

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(2) *Working thermometers.*

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(ii) Working thermometers may be glass, dial or electronic and shall be calibrated against a certified NIST-reference thermometer as follows:

(A) Glass **[and electronic thermometers and continuous recording devices], 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. **[Dial thermometers that cannot be calibrated may not be 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] document** 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.

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(iv) A working thermometer that differs by more than **[1.0C] 2.0°C** from the reference thermometer may not be used.

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

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

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(4) *Analytical or pan balances.*

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

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

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(5) *pH meter.*

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

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

(6) *Conductivity meter.*

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

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

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

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

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(iv) Calibration-corrected temperatures for each incubator, water bath **[or],** heating block **or oven** shall be recorded once a day for each day in use for all laboratory activities. When used as an incubation unit for microbiology, the calibration-corrected temperature shall be recorded at least twice per day in use with the readings separated by at least 4 hours. The incubator, water bath **[~~or~~],** heating block **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, mechanical volumetric dispensing devices including burettes, autopipetors and dilutors, must be of sufficient sensitivity for the application. Delivery volumes of mechanical volumetric dispensing devices shall be checked **[~~using~~] [a gravimetric] [~~an appropriate~~] [~~method~~]** at least once every 3 months.

(ii) Verification will 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 may not be used.

(10) *Graduated sample containers.*

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

(ii) Verification will 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 may not be used to measure sample volumes.

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

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

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

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

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

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

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

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

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:

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

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

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

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

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

(6) Standards, reagents and media may not be used past the date of expiration unless reevaluated and validated by a [~~Department approved~~] procedure APPROVED BY THE DEPARTMENT PRIOR TO USE.

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

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

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

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§ 252.307. Methodology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

§ 252.401. Basic requirements.

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

(1) The full name and physical address of the laboratory.

(2) The name, address (if different from paragraph (1)), and telephone number of the 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.

(5) The procedures for detecting and permitting departures from established procedures as specified in subsections (i) and (h).

(6) The procedures for detecting and preventing improper practices as specified in § 252.304 (relating to personnel requirements).

(7) The sample handling and acceptance procedures as specified in subsections (f) and (g).

(8) The reporting of analytical results as specified in subsection (j).

(9) The monitoring of the quality of analysis as specified in subsection (l).

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

(1) The laboratory shall **[have] implement** procedures for educating and training personnel in their ethical and legal responsibilities under the act.

(2) The laboratory shall provide training in ethical and legal responsibilities within 2 months of employment to the laboratory and at least every 14 months thereafter for all employees.

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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. The results of these checks shall be recorded.

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

(i) The client/project name.

(ii) The date, time and location of sample collection, name of sample collector and field identification code.

(iii) The date and time of laboratory receipt.

(iv) Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

(v) A unique laboratory ID code that corresponds to the information required by this paragraph.

(vi) An identification of the person making the entries.

* * * * *

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

(1) The name and address of the laboratory.

(2) The total number of pages in the report, including any addendums, in the format of Page x of y.

(3) The name and address of the client.

(4) An identification of the test method used.

(5) An identification of the samples including the client identification code.

(6) The date and time of sample collection.

(7) The date of sample analysis.

(8) The 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) [~~Results~~] AN IDETIFICATION OF RESULTS reported on a basis other than as received (for example, dry weight).

(13) An identification of testing or analysis results not covered by the laboratory's scope of accreditation.

(14) An identification of results that do not meet the requirements of this chapter.

(15) An identification of subcontracted results.

(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 [~~laboratory sample handling procedures~~] PROCEDURES FOR REPORTING RESULTS, provided the information required by subsection (j) is maintained under § 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:

* * * * *

[(l)] (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 [~~and~~] 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.

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

§ 252.402. Essential quality control requirements--chemistry.

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(c) Initial calibration requirements are as follows:

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(6) **[Results not bracketed by the initial calibration standards shall be reported with appropriate qualifiers.**

(7)] The lowest standard used for initial calibration may not be below the detection limit. The lowest standard must be at or below the lower limit of the range of quantitation.

(d) Except for methods that explicitly allow initial calibration using a single concentration of standard, initial calibration shall be done using multiple concentrations of standards according to the requirements of this subsection.

(1) Unless otherwise specified in the method, the initial calibration must meet one of the following criteria:

* * * * *

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

(iii) A **[correlation]** coefficient **[(r)]** **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.

* * * * *

(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:

* * * * *

(f) Calibration verification requirements are as follows:

* * * * *

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

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(h) Laboratory control sample requirements are as follows:

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(2) **[The laboratory control sample must consist of a defined matrix containing known and verified concentrations of analytes. The Department will allow the use of an artificial or simulated matrix when a defined matrix is not commercially available]** **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.**

* * * * *

(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 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.

[(2)] (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.

[(3)] (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 determine internal criteria and document the procedure used to establish the acceptance limits.

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

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(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 must detail the steps taken to perform the integrations and 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) The confirmations shall be performed when analysis involves the use of an organic chromatography method not utilizing a mass spectrometer.

(2) The confirmations shall be documented.

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

§ 252.403. Essential quality control requirements--toxicity testing.

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(g) Records of all equipment, reference materials, reagents and supplies shall be maintained in accordance with § 252.306 (relating to equipment, supplies and reference materials).

§ 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. **[Pressure cookers may not be used.]** **Because of safety concerns and difficulties with operational control, pressure cookers should not be used. Pressure cookers may not be used for sterilization of media.**

(ii) **[Prior to first use, an environmental laboratory shall evaluate and document the performance of an autoclave by establishing its functional properties and performance (for example, heat distribution characteristics with respect to typical uses).**

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

[(iv)] **(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.

[(v)] **(iv)** An environmental laboratory shall verify the mechanical timing device, if used, for each autoclave every 3 months. Records of mechanical timer verification shall be maintained **[in a laboratory notebook]** and include the autoclave identification, date, mechanical timing device time, actual time and initials of the responsible individual. Correction factors shall be documented and used.

[(vi)] **(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 shall be kept.

[(vii)] (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.

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[(viii)] (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.

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

(2) *Hot air oven.*

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

(ii)] 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.

[(iii)] (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.

[(iv)] (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.

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

(3) **[*Optical counting equipment.***

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

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

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

[(4)] *Inoculating equipment.*

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

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

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

* * * * *

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

(vi)] 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.

[(6)] (5) *Culture dishes.*

* * * * *

[(7)] (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.

[(8)] (7) *Pipettes.*

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

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[(9)] (8) *Sample containers.*

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

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[(11)] (10) *Ultraviolet lamp.* An environmental laboratory shall use a 365-nm, 6-watt ultraviolet lamp in a darkened room to view sample fluorescence.

[(12)] (11) *Quanti-Tray™ Sealer.*

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

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

* * * * *

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

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

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

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

(f) The requirements for media are as follows:

* * * * *

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

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

(4)] (3) Media may not be reautoclaved.

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

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

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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:

* * * * *

(2) For each **reuseable** membrane filtration unit used during a filtration series, the laboratory shall prepare at least one sterility blank at the beginning **[~~, after every ten samples,~~]** and at the end of the series **[and record the results. If the membrane filtration unit sterility blank indicates contamination, the data from affected samples shall be invalidated and an immediate resampling requested. When a**

filtration series is interrupted for more than 30 minutes, the filtration funnels shall be resterilized]. **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 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. If sterility blanks indicate contamination, the laboratory must treat EACH affected sample according to program requirements.**

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

* * * * *

(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 **[~~by the laboratory~~]**. Records shall be maintained and include the date, media lot or batch number, type of media, positive culture control organism identification, results and initials of responsible individual. If positive culture control checks do not meet expected results, the affected media may not be used.

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

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

(6) For cultures maintained by the laboratory, the following criteria must be met:

(i) Reference control cultures may be revived and subcultured 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 refrozen and reused.

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

(iv) If the laboratory sequentially cultures working stocks, the laboratory shall 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 may not be sequentially cultured more than five times and may not be subcultured to replace reference stocks.

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

(i) **[The requirements for test variability/reproducibility are as follows:**

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

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

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

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

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

§ 252.405. Essential quality control requirement--radiochemistry.

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

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

§ 252.501. Proficiency test study requirements.

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

* * * * *

(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).

Subchapter F. ONSITE ASSESSMENT REQUIREMENTS

§ 252.601. Onsite assessment requirements.

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

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(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.

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

[(h)] (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

§ 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:

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(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 SUPERIVSOR).**

§ 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 volunatily relinquishes its certificate of accreditation shall **[~~insure~~] ENSURE** records are maintained in accordance with § 252.706 (relating to recordkeeping).

* * * * *

§ 252.705. Use of accreditation.

(a) Environmental laboratories accredited by the Department shall:

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

* * * * *

§ 252.706. Recordkeeping.

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

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§ 252.707. Subcontracting.

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

§ 252.708. Reporting and notification requirements.

(a) An environmental laboratory conducting testing or analysis of drinking water under Chapter 109 (relating to safe drinking water) shall **[meet the reporting and notification requirements of that chapter.]:**

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

(2) Review all sample analysis data within 24 hours of acquisition of the initial sample results for microbilogical, [~~inorganic and wet chemistry analysis~~] 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 analyses, review] REVIEW all sample analysis data within 7 days of acquisition of the initial sample results for organic AND RADIOCHEMICAL [~~anaylsis~~] ANALYSES.

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

* * * * *

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

(f) An out-of-State environmental laboratory with either primary or secondary accreditation from the Department shall notify, in writing, the Department within 48 hours of any changes in the laboratory's accreditation status from any other primary **[~~accrediting authority~~]** **ACCREDITATION BODY**.

[(f)] **(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.

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