PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 252]

Environmental Laboratory Accreditation

The Environmental Quality Board (Board) proposes to amend Chapter 252 (relating to environmental laboratory accreditation). This proposed rulemaking clarifies existing requirements, deletes or amends overly restrictive and cost prohibitive requirements, and proposes additional requirements necessary for laboratory accreditation. This proposed rulemaking also amends the fee structure in § 252.204 (relating to fees).

This proposed rulemaking was adopted by the Board at its meeting of May 17, 2016.

A. *Effective Date*

This proposed rulemaking will go into effect upon final-form publication in the *Pennsylvania Bulletin*.

B. *Contact Persons*

For further information contact Aaren S. Alger, Chief, Laboratory Accreditation Program, P.O. Box 1467, Harrisburg, PA 17105-1467, (717) 346-8212; or William S. Cumings, Jr., Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposed rulemaking is available on the Department of Environmental Protection's (Department) web site at www.dep.pa.gov (select "Public Participation," then "Environmental Quality Board (EQB)").

C. *Statutory Authority*

This proposed rulemaking is being made under the authority of 27 Pa.C.S. §§ 4103(a), 4104 and 4105 (relating to establishment of program; powers and duties; and powers and duties of Environmental Quality Board) and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20), authorizing and directing the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. *Background and Purpose*

Chapter 252 became effective on January 28, 2006, and was amended on April 10, 2010. While completing ongoing rounds of laboratory assessments under Chapter 252, the Laboratory Accreditation Program (Program) discovered various provisions that are unclear, the regulations are lacking sufficient detail to ensure full compliance with the regulatory requirements or standards are overly restrictive and cost prohibitive. The Program also determined that several necessary standards for accreditation are lacking. The scope of Chapter 252 remains unchanged.

Under 27 Pa.C.S. § 4104(6), the accreditation fees must be "in an amount sufficient to pay the department's cost of implementing and administering the accreditation program." In addition, § 252.204(b) requires the Department to recommend to the Board regulatory changes to the accreditation fees every 3 years to address any disparity between Program income generated by the fees and Program costs. In accordance with this requirement, the Program performed a workload analysis to evaluate the costs associated with the Program. Based on this workload analysis, the Department determined that the accreditation fees in § 252.204 are not sufficient to recover the Department's costs to implement the Program. This proposed rulemaking provides a new fee structure to cover the costs of the Program.

The Department worked with the Laboratory Accreditation Advisory Committee (LAAC) to propose amendments to Chapter 252 in a manner that ensures appropriate requirements for environmental laboratory accreditation. The Department, with the assistance of the LAAC, ensured that the interests, concerns and needs of the regulated community were considered and implemented appropriately. The LAAC met throughout 2014 and 2015 to review and comment on drafts of the proposed Chapter 252 amendments presented by the Department. On December 2, 2015, the LAAC unanimously voted to recommend the proposed Chapter 252 amendments for presentation to the Board.

E. *Summary of Regulatory Requirements*

Federal regulations exist for the certification of the analysis of drinking water samples but Federal regulations do not exist for the accreditation of the analysis of nonpotable water (wastewater) or solid and chemical materials. This proposed rulemaking is more stringent than the Federal requirements for laboratory accreditation but not more stringent than the current environmental laboratory accreditation regulations. This proposed rulemaking does not expand the Department's oversight or regulatory authority over environmental testing laboratories.

Federal regulations cover the testing and analysis of samples from public drinking water suppliers. The Federal drinking water laboratory certification program consists of requiring the use of Federally promulgated methods for testing and analysis and recommended laboratory practices. Some of the requirements in these regulations are more stringent than the Federal standards for the certification of environmental laboratories performing testing or analysis on samples from public drinking water suppliers because the Federal standards offer recommendations or guidance that are mandated in Chapter 252.

There are no Federal standards or regulations for accreditation of environmental laboratory testing for nonpotable water (wastewater) and solid and chemical materials. The Federal regulations do mandate specific test methods and performance of the testing laboratories, but do not mandate that the laboratories seek and obtain accreditation. Because there is no Federally mandated accreditation program for environmental laboratories testing nonpotable water (wastewater) and solid and chemical materials and the Federal certification program for testing of potable water consists mostly of recommended practices, most of these regulations are more stringent than the Federal program. This proposed rulemaking contains the minimum requirements for an environmental laboratory performing testing or analysis on wastewater and solid and chemical materials as well as drinking water.

An effective laboratory accreditation program is a proactive measure to protect the public health and the environment and to help ensure that the results used to make critical decisions about the public health and

environment obtained using Department and United States Environmental Protection Agency (EPA) approved procedures and that the data are of known and documented quality. In recent years, the Program has observed an increase in the number and severity of violations committed by commercial environmental laboratories. These violations directly impact the quality of the data used for compliance decisions in the Commonwealth. The Program continues to investigate, enforce and penalize these noncompliant laboratories based on 27 Pa.C.S. Chapter 41 (relating to environmental laboratory accreditation) and its regulations. Nonregulation would result in a system that does not ensure the procedures that produce the overwhelming majority of data used for environmental decisions in the Commonwealth are being performed accurately. Without periodic in-depth onsite and offsite laboratory assessments, the Department cannot have confidence in the data submitted.

Subchapter A. General Provisions

Sections 252.1 and 252.5 (relating to definitions; and NELAP equivalency) are proposed to be amended to correctly state that the Department offers and grants National Environmental Laboratory Accreditation Program (NELAP) accreditation.

Laboratories reporting analytical testing results for any of the 12 statutes referenced in § 252.4(a) (relating to general requirements) are proposed to be included among the types of laboratories which fall within the scope of Chapter 252. Currently, only laboratories which test or analyze environmental samples fall within the scope of Chapter 252.

The proposed rulemaking includes specific requirements for laboratories regarding development and maintenance of instructions for sample collection, preservation and sample receipt. To ensure that laboratories generating compliance data for the Department meet the same standards of performance, the requirement of NELAP laboratories to adhere to §§ 252.307 and 252.401 (relating to methodology; and basic requirements) is proposed to be added to § 252.5. The term "onsite" with respect to onsite assessments is proposed to be deleted throughout Chapter 252, with the exception for requiring onsite assessments for initial accreditation, to allow for the Department to explore cost-saving alternatives such as offsite assessments.

Section 252.6 (relating to accreditation-by-rule) is proposed to be amended to specify that all laboratories performing testing or analysis for compliance testing or reporting results of compliance testing shall meet the requirements of this section and that laboratories are deemed to be accreditation-by-rule if, among other things, they only report the accredited-action-rule parameters in subsections (c) and (f).

Subchapter B. Application, fees and supporting documents

Sections 252.201(a) and 252.203(a) (relating to application and supporting documents; and accreditation renewal) are proposed to be amended by deleting "in writing" and adding "in the format specified by the Department" to allow for advances in technology and submission of electronic applications.

Section 252.203(d) is proposed to be added to require laboratories to provide notification to each affected customer of an expiration of the certificate of accreditation within 48 hours of the expiration.

Section 252.204(a) is proposed to be amended to allow applicant laboratories to pay the accreditation fees by credit card when the Department can accept credit card payments. Laboratories choosing to pay by credit card will be required to pay all service charges or administrative fees in addition to the accreditation fees established by this section.

An environmental laboratory will pay an initial application fee and annual renewal fees based on the appropriate accreditation categories sought. Under 27 Pa.C.S. Chapter 41, the fees provided in § 252.204 must be sufficient to pay the Department's cost of implementing and administering the Program, including processing applications for certificates of accreditation, the issuance, renewal, modification or other action relating to the certificate. Laboratories pay fees based on the number and complexity of the categories for which they request accreditation. The cost of each fee category is based on the number of assessor hours necessary to accredit an environmental laboratory for that given category.

To appropriately distribute the cost of the implementation of the Program, the fee structure in § 252.204 is proposed to be amended to reflect the costs associated with implementation of the Program.

Section 252.205(a)(2)(i) (relating to out-of-State laboratories) is proposed to be amended to add clarification that laboratories seeking secondary NELAP accreditation shall meet the requirements of § 252.5.

In § 252.206 (relating to out-of-State onsite reimbursement), the rate for reimbursement of out-of-State travel for assessors is proposed to be changed from $50 to $75 per hour.

Subchapter C. General standards for accreditation

Section 252.301(h) (relating to laboratory supervisor) is proposed to be amended to specify that the laboratory shall designate a Department-approved temporary laboratory supervisor if the primary laboratory supervisor is absent. The number of days that a laboratory supervisor may be absent is proposed to be amended from 16 days to 21 days.

Terminology is proposed to be added to § 252.302(a) and (b) (relating to qualifications of the laboratory supervisor) to better explain the current requirements for laboratory supervisors at laboratories accredited to perform organics, trace metals and inorganic nonmetals analyses. The education and experience requirements for organics and trace metals analyses remains unchanged while the experience requirements for laboratory supervisors supervising inorganic nonmetals, basic microbiology, basic drinking water, basic nonpotable water and supervisors approved through the operator certification program are proposed to be reduced from 2 years to 1 year.

Section 252.302(c) is proposed to be amended to explain that the requirements for a laboratory supervisor of an environmental laboratory performing microbiological testing require a minimum of 4 microbiology credits. The analysis of *E. coli* is proposed to be added to subsection (d) as one of the testing types allowed to be supervised by an individual meeting the less stringent laboratory supervisor requirements for "basic" microbiology. The "basic" microbiology laboratory supervisor's experience requirements in subsection (d) is proposed to be reduced from 2 years to 1 year.

The educational requirements for laboratory supervisors of laboratories performing radiochemical analyses in § 252.302(e) is proposed to be changed to include credits in health physics instead of limiting the educational credits to chemistry.

The operator certification exam for laboratory supervisors became available in July 2015. Therefore, § 252.302(h) allowing 2 years of testing experience to substitute for the laboratory supervisor subclassification for operator certification is no longer applicable and is proposed to be deleted and replaced with a minimum requirement of 1 year of analytical testing experience.

Section 252.302(j) is proposed to be added to include experience and education requirements for whole effluent toxicity testing, which was previously included in the microbiology supervisor qualifications.

Section 252.302(k) is proposed to be added to clarify that all college-semester credit hours shall be obtained from an accredited college or university and subsection (l) is proposed to be added to state that all foreign transcripts must be translated into English and evaluated for United States semester credit hour equivalency to ensure that all laboratory supervisors meet the same educational requirements.

The EPA granted the Department primacy for the certification of cryptosporidium in 2014. The EPA mandates specific experience requirements for analysts performing testing of cryptosporidium that are not listed in Chapter 252. Accordingly, § 252.302(m) is proposed to be added to specify that if any method, regulation or program requires more stringent qualifications than those listed in § 252.302, then those requirements shall be met.

Section 252.304(b)(3)(vi) and (vii) (relating to personnel requirements), regarding initial and ongoing demonstration of capability requirements, is proposed to be amended to include additional detail regarding the concentration at which to prepare the four aliquots of the analyte. The proposed amendments clarify that the analyses of the four aliquots shall be analyzed consecutively but can occur on one or multiple days and provides additional clarification to explain how to evaluate the final results.

Editorial changes and clarifications are proposed throughout § 252.306 (relating to equipment, supplies and reference materials). Clarifications are proposed to the requirements for equipment, supplies and reference materials in subsection (c) to explain that the laboratory shall ensure that equipment, supplies and reference materials, including test instruments, meet the specifications required of the application for which it is used.

Additional detail is proposed to be added to § 252.306(f) to explain the documentation requirements for both balance calibrations and verifications, pH meter calibrations, refrigerators, incubators and other laboratory equipment. The term "working" is proposed to be added to subsection (f)(7)(ii) and (8)(iv) under "refrigeration equipment and freezers" and "incubators, water baths, heating blocks and ovens," respectively. The laboratories would be required to monitor the temperatures of these types of equipment each "working day" when "in use." The term "working day" would be interpreted as a day when the laboratory is open for business or laboratory staff are working in the laboratory, or both. As an example, when laboratories are closed for business and laboratory staff are not working in the laboratory, temperatures would not need to be taken. Conversely, in subsection (f)(8)(iv), when an incubator, water bath, heating block or oven is used as an incubation unit for microbiology, the temperature shall be monitored each day that the incubator is in use. Thus, a laboratory shall monitor microbiology incubators even when the laboratory is closed for business when the microbiology incubation units are in use. The requirement to calibrate a pH meter with standards that bracket the pH range of samples is proposed to be deleted from subsection (f)(5). Specific detail is proposed to be added to the requirements for volumetric dispensing devices and graduated sample containers in subsection (f)(9) and (10). Subsection (g) is proposed to be amended to include a requirement to track laboratory supplies that are essential to obtain analytical results in the laboratory's recordkeeping system.

Subsection (h) is proposed to be amended to add "media" to ensure that media records are maintained in the same manner as standards and reagents. Laboratories are not permitted to use expired materials for testing or analysis of compliance samples. During discussions with the LAAC, the Department suggested that the laboratories be required to remove expired materials from the laboratory. However, the public and the LAAC suggested that these materials did not need to be removed, but segregated to ensure they were not used. The requirement to segregate expired materials from unexpired materials in the laboratory is proposed to be added to subsection (h)(6) to ensure that they cannot be used.

During recent onsite assessments performed by the Program, laboratories have increasingly been found to be in violation of temperature requirements for microbiology incubators. They were either using incubators that cannot maintain the mandated temperature ranges or were overloading the incubators and they could not recover back to the minimum temperature within acceptable time frames. In light of this, subsection (j) establishing a requirement to perform temperature distribution studies for microbiology incubators is proposed to be added. The requirements for frequency and minimum requirements are outlined. Laboratories will be required to develop a procedure to perform this study and the procedure must be based on the specific type and size of incubation unit and incubators that do not maintain constant temperatures cannot be used.

Editorial changes to § 252.307 are proposed. This section does not regulate the collection of compliance samples when these samples are not collected by accredited laboratories. Many sample collections are performed by individuals with little or no experience in proper sample handling, collection and preservation procedures. To the best of their ability, the laboratories that collect, receive and analyze the compliance samples shall ensure that the samples meet the requirements for a valid sample analysis. Subsection (j) is proposed to be added for laboratories to develop and maintain instructions for sample collection and preservation. The proposed subsection specifies what types of information these instructions must include, which will be dependent on the type of analyte being tested and for what compliance purpose, and that these instructions shall be made available to both laboratory employees that collect the samples and customers and clients that collect samples.

Subchapter D. Quality assurance and quality control requirements

During public meetings with the LAAC, procedures for handling environmental samples outlined in § 252.401(f) were repeatedly discussed and comments regarding the Department's proposals and expectations were received. It was suggested that additional detail is needed to more fully explain how and when samples shall be checked and how the documentation of these checks shall be maintained. The existing regulation does not specify when the checks shall be made, only that the environmental laboratory is responsible for these checks and that the labora-

tory shall ensure that each check is appropriate to determine the validity of the test and that the checks shall be recorded. The requirement to verify and document the condition of the samples by the environmental laboratory is proposed to be clarified to explain that both chemical and thermal preservation shall be checked for all samples, that sample pH for all samples is analyzed for chemistry; whole effluent toxicity and radiochemistry fields; and that samples shall be checked for residual chlorine if the requested test will be negatively impacted by the presence of chlorine. A requirement to include the identification of the individual receiving the sample at the laboratory is proposed to be added.

Subsection (j) does not currently require unique identification for test reports or a requirement to identify amendments to test results or reports. This has resulted in test reports and results being issued or amended by laboratories that are easily misunderstood and untraceable to the original report. The proposed amendment to subsection (j) adds items to be included in a test report from the laboratory, including the date in addition to the time of sample preparation and analysis for tests with short holding times, a unique test report identifier or code, and requirements for amendments to test reports.

Subsection (o) is proposed to be added to mandate that laboratories identify all opinions and interpretations on test reports and include an explanation for the basis of the opinion or interpretation.

Section 252.402 (relating to essential quality control requirements—chemistry) is proposed to be amended to add additional detail with regard to the raw data records that are necessary to permit reconstruction of the analytical testing, such as initial calibration (subsection (c)), method blank (subsection (g)) and laboratory control samples (subsection (h)).

This section is proposed to be amended to add standards necessary for the quality control protocols mandated by Chapter 252 when the approved methods do not include acceptance criteria requirements. Many analytical methods do not include specific acceptance criteria for one or more required quality control elements that Chapter 252 mandates. The proposed amendment to subsection (f)(6) provides that when a method exists that does not include minimum acceptance criteria for one or more quality control measures the environmental laboratory shall use the acceptance criteria established in an equivalent method. An equivalent method would be one where the same or similar analyte is analyzed using the same or similar methodology/technology. For example, a laboratory is using a spectrophotometric method for the analysis of nitrate that does not have acceptance criteria for the LCS recovery, such as Standard Methods 4500-NO3 E. EPA 353.2 is also a spectrophotometric method for the analysis of nitrate and the LCS recovery for the LCS is 90—110% of the true value. The laboratory would use the 90—100% recovery limits for the evaluation of the LCS when analyzed by SM 4500-NO3 E. The proposed amendment also provides specific information regarding how to develop acceptance criteria for quality control measures when an equivalent method is not available.

Many laboratories have been under the misunderstanding that because Chapter 252 states that data may be reported with data qualifiers, then the data associated with data qualifiers is acceptable to be reported without determining if qualified data is acceptable to the Department. To address this misconception, it is proposed to delete language in § 252.402(f)(8) that describes when sample results may be useable because the laboratories regulated by this section should not be making the decision about usability of data.

Editorial changes and amendments are proposed throughout § 252.404 (relating to essential quality control requirement—microbiology). The documentation requirements for equipment, supplies and reference materials in this section were updated to ensure that necessary items for the reconstruction of the measurement are maintained. Subsection (d)(7) is proposed to be added to clarify that the heterotrophic plate count and bacteriological water quality test ratio analyses shall be performed by a laboratory accredited under Chapter 252. Subsection (g)(7) is proposed to be added to explain the requirements for sterility checks of Quanti-Tray™ sample trays. Proposed subsection (h) includes language that mirrors current language from § 252.401 explaining that laboratory materials cannot be used after their expiration date unless re-evaluated by a procedure approved by the Department.

Subsection (j) is proposed to be added to clarify that all quality control checks outlined in this section shall be performed after the laboratory receives the material. The sterility and efficacy of media and other microbiological supplies are directly affected by exposure to extreme temperatures and other environmental factors. The Department requires that laboratories verify the sterility and efficacy of the received materials for microbiological testing after the material is received by the laboratory.

Subchapter E. Proficiency test study requirements

Section 252.501(p) (relating to proficiency test study requirements) is proposed to be added to explain that proficiency test studies that are not handled, managed, analyzed or reported in accordance with this section will be invalidated. This section includes the specific requirements for a laboratory when ordering, receiving, handling, analyzing and reporting proficiency testing studies. Laboratories that do not manage proficiency test studies in accordance with this section may not use the inappropriate proficiency test study results for accreditation purposes.

Subchapter F. Assessment requirements

The term "onsite" is proposed to deleted from § 252.601 (relating to assessment requirements) as used in the context of onsite assessments, when appropriate, to allow the Department to explore and implement alternative assessment procedures in lieu of onsite assessments. Subsection (d) is proposed to be amended to explain that the Department may deny, suspend or revoke a laboratory's accreditation in accordance with Subchapter G (relating to miscellaneous provisions) if the Department finds that the laboratory's noncompliance is so severe that action is warranted before the Department issues an assessment report or the laboratory submits a corrective action report. Subsections (e) and (h) are proposed to be amended to better explain the requirements for a corrective action report, including how to prepare the report and what information and other supporting documentation shall be provided as evidence of the laboratory's implementation of its corrective action.

Subchapter G. Miscellaneous provisions

Editorial changes are proposed throughout this subchapter, including deletion of "onsite" as previously explained. Sections 252.702(d), 252.703(e) and 252.704(c) (relating to revocation; suspension; and voluntary relinquishment) are proposed to be amended to state that the laboratory may notify the customers of a revocation or

suspension in a manner approved by the Department instead of on a form approved by the Department. It is proposed to add failure to maintain test instruments, equipment, supplies and reference materials meeting the specifications required to produce valid analytical results as grounds for denial, suspension and revocation of accreditation in § 252.701(b)(17) (relating to denial of application) and §§ 252.702(b)(18) and 252.703(c)(7). Failure to manage proficiency test study results in accordance with § 252.501 is proposed to be added as a cause for revocation and suspension of accreditation in §§ 252.702(b)(11) and 252.703(c)(8). Three additional reasons for suspension of accreditation are proposed in § 252.703(c), including failure to submit an acceptable corrective action report, failure to correct deficiencies from an assessment and failure to implement corrective action. This would provide the Department greater flexibility in enforcement of Chapter 252 and 27 Pa.C.S. Chapter 41. Currently, the Department's only option in response to a violation of these provisions is revocation of accreditation.

Editorial changes are proposed throughout § 252.705 (relating to use of accreditation), including deleting "NELAC." Subsection (c) is proposed to be amended to include expiration of accreditation as one of the events precipitating the sanctions outlined in that subsection.

The Department found numerous continued violations of the recordkeeping requirements in § 252.706 (relating to recordkeeping) during its regular onsite assessments and data review. To address this and to clarify the recordkeeping requirements, proposed amendments to subsection (b) specify some of the specific requirements for records that shall be maintained to allow reconstruction of laboratory activities. Subsection (c) is proposed to be amended to clarify that records, not just data, shall be recorded promptly and legibly and that if the individual making the observation is not the individual creating the record, then both individuals and their responsibilities shall be identified and documented.

Section 252.708 (relating to reporting and notification requirements) incorporates the reporting and notification requirements in Chapter 109 (relating to safe drinking water) by reference. In the previous amendment to this section, subsection (a) incorrectly included "microbiological" as a type of test that could be reviewed within 24 hours of acquisition of sample results and radiochemistry was missing from this section. The term "microbiological" is proposed to be deleted from subsection (a)(2) and "radiochemical" is proposed to be added to subsection (a)(3). Paragraphs (4)—(6) are proposed to be added to subsection (a) to provide that microbiological results shall be read within 30 minutes of the end of the incubation, laboratory control samples shall be analyzed at or below the Maximum Contaminant Level and a clarification that only those analytical results that meet all method, regulatory and permit requirements for sample collection, preservation, holding time, sample analysis and quality control performance may be reported to the Drinking Water Environmental Reporting system unless the Department specifically approves the results to be reported.

F. *Benefits, Costs and Compliance*

Benefits

The most significant benefit of this proposed rulemaking will be the benefit of clear, concise and improved regulations for the regulated community. The proposed amendments will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories. Laboratories, particularly small laboratories, will benefit from allowing a laboratory supervisor to be absent for up to 21 days, rather than the current 16 days, and be replaced by a qualified staff member. Several of the laboratory supervisor areas of experience qualifications were reduced from 2 years to 1 year. The proposed rulemaking deletes the requirement for the Department to conduct onsite assessments, thus allowing the Department to explore and utilize advances in technology to perform offsite assessments which can substantially reduce overall costs to the Program and the regulated laboratories.

This proposed rulemaking also adds specific requirements for NELAP laboratories. The current TNI Standard, which NELAP laboratories shall meet, is silent or lacking in specific requirements for several necessary standards. Requiring that all NELAP laboratories adhere to these regulations will ensure that all laboratories performing testing or analysis of compliance samples for the Department are meeting the same minimum standard.

Improved data quality will allow the Department, the regulated community and the citizens of this Commonwealth to make better and more informed decisions concerning the protection of the environment and the protection of public health, safety and welfare. Accurate laboratory results are critical to achieving the goals of the environmental laws which are covered by the regulations.

Compliance costs

The direct costs of the proposed rulemaking will be payment of the proposed fees. Chapter 41 of 27 Pa.C.S. requires that the fees be set in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program. These costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. Laboratories that require extensive staff time to accredit such as large commercial laboratories and NELAP laboratories will pay a higher accreditation fee.

The renewal fee for State accreditation is proposed to be increased by $200 per year while the renewal fee for NELAP applicants is proposed to be increased by $750 per year. The proposed renewal application fees will increase for all laboratories at a rate of approximately 28%. Each laboratory is also responsible for paying the appropriate category fee associated with its requested scope of accreditation, such as microbiology, trace metals, volatile organics, and the like. The total accreditation fee for each laboratory is the renewal application fee plus each appropriate category fee. Each proposed category fee is proposed to be increased by between $100—$200 depending on the complexity of each category. The proposed fees for medium to large accredited laboratories are likely to increase by approximately 20—30% depending on the requested scope of accreditation. The proposed rulemaking contains a fee structure that is responsive to the needs of small laboratories. Specifically, increased category costs for smaller laboratories will be minimal as the fees for the Basic Non-Potable Water and Basic Drinking Water fee categories are proposed to be increased by $300. The current annual fee paid by these environmental laboratories is $1,250, and the proposed fee change would result in an annual fee of $1,550. Laboratories seeking accreditation for these two categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories. In addition, the proposed fee structure includes changes

including separation of the microbiology category into "basic" and "complex" to ensure that laboratories that are performing the more complex testing, which requires additional staff time and oversight, cover the costs of the accreditation.

Indirect costs will be related to the individual laboratory's implementation of the new requirements. Many in the regulated community are already in compliance with the additional requirements itemized in this proposed rulemaking and will not incur any additional costs for implementation. Others will be required to update or develop standard operating procedures and update recordkeeping procedures.

Cost savings will occur in the regulated community because the new and clarified requirements will enable laboratories to better understand the applicable requirements and should reduce the number of violations found during assessments, thus reducing the amount of time and money necessary to correct these violations.

Compliance assistance plan

Aside from the proposed fee changes, the proposed amendments are minor and in most cases clarify existing requirements or make current requirements less stringent. The Department does not believe that a compliance assistance plan tailored to the proposed rulemaking is necessary. However, the Department will continue its ongoing compliance assistance efforts.

The ultimate goal of the compliance assistance effort will be improving an environmental laboratory's ability to produce valid and defensible data for use by the Department, the regulated community and the public. Several areas where compliance assistance is necessary are general laboratory operation, correct performance of specific test procedures and documentation of laboratory activities. Compliance assistance in these areas has been made available to all environmental laboratories regardless of size throughout this Commonwealth.

Paperwork requirements

This proposed rulemaking does not include any additional forms, reports or other paperwork to be submitted.

G. *Pollution Prevention*

This is not applicable to this proposed rulemaking.

H. *Sunset Review*

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 29, 2016, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The Regulatory Review Act specifies detailed procedures for review prior to final publication of the rulemaking by the Department, the General Assembly and the Governor.

J. *Public Comments*

Interested persons are invited to submit written comments, suggestions, support or objections regarding the proposed rulemaking to the Board. Comments, suggestions, support or objections must be received by the Board by September 19, 2016. In addition to the submission of comments, interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by the Board by September 19, 2016. The one-page summary will be distributed to the Board and available publicly prior to the meeting when the final-form rulemaking will be considered.

Comments including the submission of a one-page summary of comments may be submitted to the Board online, by e-mail, by mail or express mail as follows.

Comments may be submitted to the Board by accessing eComment at http://www.ahs.dep.pa.gov/eComment.

Comments may be submitted to the Board by e-mail at RegComments@pa.gov. A subject heading of the proposed rulemaking and a return name and address must be included in each transmission.

If an acknowledgement of comments submitted online or by e-mail is not received by the sender within 2 working days, the comments should be retransmitted to the Board to ensure receipt. Comments submitted by facsimile will not be accepted.

Written comments should be mailed to the Environmental Quality Board, P.O. Box 8477, Harrisburg, PA 17105-8477. Express mail should be sent to the Environmental Quality Board, Rachel Carson State Office Building, 16th Floor, 400 Market Street, Harrisburg, PA 17101-2301.

PATRICK McDONNELL,
Acting Chairperson

Fiscal Note: 7-495. No fiscal impact; (8) recommends adoption.

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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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.

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

(b) An environmental laboratory testing **[or],** analyzing **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.

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

(b) An environmental laboratory seeking NELAP accreditation shall:

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

(2) Comply with Subchapter E (relating to proficiency test study requirements).

(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.

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

§ 252.6. Accreditation-by-rule.

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

* * * * *

(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.

* * * * *

Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

§ 252.201. Application and supporting documents.

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

* * * * *

§ 252.203. Accreditation renewal.

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

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

(c) Failure to submit an application for renewal in accordance with this section will result in a lapse in accreditation if the Department has not approved the renewal application prior to the expiration of the current certificate of accreditation. If a lapse in accreditation occurs, the environmental laboratory shall cease all testing or analysis of environmental samples for the affected fields of accreditation.

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

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§ 252.204. Fees.

(a) The appropriate fee in accordance with the following schedule must accompany an application for accreditation, renewal of accreditation, change of ownership, change in administrative information, 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 by 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*	
Aplication 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**

Category	*Fee*	
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**

* * * * *

§ 252.205. Out-of-State laboratories.

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

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

(2) *Secondary accreditation.*

(i) The Department will recognize accreditation granted by a primary NELAP**[/TNI]** accreditation body for the same fields of accreditation for which the Department is a primary NELAP**[/TNI]** accreditation body **provided the environmental laboratory meets the requirements of § 252.5 (relating to NELAP equivalency)**.

* * * * *

§ 252.206. Out-of-State onsite reimbursement.

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

(1) Transportation costs, including airfare, mileage, tolls, car rental, public transportation and parking.

(2) Meals and lodging.

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

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

§ 252.301. Laboratory supervisor.

* * * * *

(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).

* * * * *

§ 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:

(1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) At least 24-college semester credit hours in chemistry.

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

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

(1) At least an earned associate's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering, or 2 years of equivalent and successful college education.

(2) At least 16-college semester credit hours in chemistry.

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

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

(1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

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

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

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

(1) At least an associate's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

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

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

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

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

(1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

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

(3) At least 2 years of experience in the testing or analysis of environmental samples in representative radiological fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation. An earned master's or doctoral degree in

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

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

(1) For procedures requiring the use of a transmission electron microscope, a bachelor's degree, successful completion of formal course work in the use of the instrument**[,]** and 1 year of experience, under supervision, in the use of the instrument. The experience must include the identification of minerals.

(2) For procedures requiring the use of a polarized light microscope, an associate's degree or 2 years of college study, successful completion of formal coursework in polarized light microscopy**[,]** and 1 year of experience, under supervision, in the use of the instrument. The experience must include the identification of minerals.

(3) For procedures requiring the use of a phase contrast microscope, an associate's degree or 1 year of college study, documentation of successful completion of formal coursework in phase contrast microscopy**[,]** and 1 year of experience, under supervision, in the use of the instrument.

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

(1) At least 16-college semester credit hours in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) At least **[2 years] 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.

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

(1) The employee holds a valid treatment plant operator's certificate under the Water and Wastewater Systems Operators' Certification Act (63 P.S. §§ 1001—1015.1) in the appropriate water or wastewater subclassification for the facility.

(2) The employee holds a valid certificate under the Water and Wastewater Systems Operators' Certification Act for laboratory supervisor in the appropriate water or wastewater subclassification.

(3) **[Until 12 months after a certificate under the Water and Wastewater Systems Operators' Certification Act for laboratory supervisor in the appropriate water or wastewater subclassification becomes available from the Department, 2 years of experience performing testing or analysis of environmental samples using the methods and procedures currently in use by the environmental laboratory may be substituted for a laboratory supervisory certificate.] At least 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.**

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

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

(l) Foreign transcripts must be translated into English and evaluated for United States semester credit hour equivalency by a credential evaluation agency accredited by the National Association of Credentials Evaluation Services or a 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.

* * * * *

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

* * * * *

(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:

* * * * *

(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:

* * * * *

(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 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 must be less than 20%.** To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

* * * * *

(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:

* * * * *

(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 (vi)**.

* * * * *

§ 252.306. Equipment, supplies and reference materials.

* * * * *

(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.

* * * * *

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

* * * * *

(4) *Analytical or pan balances.*

* * * * *

(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**.

* * * * *

(5) *pH meter.*

* * * * *

(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]**.

* * * * *

(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.

* * * * *

(7) *Refrigeration equipment and freezers.*

* * * * *

(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.

* * * * *

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

* * * * *

(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.

* * * * *

(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:

* * * * *

(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.

* * * * *

(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 and standard solutions] Reagents, standards and media** shall be checked regularly for signs of decomposition and evaporation. **[Reagent and standard solutions] Reagents, standards and media** exhibiting signs of decomposition or evaporation shall be discarded.

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

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

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

(j) The laboratory shall perform temperature distribution studies 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 3 years by the following procedure:

(i) The laboratory shall develop a procedure to determine the temperature distribution and fluctuations within an incubator. 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.

* * * * *

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

(j) 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" and "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 customers and clients that collect samples.

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

§ 252.401. Basic requirements.

* * * * *

(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:

(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 **and identification of the individual receiving the sample at the laboratory**.

* * * * *

(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).

* * * * *

(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.

* * * * *

(15) An identification of subcontracted results.

(16) A unique test report identifier code, such as a serial number or other unique code.

(17) An identification of amendments to the test report. The laboratory shall uniquely identify all amendments to a test report. 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 the identification of the unique laboratory code that meets the requirements of paragraph (16).

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

* * * * *

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

(o) The environmental laboratory shall clearly identify opinions and interpretations as opinions and interpretations 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.

* * * * *

(c) Initial calibration requirements are as follows:

* * * * *

(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, dates of analysis, instrument identification, results of the initial calibration, calibration criteria and analyst identification**.

* * * * *

(f) Calibration verification requirements are as follows:

* * * * *

(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 the 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.

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

(8) To the extent possible, and as provided by paragraph (1), environmental samples not bracketed by acceptable calibration verification standards shall be reanalyzed. If the calibration verification standard is found to be out of control, and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the failed calibration verification standard shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers. **[Sample results associated with an unacceptable calibration verification may be useable under the following conditions:**

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

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

(g) Method blank requirements are as follows:

* * * * *

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

(6) Raw data records shall be retained to permit reconstruction of the method blank.

[(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:

* * * * *

(6) Each individual laboratory control sample **[must] 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 the 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] shall** 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:

* * * * *

(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 the 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.

* * * * *

(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 the 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.

* * * * *

§ 252.404. Essential quality control requirement—microbiology.

* * * * *

(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]**.

* * * * *

(9) *Plastic and glassware washing procedure.*

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

(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 **the** 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) shall be performed by an environmental laboratory accredited under this chapter for the appropriate field of accreditation.

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

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

(2) Stock buffers shall be autoclaved or filter-sterilized. Stock buffers shall be refrigerated and must be free from turbidity.

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

(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] 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 **the** responsible **[individual] individuals**. 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] ten** 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] shall** 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 individuals**. If sterility blanks indicate contamination, the laboratory must treat each affected sample according to program requirements.

(3) For presterilized single use filtration funnel units, a sterility check shall be performed on one funnel unit per lot.

(4) Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, presterilized containers with an appropriate nonselective growth media. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with an appropriate nonselective growth media. Results shall be maintained and include sample container identification, date **and time of the start and end of incubation**, results and initials of responsible **[individual] individuals.** 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] nonselective** 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[individuals**. 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] individuals**. 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 nonselective growth media. Results shall be maintained and include sample tray identification, date and time of the start and end of incubation, results and initials of the responsible individuals. 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] individuals**. 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] individuals**. If negative culture control checks do not meet expected results, the affected media may not be used.

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

(4) Stock positive and negative culture controls shall be discarded upon the manufacturer's expiration date unless **[it is shown through appropriate biochemical and purity tests] re-evaluated and validated by a proce-**

dure 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.

* * * * *

(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) 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 shall 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 § 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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(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 a 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] when** the Department has found deficiencies. The corrective action report **[shall document the corrective action taken by the laboratory to correct each deficiency.] must:**

(1) Document the corrective action taken by the laboratory to correct each deficiency and the time frame 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] when** 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] must** document the corrective action taken by the laboratory to correct each deficiency.

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

(h) Unless otherwise **required or** approved by the Department, **[deficiencies shall be corrected within 120 calendar days of receipt of the onsite assessment report.] 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 time frames specified in the corrective action report 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:

(1) Purchase new equipment.

(2) Revise the quality manual.

(3) Replace significant laboratory personnel.

Subchapter G. MISCELLANEOUS PROVISIONS

§ 252.701. Denial of application.

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

(1) The environmental laboratory is in continuing violation of or demonstrates an inability or lack of intention to comply with this chapter or other laws administered by the Department.

(2) The Department revoked the environmental laboratory's certificate of accreditation for all fields of accreditation for failure to correct deficiencies identified in an **[onsite]** assessment report within the previous 6 months.

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

* * * * *

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

(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.

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

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

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

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

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

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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 time frames.

(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 test study requirements).

(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.

(a) An environmental laboratory wishing to voluntarily relinquish its certificate of accreditation or accreditation for fields of accreditation shall notify the Department in writing.

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

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

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

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

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

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

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

§ 252.706. Recordkeeping.

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

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

(1) Start and end dates and times of incubations, drying cycles, digestion, distillations, and the like, 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, and the like, used during sample preparation or 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, except data] records, except 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 must be identified by initials or signature and the individual making the observation must 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 apply to electronically maintained records.

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

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

§ 252.708. Reporting and notification requirements.

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

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

(2) 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 at a concentration at or below the maximum contaminant level.

(6) Report to the Drinking Water Environmental Lab Reporting system only those analytical test results that meet the 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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