Regulatory Analysis Form

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IRRC

Independent Regulatory Review Commission

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INDEPENDENT REGULATORY REVIEW COMMISSION

SECTION I: PROFILE

(1) Agency:

Department of Environmental Protection

(2) Agency Number:

Identification Number: #7-434

IRRC Number: 2770

(3) Short Title:

Environmental Laboratory Accreditation Regulation

(4) PA Code Cite:

25 Pa Code Chapter 252

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact: Michele Tate, 717-772-4768, RCSOB, 400 Market Street, Harrisburg, PA 17105, 717-783-8926, mtate@state.pa.us

Secondary Contact: Daniel Lapato, 717-705-3769, RCSOB, 400 Market Street, Harrisburg, PA 17105, 717-783-8926, dlapato@state.pa.us

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5:
Aaren S. Alger, 717-346-8212, Bureau of Laboratories, PO Box 1467, Harrisburg, PA 17105, 717-346-8590, aaalger@state.pa.us
(All Comments will appear on IRRC'S website)

(7) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

Regulatory Analysis Form

This final-form rulemaking amends the Environmental Laboratory Accreditation Regulation, Chapter 252. The majority of the changes encompass clarifying the current regulatory language. Additionally, the fee assessment outlined in the regulation does not adequately fund the Laboratory Accreditation Program as mandated by the Environmental Laboratory Accreditation Act (Act 90 of 2002, 27 Pa C.S. §§ 4101 et seq), nor does the fee assessment equally distribute the cost of the program over the regulated community. Finally, the National Environmental Laboratory Conference (NELAC) disbanded and has been replaced with The NELAC Institute, and the regulations must be revised to reflect that change. The rulemaking offers amendments to the following areas of the laboratory accreditation regulation, Chapter 252: (a) Fee Structure, (b) Definitions, (c) NELAP Equivalency, (d) Quality Assurance/Quality Control Procedures, (e) Analytical Procedures, (f) Record Keeping Procedures, and (g) Notification Requirements.

(9) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: N/A

B. The date or dates on which public meetings or hearings will be held: N/A

C. The expected date of promulgation of the proposed regulation as a final-form regulation: March 2010

D. The expected effective date of the final-form regulation: March 2010

E. The date by which compliance with the final-form regulation will be required: March 2010

F. The date by which required permits, licenses or other approvals must be obtained: N/A

(10) Provide the schedule for continual review of the regulation.

Chapter 252, § 252.204(b) requires that the Department review and recommend any regulatory changes to the accreditation fees at least once every three years. During the fee review, the Department will also review the regulation in whole and propose any changes simultaneously.

SECTION II: STATEMENT OF NEED

(11) State the statutory authority for the regulation. Include specific statutory citation.

The Act of June 29 2002 (P.L. 596, No. 90) (dealing with Environmental Laboratory Accreditation) (Title 27 Pa. C.S. §§ 4101 – 4113)

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

Yes. 27 Pa. C.S. §§4103(a); 4104(1); and 4105(a)

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The Environmental Laboratory Accreditation Regulation sets forth the requirements that laboratories must meet in order to become accredited to perform testing for the Commonwealth's 12 environmental statutes. While completing the first round of laboratory assessments under the Chapter 252 regulation, effective January 28, 2006, the Laboratory Accreditation Program discovered various portions of the regulation that are unclear or where the rules are overly restrictive and cost prohibitive to the regulated community. These changes to the regulation will benefit the entire regulated community.

The final-form fee structure is simpler in nature and will distribute the cost in a manner that reflects the Department's workload based on the scope of accreditation for a facility. Additionally, implementation of the NELAP accreditation program incurs added costs over those associated with the accreditation program outlined in Chapter 252, but the current fee structure does not require NELAP applicant laboratories to pay additional fees. The final-form fee structure includes an additional fee for laboratories requesting NELAP accreditation.

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

N/A

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

The final-form rulemaking contains a fee structure that is responsive to the needs of small laboratories.

Categories of testing are included for basic drinking water parameters and for basic wastewater parameters as a group. Additional tests were added to the basic wastewater parameter group in response to comments received by the Laboratory Accreditation Advisory Committee. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. The fees for the laboratories accredited in these categories increase by only $50 per year and the majority of the accredited laboratories fall into these categories. The fees assessed to a small environmental laboratory will increase from an annual fee of $1200 to an annual fee of $1250.

For the environmental laboratories required to maintain accreditation in accordance with the Chapter 252 regulation, the direct costs for compliance will be payment of the required fees. These costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. The annual application fees will range from $900 to $15,000. The average fee for a medium environmental laboratory will increase from $3,700 to $4,900 and the increase for a large accredited environmental laboratory will increase from $8,100 to $10,600. A NELAP accreditation for any lab would be an additional $2,000. The Department believes that the increased accreditation fees will not result in prohibitive cost increases for any environmental laboratory. The Department is required to set fees in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program.

(16) List the persons, groups, or entities that will be required to comply with the regulation. Approximate the number of people who will be required to comply.

Those persons to be affected by the regulation include any individual, corporation, institution, or group that applies for environmental laboratory accreditation. The Department currently has 550 accredited laboratories.

SECTION III: COST AND IMPACT ANALYSIS

(17) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

It is anticipated that additional legal, accounting, or consulting procedures will not be required. However, the fees associated with the regulatory requirements are an annual application fee that depends on the desired scope of accreditation. For the environmental laboratories required to maintain accreditation in accordance with the Chapter 252 regulation, the direct costs for compliance will be payment of the required fees. These costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. The annual application fees will range from $900 to $15,000. The average fee for a medium environmental laboratory will increase $3,700 to $4,900 and the increase for a large accredited environmental laboratory will increase from $8,100 to $10,600. A

NELAP accreditation for any lab would be an additional $2,000. The Department believes that the increased accreditation fees will not result in prohibitive cost increases for any environmental laboratory. The Department is required to set fees in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program.

It should be noted however that the Department also estimates that a number of laboratories (approximately 150) will collectively save about $100,000 per year due to amendments in the rulemaking that eliminate costly requirements such as those that require laboratories to purchase and maintain an autoclave. The final-form rulemaking also includes amendments that modify some of the more time-consuming quality control requirements, which the Department believes will translate into cost savings for laboratories.

(18) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The final-form rulemaking contains a fee structure that is responsive to the needs of small laboratories. Categories of testing are included for basic drinking water parameters and for basic wastewater parameters as a group. Additional tests were added to the basic wastewater parameter group in response to comments received by the Laboratory Accreditation Advisory Committee. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. The fees for the laboratories accredited in these categories increase by only $50 per year and the majority of the accredited laboratories fall into these categories. The fees assessed to a small environmental laboratory will increase from an annual fee of $1200 to an annual fee of $1250.

(19) Provide a specific estimate of the costs and/or savings to **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Environmental Laboratory Accreditation Act requires the Department to establish fees at a level that covers the cost of administering the accreditation program. Commonwealth agencies that have accredited laboratories are not required to pay the accreditation fees.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community	0	$100,000	$100,000	$100,000	$100,000	$100,000
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0

Total Savings	0	$100,000	$100,000	$100,000	$100,000	$100,000
COSTS:						
Regulated Community	0	350,000	350,000	350,000	350,000	350,000
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	0	350,000	350,000	350,000	350,000	350,000
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

(20a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3 2006-2007	FY-2 2007-2008	FY-1 2008-2009	Current FY 2009-2010
Environmental Protection Operations (#160-10381)	$89,847,000	$98,574,000	$98,544,000	$85,069,000

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The benefit of a clear, concise, and improved regulation for the regulated community allows for better understanding and increased compliance with the requirements. The final-form rulemaking also eliminates any of the overly restrictive and cost prohibitive requirements of the initial Chapter 252 regulation.

The only adverse effects of the regulation include increased fees to the regulated community. The Department is required assess accreditation fees in an amount sufficient to recover its costs for administering an accreditation program. The fees assessed to a small environmental laboratory will increase from an annual fee of $1200 to an annual fee of $1250. The average fee for a medium environmental laboratory will increase from $3,700 to $4,900 and the increase for a large accredited environmental laboratory will increase from $8,100 to $10,600. A NELAP accreditation for any lab would be an additional $2,000.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in development of the draft regulations. The LAAC held meetings on July 9, 2008, September 29, 2008, December 11, 2008, and September 10, 2009 to review the Department's proposed and final amendments of the Chapter 252 regulations. The LAAC provided invaluable advice and insight to the Department during these meetings. The Department considered all and agreed to the majority of the recommendations made by the LAAC.

The LAAC reviewed the final-form rulemaking on September 10, 2009, and unanimously supported moving the final-form rulemaking forward to the Board for consideration.

(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

There are no effective regulatory alternatives.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

Federal regulations exist for the accreditation of the analysis of drinking water samples but no federal regulations exist for the accreditation of the analysis of non-potable water (wastewater) or solid and chemical materials. 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 promulgated methods for testing and analysis and recommended laboratory practices. Some of the requirements listed in these regulations are more stringent than the federal standards for the accreditation of environmental laboratories performing testing or analysis on samples from public drinking water suppliers because the federal standards offer recommendations that are now mandated in this regulation.

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

These amendments are in line with those of other states. This regulation will not adversely affect Pennsylvania's ability to compete with other states.

(26) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No

(27) Submit a statement of legal, accounting, or consulting procedures and additional reporting,

recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

This final-form rulemaking will require no changes to the implementation requirements for the citizens of the Commonwealth, the Department, or the regulated community.

(28) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The amendments to the Chapter 252 regulation eliminate the overly restrictive and cost prohibitive requirements of the initial Chapter 252 regulation. The final-form fee structure is simpler in nature by listing the fees based on the number of requested matrices rather than different fees based on the type of matrix requested. Additionally, implementation of the NELAP accreditation program incurs added costs over those associated with the accreditation program outlined in Chapter 252, but the current fee structure does not require NELAP applicant laboratories to pay additional fees. The final-form fee structure includes an additional fee for laboratories requesting NELAP accreditation.

The final-form rulemaking contains a fee structure that is responsive to the needs of small laboratories. Categories of testing are included for basic drinking water parameters and for basic wastewater parameters as a group. Additional tests were added to the basic wastewater parameter group in response to comments received by the Laboratory Accreditation Advisory Committee. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. The fees for the laboratories accredited in these categories increase by only $50 per year and the majority of the accredited laboratories fall into these categories.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

By:
(Deputy Attorney General)

DATE OF APPROVAL

☐ Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 7-434

DATE OF ADOPTION December 15, 2009

BY John Hanger

TITLE JOHN HANGER
CHAIRPERSON

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality Executive or Independent Agencies

BY Andrew C. Clark

DATE OF APPROVAL JAN 20 2010

(Deputy General Counsel)
(Chief Counsel - ~~Independent Agency~~)
(Strike inapplicable title)

☐ Check if applicable. No Attorney General Approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Environmental Laboratory Accreditation

25 *Pa. Code,* Chapter 252

NOTICE OF FINAL RULEMAKING
DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

[25 *Pa. Code* Ch. 252]

Environmental Laboratory Accreditation

Order

The Environmental Quality Board (Board) amends 25 *Pa. Code* Chapter 252 (relating to environmental laboratory accreditation). The final-form rulemaking clarifies existing requirements, eliminates unnecessary requirements and proposes additional requirements necessary for laboratory accreditation. The final-form rulemaking also revises the fee structure found at 25 *Pa. Code* § 252.204.

This proposal was adopted by the Board at its meeting of December 15, 2009.

A. Effective Date

These final-form rulemaking amendments will go into effect upon 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 Scott Perry, 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 AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposal is available electronically through the Department of Environmental Protection's (Department) website http://www.dep.state.pa.us.

C. Statutory Authority

This final-form rulemaking is being made under the authority of § 4103 (a) of the Act of June 29, 2002 (P.L. 596, No. 90) (dealing with Environmental Laboratory Accreditation) (Title 27 Pa. C.S. §§ 4101 – 4113), which directs the Department to establish an accreditation program for environmental laboratories, § 4104 which directs the Department to establish, administer and enforce an environmental laboratory accreditation program which shall include the standards necessary for a State certification program, § 4105, delegating the Board the power to adopt the regulations of the Department to implement the Act, and § 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

The regulations governing environmental laboratory accreditation at 25 *Pa. Code* Chapter 252 became effective on January 28, 2006. While completing the first round of laboratory assessments under these regulations, the Laboratory Accreditation Program discovered various provisions that are unclear or where the rules are overly restrictive and cost prohibitive to the regulated community. The Laboratory Accreditation Program also determined that several necessary standards for accreditation were missing.

Pursuant to section 4104(6) of the Act, the accreditation fees must be "in an amount sufficient to pay the Department's cost of implementing and administering the accreditation program." In addition, 25 *Pa. Code* § 252.204(b) requires the Department to recommend to the Board regulatory changes to the accreditation fees every three years to address any disparity between the program income generated by the fees and program costs. In accordance with this requirement, the Laboratory Accreditation 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 contained in 25 *Pa. Code* § 252.204 were not sufficient to recover the Department's costs to implement to the program. These final-form regulations provide a new fee structure to cover the costs of the Laboratory Accreditation Program.

The Department worked with the Laboratory Accreditation Advisory Committee (LAAC) to amend Chapter 252 in a manner that ensures appropriate requirements for environmental laboratory accreditation. The Department and the LAAC ensured that the interests, concerns, and needs of the regulated community were considered and implemented as appropriate. The LAAC met throughout 2008 and 2009 to review and comment on the Chapter 252 amendments presented by the Department. On September 10, 2009, the LAAC unanimously voted to recommend the final-form Chapter 252 amendments for presentation to the Board.

E. Summary of Changes Made in the Final-form Rulemaking

Subchapter A.

§ 252.1 At final rulemaking, the term and definition for "laboratory notebook" was reinstated throughout the regulation in response to a comment by the Independent Regulatory Review Commission concerning recordkeeping format. A definition for proficiency test reporting limit was also added at final rulemaking. This definition was necessary because the proposed TNI standard does not mandate that proficiency testing samples be evaluated to this level. This term was used in § 252.501 (relating to proficiency test study requirements).

§ 252.5 The requirement of NELAP or TNI laboratories to adhere to the provisions of Subchapter E (relating to proficiency test study requirements) was included at final rulemaking. Because TNI's proposed standard does not require NELAP laboratories to meet the SDWA requirements, it was necessary for the Department to include this requirement at final rulemaking.

§ 252.205 At final rulemaking, all of the terms "accrediting authority" were changed to "accreditation body" to be consistent with the terms used by TNI. The requirement for secondarily accredited laboratories to submit copies of their proficiency testing studies was deleted.

§ 252.301 Clarification was made at final rulemaking to subsection (g) to specify that a temporary absence of a laboratory supervisor requires notification to the Department within 30 calendar days.

§ 252.304 Based on comments received the Department revised section 304 to included specific recordkeeping requirements that laboratories must meet in order to demonstrate that an analyst has demonstrated capability. Additionally, the requirement of a new member of a work cell to work with an experienced member of the work cell has been deleted from the proposed rulemaking.

§ 252.306 Editorial changes were made to this section at final rulemaking, such as changing all of the terms "standardization" to "calibration." Subsection (h) was amended to specify that the laboratory may choose to use reagents, standards, or reference materials past their expiration dates as long as they are re-evaluated and validated by a procedure approved by the Department. The Department will evaluate each laboratory-developed procedure on a case-by-case basis and determine acceptability.

§ 252.401 Subsections (j), (k) and (m) were amended at final rulemaking by making minor editorial revisions that provide greater clarity to the regulatory requirements.

§ 252.404 Minor editorial changes and amendments were made throughout this section at final rulemaking. These changes include reinstating the term "laboratory notebook" and clarification to subsection (g) by instructing the laboratory that a sterility blank must be filtered through each membrane filtration unit after every 10 samples.

§ 252.501 Subsections (n) and (o) were added at final rulemaking to specify that laboratories seeking to obtain or maintain accreditation in the drinking water matrix must also meet the proficiency testing requirements of the Safe Drinking Water Act and 40 CFR, Part 141. Laboratories must also continue to report proficiency testing results to the proficiency test reporting limit (PTRL) established by the Department. These PTRLs will be published in the *PA Bulletin*.

§ 252.703 Clarification to paragraph (c)(3) was made at final rulemaking to point the reader to the personnel requirements for a laboratory supervisor.

§ 252.704 Subsection (a) was amended at final rulemaking to specify that in addition to a laboratory wishing to voluntarily relinquish its accreditation in full, a laboratory wishing to voluntarily relinquish accreditation for a particular field of accreditation must notify the Department in writing. An editorial change was made to subsection (b) at final rulemaking to change the term "insure" to "ensure".

§ 252.705 The requirement to post the fields of accreditation listing in the laboratory was removed at final rulemaking.

§ 252.706 Subsection (b) was amended at final rulemaking to include proficiency test studies, initial demonstration of capability, and demonstration of continued proficiency to those records that must be maintained in a manner that allows reconstruction of all laboratory activities. These additions will aid the regulated community in understanding the Department's intent. These additions do not impose additional requirements, but more clearly instruct the reader.

§ 252.708 Editorial changes were made throughout this section at final rulemaking. These include changing the terms "inorganic and wet chemistry" to "trace metals and inorganic non-metals" in subparagraph (a)(2), adding the term "radiochemistry" to subparagraph (a)(3), clarifying that the laboratory supervisor notification in paragraph (b) relates to a permanent change, and changing the term "accreditation authority" to "accreditation body" in paragraph (f).

F. Summary of Comments and Responses on the Proposed Rulemaking

The Board approved publication of the proposed rulemaking at its April 21, 2009 meeting. The proposed rulemaking was published at 39 *Pa.B.* 3051 on June 21, 2009, with a 30-day public comment period. Comments were received from two commentators, including the Independent Regulatory Review Commission as a result of the public comment period. Several comments were received regarding the laboratory supervisor qualifications and recordkeeping requirements. Most of the comments received were requests for clarification.

A description of the comments received and the Department's response follows:

Laboratory Supervisor: One commentator stated that the current regulations should allow additional time to replace a laboratory supervisor. The revised regulations should extend the time to at least 90 days instead of the current 30 days to find a supervisor. Small wastewater treatment laboratories that do not have several chemists with bachelor's degrees on staff do not have the depth to name a person on staff as a supervisor with the resignation of a supervisor. As the current "grandfathered" supervisors retire and/or seek other positions, it will be harder for the municipal sector to quickly hire qualified applicants.

The Department disagrees with the commentator's argument. The regulation requires designation of an alternate laboratory supervisor for temporary absences greater than 16 days but does not require that the Department be notified unless the temporary absence is greater than 30 days. An absence of a laboratory supervisor for greater than 16 days could adversely affect the quality of the data produced by the laboratory, especially in the case of a laboratory that operates 7 days a week. The Department believes that allowing a laboratory to continue to operate unsupervised for longer than 16 days would create a situation that could result in unacceptable data generation. In the case of permanent changes to a laboratory supervisor, the Department expects the laboratory to provide notification within 20 days of the change. The notification of a permanent change within 20 days allows the Department be made aware earlier in the replacement process and available to offer guidance to the laboratory with regard to the laboratory supervisor qualification requirements.

One commentator requested that consideration should be made to allow supervisors to take a test in the laboratory methods to be certified as a supervisor. The operator certification program does not have anything to do with the current job responsibilities of a laboratory supervisor. There needs to be a way to certify supervisors with a specific laboratory test to allow those with extensive experience to be qualified.

The Department agrees with the commentator. The Department is currently developing the laboratory supervisor sub-classification under the Water and Wastewater Systems Operators' Certification Act. The provision § 252.302 (h)(2) and (3) is included because the regulations authorizing the sub-classification are also in the regulatory development process and are expected to be completed in the near future.

One commentator stated that the current regulations require extensive education for the laboratory supervisor or the operator's exam. Stating that additional education has been added to § 252.302 to require that supervisors have four semester hours of general microbiology, and that now supervisors must have educational credits in microbiology as well as chemistry. Thus placing an additional burden on wastewater treatment plants that now have one person in charge of the laboratory.

The Department disagrees with the commentator. Section 252.302(d) does not include additional requirements. The Department made the educational requirements more lenient by changing the requirement for semester credit hours in "general microbiology" to "biology."

Record Retention and Documentation: One commentator stated that several sections of this regulation require record retention or recording of information, but are unclear in regard to a specific method of retention or recording and that the duration of the required retention is not set forth.

The Department agrees with the commentator. Section 252.706(d) requires that all records that are required by the Chapter 252 regulation be maintained for a minimum of five years. The Department reinstated the definition for a laboratory notebook and included the phrase "in a laboratory notebook" where the proposed rulemaking deleted these phrases.

One commentator stated that § 252.304(b)(3)(vi)(F) requires labs to retain "all data necessary" to reproduce the initial demonstration of capability and suggested that the regulation include the specific record-keeping requirements necessary to meet this requirement.

The Department agrees with the commentator. The Department added the specific documentation to be maintained by the laboratory in order to document initial demonstration of capability and demonstrations of continued proficiency. Subsection 252.706(b) requires each "environmental laboratory to maintain records that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples." The Department added "proficiency test study samples, initial demonstrations of capability and demonstrations of continued proficiency" to this subsection.

General Comments: One commentator stated that the quality control requirements in the regulations are extensive. The PADEP should consider additional training to allow the small water and wastewater treatment plants to continue to operate their laboratories. The requirements may be forcing plants to abandon their laboratories and contract work out at a high cost to the utility customers. There needs to be a balance on quality control. There should be consideration for more outreach to help the small laboratories.

The Department agrees with the commentator. The Department continues to develop and provide training courses to assist applicant laboratories in remaining compliant with the laboratory accreditation requirements. These courses are approved for continuing education credits for the Operators' Certification Program. Further opportunities for assistance are available thorough the Laboratory Accreditation Program's website, direct contact with the laboratory's accreditation officer, and the on-site assessment process.

One of the commentators stated that § 252.304(b)3)(vi)(E) allows laboratory methods used prior to January 1, 2005 to be exempt from the initial demonstration of capability and asked why this date was chosen.

The Department disagrees. This language is the same language from the January 28, 2006 version of Chapter 252; it has been re-located to this section to keep all demonstration of capability requirements located in the same section of the regulation. The January 1, 2005 date was chosen because it was one year before the environmental laboratory accreditation rulemaking was originally promulgated.

One of the commentators stated that under the provisions of § 252.304(b)(3)(vi)(G)(I) a new employee in a work cell must work with an experienced analyst, but does not include a specified timeframe for how long this must occur.

The Department agrees with this commentator and deleted clause § 252.304(b)(3)(G)(I).

One of the commentators stated that § 252.304(b)(3)(vi)(G)(II) mentions "acceptable" quality control performance checks but does not instruct the regulated laboratory as to an acceptable procedure.

The Department disagrees with the commentator. The term "acceptable" refers to the requirements of the specific method, regulation, laboratory SOP, or client-specific requirement. The next sentence in this clause specifies that the quality control must meet acceptance criteria. "Acceptable quality control" is a term that is well understood by environmental laboratory personnel and must be defined in each laboratory SOP.

One of the commentators requested clarification for § 252.306(f)(9)(i), asking what is an "appropriate" method for checking delivery volumes of mechanical volumetric dispensing devices?

The Department agrees with the commentator and deleted the phrase, "using an appropriate method."

One commentator requested clarification regarding § 252.306(h)(6) and the term "Department approved procedure" used to reevaluate and validate certain materials used past their expiration date.

The wording was changed to clarify that it is not a procedure developed by the Department, but a laboratory-developed procedure that is approved by the Department. A laboratory would apply for permission by submitting a request in writing to the Department. The Department is not requiring a specific format at this time to allow laboratories the flexibility to use laboratory-developed procedures. The method for validation of an expired chemical would be dependent upon the chemical. The Department will notify the laboratory by mail of its decision.

G. Benefits, Costs, and Compliance

Benefits

The most significant benefit of these final-form regulations will be the benefit of a clear, concise, and improved regulation for the regulated community. The final-form 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.

Improved data quality will allow the Department, the regulated community, and the citizens of the Commonwealth to make better 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.

Compliance Costs

The direct costs of the final-form regulation will be payment of the required fees. The Department is required to set fees 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 final-form regulations contain a fee structure that is responsive to the needs of small laboratories. Categories of testing for basic drinking water parameters and for basic wastewater parameters have been increased by only $50 per category. These smallest environmental laboratories currently pay $1200 annually and the final-form fee structure will require an annual fee of $1250. In addition, changes to the fee structure include payment of fees based on the number of matrices requested rather than a fee for a specific type of matrix. This structure allows for a laboratory performing a combination of matrices to pay a lower fee.

Compliance Assistance Plan

The final-form regulations are minor and in most cases clarify existing requirements or eliminate unnecessary requirements. As such, the Department does not believe that a

compliance assistance plan tailored to the final-form regulations 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 the Commonwealth.

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)), the Department submitted a copy of the notice of proposed rulemaking, published at 39 *Pa.B.* 3051 on June 20, 2009 to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing these final-form regulations, the Department has considered all comments from IRRC, the Committees, and the public.

Under section 5.1(j.2) of the Act, on (blank), these final-form regulations were deemed approved by the House and Senate Committees. Under section 5.1(e) of the Act, IRRC met on (blank) and approved the final-form regulations.

J. Findings of the Board

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and regulations promulgated there under at *1 Pennsylvania Code* §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law, and all comments were considered.

(3) These regulations do not enlarge the purpose of the proposal published at 39 *Pa.B.* 838 on June 20, 2009.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

K. Order of the Board

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department of Environmental Protection, 25 *Pennsylvania Code,* Chapter 252, are amended to read as set forth in Annex A.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson of the Board shall submit this order and Annex A to the Independent Regulatory Review Commission and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act.

(d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(e) This order shall take effect immediately.

BY:

_____

JOHN HANGER
Chairperson
Environmental Quality Board

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:

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

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

* * * * *

Nonpotable water--

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

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

* * * * *

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

* * * * *

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

* * * * *

§ 252.4. General requirements.

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

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

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

§ 252.5. NELAP/TNI equivalency.

* * * * *

(b) An environmental laboratory seeking NELAP accreditation shall:

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

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

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

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

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

* * * * *

§ 252.6. Accreditation-by-rule.

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

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

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

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

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

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

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

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Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

§ 252.202. Application for transfer of laboratory accreditation.

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

* * * * *

§ 252.204. Fees.

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

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

Trace metal and inorganic nonmetal category--drinking water	**$800**
Volatile organic chemicals--drinking water	**$500**
Extractable and semivolatile organic chemicals--drinking water	**$750**
Dioxin--drinking water	**$600**
Radiochemical category--drinking water	**$700**
Basic nonpotable water category (one method for each of the following: fecal coliform bacteria, BOD, CBOD, nitrate, ammonia, total nitrogen, total kjeldahl nitrogen, nitrite, phosphorus and one method for each type of residue)	**$700**
Asbestos--nonpotable water	**$350**
Microbiology--nonpotable water	**$400**
Trace metal category--nonpotable water	**$450**
Inorganic nonmetal category--nonpotable water	**$550**
Trace metal and inorganic nonmetal category--nonpotable water	**$900**
Volatile organic chemicals--nonpotable water	**$500**
Extractable and semivolatile organic chemicals--nonpotable water	**$950**
Dioxin--nonpotable water	**$600**
Radiochemical category--nonpotable water	**$600**
Whole effluent toxicity testing category	**$600**
Microbiology--drinking water and nonpotable water	**$750**
Trace metal category--drinking water and nonpotable water	**$800**
Inorganic nonmetal category--drinking water and nonpotable water	**$1,000**
Trace metal and inorganic nonmetal category--drinking water and nonpotable water	**$1,550**
Volatile organic chemicals--drinking water and nonpotable water	**$900**
Extractable and semivolatile organic chemicals--drinking water and nonpotable water	**$1,650**
Dioxin--drinking water and nonpotable water	**$1,050**
Radiochemical category--drinking water and nonpotable water	**$1,050**
Asbestos--solid and chemical materials	**$350**
Microbiology--solid and chemical materials	**$450**
Trace metal category--solid and chemical materials	**$450**
Inorganic nonmetal category--solid and chemical materials	**$550**
Volatile organic chemicals--solid and chemical materials	**$550**
Extractable and semivolatile organic chemicals--solid and chemical materials	**$1,200**
Dioxin--solid and chemical materials	**$600**
Radiochemical category--solid and chemical materials	**$600]**
Application fee--Initial Application for State Accreditation	**$750**
Application fee--Renewal Application for State Accreditation	**$500**

Application fee--Ownership Transfer or Change in Administrative Information	$150
Application fee--Initial Application for NELAP/TNI Accreditation	$2,500
Application fee--Renewal Application for NELAP/TNI Accreditation	$2,000
Application fee--Addition of Field of Accreditation	$250
Application fee--Supplemental Onsite Assessment	$500
Basic Drinking Water Category--Includes one method for each of the following: Total Coliform Bacteria, Fecal Coliform Bacteria, *E. coli* Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	$650
Basic Nonpotable Water Category--Includes one method for each of the following: Fecal Coliform Bacteria, BOD, CBOD, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, and one method for each type of residue including % Solids for land applied biosolids	$750
Asbestos--first matrix	$400
Microbiology--first matrix	$500
Trace Metal Category--first matrix	$550
Inorganic Nonmetal Category--first matrix	$600
Volatile Organic Chemicals--first matrix	$650
Extractable and Semivolatile Organic Chemicals--first matrix	$1,500
Dioxin--first matrix	$650
Radiochemical Category--first matrix	$750
Whole Effluent Toxicity Testing--first matrix	$700
Asbestos--second matrix	$350
Microbiology--second matrix	$450
Trace Metal Category--second matrix	$500
Inorganic Nonmetal Category--second matrix	$550
Volatile Organic Chemicals--second matrix	$600
Extractable and Semivolatile Organic Chemicals--second matrix	$1,400
Dioxin--second matrix	$600
Radiochemical Category--second matrix	$700
Asbestos--third matrix	$300
Microbiology--third matrix	$400
Trace Metal Category--third matrix	$450
Inorganic Nonmetal Category--third matrix	$500
Volatile Organic Chemicals--third matrix	$550
Extractable and Semivolatile Organic Chemicals--third matrix	$1,300
Dioxin--third matrix	$550

Radiochemical Category--third matrix	**$650**

* * * * *

§ 252.205. Out-of-State laboratories.

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

* * * * *

(2) *Secondary accreditation.*

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

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

* * * * *

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

* * * * *

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

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

* * * * *

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

* * * * *

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

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Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

§ 252.301. Laboratory supervisor.

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

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

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

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

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

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

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

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

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

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

(2) The adequacy of supervision in each laboratory.

§ 252.302. Qualifications of the laboratory supervisor.

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

* * * * *

(2) At least 16-college semester credit hours in general microbiology **OR** biology.

* * * * *

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

* * * * *

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

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

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§ 252.304. Personnel requirements.

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

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

(i) AN IDENTIFICATION OF THE ANALYSTS INVOLVED IN THE REPARATION OR ANALYSIS, OR BOTH.

(ii) THE SAMPLE MATRIX.

(iii) THE ANALYTE, CLASS OF ANALYTE, OR MEASURED PARAMETER.

(iv) AN IDENTIFICATION OF THE TEST METHOD PERFORMED.

(v) AN IDENTIFICATION OF THE LABORATORY-SPECIFIC STANDARD OPERATING PROCEDURE USED FOR ANALYSIS, INCLUDING REVISION NUMBER AND EFFECTIVE DATE.

(vi) THE DATES OF PREPARATION OR ANALYSIS, OR BOTH.

(vii) THE SUMMARY OF ANALYSES, INCLUDING RESULTS.

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

* * * * *

(vi) An initial demonstration of capability for each method that relates to the employee's job responsibilities**[.]** **has been performed. The initial demonstration of capability requirements are as follows:**

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

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

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

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

(I) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not

specify a concentration, the concentration must be approximately ten times the detection limit.

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

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

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

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

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

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

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

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

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

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§ 252.306. Equipment, supplies and reference materials.

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

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(2) *Working thermometers.*

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

(A) Glass **[and electronic thermometers and continuous recording devices], liquid filled thermometers** shall be calibrated every 12 months at the temperature used.

(B) Dial **and electronic** thermometers shall be calibrated every 3 months at the temperature used. **[Dial thermometers that cannot be calibrated may not be used.] Electronic thermometers accompanied by a valid NIST traceable certificate of acceptance may be used for 12 months from the date of receipt before re-calibration.**

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

* * * * *

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

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

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

* * * * *

(4) *Analytical or pan balances.*

* * * * *

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

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

* * * * *

(5) *pH meter.*

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

* * * * *

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

(6) *Conductivity meter.*

* * * * *

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

* * * * *

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

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

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

* * * * *

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

(9) *Volumetric dispensing devices.*

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

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

(10) *Graduated sample containers.*

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

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

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

* * * * *

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

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

(2) Reagent and standard solutions shall be checked regularly for signs of decomposition, evaporation, and expiration. An environmental laboratory shall maintain standard and reagent preparation logs for all stack and working standards

solutions in a laboratory notebook. Standards and reagent preparation logs must contain identification of the compound, concentration, date prepared, initials of the individual preparing the solution and expiration date.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* * * * *

§ 252.307. Methodology.

* * * * *

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

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

* * * * *

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

* * * * *

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

§ 252.401. Basic requirements.

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

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

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

(3) A revision number and effective date.

(4) A table of contents, and applicable lists of references, glossaries and appendices.

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

(1) An ethics policy statement as specified in subsection (d).

(2) A document control system as specified in subsection (c).

(3) Recordkeeping as specified in § 252.706 (relating to recordkeeping).

(4) The procedures for termination of operations and transfer of records as specified in § 252.706.

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

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

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

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

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

* * * * *

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

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

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

* * * * *

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

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

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

(i) The client/project name.

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

(iii) The date and time of laboratory receipt.

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

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

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

* * * * *

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

(1) The name and address of the laboratory.

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

(3) The name and address of the client.

(4) An identification of the test method used.

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

(6) The date and time of sample collection.

(7) The date of sample analysis.

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

(9) The test results and units of measurement.

(10) The quantitation limit.

(11) The names, functions and signatures of the persons authorizing the test report.

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

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

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

(15) An identification of subcontracted results.

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

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

* * * * *

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

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

§ 252.402. Essential quality control requirements--chemistry.

* * * * *

(c) Initial calibration requirements are as follows:

* * * * *

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

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

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

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

* * * * *

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

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

* * * * *

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

* * * * *

(f) Calibration verification requirements are as follows:

* * * * *

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

* * * * *

(h) Laboratory control sample requirements are as follows:

* * * * *

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

* * * * *

(i) Sample duplicate requirements are as follows:

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

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

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

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

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

* * * * *

(m) When manual integrations are performed for chromatography methods, the laboratory shall have written procedures for manual integrations and instrument manipulations.

(1) The manual integration procedures must detail the steps taken to perform the integrations and define proper and improper integrations.

(2) The laboratory shall document manual integrations with the reason for the integration and the initials of the individual performing the integration.

(3) The laboratory shall retain a copy of the data before and after manual integration.

(n) The laboratory shall employ confirmation techniques to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory or for a sample location that has not previously yielded detectable results for a particular compound.

(1) The confirmations shall be performed when analysis involves the use of an organic chromatography method not utilizing a mass spectrometer.

(2) The confirmations shall be documented.

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

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

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

§ 252.404. Essential quality control requirement--microbiology.

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(c) The following pieces of equipment shall be maintained according to this subsection:

(1) *Autoclave.*

(i) An environmental laboratory shall use autoclaves that meet specified temperature tolerances of the method. **[Pressure cookers may not be used.]** **Because of safety concerns and difficulties with operational control, pressure cookers should not be used. Pressure cookers may not be used for sterilization of media.**

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

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

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

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

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

[(vii)] **(vi)** Required times for autoclaving items at 121°C are set forth in this subparagraph. The following items must be at temperature for the required amount of time. Except for membrane filters and pads and carbohydrate-containing media, indicated times are minimum times and may necessitate adjustment depending upon volumes, containers and loads. For autoclave runs that include membrane filters and pads and

media, the total cycle time may not exceed 45 minutes. Autoclaved membrane filters and pads and media shall be removed immediately after completion of the autoclave cycle.

* * * * *

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

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

(2) *Hot air oven.*

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

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

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

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

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

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

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

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

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

(4)] *Inoculating equipment.*

* * * * *

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

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

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

* * * * *

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

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

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

* * * * *

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

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

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

* * * * *

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

* * * * *

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

* * * * *

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

[(12)] **(11)** *Quanti-Tray™ Sealer.*

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

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

* * * * *

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

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

* * * * *

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

* * * * *

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

(f) The requirements for media are as follows:

* * * * *

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

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

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

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

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

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

* * * * *

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

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

* * * * *

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

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

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

* * * * *

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

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

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

(ii) Reference stocks shall be preserved using a method which maintains the characteristics of the organism strains. If reference stocks are thawed, they may not be refrozen and reused.

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

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

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

(vi) Working stocks may not be sequentially cultured more than five times and may not be subcultured to replace reference stocks.

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

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

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

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

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

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

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

§ 252.405. Essential quality control requirement--radiochemistry.

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

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

§ 252.501. Proficiency test study requirements.

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

* * * * *

(n) AN ENVIRONMENTAL LABORATORY SEEKING TO OBTAIN OR MAINTAIN ACCREDITATION IN THE DRINKING WATER MATRIX SHALL PARTICIPATE IN PROFICIENCY TEST STUDIES THAT MEET THE REQUIREMENTS OF 40 CFR, PART 141.

(o) AN ENVIRONMENTAL LABORATORY SHALL EVALUATE AND REPORT THE ANALYTICAL RESULT OF EACH PROFICIENCY TEST STUDY SAMPLE TO THE PROFICIENCY TEST REPORTING LIMIT FOR EACH FIELD OF ACCREDITATION, WHEN AVAILABLE, AS OUTLINED IN SUBSECTION (a).

Subchapter F. ONSITE ASSESSMENT REQUIREMENTS

§ 252.601. Onsite assessment requirements.

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

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

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

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

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

* * * * *

Subchapter G. MISCELLANEOUS PROVISIONS

§ 252.703. Suspension

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(c) The Department may suspend a laboratory's accreditation in total or in part for one or more of the following reasons:

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(3) Failure to employ staff that meets the personnel qualifications for education, training and experience **AS SPECIFIED IN § 252.302 (RELATING TO QUALIFICATIONS OF THE LABORATORY SUPERIVSOR).**

§ 252.704. Voluntary Relinquishment.

(a) An environmental laboratory wishing to voluntarily relinquish its certificate of accreditation **OR ACCREDITATION FOR FIELDS OF ACCREDITATION** shall notify the Department in writing.

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

* * * * *

§ 252.705. Use of accreditation.

(a) Environmental laboratories accredited by the Department shall:

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

* * * * *

§ 252.706. Recordkeeping.

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

(b) An environmental laboratory shall maintain records, including original handwritten data, that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples, **PROFICIENCY TEST STUDIES, INITIAL DEMONSTRATION OF CAPABILITY, OR DEMONSTRATION OF CONTINUED PROFICIENCY.**

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§ 252.707. Subcontracting.

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

§ 252.708. Reporting and notification requirements.

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

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

(2) Review all sample analysis data within 24 hours of acquisition of the initial sample results for microbiological, [~~inorganic and wet chemistry analysis~~] INORGANIC NONMETALS AND TRACE METALS ANALYSES. The 24-hour deadline may be extended to a maximum of 72 hours to accommodate a holiday or weekend when the laboratory is closed for business.

(3) [For organic analyses, review] REVIEW all sample analysis data within 7 days of acquisition of the initial sample results for organic AND RADIOCHEMICAL [~~anaylsis~~] ANALYSES.

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

* * * * *

(e) **An environmental laboratory shall notify the Department, in writing, if a change in the laboratory's capability to produce valid analytical results persists for**

more than 90 calendar days for any field of accreditation listed on the laboratory's scope of accreditation.

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

[(f)] (g) The Department may require additional information or proof of continued capability to perform the testing or analysis for affected fields of accreditation upon receipt of notification under this subsection.

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

ENVIRONMENTAL LABORATORY ACCREDITATION REGULATION
COMMENT AND RESPONSE DOCUMENT

List of Commentators

1. Christine Volkay-Hilditch, P.E., DEE
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COMMENTS AND RESPONSES

Laboratory Supervisor

1. Comment: The current regulations should allow additional time to replace a laboratory supervisor. The revised regulations should extend the time to at least 90 days instead of the current 30 days to find a supervisor. Small wastewater treatment laboratories that do not have several degreed chemists on staff do not have the depth to name a person on staff as a supervisor with the resignation of a supervisor. As the current "grandfathered" supervisors retire and/or seek other positions, it will be harder for the municipal sector to quickly hire qualified applicants. (1)

Response: The regulation requires designation of an alternate laboratory supervisor for temporary absences greater than 16 days but does not require that the Department be notified unless the temporary absence is greater than 30 days. An absence of a laboratory supervisor for greater than 16 days could adversely affect the quality of the data produced by the laboratory, especially in the case of a laboratory that operates 7 days a week. The Department believes that allowing a laboratory to continue to operate unsupervised for longer than 16 days would create a situation that could result in unacceptable data generation.

In the case of permanent changes to a laboratory supervisor, the Department expects the laboratory to provide notification within 20 days of the change. The notification of a permanent change within 20 days allows the Department be made aware earlier in the replacement process and available to offer guidance to the laboratory with regard to the laboratory supervisor qualification requirements.

2. Comment: Consideration should be made to allow supervisors to take a test in the laboratory methods to be certified as a supervisor. The operator certification program does not have anything to do with the current job responsibilities of a laboratory supervisor. There needs to be a way to certify supervisors with a specific laboratory test to allow those with extensive experience to be qualified. (1)

Response: The Department is currently developing the laboratory supervisor sub-classification under the Water and Wastewater Systems Operators' Certification Act. The provision § 252.302 (h)(2) and (3) is included because the regulations authorizing the sub-classification are also in the regulatory development process and are expected to be completed in the near future.

3. Comment: The current regulations require extensive education for the laboratory supervisor or the operator's exam. Additional education has been added to § 252.302 to require that supervisors have four semester hours of general microbiology. Now in addition to chemistry credits, supervisors must have educational credits in microbiology. This puts an additional burden on wastewater treatment plants that now have one person in charge of the laboratory. (1)

Response: Section 252.302(d) does not include additional requirements. The Department made the educational requirements more lenient by changing the requirement for semester credit hours in "general microbiology" to "biology."

Record Retention and Documentation

4. Comment: Several sections of this regulation require record retention or recording of information. However, it is unclear what method of retention or recording the Board requires and the duration of the required retention is not set forth. The final-form regulation should clarify these requirements. (2)

Response: Section 252.706(d) requires that all records that are required by the Chapter 252 regulation be maintained for a minimum of five years. The Department will reinstate the definition for a laboratory notebook and included the phrase "in a laboratory notebook" where the proposed rulemaking deleted these phrases.

5. Comment: § 252.304(b)(3)(vi)(F) This subsection requires labs to retain "all data necessary" to reproduce the initial demonstration of capability. What types of data would meet this requirement? The final-form regulation should clarify the Board's intent. (1)

Response: The Department will include the specific documentation to be maintained by the laboratory in order to document initial demonstration of capability and demonstrations of continued proficiency. Subsection 252.706(b) requires each "environmental laboratory to maintain records that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples." The Department added "proficiency test study samples, initial demonstrations of capability and demonstrations of continued proficiency" to this subsection.

General Comments

6. Comment: The quality control requirements in the regulations are extensive. The PADEP should consider additional training to allow the small water and wastewater treatment plants to continue to operate their laboratories. The requirements may be forcing plants to abandon their laboratories and contract work out at a high cost to the utility customers. There needs to be a balance on quality control. There should be consideration for more outreach to help the small laboratories. (1)

Response: Thank you for your suggestion. The Department continues to develop and provide training courses to assist applicant laboratories in remaining compliant with the laboratory accreditation requirements. These courses are approved for continuing education credits for the Operators' Certification Program. Further opportunities for assistance are available thorough the Laboratory Accreditation Program's website, direct contact with the laboratory's accreditation officer, and the on-site assessment process.

7. Comment: § 252.304(b)(3)(vi)(E) This subsection allows laboratory methods used prior to January 1, 2005 to be exempt from the initial demonstration of capability. How did the Board determine this was an appropriate date? (2)

Response: This language is the same language from the January 28, 2006 version of Chapter 252; it has been re-located to this section to keep all demonstration of capability requirements located in the same section of the regulation. The January 1, 2005 date was chosen because it was one year before the environmental laboratory accreditation rulemaking was originally promulgated.

8. Comment: § 252.304(b)(3)(vi)(G)(I) Under this subsection, a new employee in a work cell must work with an experienced analyst. However, it is not clear how long this must occur. The

final-form regulation should clearly state how long an experienced analyst must work with the new work cell employee. (2)

Response: Clause 252.304(b)(3)(vi)(G)(I) will be deleted.

9. Comment: § 252.304(b)(3)(vi)(G)(II) This subsection mentions "acceptable" quality control performance checks. This term is vague. The final-form regulation should specify what the Board considers "acceptable." (2)

Response: The term "acceptable" refers to the requirements of the specific method, regulation, laboratory SOP, or client-specific requirement. The next sentence in this clause specifies that the quality control must meet acceptance criteria. "Acceptable quality control" is a term that is well understood by environmental laboratory personnel and must be defined in each laboratory SOP.

10. Comment: § 252.306(f)(9)(i) In this subsection, what does the Board consider an "appropriate" method for checking delivery volumes of mechanical volumetric dispensing devices? This term is vague. The Board should delete this term or set forth the "acceptable" methods. (2)

Response: The phrase, "using an appropriate method," will be deleted.

11. Comment: § 252.306(h)(6) This subsection refers to a "Department approved procedure" to reevaluate and validate certain materials used past their expiration date. The final-form regulation should set forth this procedure or provide citation to an existing procedure that will be used. (2)

Response: A laboratory would apply for permission by submitting a request in writing to the Department. The Department is not requiring a specific format at this time to allow laboratories the flexibility to use laboratory-developed procedures. The method for validation of an expired chemical would be dependent upon the chemical. The wording will be changed to clarify that it is not a procedure developed by the Department, but a laboratory-developed procedure that is approved by the Department. The Department will notify the laboratory by mail of its decision.

FEE REPORT FORM

Agency: Bureau of Laboratories
Department of Environmental Protection

Contact: Aaren S. Alger, Chief
Laboratory Accreditation Program
Bureau of Laboratories

Phone: 717-346-8212

Fee Collections:	Prior Year 2007-2008 (FY)	Current Year 7/08-12/08 (Actual)	Current Year 1/09-6/09 (Anticipated)	Fiscal Year 2009/10 Projected	Fiscal Year 2010/11 Projected	Fiscal Year 2011/12 Projected
Current – Total	$880,000	$760,000	$500,000			
Proposed—Total				$1,300,000	$1,600,000	$1,600,000

FEE TITLE AND RATE:

Title: Environmental Laboratory Accreditation Fee Schedule

Current Fee Schedule:
The current fees established in 2006 are in accordance with the following schedule and must accompany an application for accreditation, renewal of accreditation, change of ownership, or addition of fields of accreditation. The fees are as follows:

CATEGORY	FEE
Application Fee--Initial Application	$600
Application Fee—Renewal Application	$500
Application Fee--Ownership Transfer	$150
Application Fee--Addition Of Fields Of Accreditation	$250
Basic Drinking Water Category (1 Method For Each Of The Following: Total Coliform Bacteria, Fecal Coliform Bacteria, *E-Coli* Bacteria, Heterotropic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide)	$600
Asbestos--Drinking Water	$350
Microbiology--Drinking Water	$450
Trace Metal Category--Drinking Water	$450
Inorganic Nonmetal Category--Drinking Water	$500
Trace Metal And Inorganic Nonmetal Category--Drinking Water	$800
Volatile Organic Chemicals--Drinking Water	$500
Extractable And Semivolatile Organic Chemicals--Drinking Water	$750
Dioxin--Drinking Water	$600
Radiochemical Category--Drinking Water	$700
Basic Nonpotable Water Category (1 Method For Each Of The Following: Fecal	$700

CATEGORY	FEE
Coliform Bacteria, Bod, Cbod, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, And 1 Method For Each Type Of Residue)	
Asbestos--Nonpotable Water	$350
Microbiology--Nonpotable Water	$400
Trace Metal Category--Nonpotable Water	$450
Inorganic Nonmetal Category--Nonpotable Water	$550
Trace Metal And Inorganic Nonmetal Category--Nonpotable Water	$900
Volatile Organic Chemicals--Nonpotable Water	$500
Extractable And Semivolatile Organic Chemicals--Nonpotable Water	$950
Dioxin--Nonpotable Water	$600
Radiochemical Category--Nonpotable Water	$600
Whole Effluent Toxicity Testing Category	$600
Microbiology--Drinking Water & Nonpotable Water	$750
Trace Metal Category--Drinking Water & Nonpotable Water	$800
Inorganic Nonmetal Category--Drinking Water & Nonpotable Water	$1,000
Trace Metal And Inorganic Nonmetal Category--Drinking Water & Nonpotable Water	$1,550
Volatile Organic Chemicals--Drinking Water & Nonpotable Water	$900
Extractable And Semivolatile Organic Chemicals--Drinking Water & Nonpotable Water	$1,650
Dioxin--Drinking Water & Nonpotable Water	$1,050
Radiochemical Category--Drinking Water & Nonpotable Water	$1,050
Asbestos--Solid And Chemical Materials	$350
Microbiology--Solid And Chemical Materials	$450
Trace Metal Category--Solid And Chemical Materials	$450
Inorganic Nonmetal Category--Solid And Chemical Materials	$550
Volatile Organic Chemicals--Solid And Chemical Materials	$550
Extractable And Semivolatile Organic Chemicals--Solid And Chemical Materials	$1,200
Dioxin--Solid And Chemical Materials	$600
Radiochemical Category--Solid And Chemical Materials	$600

At least every three years, the department will recommend regulatory changes to the fees in this section to the environmental quality board to address any disparity between program income generated by the fees and program costs. The regulatory amendment will be based upon an evaluation of the accreditation program fees income and the department's costs of administering the accreditation program. An environmental laboratory owned or operated by a Commonwealth agency is exempt from this fee requirement, but shall apply for accreditation under this chapter. The fees are nonrefundable. 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.

Final Rulemaking Fee Schedule:
The final rulemaking fees would be in accordance with the following schedule and must accompany an application for accreditation, renewal of accreditation, change of ownership and change in administrative information addition of fields of accreditation. The fees are as follows:

CATEGORY	FEE
Application Fee – Initial Application for State Accreditation	$750
Application Fee – Renewal Application for State Accreditation	$500
Application Fee – Ownership Transfer or Change in Administrative Information	$150
Application Fee – Initial Application for NELAP/TNI Accreditation	$2,500
Application Fee – Renewal Application for NELAP/TNI Accreditation	$2,000
Application Fee – Addition of Field of Accreditation	$250
Application Fee – Supplemental On-Site Assessment	$500
Basic Drinking Water Category – includes 1 method for each of the following: Total Coliform Bacteria, Fecal Coliform Bacteria, *E. coli* Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	$650
Basic Non-potable Water Category – includes 1 method for each of the following: Fecal Coliform Bacteria, BOD, CBOD, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, and 1 method for each type of residue including % Solids for land-applied biosolids	$750
Asbestos—first matrix	$400
Microbiology—first matrix	$500
Trace Metal Category—first matrix	$550
Inorganic Non-metal Category—first matrix	$600
Volatile Organic Chemicals —first matrix	$650
Extractable and Semi-volatile Organic Chemicals—first matrix	$1,500
Dioxin—first matrix	$650
Radiochemical Category—first matrix	$750
Whole Effluent Toxicity Testing—first matrix	$700
Asbestos—second matrix	$350
Microbiology—second matrix	$450
Trace Metal Category—second matrix	$500
Inorganic Non-metal Category—second matrix	$550
Volatile Organic Chemicals—second matrix	$600
Extractable and Semi-volatile Organic Chemicals—second matrix	$1,400
Dioxin—second matrix	$600
Radiochemical Category—second matrix	$700
Asbestos—third matrix	$300
Microbiology—third matrix	$400
Trace Metal Category—third matrix	$450
Inorganic Non-metal Category—third matrix	$500
Volatile Organic Chemicals—third matrix	$550
Extractable and Semi-volatile Organic Chemicals—third matrix	$1,300
Dioxin—third matrix	$550

Radiochemical Category—third matrix $650

At least every 3 years, the Department will recommend regulatory changes to the fees in this section to the EQB to address any disparity between the program income generated by the fees and program costs. The regulatory amendment will be based upon an evaluation of the accreditation program fees income and the Department's costs of administering the accreditation program. An environmental laboratory owned or operated by a Commonwealth agency is exempt from this fee requirement, but shall apply for accreditation under this chapter. Fees are nonrefundable. 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.

Fee Objective:

The fees have been calculated to cover the reasonable costs to the Department to implement and administer the environmental laboratory accreditation program and for the processing of an application for a certificate of accreditation, including the issuance, renewal, modification or other action relating to the certificate as required by 27 Pa C.S. § 4104(6).

Fee Related Activities and Costs:

Examples of environmental laboratory accreditation activities supported by the fees associated with laboratory accreditation program:

1. Assessment of Applicant Laboratories—Includes performing on-site evaluations, writing assessment reports, reviewing corrective action reports submitted by the laboratory, and updating a laboratory's accreditation status resulting from the completed on-site evaluation. A laboratory on-site evaluation includes the evaluation of laboratory's facilities, equipment, methodologies, quality control practices, and personnel.
2. Application Review—Includes review of a laboratory's application for accreditation, evaluation of appropriate fee payment, updating a laboratory's scope of accreditation based on their application requests, and issuing a new certificate of accreditation. Review of a laboratory's application for accreditation includes the review and evaluation of laboratory supervisors for compliance with Chapter 252 requirements.
3. Review and Approval of Proficiency Testing (PT) Results—Includes review of a laboratory's current scope of accreditation, review of the laboratory's history of pass and fail rates in past PT studies, changes to a laboratory's accreditation status based on the laboratory's performance on PT studies, or lack thereof.
4. Provide Technical Assistance to Applicant Laboratories Required by 27 Pa C.S. § 4104 (7)—Includes responding to phone calls, e-mails, and other correspondence from applicant laboratories within approved timeframes. The Laboratory Accreditation staff also attend meetings and training sessions offered to applicant laboratories and interpret

the State, National, and EPA rules and regulations that apply to applicant laboratories when guidance is requested.

5. Maintain Approval as a NELAP Accreditation Body—Includes review and approval by The NELAC Institute (TNI), maintenance of the Laboratory Accreditation Program's quality system, a requirement for biennial on-site assessments of NELAP accredited laboratories, a requirement for annual training of all Laboratory Accreditation Program staff, participation in TNI committees and attendance at the biannual face-to-face meetings.

Analysis:

Section 4104(6) of the Act of June 29, 2002 (P.L. 596, No. 90) (dealing with Environmental Laboratory Accreditation) (27 Pa C.S. §§ 4101 – 4113) authorizes the Department to "require a fee for the processing of an application, including the issuance, renewal, modification or other action relating to the certificate, in an amount sufficient to pay the department's cost of implementing and administering the accreditation program." The Department is required to set fees in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program. These fees are intended to reflect the costs of implementing and administering the environmental laboratory accreditation program to the environmental laboratories.

For the environmental laboratories required to maintain accreditation in accordance with the Chapter 252 regulation, the costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. The annual application fees will range from $900 to $15,000. The Department believes that the increased accreditation fees will not result in prohibitive cost increases for any environmental laboratory.

The final rulemaking contains a fee structure that is responsive to the needs of small laboratories. Categories of testing are included for basic drinking water parameters and for basic wastewater parameters as a group. Additional tests were added to the basic wastewater parameter group in response to comments received by the Laboratory Accreditation Advisory Committee. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. The fees for the laboratories accredited in these categories increase by only $50 per year and the majority of the accredited laboratories fall into these categories. The fees assessed to these smallest of environmental laboratories will increase from an annual fee of $1200 to an annual fee of $1250. The average fee for a medium environmental laboratory will increase from $3,700 to $4,900 and the increase for a large accredited environmental laboratory will increase from $8,100 to $10,600. A NELAP accreditation for any lab would be an additional $2,000.

The calculated fees were rounded to the nearest $50 increment for ease of calculation by the regulated laboratories. The reimbursement rate for travel time to an out-of-State environmental laboratory is based upon salary and benefit costs for an assessor and would be $50 per hour for each assessor.

The estimated cost of the Laboratory Accreditation Program for the first full year, fiscal year 2011/2012, is $ 1,580,000 and the projected revenue is $ 1,600,000. Thus the projected amount collected in revenue covers the estimated cost of the program.

Comment:

The Environmental Laboratory Accreditation Regulation sets forth the requirements that laboratories must meet in order to become accredited to perform testing for 12 environmental statutes. While completing the first round of laboratory assessments under the Chapter 252 regulation, effective January 28, 2006, the Laboratory Accreditation Program discovered various portions of the regulation that are unclear or where the rules are overly restrictive and cost prohibitive to the regulated community. These changes to the regulation will benefit the entire regulated community. The Department developed a simpler fee structure. Additionally, implementation of the NELAP accreditation program incurs added costs over those associated with the accreditation program outlined in Chapter 252, but the current fee structure does not require NELAP applicant laboratories to pay additional fees. The final rulemaking fee structure includes an additional fee for laboratories requesting NELAP accreditation.

At least every three years, the Department will recommend regulatory changes to the fees in this section to the environmental quality board to address any disparity between program income generated by the fees and program costs. The regulatory amendment will be based upon an evaluation of the accreditation program fees income and the Department's costs of administering the accreditation program.

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in development of the proposed and final regulations. The LAAC held meetings on July 9, 2008, September 29, 2008, December 11, 2008, and September 10, 2009 to review the Department's proposed and final drafts of the Chapter 252 regulations. The LAAC provided invaluable advice and insight to the Department during these meetings. The Department considered all and agreed to the majority of the recommendations made by the LAAC.

The LAAC reviewed the final rulemaking on September 10, 2009, and unanimously supported moving the final rulemaking forward to the Board for consideration.

#2770

Pennsylvania Department of Environmental Protection

Rachel Carson State Office Building
P.O. Box 2063
Harrisburg, PA 17105-2063
January 25, 2010

Policy Office 717-783-8727

Kim Kaufman, Executive Director
Independent Regulatory Review Commission
14th Floor
333 Market Street
Harrisburg, PA 17120

Re: Final-Form Rulemaking – Blue Eye Run, et al (Water Quality Network Package) (#7-436);
Final-Form Rulemaking – Environmental Laboratory Accreditation (#7-434)

Dear Mr. Kaufman:

Pursuant to Section 5.1(a) of the Regulatory Review Act, please find enclosed copies of two final-form rulemakings for review and comment by the Independent Regulatory Review Commission (IRRC). The Environmental Quality Board (EQB) approved these is final-form rulemakings at its December 15, 2009, meeting.

The Blue Eye Run, et al (Water Quality Network Package) final rulemaking includes revisions to the Designated Uses and Water Quality Criteria to all or part of the following waterbodies as included in 25 *Pa Code*, Sections 93.9b, 93.9i, 93.9l, 93.9q,: East Branch Dyberry Creek (Wayne County), UNT 29200 to Tunkhannock Creek (Susquehanna County), Young Womans Creek (Clinton County), Muncy Creek (Sullivan County), Spruce Run (Union County), Blue Eye Run (Warren County), and East Hickory Creek (Warren County). The data that substantiates the regulatory revisions in this final rulemaking was obtained from the Department of Environmental Protection's (Department) Surface Water Quality Network (WQN) – a long-term, fixed station network of monitoring stations on rivers and streams throughout the state. WQN reference sites are selected from various areas across the state and are monitored in five year rotations for chemical and biological quality to describe best-attainable conditions. After reviewing the results of this monitoring, the Department found that several of the reference stations displayed Existing Use stream conditions indicative of Exceptional Value (EV) waters. Based on this data and appropriate regulatory criteria, the Department developed revisions to the Designated Uses and Water Quality Criteria to the above listed waterbodies contained in the Blue Eye Run, et al final rulemaking package. The amendments affect approximately 264.2 stream miles in the Commonwealth, which will be redesignated to Exceptional Value, if approved. The rulemaking also includes spelling corrections to designations in Sections 93.9b, 93.9d, 93.9f, 93.9g, 93.9l, and 93.9p. These corrections will not affect the current stream designations.

The EQB approved the proposed rulemaking at its April 21, 2009, meeting. The proposed rulemaking was published in the *PA Bulletin* on June 20, 2009 at 39 *Pa.B.* 3043, with provision for a 45-day public comment period that closed on August 4, 2009. The only commentator on the proposal was the U.S. Environmental Protection Agency (EPA) Region 3 who commended the Department on its continuing effort to upgrade streams into its highest level of the Special Protection Waters Program.

IRRC reviewed the proposal as well, but did not issue any comments, recommendations, or objections to the proposed rulemaking. The Department did not make any changes to the rulemaking from its proposed form.

The Environmental Laboratory Accreditation final-form rulemaking includes amendments to 25 *Pa. Code* Chapter 252 concerning requirements for environmental laboratory accreditation. The rulemaking affects any person, facility or group that performs testing or analysis on drinking water, non-potable water, and/or solid and chemical material environmental samples required by Department statutes or regulations. The majority of amendments in the final rulemaking include modifications that clarify existing requirements in order to facilitate greater understanding and compliance among the regulated community with the Department's regulations. The rulemaking also includes amendments that eliminate unnecessary or cost prohibitive requirements and amendments to include several necessary standards for accreditation. Lastly, the rulemaking includes adjustments to the current accreditation fees, as they do not adequately fund the Laboratory Accreditation Program as mandated by the Environmental Laboratory Accreditation Act (Act 90 of 2002). Specific changes to the fees attempt to not only simplify the fee structure, but to equally distribute the costs of the program over the regulated community.

The EQB adopted the proposed rulemaking on April 21, 2009. The proposal was published in the *PA Bulletin* on June 20, 2009, at 39 *Pa.B.* 3051, with a 30-day public comment period. Two commentators provided comments on the proposal, including the Delaware County Regional Water Quality Control Authority and the Independent Regulatory Review Commission (IRRC), who requested greater clarification from the Department on several elements of the rulemaking, including recordkeeping and documentation requirements, the qualifications of a laboratory supervisor and training requirements. At final rulemaking, amendments were made concerning Federal Safe Drinking Water Act Proficiency Testing (PT) study requirements for laboratories, as well as amendments pertaining to recordkeeping procedure requirements for demonstrations of capability.

The Department worked with the Laboratory Accreditation Advisory Committee (LAAC) to amend Chapter 252 in a manner that ensures appropriate requirements for environmental laboratory accreditation. On September 10, 2009, the LAAC unanimously voted to recommend the Chapter 252 final rulemaking for presentation to the Board.

The Department will provide assistance as necessary to facilitate the Commission's review of these final-form rulemakings under Section 5.1(e) of the Regulatory Review Act. Please contact me at the number above if you have any questions or need additional information.

Sincerely,

Michele L. Tate

Michele L. Tate
Regulatory Coordinator

Enclosures

0120-FM-PY0011 8/2006

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
OFFICE OF POLICY

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7- 434

SUBJECT: Environmental Laboratory Accreditation

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Regulation with Notice of Proposed Rulemaking Omitted
- ☐ 120-day Emergency Certification of the Attorney General
- ☐ 120-day Emergency Certification of the Governor
- ☐ Delivery of Tolled Regulation
  a. ☐ With Revisions b. ☐ Without Revisions

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INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
1-25-10	D Newton	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Rep. Camille George
1-25-10	RG Watson	Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
1-25-10	D Costello	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Mary Jo White
1-25-10	A. Pebarger	Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
1/25/10	Tony Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)