| Regulatory Analysis Form | This space for use by IRRC |
|---|---|
| (1) Agency<br><br>Department of Environmental Protection | RECEIVED<br>2003 OCT 23 PM 3:23<br>REVIEW COMMISSION |
| (2) I.D. Number (Governor's Office Use)<br><br>**7-392** | IRRC Number: 2454 |

(3) Short Title

Environmental Laboratory Accreditation Regulation

| (4) PA Code Cite | (5) Agency Contacts & Telephone Numbers |
|---|---|
| 25 Pa. Code Chapters 78, 109, and 252 | Primary Contact: Marjorie Hughes, 783-8727<br><br>Secondary Contact: Michele Tate, 783-8727 |

| (6) Type of Rulemaking (Check One) | (7) Is a 120-Day Emergency Certification Attached? |
|---|---|
| ___Proposed Rulemaking<br>_X_Final Order Adopting Regulation<br>___Final Order, Proposed Rulemaking Omitted | _X_ No<br>___ Yes: By the Attorney General<br>___ Yes: By the Governor |

(8) Briefly explain the regulation in clear and nontechnical language.

This rulemaking amends 25 Pa. Code Chapters 78 (relating to Oil and Gas Wells) and 109 (relating to Safe Drinking Water) and adds Chapter 252 (relating to environmental laboratory accreditation). The rulemaking delineates and consolidates the requirements for accreditation of environmental laboratories in Chapter 252. These regulations provide the requirements for an environmental laboratory accreditation program for laboratories that test or analyze samples that are used to comply with statutes administered by the Department. These requirements are outlined very specifically with regard to the scope of accreditation, application procedures, fees, standards for accreditation - including personnel requirements, essential quality control procedures, proficiency test studies, on-site assessments, record keeping, and reporting and notification requirements.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

1. The Act of June 29 2002 (P.L. 596, No. 90) (dealing with Environmental Laboratory Accreditation) (Title 27 Pa. C.S. §§ 4101 – 4113)
2. Section 1920-A of the Administrative Code, April 9.1929 (P.L. 177, No. 175), as amended, 71 P.S. Sec. 510-20.

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

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

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Valid and accurate laboratory data are essential to assure compliance with the laws administered by the Department. Additionally, throughout Pennsylvania, numerous decisions made everyday by the public, the regulated community, and the government are based upon data generated by environmental laboratories. Recently, several highly publicized instances of laboratory fraud or faulty data have undermined the public's confidence in the data generated by environmental laboratories both here in Pennsylvania and throughout the United States.

Only the Drinking Water Program and the Oil and Gas Program currently address the issue of data quality through a laboratory accreditation program. At this time, the quality of laboratory data used to determine compliance with the remaining Department regulations is unknown. The proposed regulations would address this deficiency by requiring environmental laboratories that test or analyze non-potable (wastewater), solid and chemical materials, or drinking water samples to undergo periodic on-site inspections that will evaluate the laboratory procedures in place in that facility. These on-site inspections, coupled with other requirements in the proposed regulations will help to ensure accurate and valid data, and therefore, enable the Department and the regulated community to meet their environmental protection goals.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Non-regulation would leave in place a system that does not ensure the procedures that produce the overwhelming majority of data used for environmental decisions in the Commonwealth are performed accurately. Without periodic in-depth on-site laboratory evaluations, the Department cannot have confidence in the data submitted. Unless the specific requirements contained in these regulations are adopted, environmental laboratories would continue to be able to produce data of unknown quality with very little regulatory oversight

## Regulatory Analysis Form

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

These regulations will benefit all data users and anyone who lives in the Commonwealth. These data users include the Department, facilities that rely on laboratories to demonstrate compliance with their permits, geologists, and engineers. The citizens of the Commonwealth depend on environmental laboratories to accurately test environmental samples to protect their health, safety, and welfare. The environment will benefit because more accurate and reliable data will result in better regulatory decision making and better compliance with environmental laws.

## Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effect as completely as possible and approximate the number of people who will be adversely affected.)

No individual, facility, or environmental laboratory will be adversely affected by the regulation. An environmental laboratory that is accredited-by-rule will incur no additional compliance costs. For other environmental laboratories, the direct costs for compliance will be payment of the required fees and the purchase of proficiency test samples. 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 $850 to $13,600. The cost for the proficiency test samples range from less than $100 to approximately $13,000. The Department believes that the accreditation requirements 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.

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. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. Additionally, it has been the Department's experience in the drinking water laboratory accreditation program that accreditation is affordable for many small laboratories. Many small and municipal laboratories have met similar requirements under the Drinking Water Program regulations in Chapter 109.

(15) 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, groups, or entities affected by this regulation include 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. This regulation lists 12 specific statutes that will be included in the scope of this regulation.

The proposed regulations specifically exclude the following testing:

1. Corrosion protection system testing or testing of a storage tank system for tightness or structural soundness under Chapter 245 (relating to the Administration of the Storage Tank and Spill Prevention Program).
2. Routine release detection monitoring under § 245.442 (relating to requirements for petroleum underground storage tank systems), § 245.443 (relating to requirements for hazardous substance underground storage tank systems), § 245.444 (relating to methods of release detection for tanks), § 245.445 (relating to methods of release detection for piping), § 245.543 (relating to leak detection requirements), and § 245.613 (relating to monitoring standards).
3. Analyses to determine the acceptability of soils for protective, daily, intermediate and final cover material, subbase, clay liner, clay cap, attenuating soil base and liner system construction material pursuant to chapters 271-285 (relating to municipal waste) and chapters 287 – 299 (relating to residual waste).
4. Testing or analysis of the physical, chemical, mechanical, and thermal properties of liners, liner systems, leachate detection zones and barriers pursuant to chapters 271-285 (relating to municipal waste) and chapters 287 – 299 (relating to residual waste.)

Approximately 750 laboratories will be required to comply with this regulation. Of those 750 laboratories, approximately 225 laboratories are currently regulated under the Safe Drinking Water Program (25 Pa Code Chapter 109, Subchapter H) or the Oil and Gas Program (25 Pa Code Chapter 78, Subchapter F).

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance throughout the development of the rulemaking. The LAAC met approximately every other month from August 2002 through April 2004 and advised the Department on the development of proposed Chapter 252. Additionally, the LAAC and the Certification Program Advisory Committee (CPAC) met jointly on January 23, 2004, to discuss and provide recommendations on several key concepts (fee structure, qualifications of a laboratory supervisor and parameters to be included in accreditation-by-rule).

The LAAC reviewed the draft final-form rulemaking on June 1, 2005, and unanimously supported moving the draft rulemaking forward to the Board.

Department representatives also met with the following groups during the development of the proposed regulations:

- Agricultural Advisory Board
- Air Quality Technical Advisory Committee
- Oil & Gas Technical Advisory Board
- Radiation Protection Advisory Committee
- Small Business Compliance Advisory Committee
- Solid Waste Advisory Committee
- Storage Tank Advisory Committee
- Technical Assistance Center for Small Water Systems
- PA Municipal Authorities Association (PMAA)
- PA Water Environment Association (PWEA)
- Pennsylvania Association of Accredited Environmental Laboratories (PaAAEL)
- Eastern, Central, and Western Sections of the Water Pollution Control Operators Associations

(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.

It is not anticipated that additional legal, accounting or consulting procedures will be required. However, the fees associated with the regulatory requirements are an annual application fee that depends on the desired scope of accreditation (see Attachment A fee table) and participation in annual proficiency test studies. It is difficult to quantify the benefit or savings to the regulated community of improved data quality in specific dollar amounts. One way to partially quantify the benefit is to examine the extra costs associated with unacceptable data. Fines assessed against environmental laboratories guilty of producing fraudulent data or data that does not meet the regulatory requirements range from several thousand dollars to over 9 million dollars. These fines reflect the amount of harm done to the environment or to public health by poorly operated laboratories. When laboratories fail to provide accurate and valid data, additional testing and analysis and costly remediation is often required. An environmental laboratory accreditation program is a proactive approach designed to prevent problems before they become critical.

(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.

There are no additional costs or savings for local governments to comply with these regulations. The cost of accreditation for local governments is the same as those for the rest of the regulated community. See (17) above.

(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.

There is no net cost or benefit to state government agencies associated with implementing these regulations. 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 are not required to pay the accreditation fees. A saving which can not be quantified is the saving in Department staff time dealing with questionable data from environmental laboratories that are not currently required to be accredited. Often the Department or the regulated entity is required to perform additional testing and analyses and thereby incur additional costs associated with this repeat sampling, testing and analyses. An effective laboratory accreditation program is a proactive measure to help ensure that the data used to make critical decisions about the environment are of known and documented quality.

(20) In the table below, provide an estimate of the fiscal savings and cost 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 | ** | ** | ** | ** | ** | ** |
| Local Government | ** | ** | ** | ** | ** | ** |
| State Government | ** | ** | ** | ** | ** | ** |
| Total Savings | ** | ** | ** | ** | ** | ** |
| COSTS: | ** | ** | ** | ** | ** | ** |
| Regulated Community | ** | ** | ** | ** | ** | ** |
| Local Government | ** | ** | ** | ** | ** | ** |
| State Government | ** | ** | ** | ** | ** | ** |
| Total Costs | ** | ** | ** | ** | ** | ** |
| REVENUE LOSSES: | ** | ** | ** | ** | ** | ** |
| Regulated Community | ** | ** | ** | ** | ** | ** |
| Local Government | ** | ** | ** | ** | ** | ** |
| State Government | ** | ** | ** | ** | ** | ** |
| Total Revenue Losses | ** | ** | ** | ** | ** | ** |

**** Undetermined**

(20a) Explain how the cost estimates listed above were derived.

See comments above in Sections 17 through 19.

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

Environmental Protection Operations

| Program | FY-3 2002-2003 | FY-2 2003-2004 | FY-1 2004-2005 | Current FY 2005-2006 |
|---|---|---|---|---|
| General Government Operations | $20,256,000 | $22,171,000 | * | * |
| Environmental Protection Operations | * | * | $81,951,000 | $87,897,000 |

* Prior to July 1, 2004, this program was funded from General Government Operations. Beginning July 1, 2004, the program is funded under Environmental Protection Operations

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

It is difficult to quantify the benefit or savings to the regulated community of improved data quality in specific dollar amounts. One way to partially quantify the benefit is to examine the extra costs associated with unacceptable data. Fines assessed against environmental laboratories guilty of producing fraudulent data or data that does not meet the regulatory requirements range from several thousand dollars to over 9 million dollars. These fines reflect the amount of harm done to the environment or to the public health by poorly operated laboratories. When laboratories fail to produce accurate and valid data, additional testing and analysis and costly remediation is often required. An environmental laboratory accreditation program is a proactive approach designed to prevent problems before they become critical.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

There are no equivalent non-regulatory alternatives. Optional training programs will be offered, but training alone will not assure compliance with the promulgated laboratory methods.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

There are no cost effective regulatory alternatives. The National Environmental Laboratory Accreditation Conference (NELAC) developed a standard for the accreditation of environmental laboratories performing testing and analysis of environmental samples. At the time the current NELAC Standard was being developed, NELAC was a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. The NELAC Standard was developed using a consensus-based approach. The alternative to the proposed regulations would be adoption or incorporation of the NELAC Standard into this regulation. The requirements outlined in this regulation for the State environmental laboratory accreditation are less stringent than the NELAC Standard. Currently, a relatively small number of Pennsylvania accredited laboratories are accredited by NELAC. The costs associated with complying with the NELAC Standard are higher than those anticipated with this regulation. To meet the requirements contained in the NELAC Standard, an environmental laboratory is required to participate in at least double the number of proficiency test (PT) studies. The cost of the PT studies varies widely depending on the laboratory's scope of accreditation. The cost ranges from $88 for a single microbiology PT to approximately $13000 to acquire PT samples for the entire scope of PT samples available for accreditation. NELAC accredited laboratories must implement a very rigorous quality system that requires highly specific documentation and quality assurance procedures. The cost for an environmental laboratory to become accredited under the NELAC program is significantly higher than the anticipated cost for the proposed regulations.

(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 regulation.

Yes. There are no federal standards for accreditation of environmental laboratories testing for non-potable water (wastewater) and solid and chemical materials. The federal program only regulates drinking water analysis and consists of requiring the use of promulgated methods for testing and analysis and recommended laboratory practices. The proposed regulations contain the minimum requirements for an environmental laboratory performing testing or analysis on wastewater and solid and chemical materials as well as drinking water. Several 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. However, the Department has used these standards to certify or accredit drinking water laboratories since 1984. These regulations will not impose any new requirements on drinking water laboratories. Pennsylvania needs regulations for the testing and analyses required by these programs because without the mandatory specific requirements contained in this regulation, an environmental laboratory would be free to produce data with very little regulatory oversight from the Department. The quality of the data used to make important decisions about the environment and the health, safety, and welfare of the citizens of the Commonwealth would continue to be of unknown quality.

(25) How does the regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This regulation is very comparable to other state accreditation programs for drinking water, wastewater, and solid and chemical materials. A survey of 40 other states indicated that at least 22 states have mandatory wastewater and solid and chemical materials accreditation programs. All environmental laboratories that perform testing or analysis on samples from public drinking water suppliers must be accredited either by a state or the US Environmental Protection Agency. The costs of the laboratory accreditation programs in other states vary widely and largely depend on the mechanism each state uses to fund the program. Some states require that the fees charged to the environmental laboratories cover the cost of the laboratory accreditation program while other states provide funding for the program from general revenue. The actual fee structures vary. The regulation should give Pennsylvania laboratories an advantage with regard to competition with other states. Many Pennsylvania laboratories are already certified for testing and analysis of wastewater and solid and chemical materials in and through other states. The institution of an environmental laboratory accreditation program should lower the number of laboratories that are required to seek accreditation for wastewater and solid and chemical materials from other states. As a result, this should also lower some of the costs charged to those laboratories with respect to reimbursing the other states for travel expenses. This regulation should also lower the number of on-site evaluations in which some laboratories are required to participate.

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

Yes. This final-form rulemaking transfers the laboratory accreditation program, currently under the Safe Drinking Water Program (25 Pa. Code Chapter 109 (relating to safe drinking water)), to Chapter 252. The Safe Drinking Water Act (42 U.S.C.A. §§ 300f--300j-10) requires that laboratories performing drinking water analysis be accredited. Additionally, the final-form rulemaking transfers the laboratory accreditation program, currently under the Oil and Gas Program (25 Pa. Code Chapter 78 (relating to oil and gas wells)), to Chapter 252. The affected sections are 25 Pa. Code Chapter 78 Subchapters A, C, and F and Chapter 109 Subchapter H.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

Yes. Environmental laboratories will be required to apply and annually renew their accreditation on forms provided by the Department (see Attachments B1 and B2 – application forms). Previously unregulated environmental laboratories will be required to retain records for five years.

(29) 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.

To the extent possible, the unique needs of small businesses, municipalities, municipal authorities and in-house laboratories (hereafter referred to as "small laboratories") have been considered and are addressed throughout the proposed regulations where compatible with the goals of an effective and appropriate environmental laboratory accreditation program. The goal of the environmental laboratory program and these regulations is to assure the quality of the data used to make environmental decisions and thus better protect the environment and the public health, safety, and welfare of the citizens of the Commonwealth. These regulations include only those items that are essential for the production of good quality data.

While certain minimum requirements are necessary to ensure quality data, these regulations contain several provisions that specifically address the needs of small laboratories. These provisions include: an accreditation-by-rule section that addresses the testing and analyses conducted by many of the smallest laboratories; laboratory supervisor qualifications that are tailored to the complexity of the analysis; provisions concerning certified operators and experienced supervisors; and a fee structure that addresses the needs of laboratories that perform only a few types of tests.

A section outlining accreditation-by-rule is included to specifically address the unique needs of small laboratories. Accreditation-by-rule is a mechanism to permit an environmental laboratory to perform testing or analysis with only minimal oversight by the Department.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The final rulemaking will become effective upon publication in the *Pennsylvania Bulletin*, which is anticipated to occur in the fall of 2005. An environmental laboratory will have 6 months from the effective date of the regulations to apply for accreditation. The submission of an application will provide interim authorization to continue operations until the Department takes final action on the application.

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

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.

CDL-1

# FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU

## (Pursuant to Commonwealth Documents Law)

#2454



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. 7-392

DATE OF ADOPTION _____

BY Kathleen A McGinty

TITLE KATHLEEN A MCGINTY
CHAIRPERSON

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

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

BY Andrew C. Clark

10.24.05
DATE OF APPROVAL

(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 Regulations

## 25 *Pa. Code*, Chapters 78, 109 and 252

# Notice Of Final Rulemaking
# Department of Environmental Protection
# Environmental Quality Board
# 25 PA. Code Chapters 78, 109, and 252
# Oil and Gas Wells, Safe Drinking Water, and Environmental Laboratory Accreditation

## Order

The Environmental Quality Board (Board) by this order amends 25 Pa. Code Chapters 78 (relating to Oil and Gas Wells) and 109 (relating to Safe Drinking Water) and adds Chapter 252 (relating to environmental laboratory accreditation). The rulemaking delineates and consolidates the requirements for accreditation of environmental laboratories in Chapter 252.

This order was adopted by the Board at its meeting of August 16, 2005.

### A. Effective Date

The amendments will go into effect upon publication in the *Pennsylvania Bulletin* as final rulemaking.

### B. Contact Persons

For further information contact Richard H. Sheibley, Chief, Laboratory Accreditation Program, P. O. Box 1467, 2575 Interstate Drive, Harrisburg, PA 17105-1467, (717) 346-8215; 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 final-form rulemaking is available on the Department of Environmental Protection's (Department) website: www.dep.state.pa.us.

### C. Statutory Authority

This final-form rulemaking is being made under the authority of 27 Pa.C.S. § 4103(a) (relating to establishment of program), which directs the Department to establish an accreditation program for environmental laboratories, 27 Pa.C.S. § 4104 (relating to powers and duties), 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, 27 Pa.C.S. § 4105 (relating to powers and duties of Environmental Quality Board),

delegating the Board the power to adopt the regulations of the Department to implement 27 Pa.C.S. §§ 4101--4113 (act) (relating to environmental laboratory accreditation), and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), authorizing and directing the Board to adopt regulations necessary for the proper performance of the work of the Department.

**D. Background of the Amendments**

Over the past 25 years, the General Assembly and the United States Congress have enacted numerous statutes protecting air, water and soil and regulating activities that might otherwise pose a threat to the environment. Valid and accurate laboratory data are essential to assure compliance with the laws administered by the Department. Additionally, throughout this Commonwealth numerous decisions made everyday by the public, the regulated community and the government are based upon data generated by environmental laboratories. Recently however, several highly publicized instances of laboratory fraud or reliance on faulty data have undermined the public's confidence in the data generated by environmental laboratories. Presently, in this Commonwealth only the Drinking Water Program and the Oil and Gas Program address the issue of data quality through a laboratory accreditation program. The quality of laboratory data used to determine compliance with the remaining Department regulations is unknown. Without these regulations, verification of the accuracy of data submitted to the Department is a very costly and time-consuming task.

The goal of the rulemaking is to assure the quality of the data used to make environmental decisions and thus better protect the environment and the health, safety and welfare of the citizens of this Commonwealth. This goal is achieved by requiring affected environmental laboratories to perform proficiency test (PT) samples, data verification requirements and undergo periodic onsite inspections where the Department evaluates laboratory procedures in place in that facility. The final-form rulemaking includes only items that are essential for the production of good quality data.

The rulemaking applies to environmental laboratories that test or analyze nonpotable water (wastewater), solid and chemical materials or drinking water samples as required by the following statutes:

1. The Oil and Gas Act (58 P. S. §§ 601.101--601.605).

2. The Clean Streams Law (35 P. S. §§ 691.1--691.1001).

3. The Hazardous Sites Cleanup Act (35 P. S. §§ 6020.101--6020.1305).

4. The Land Recycling and Environmental Remediation Standards Act (35 P. S. §§ 6026.101--6026.908).

5. The Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1--721.17).

6. The Solid Waste Management Act (35 P. S. §§ 6018.101--6018.1003).

7. The Storage Tank and Spill Prevention Act (35 P. S. §§ 6021.101--6021.2104).

8. The Pennsylvania Bituminous Coal Mine Act (52 P. S. §§ 701.101--701.706).

9. The Surface Mining Conservation and Reclamation Act (52 P. S. §§ 1396.1--1369.31).

10. The Coal Refuse Disposal Control Act (52 P. S. §§ 30.51--30.206).

11. The Bituminous Mine Subsidence and Land Conservation Act (52 P. S. §§ 1406.1--1406.21).

12. The Noncoal Surface Mining Conservation and Reclamation Act (52 P. S. §§ 3001--3326).

This final-form rulemaking transfers the laboratory accreditation program, currently under the Safe Drinking Water Program (25 Pa. Code Chapter 109 (relating to safe drinking water)), to Chapter 252. The Safe Drinking Water Act (42 U.S.C.A. §§ 300f--300j-10) requires that laboratories performing drinking water analysis be accredited. Additionally, the final-form rulemaking transfers the laboratory accreditation program, currently under the Oil and Gas Program (25 Pa. Code Chapter 78 (relating to oil and gas wells)), to Chapter 252. The Federal drinking water laboratory accreditation program consists of requiring the use of promulgated methods for testing and analysis and recommending good laboratory practices, including the use of appropriate quality control measures. There are no Federal standards for accreditation of an environmental laboratory testing nonpotable water (wastewater) and solid and chemical materials.

The National Environmental Laboratory Accreditation Conference (NELAC) developed a set of standards for the accreditation of environmental laboratories performing testing and analysis of environmental samples. At the time the current NELAC Standard was being developed, NELAC was a voluntary organization of state and Federal environmental officials and interest groups. NELAC's primary mission was to establish mutually acceptable standards for accrediting

environmental laboratories. The NELAC Standard provides uniform requirements for accreditation of environmental laboratories and facilitates mutual recognition among laboratory accreditation programs using the NELAC Standard. The NELAC Standard was developed using a consensus-based approach. The Department would offer a dual accreditation system whereby accreditation to the NELAC Standard is available as a voluntary option for environmental laboratories.

At the request of small laboratories, the requirements outlined in the final-form rulemaking for the State environmental laboratory accreditation are less stringent than the NELAC Standard. Currently, a relatively small number of accredited laboratories in this Commonwealth are accredited to the NELAC Standard. The costs associated with complying with the NELAC Standard are higher than those anticipated with this final-form rulemaking. To meet the requirements contained in the NELAC Standard, an environmental laboratory is required to participate in at least double the number of PT studies. The cost of the PT studies varies widely depending on the laboratory's scope of accreditation. The cost ranges from $88 for a single microbiology PT to approximately $13,000 to acquire PT samples for the entire scope of PT samples available for accreditation. An environmental laboratory accredited to the NELAC Standard must implement a very rigorous quality system that requires highly specific documentation and quality assurance procedures.

The final-form rulemaking is very comparable in terms of the range and stringency of requirements to other state (non-NELAC based) laboratory accreditation programs for drinking water, wastewater and solid and chemical materials. A survey of 40 other states indicated that at least 22 states have mandatory accreditation programs for environmental laboratories testing wastewater and solid and chemical materials.

An environmental laboratory may choose State accreditation, described by this final-form rulemaking, or seek accreditation using the NELAC Standard as a voluntary alternative to this final-form rulemaking. Accreditation to either set of standards would be equivalent and acceptable and meet the requirements for accreditation required by the Act. An environmental laboratory may be accredited to the NELAC Standard and also be accredited under Pennsylvania State accreditation standards described by this final-form rulemaking for fields of accreditation not included under the NELAC Standard.

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance throughout the development of the rulemaking. The LAAC met approximately every other month from August 2002 through April 2004 and advised the Department on the development of proposed Chapter 252. Additionally, the LAAC and the Certification Program

Advisory Committee (CPAC) met jointly on January 23, 2004, to discuss and provide recommendations on several key concepts (fee structure, qualifications of a laboratory supervisor and parameters to be included in accreditation-by-rule).

The LAAC reviewed the draft final-form rulemaking on June 1, 2005, and unanimously supported moving the draft rulemaking forward to the Board.

To the extent possible, the unique needs of small businesses, municipalities, municipal authorities and in-house laboratories (collectively referred to as "small laboratories") have been considered and addressed throughout this final-form rulemaking where compatible with the goals of creating an effective and sensible environmental laboratory accreditation program. Specific provisions that address these unique needs include: an accreditation-by-rule section addressing the testing and analyses conducted by many of the smallest laboratories; laboratory supervisor qualifications tailored to the complexity of the analysis; provisions concerning certified operators and experienced supervisors; and a fee structure that addresses the needs of laboratories that perform only a few types of tests.

A section outlining accreditation-by-rule is included in Chapter 252 to specifically address the unique needs of small laboratories. Accreditation-by-rule is a mechanism permitting an environmental laboratory to perform testing or analysis with only minimal oversight by the Department. Therefore, only certain tests or analyses are appropriate for inclusion under accreditation-by-rule.

The final-form accreditation-by-rule section continues the exemptions provided in the current Drinking Water Program regulations under §§ 109.304(c) and 109.704 (relating to analytical requirements; and operator certification). Reference is made in this final-form rulemaking to the Chapter 109 drinking water regulations. Because of the significance of these parameters in assessing environmental quality and because of the technical skills necessary to perform these tests correctly, total residue testing, biochemical oxygen demand testing and fecal coliform testing are not included under accreditation-by-rule.

Consistent with the requirements of the act, the final-form rulemaking establishes qualifications for laboratory supervisors. The laboratory supervisor may have different titles in different laboratories, such as lead analyst or technical director. The act identifies a laboratory supervisor as the individual who supervises laboratory procedures and reporting of analytical data. Specific educational qualifications are not established for other technical personnel or analysts in the laboratory. The unique needs of small laboratories are addressed by basing the laboratory supervisor

requirements upon the testing or analysis performed in the laboratory. A person who is functioning as a laboratory supervisor now would be able to continue in that position under the grandfathering provisions as provided in § 252.303 (relating to grandfathering provisions for laboratory supervisors).

The final-form rulemaking also recognizes that a drinking water or wastewater operator with a valid treatment plant operator's certificate for laboratory supervisor in the appropriate water or wastewater subclassification would qualify as a laboratory supervisor. To provide a smooth transition during the period when the laboratory supervisor subclassification may not be available, a contingency provision is included in the final-form rulemaking. The final-form rulemaking provides that for the period up to 12 months after a certificate for laboratory supervisor in the appropriate water or wastewater subclassification becomes available from the Department, 2 years of experience performing testing or analysis of environmental samples using the methods and procedures currently in use by the environmental laboratory may be substituted for a laboratory supervisory certificate.

All laboratory supervisors will be required to have experience in the areas for which they will be responsible. In addition, minimum levels of college credits in basic science are identified for laboratory supervisors, when appropriate. Consistent with the requirements of the act, the final-form rulemaking identifies the responsibilities of a laboratory supervisor. The final-form rulemaking provides that a person may be a supervisor of more than one laboratory under certain conditions.

**E. Summary of Changes to the Proposed Rulemaking**

**CHAPTER 78**

*Subchapter A*

The definition for certified laboratory was changed to accredited laboratory and revised to refer to Chapter 252 instead of subchapter F.

*Subchapter C*

Section 78.52 (c) certified laboratory was changed to accredited laboratory and the text was revised to refer to Chapter 252 instead of subchapter F

*Subchapter F*

Subchapter F was deleted and reserved.

**CHAPTER 109**

*Subchapter H*

§ 109.801 certified laboratory was changed to accredited laboratory and the text was revised to refer to Chapter 252.

§§ 109.802 through 109.809 were deleted and reserved.

§ 109.810 (a) and (b) certified laboratory was changed to accredited laboratory and the text was revised to refer to Chapter 252.

§ 109.810 (c), (d), and (e) were deleted.

**CHAPTER 252**

*Subchapter A*

*§ 252.1*—Additional clarifying language was added to the definitions for *Laboratory notebook*, *Matrix spike*, and *Method blank*. The word "analytical" added to the definition of *Laboratory supervisor* to be consistent with the definition in the Act. Definitions were added for *Spike* and *Surrogate* and the definition for Relative standard deviation was deleted.

*§ 252.3*—Corrected the reference to the Bituminous Mine Subsidence and land Conservation Act.

*§ 252.4*—Added clarifying language regarding the provision for interim accreditation for laboratories that apply during the 6 months immediately following the effective date of the final-form rulemaking.

*§ 252.5*—Reordered paragraphs c and d for clarity.

*§ 252.6*—Revised paragraphs (a)(1), (a)(2), (c) and (f) for clarity and added sludge to (f)(25) for completeness.

*Subchapter B*

*§ 252.203*—Added paragraph (b) for clarity.

*§ 252.204*—Revised the fee structure by differentiating between renewal of accreditation and an initial application. Eliminating the fee for each additional method and establishing category groups simplified the remaining categories. The provision linking fee increases to the Consumer Price Index was eliminated. However, the Act requires the

Department to establish fees in an amount sufficient to recover the Department's costs to implement and administer the accreditation program. Therefore, the Department will evaluate its costs to administer the accreditation program at least every three years and if necessary, revise the accreditation fees through future rulemakings.

*§ 252.205(b)*—In response to a commentator, § 252.205(b) has been revised for additional clarity.

*§ 252.206*—Deleted paragraph (4)

*§ 252.207*—Moved § 252.701 to *Subchapter B* and created a new § 252.207.

*Subchapter C*

*§ 252.301*—Added clarifying language to paragraph (b) to provide additional detail on the meaning of "certify". Added a new paragraph (c) clarifying the laboratory supervisor's responsibility for maintaining records. Corrected an incorrect reference that was created by deletion of a paragraph in *Subchapter G.*

*§ 252.302*—Moved § 252.302(b) at the end of § 252.302 to immediately follow a related section on laboratory supervisor qualifications. Renumbered sections appropriately.

*§ 252.303*—Added specific language to indicate that the date an environmental laboratory becomes subject to accreditation is the effective date of the rulemaking. Clarified in the rulemaking that approval under the grandfathering provision will be limited to the current facility and may not be transferred to a different environmental laboratory.

*§ 252.304*—Corrected the incorrect method reference in § 252.304(b)(3)(vii)(C) and removed § 252.304(4) and (8) because these sections are redundant and not needed.

*§ 252.306*—Combined § 252.306(f)(4)(ii) and (iii) for simplicity.

*§ 252.307*—Added clarifying language to § 252.307(b)(2). Provided additional details in § 252.307(c)(4) and (5).

*Subchapter D*

*§ 252.403*—Replaced the general reference to guidance with a reference to a specific regulation.

*Subchapter E*

*§ 252.501*—Clarified that failure to successfully analyze a proficiency test study only affects an individual field of accreditation.

*Subchapter G*

*§ 252.701--252.708*—Moved § 252.701 to *Subchapter B* for readability and revised numbering of the remaining sections and internal reference numbers. Clarified and simplified several sections dealing with Denial and Revocation. Added language clarifying the records an environmental laboratory is required to maintain. Reordered the paragraphs under Subcontracting for clarity. Simplified the reporting and notification requirements.

**F. Summary of Comments and Responses on the Final-form Rulemaking**

Comments were received from 20 commentators including the Independent Regulatory Review Commission (IRRC), the Chairs of the Senate Environmental Resources and Energy Committee, and the Chairs of the House Environmental Resources and Energy Committee as a result of the public comment period. None of the commentators opposed the technical requirements or merits of the regulation. Several commentators opposed linking the fee increases to the Consumer Price Index. Other commentators provided comments on the technical aspects of the regulation. Several commentators indicated that particular tests or types of environmental laboratories should be included under the accreditation-by-rule provision effectively removing the suggested tests or analyses from the requirements of the proposed regulations.

Comments on the fees and fee structure from commentators and LAAC members indicated that the proposed fee structure was difficult to understand and that the fees favored (depending upon the commentator) large, mid-size or small laboratories. This clarity concern was addressed in final regulation. The changes to the fee structure include: charging a fee per category per matrix, thus eliminating the individual method charges; different fees for an initial application fee and a renewal application fee; reducing the fees for both basic drinking water and non-potable water categories; adding categories that are combinations of several categories; and removing the provision linking fee increases to the Consumer Price Index. In addition to improved clarity, all these changes make fee structure more responsive to the unique needs of small, in-house environmental laboratories.

Several comments were received about the Accreditation-by-rule provision or the definition of environmental laboratory. Most of these comments were requests for inclusion of specific tests or analysis under the accreditation-by-rule section or

exclusion of a group of laboratories from the regulations entirely. Because of the significance of these parameters in assessing environmental quality and because of the technical skills necessary to perform these tests correctly, the final regulation was not changed and additional tests were not included under accreditation-by-rule. Differentiating between in house and commercial laboratories is not appropriate. The purpose of these regulations is to improve the quality of data for any testing or analysis of environmental samples that is required by the Department. Data from these tests are essential for making decisions that affect the environment and the public health, safety and welfare of the citizens of the Commonwealth. Additional tests should not be included under the accreditation-by-rule provision. The location of the testing nor the firm or individual performing the testing should be the basis for inclusion under the regulations.

Several commentators indicated that the regulations would discourage out-of-State laboratories from doing business in Pennsylvania or raise costs to Pennsylvania based businesses. It is neither the Department's desire nor intent to discourage out-of-State laboratories from doing business in Pennsylvania. The Act states that a laboratory meeting Pennsylvania accreditation standards may perform any required testing and analysis. Section 4104 (1) of the Act limits the recognition of other accreditation programs to Federal or State accreditation programs. Additionally, the National Environmental Laboratory Accreditation Conference Standard requires that an accrediting authority be a state or federal agency. The regulation as proposed and final conforms to both the NELAC Standard and the Act. The regulations and the accreditation program are designed to assure that the tests and analyses are performed according to the minimum documentation, quality control and method requirements, and that the laboratory's procedures have been reviewed to assure these requirements are being met. The Department does not believe that including a provision for a variance for out-of-State laboratories is consistent with the intent of the Act.

Several commentators thought that the proposed regulations did not adequately address the unique needs of small businesses, municipalities, municipal authorities and in-house laboratories. The Department disagrees, specific provisions that address these unique needs include: an accreditation-by-rule section addressing the testing and analyses conducted by many of the smallest laboratories; laboratory supervisor qualifications tailored to the complexity of the analysis; provisions concerning certified operators and experienced supervisors; and a fee structure that addresses the needs of laboratories that perform only a few types of tests.

A description of comments received by section of the proposed regulation and the Department's response follows:

*Scope:* Several commentators requested additional clarification regarding testing that is required by the Clean Air Act and the Pennsylvania Air

Pollution Control Act. The commentators requested specific exclusions for all sampling and monitoring of air emissions and air quality, including any sampling and analysis requirements covered by the Clean Air Act and Air Pollution Control Act, whether or not the air related requirements are referenced regulations or permits issued under environmental statures listed in 252.3(a).
Department Response: Because, the regulation lists only those specific statutes included in the scope of the regulation, the Department believes that this section is sufficiently clear. In contrast, specifically exempting the Clean Air Act or the Air Pollution Control act would create confusion. The Department administers other statutes related to the protection of the environment and the health, safety, and welfare of the citizens of the Commonwealth that are not included within the scope of this regulation. New statutes may be enacted that will be administered by the Department. Listing an exemption for only 1 or 2 specific statutes could lead to questions concerning the applicability of the regulation to the other unlisted statutes. The Department believes that additional clarifying language is not necessary in the regulation. Facilities that test environmental samples in order to comply with the Clean Air Act or the Air Pollution Control Act do not need to be accredited to perform these tests.

Two commentators requested additional clarification exempting industries that are subject to the Federal pretreatment standards.
Department Response: The final-form regulation is applicable to testing or analysis required by the Department. Testing performed to satisfy only Federal requirements is outside the scope of the Act and could not be covered by the regulation. Additional clarifying language is not necessary in the regulation and might lead to confusion.

*Definitions*: Several commentators requested removal of terms that were defined but not used, clarification of existing terms, rewording of definitions to be consistent with the Act, and addition of new terms for clarity.
Department Response: The Department agreed with most of the comments and made appropriate changes to the final-form regulations. Additionally, the Department added clarifying language to other definitions. The Department did not agree to change the definition of environmental laboratory or environmental sample as the definitions used in the draft and the final-form regulations is identical to the definition given in the Act.

Two commentators indicated that the meaning of "direct supervision" as used in §252.301(a) is unclear.

Department Response: Section 4106(c) of the Act requires "testing, analysis and reporting of data by an accredited laboratory shall be under the direct supervision of a laboratory supervisor." This section of the Act provides additional detail for the responsibilities of the laboratory supervisor. Section 252.301 of the regulations reflects these requirements. The laboratory supervisor is not required to be in the laboratory during all times that testing and analysis is being performed. A laboratory supervisor would be required to be available, be able to exercise appropriate control over the operations of the laboratory, and be responsible for the accuracy and validity of the data provided by the laboratory. The requirements are described in the Act, § 4106 (c), and the proposed regulations, Subchapter C, especially 252.301 and 252.304. Should multiple environmental laboratories wish to use the same individual as the laboratory supervisor, each laboratory would need to demonstrate the adequacy of the supervision as required by Section 252.301 (g).

Two commentators requested addition of a definition for "Failure" as it applies in §252.501(k).
Department Response: The Department added clarifying language that indicates failure applies to each individual field of accreditation.

*Interim Accreditation and Time of Application for Accreditation:* Several commentators noted that the proposed regulation did not include a provision for interim accreditation or provide sufficient detail regarding the date an environmental laboratory would be subject to accreditation.
Department Response: The Department will change § 252.4 to reflect the requirements of Section 4107 of the Act, which provides that a laboratory that submits an application within 6 months of the effective date of the regulation will be granted interim authorization to continue operations until the Department takes a final action on the application. Additional language was added indicating that the effective date for environmental laboratories is the date of publication of the regulations in the *Pennsylvania Bulletin.*

*Accreditation-by-rule:* Several commentators requested inclusion of additional tests or analyses, including Biological Oxygen Demand, and Total Suspended Solids under the accreditation-by-rule provision. Other commentators requested that specific types of environmental laboratories be included under the accreditation-by-rule provision or exempted from the regulation. Several commentators requested more flexibility by allowing individual cases where the intent of the law is being followed. The commentators suggested adding an exemption for a variety of other reasons.

Department Response: Because of the significance of these parameters in assessing environmental quality and because of the technical skills necessary to perform these tests correctly, these tests were not included under accreditation-by-rule. Differentiating between in house and commercial laboratories is not appropriate. The purpose of these regulations is to improve the quality of data for any testing or analysis of environmental samples that is required by the Department. Because these data are essential for making decisions that affect the environment and the public health, safety and welfare of the citizens of the Commonwealth, the Department believes these tests should not be included under the accreditation-by-rule provision. The Department does not agree that the location of the testing nor the firm or individual performing the testing should be the basis for inclusion under the regulations.

Several commentators indicated that major NPDES dischargers are already required to participate in the USEPA's annual Discharge Monitoring Report-Quality Assurance (DMRQA) Study. As long as an in-house lab (one that only performs analyses for its own facility's permit requirements) successfully performs the analytical procedures under the DMRQA program, it should be deemed accredited-by-rule.
Department Response: Successful performance on one Proficiency Test Sample per year (e.g. a DMRQA Study) is only one indicator that a laboratory is producing good quality data. A more thorough evaluation is necessary to insure that a laboratory is producing adequate quality data and is in conformance with all of the requirements of the laboratory accreditation regulation, the promulgated method, and all other applicable federal and State regulations. The accreditation process includes other aspects of data evaluation and an on-site review of the laboratory, which include, but is not limited to, consideration of facilities, personnel, equipment, methodology, quality assurance, record keeping, and performance.

Several commentators questioned the rationale for inclusion or exclusion of the analytical parameters under accreditation-by-rule.
Department response: The preamble to the proposed regulation indicated that to be considered for accreditation by rule the test would need to meet one of the criteria listed in the preamble. The LAAC agreed to these criteria following an extensive discussion of the merits of the proposed items. Tests proposed for inclusion under accreditation-by-rule were then evaluated against these criteria, especially with regard to the impact that an improperly performed test would have on the environment or the public health, safety and welfare. Short holding times, sample degradation during transport and non-instrumented tests were factors for consideration for inclusion of a particular test or analysis under accreditation-by-rule provided that mistakes in testing would not necessarily result in a significant threat of harm to the environment. The Department, in

conjunction with the LAAC, subsequently selected the accreditation-by-rule parameters included in the proposed regulation. The final-form regulation retains the original listing of parameters.

Two commentators indicated that §252.6(d) states that those tests not mandated by Department statute are accredited-by-rule. These regulations should not refer to tests and analysis not mandated by the PA-DEP. The scope of this regulation is to regulate only those tests mandated by specific environmental statutes.
Department Response: Discussion with individuals, advisory committees and other groups affected by this regulation indicated a need to clarify applicability of the regulation to this type of testing. In particular, testing for certain parameters may not be required by the Department. However if such a test is conducted, the results must be reported. Laboratories were concerned that they would be required to be accredited to perform these types of tests. Requests were made to emphasize this point in the regulation. This section was added and is being retained for additional clarification.

Two commentators requested that the accreditation-by-rule section be expanded to include all analyses or tests that are required by state or Federal laws, regulations, an order, or permit conditions.
Department Response: The Department strongly disagrees with the commentators, as the suggested exclusion would exempt in-house laboratories from accreditation requirements. The Department does not believe exclusion of these laboratories was the intent of the Act. The purpose of this regulation is to improve the quality of data for any testing or analysis of environmental samples that is required by the Department. Because these data are essential for making decisions that affect the environment and the public health, safety and welfare of the citizens of the Commonwealth, accreditation of the facilities performing this type of testing is appropriate. The Department does not agree that the location of the testing nor the firm or individual performing the testing should be the basis for inclusion under the accreditation-by-rule regulations.

*Mobile Laboratories:* Two commentators indicated that requiring separate accreditation for mobile laboratories convolutes the field testing process. One commentator asked whether individual accreditations would be required if the same entity owned multiple mobile laboratories. A commentator asked about the acceptability of a single individual acting as the laboratory supervisor for multiple mobile laboratories.
Department Response: Each laboratory would be considered as a separate environmental laboratory and would be required to maintain separate accreditation. Separate accreditation is required because a mobile laboratory would be expected to be operated independently of any

associated fixed facility and under a different quality manual and standard operating procedures. A mobile laboratory would not be required to apply for accreditation for each site or testing location. Accreditation of a mobile laboratory would include any methods or procedures for which it has demonstrated compliance with the requirements of Chapter 252. Even though the mobile laboratories are owned or operated by the same entity, they may be performing testing and analysis at geographically separate locations. A single individual could serve as the laboratory supervisor for more than one mobile laboratory provided the requirements of §252.301(g) are met. The Department does not think the regulation will be too burdensome for mobile laboratories.

*Fees:* Several commentators indicated that the fees were prohibitive and favored small, medium or large laboratories, depending upon the commentator. Several commentators indicated that the fee structure was difficult to understand or unnecessarily complex. Other suggested changes to the fee structure included charging a different fee for an initial and for a renewal application and basing the fee on the number of samples analyzed by the laboratory.

Department Response: After reviewing the comments regarding the fees and their structure, the Department reexamined the fee structure. As a result of some recently implemented and planned cost saving measures, including the use of newly developed database technology, the Department was able to make some changes to the fee structure. These changes include: charging a fee per category per matrix, thus eliminating the individual method charges; different fees for an initial application fee and a renewal application fee; reducing the fees for both basic drinking water and non-potable water categories; and adding categories that are combinations of several categories. All changes make fees more responsive to the unique needs of small, in-house environmental laboratories.

The Act requires that the fees be sufficient to pay the department's cost of implementing and administering the accreditation program. 27 Pa C.S. §4104(6). Based upon the Department's experience with the drinking water laboratory accreditation program, the cost of an accreditation program is related to the complexity of the analytical method and to the number of methods for which a laboratory is seeking accreditation. The fee structure distributes the costs accordingly. The number of samples analyzed by the laboratory does not affect the time required by Department staff to perform on-site evaluations, review proficiency test results, and perform other activities that are required for determining the accreditation status of a laboratory.

Several commentators indicated that the Consumer Price Index escalator is a circumvention of the regulatory process. Linking fee increases to the

changes in the CPI does not allow for consideration of actual program costs to determine the fee charged to the regulated community. The escalator does not account for any future changes in the scope of the accreditation program. The establishment and change of fees is a fundamental regulatory step. The purpose of the regulatory review process is to avoid unchallenged or hurried decision-making. The change of fees should be subject to full public disclosure. This language regarding an automatic escalator should be removed from the proposed rulemaking.
Department Response: The Department removed the section that links increasing fees based upon increases to the CPI.

*Out-of-State Laboratories:* Two commentators requested clarification about the time included in "travel time."
Department Response: Travel time only includes time spent traveling to and from the home office to the location of the out-of-State laboratory and does not include overnight time spent in a hotel before or after the assessment.

Several commentators indicated that the Department should consider reciprocating with other accreditation programs other than NELAP. These commentators suggested that the rulemaking should include language giving the Department the ability to recognize reciprocal accreditation when granted by a program with guidelines similar to those of the Commonwealth.
Department Response: Section 4104 (1) of the Act limits the recognition of other accreditation programs to Federal or State accreditation programs. Additionally, the National Environmental Laboratory Accreditation Conference Standard requires that an accrediting authority be a state or federal agency. The final-form regulation conforms to both the NELAC Standard and the Act.

One commentator requested clarification on the criteria the Department planned to use to evaluate other accreditation programs in order to determine if they are substantially equivalent and meet the statutory requirements.
Department Response: The Department will consider the following items to determine if a state accreditation program is substantially equivalent to the requirements of the regulation (§252.205(a)(2)(ii)): frequency and rigor of on-site evaluation; requirements for corrective action for deficiencies identified during the on-site evaluation; qualification requirements for laboratory supervisor and other laboratory personnel; proficiency test requirements; authority to deny, revoke, or suspend accreditation; record keeping requirements; quality manual requirements; and other quality control requirements. In accord with § 4104 (1) of the

Act, recognition of other accreditation programs will be limited to Federal or State accreditation programs.

*Laboratory Supervisor:* Two commentators suggested changes to the requirements regarding designation of an alternate laboratory supervisor when the designated supervisor is absent for greater than 15 days.
Department Response: An absence of a laboratory supervisor for greater than 15 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 does not believe that designation of an alternate supervisor imposes an unreasonable burden on a laboratory. To accommodate the situation when the laboratory supervisor is absent for 2-weeks vacation, including the initial and final weekends, the Department changed the final-form regulation to read greater than 16 days, 6 weekend days plus 10 weekdays.

Several commentators indicated that the notification requirements concerning changes in supervisors, analysts, supervisor/analyst relationships, testing or analysis equipment or facilities were overly burdensome.
Department Response: The Department modified the notification requirements to limit the notification requirement to changes to information provided on the application for accreditation.

Several commentators objected to the inclusion of a reference to the laboratory supervisor sub-classification for certified operators when the regulation delineating the requirements for the sub-classification does not exist.
Department Response: The provision § 252.302 (h)(2) and (3) is included because the regulation authorizing the sub-classification is in the regulatory development process and the Department expects that regulation will be submitted for consideration in the near future. There was no reason to postpone inclusion of this section. The section addresses the concerns of certified operators about being able to meet the formal educational requirements contained elsewhere in the regulations. Certified operators who meet the laboratory supervisor grandfather provision can continue to act as the laboratory supervisor.

*Personnel Requirements and Training:* One commentator asked: how will an environmental laboratory know that it has sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions? How will a laboratory know when it has satisfied this requirement? How will the requirement be enforced?

Department Response: A laboratory will have sufficient trained personnel when it is able to meet all quality control, documentation and reporting requirements of the regulation and the promulgated method. The Department will review the practices and procedures of the laboratory for conformance with the requirements of the regulation. Failure to analyze samples within required holding times, failure to maintain documentation, failure to perform required quality control, and failure to follow method requirements would be evidence of lack of sufficient trained personnel.

One commentator indicated that the requirements for the documentation required under § 252.304(b) (4) and (8) were vague. Both items should be expanded to describe what documentation is required.
Department Response: Other areas of the regulation contain more specific provisions that address the intent of §§ 252.304(b)(4) and 252.304(b)(8). The Department removed these sections from the final-form regulation. Changes were made to § 252.706 to clarify the records that an environmental laboratory must maintain.

Several commentators indicated the provisions for the ongoing demonstrations of capability for analysts go beyond the required quarterly QC samples and annual PTs. Requiring each member to be retested for proficiency in each method that a lab performs would be arduous. Repeated proficiency testing should only be required when there is a change in instrumentation or method.
Department Response: The Department strongly believes that demonstrating continued proficiency at least once every 12 months is a reasonable minimum. The analysts must only demonstrate continued proficiency for those tests he or she performs. This demonstration does not require analysis of purchased proficiency test samples. Options are provided that can easily be met by an individual that routinely performs a particular test or analysis. Specifically, the provision allowing for the use of four consecutive laboratory control samples would not add cost to the laboratory. Analyses of the laboratory control samples are necessary to meet other method and Chapter 252 requirements.

*Equipment:* Two commentators indicated the term visual comparison devices was vague and confusing.
Department Response: The Department agreed and replaced the term in the final-form regulation with spectrophotometer or colorimeter.

Two commentators indicated that the requirements for equipment calibration in § 252.306 were excessively specific. The commentators further indicated that the constant calibration and measurement of laboratory equipment is an unmanageable requirement that is equally

difficult to enforce. The commentators requested that the Department draft a simpler requirement.
Department Response: Specific requirements for some commonly used equipment are included to eliminate the need for guidance documents and eliminate questions of interpretation. Small laboratories also requested that all requirements be included in a single document for ease of use. The requirements in the regulation are very similar to the requirements contained in the *US EPA Manual for the Certification of Laboratories Analyzing Drinking Water*, 5th Edition, January 2005, and in *Standard Methods for the Examination of Water and Wastewater*. The Department has been determining compliance with these requirements, or similar requirements from earlier versions of the same documents, as a routine part of the current Drinking Water Laboratory Certification Program since 1984. The Department believes the requirements are both understandable and enforceable.

One commentator asked who was considered a "qualified person" to service an analytical balance.
Department Response: A qualified person is a person that has been trained to service and calibrate an analytical balance. Service companies employ individuals who are specifically trained in servicing and calibrating analytical balances.

*Methodology:* Several commentators indicated the prescriptive nature of determining analytical methods exceeds some of the requirements of federal regulation. The EPA does not approve methods for testing that fall under a performance based measurement system (PBMS). Section 252.307(b) requires the laboratory to comply with applicable State or Federal regulations when selecting an appropriate method. The EPA Office of Solid Waste has implemented a Performance-Based Measurement System (PBMS) for all analytical measurements conducted in support of the Resource Conservation and Recovery Act. The requirement of laboratories to comply with available DEP methods denies a laboratory the flexibility to select a method that is most appropriate for that particular sample. It greatly limits the ability of laboratories to implement new and emerging technologies to meet mandated reporting requirements. The Department should amend any sections referring to methodology to allow laboratories flexibility in determining the most appropriate methodology available to them through Performance Based Measurement System (PBMS). In addition, the prescriptive nature of determining methods violates the requirements of Executive Order 1996-1, which prohibits Pennsylvania's regulations from exceeding federal Standards without a compelling reason.
Department Response: The regulation does not violate the requirements of Executive Order 1996-1 because the Laboratory Accreditation Program

does not determine or specify which tests or methods are acceptable for use in a regulated program. Other programs within the Department or the US EPA are responsible for the promulgation of methods and guidelines limiting the use of methods. No additional limitations on the acceptable use of methods are contained in this regulation. The purpose of the Laboratory Accreditation Program is to ensure that when a test or methodology is specified, the environmental laboratory analyzes the sample properly. Wording has been added to Section 252.307(b)(2) to address situations that require use of a method considered appropriate for use.

One commentator asked how a laboratory would apply for permission to use an alternative procedure, the criteria for evaluation, the process for appeal, and the mechanism for notification of the laboratory.
Department 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 various formats that are appropriate for the test method and analyte. The method for validation of an alternate or experimental procedure is dependant upon the analyte. The Department will utilize the USEPA Guidelines, e.g. *Protocol for EPA Approval of Alternate Test Procedures for Organic and Inorganic Analytes in Wastewater and Drinking Water* (EPA 821-B-98-002, March 1999), where available and when appropriate. A decision to allow or disallow an alternative or experimental procedure would be appealed to the Environmental Hearing Board. The Department will notify the laboratory by mail of its decision.

*Records and Recordkeeping:* Several commentators questioned the need to maintain records for five years when most NPDES permits only require that records be maintained for three years. On-site captive laboratories should be allowed to follow the record keeping requirements of the permit for which the tests are made.
Department Response: The Department believes the maintenance of historical laboratory records is essential to data integrity. Requiring that an environmental laboratory maintain records for 5 years helps to insure that historical records will be available to reconstruct important and vital environmental data. Under some regulations, for example the drinking water program, the permit holder is only required to retain a summary of the results.

Three commentators indicated that there is no need for in-house captive laboratories to have a written procedure to transfer and assure maintenance of records if there is a change in ownership. Normally, the former permittee for whom the tests were conducted (the seller) must retain records covering their period of operation.

Department Response: The Department believes the maintenance of historical laboratory records is essential to data integrity. The procedure for the transfer of laboratory records may reference or be linked to the plan for transfer and maintenance of records of the parent facility in the event of a sale or closure. The plan could include transferring the records to the new owner or indicate that the seller would retain the responsibility for maintenance of the records.

*Chemistry Quality Control Requirements:* One commentator requested clarification for the term "out-of-control" as the term is used in §252.401(i)(4).
Department Response: The Department does not believe that an additional clarification for the term "out-of-control" is required. This term is well understood by environmental laboratory personnel. An out-of-control situation is identified as any situation that does not conform to the requirements and/or expectations of the analytical method, regulation, or Chapter 252 requirements. Examples would include, but not be limited to, failed quality control, failed calibration curve, and retention time shifts outside established retention time windows.

*Toxicity Testing Quality Control Requirements:* One commentator suggested that for clarity the Laboratory Accreditation regulations should cross reference the guidance documents regarding the counting of neonates, algae cells and weighing of fish for selected endpoints. Also, the commentator indicated that the size requirements for an incubator should be clearer regarding the meaning of "refrigerator-sized".
Department Response: The Department agrees with the commentator and appropriate changes were made to the final-form regulations.

*Radiochemistry Quality Control Requirements:* One commentator questioned if there may be situations where the method and regulations would differ with regard to acceptance criteria for instrument suitability standards. §252.405(d)(8).
Department Response: Yes, there may be situations where the regulations impose different, and more stringent requirements, than the method. For example, the USEPA drinking water program often establishes very specific quality control requirements in regulation that exceed the requirements of the promulgated method. In that instance, the Federal program regulation requirements would take precedence.

*Coordination with other Regulations:* One commentator pointed out that the preamble to the proposed regulation indicated that the requirements found in Subchapter H of 25 Pa. Code Chapter 109 will be deleted and

moved to this regulatory package. The proposed rulemaking did not include deletion of Chapter 109 requirements.
Department Response: It has clearly been the intent of the Department that this regulation would replace and supercede the provisions of Subchapter H of 25 Pa Code Chapter 109, that describe the requirements of the laboratory certification. Appropriate changes to Chapter 109 are included in the final rulemaking package. The Department is also proposing similar changes to Chapter 78 to avoid any potential conflict or confusion.

## G. Benefits, Costs, and Compliance

### Benefits

The most significant benefit of the final-form rulemaking will be 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 this Commonwealth to make better decisions concerning the protection of the environment and protecting public health, safety and welfare. Accurate laboratory results are critical to achieving the goals of the environmental laws.

It is difficult to quantify the benefits of Chapter 252 in specific dollar amounts. One approach to partially quantify the benefit is to examine the extra costs associated with unacceptable data. Fines assessed against environmental laboratories guilty of producing fraudulent data or of producing data that does not meet the regulatory requirements range from several thousand dollars to over $9 million. These fines reflect the amount of harm done to the environment or to public health by poorly operated laboratories. When an environmental laboratory fails to provide accurate and valid data, additional testing and analysis and costly remediation is often required. This environmental laboratory accreditation program is a proactive approach designed to prevent problems before they become critical and responds to the mandate given by the General Assembly to the Department.

### Compliance Costs

An environmental laboratory that is accredited-by-rule will incur no additional compliance costs. For other environmental laboratories, the direct costs for compliance will be payment of the required fees and the purchase of PT samples. 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 $850 to $13,600. The cost for the PT samples range from less than $100 to approximately $13,000. The

Department believes that the accreditation requirements 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.

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. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. Additionally, it has been the Department's experience in the drinking water laboratory accreditation program that accreditation is affordable for many small laboratories. Many small and municipal laboratories have met similar requirements under the Drinking Water Program regulations in Chapter 109.

Laboratories performing testing in the wastewater program are already required to use approved methods, many of which have requirements similar to this final-form rulemaking. Also, many of the laboratories performing testing in the wastewater program currently participate in PT studies.

**Compliance Assistance Plan**

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. These areas, as well as others yet to be identified, will be provided to all environmental laboratories regardless of size or location within this Commonwealth. Several different ways of providing assistance have been identified.

The Department will develop a compliance guide to help an environmental laboratory understand the compliance requirements associated with any final-form or newly adopted regulations. Initially, the compliance guide would be tailored to the smallest wastewater and drinking water environmental laboratories because these laboratories are expected to be the least familiar with the requirements of a laboratory accreditation program. The guide would address the requirements for the basic testing performed by these smaller laboratories. Eventually the compliance guide may be expanded to larger laboratories. Additionally, the Department will develop and provide formal training courses or seminars that would assist environmental laboratories as they prepare for accreditation.

The training courses or seminars would present information that would be applicable to all environmental laboratories, regardless of size and would be presented across this Commonwealth at numerous locations. Possible sites include the Department's laboratory and regional and district offices, colleges or universities, hotels and other training facilities. The seminars and courses may be presented in conjunction with existing organizations, such as the Pennsylvania Rural Water Association, the Pennsylvania Association of Accredited Environmental Laboratories and the Pennsylvania Municipal Authorities Association.

Finally, a periodic newsletter may also be developed to provide updates about the environmental laboratory accreditation program in this Commonwealth. The Department may also expand the use of technology-based solutions to provide additional mechanisms for asking for and receiving assistance. Possible mechanisms for providing and making compliance assistance materials available include the use of the Department's website, e-mail and a toll-free telephone number.

**Paperwork Requirements**

An application for accreditation must be submitted each year. On the application for accreditation, the environmental laboratory will be asked to supply the Department with information about the laboratory supervisor, the areas for which accreditation is being requested and basic information about the environmental laboratory, such as the address, telephone number and hours of operation.

An environmental laboratory will be required to follow specific recordkeeping procedures. An environmental laboratory is required to maintain documentation that describes the testing and analysis performed and to permit a scientist to reconstruct all activities associated with producing the reported result. The environmental laboratory shall maintain the records for a minimum of 5 years and the laboratory shall have a written plan that specifies how records will be maintained or transferred in the event that the laboratory transfers ownership or terminates operations.

Basic documentation includes a document describing the policies and procedures that an environmental laboratory instituted to insure the production of good quality data. This document is generally referred to as a quality manual. An environmental laboratory is also required to maintain standard operating procedures ("SOPs") describing how the laboratory performs the test or analysis. The quality manual and SOPs may be separately prepared documents, a copy of a standard policy or procedure or a cut and paste copy of a method or manual. The only specific requirement is that it accurately reflects and fully describes the operation of the environmental laboratory. Thus, small laboratories that perform a

limited number of tests will only need to develop a quality manual and SOPs suited to their particular circumstances. In addition to assuring quality data and consistency among analysts, these documents may provide significant benefits to small laboratories in the event of staff turnover because the "institutional memory" of the laboratory will be preserved.

**H. Pollution Prevention**

These regulations will neither promote nor discourage a multi-media pollution prevention approach. Essentially all of the procedures or methods used for testing or analysis have a pollution prevention component incorporated into them. These regulations will assure that the laboratories are following the promulgated methods. These regulations do contain a mechanism for the approval of alternate methods that use new or innovative technologies on a case-by-case basis. Innovative technologies often use less chemicals and therefore effectively work to reduce the amount of hazardous waste generated resulting in pollution prevention.

**I. Sunset Review**

The final-form rulemaking 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.

**J. Regulatory Review**

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 20, 2004, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees. A copy of this material is available to the public upon request.

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

**K. 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 24)(45 P.S. §§1201 and 1202) and regulations promulgated thereunder at 1 *Pa 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 35 *Pa Bulletin* 519 (January 22, 2005).
(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

**L. Order of the Board**

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

(a) The regulations of the Department of Environmental Protection, 25 *Pa. Code*, Chapters 78, 109 and 252 are amended by amending sections 78.1, 78.52, 78.141 through 78.146, 109.801 through 109.810 and by adding Chapter 252 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 certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.
(d) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin.*

KATHLEEN A. MCGINTY,
Chairperson

## Annex A

# TITLE 25. ENVIRONMENTAL PROTECTION

## PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

### Subpart C. Protection of Natural Resources

### ARTICLE I. Land Resources

### CHAPTER 78 Oil and Gas Wells

Subchapter A. GENERAL PROVISIONS

§ 78.1. Definitions.

*Certified laboratory*—A laboratory [~~certified~~ ]ACCREDITED by the Department under [~~Subchapter F (relating to certified laboratories)~~]25 PA. CODE CHAPTER 252 (RELATING TO LABORATORY ACCREDITATION).

**Subchapter C. ENVIRONMENTAL PROTECTION PERFORMANCE STANDARDS**

**§ 78.52. Predrilling or prealteration survey.**

(a) A well operator who wishes to preserve its defense under section 208(d)(1) of the act (58 P. S. § 601.208(d)(1)) that the pollution of a water supply existed prior to the drilling or alteration of the well shall cause a predrilling or prealteration survey to be conducted in accordance with this section.

(b) A person who wishes to document the quality of a water supply to support a future claim that the drilling or alteration of the well affected the water supply by pollution may conduct a predrilling or prealteration survey in accordance with this section.

(c) The survey shall be conducted by an independent **CERTIFIED** laboratory [~~hat has been certified by the Department under Subchapter F (relating to certified laboratories)~~]. A PERSON INDEPENDENT OF THE WELL OWNER OR WELL OPERATOR, OTHER THAN AN EMPLOYEE OF THE CERTIFIED LABORATORY, MAY COLLECT THE SAMPLE AND DOCUMENT THE CONDITION OF THE WATER SUPPLY, IF

THE CERTIFIED LABORATORY AFFIRMS THAT THE SAMPLING AND DOCUMENTATION IS PERFORMED IN ACCORDANCE WITH THE LABORATORY'S APPROVED SAMPLE COLLECTION, PRESERVATION AND HANDLING PROCEDURE AND CHAIN OF CUSTODY.

## Subchapter F. CERTIFIED LABORATORIES

RESERVED

[~~See.~~

~~78.141. Scope.~~
~~78.142. Laboratory certification.~~
~~78.143. Application for certification.~~
~~78.144. Standards for certification.~~
~~78.145. Laboratory inspections.~~
~~78.146. Suspension or revocation of certification.~~

### ~~§ 78.141. Scope.~~

~~This subchapter governs the certification of laboratories to perform the predrilling or prealteration survey under § 78.52 (relating to predrilling or prealteration survey) and section 208 of the act (58 P. S. § 601.208).~~

### ~~§ 78.142. Laboratory certification.~~

~~(a) The laboratory shall be certified for each parameter analyzed in the category of oil and gas it reports in the predrilling or prealteration survey.~~

~~(b) The laboratory shall conduct the predrilling or prealteration surveys and perform the analysis in accordance with the requirements of this subchapter and the conditions of the certification. A person independent of the well owner or well operator other than an employe of the certified laboratory may collect the sample and document the condition of the water supply, if the laboratory affirms that the sampling and documentation is performed in accordance with the laboratories' approved sample collection, preservation and handling procedure and chain of custody under § 78.144 (relating to standards for certification).~~

~~(c) The Department may certify a laboratory to perform analyses for parameters other than those listed in the category of oil and gas.~~

~~§ 78.143. Application for certification.~~

~~(a) A laboratory may apply for certification on a form provided by the Department.~~

~~(b) In its application, the laboratory shall provide information to enable the Department to determine compliance with the standards, requirements and purpose of this chapter, including the following information:~~

~~(1) A description of the experience and job function of laboratory personnel.~~

~~(2) A description of the laboratory facility, equipment and supplies.~~

~~(3) A description of the analytical methods for each parameter.~~

~~(4) A quality assurance plan.~~

~~(5) A description of sample collection, preservation and handling procedures.~~

~~(6) A description of the chain of custody procedures.~~

~~§ 78.144. Standards for certification.~~

~~(a) Certification will be based on the applicant's demonstration of compliance with guidelines issued by the Department or alternate procedures that produce equal or better results, and the following:~~

~~(1) The laboratory is capable of routinely generating analytical data that are scientifically valid and enforceable and are of known and acceptable precision and accuracy.~~

~~(2) The laboratory employs sufficient trained, experienced personnel who perform the analysis and conduct the survey.~~

~~(3) The laboratory has the necessary facilities, equipment and supplies to perform the analysis and conduct the survey.~~

~~(4) The laboratory uses approved quality assurance procedures.~~

~~(5) The laboratory uses approved sample collection, handling and preservation procedures.~~

~~(6) The laboratory uses an approved chain-of-custody procedure.~~

~~(7) At least once a year, the laboratory successfully completes at least one set of performance evaluation samples required by the Department for the parameters for which certification is sought.~~

~~(8) If an inspection is conducted, the laboratory undergoes an onsite inspection in which the Department deems the laboratory to be satisfactory.~~

~~(9) The operator of the laboratory is willing and competent to perform the functions of a certified laboratory as required by this subchapter.~~

~~(b) The evaluation for certification will include consideration of facilities, personnel, equipment, methodology, quality assurance and performance.~~

~~§ 78.145. Laboratory inspections.~~

~~As part of the certification procedures, the Department may conduct an inspection of the laboratory and its facilities. Additional inspections may be made during the term of the certification to ensure that the laboratory is in compliance with the certification requirements and in response to a complaint or if information is received that the laboratory is in violation of the certification requirements.~~

~~§ 78.146. Suspension or revocation of certification.~~

~~A laboratory certification may be suspended or revoked for due cause, which includes one or more of the following:~~

~~(1) Violation of a condition of the certification.~~

~~(2) Violation of this subchapter.~~

~~(3) Misrepresentations made to the Department.~~

~~(4) Falsifying analysis, selectively reporting data, submitting false results or engaging in other unethical or fraudulent practices.~~

~~(5) Failure to notify the Department of substantial changes in personnel, facilities or equipment.~~

~~(6) Failure to participate in the analysis of a set of performance evaluation samples.~~

~~(7) Unacceptable performance evaluation samples results in two consecutive series of tests for the same parameter.~~

~~(8) Failure to satisfactorily complete performance evaluation samples required by the Department at least once a year, or as required by the Department.~~

~~(9) Status of personnel, equipment, procedures or work quality demonstrates that the laboratory no longer satisfies the certification requirements.~~

~~(10) Refusal to allow inspection, obstruction, delay or threats to an agent of the Department in the performance of an inspection of the laboratory, documents and records relating to the requirements of this subchapter.~~]

## ARTICLE II. Water Resources

## CHAPTER 109 Safe Drinking Water

**Subchap.**

### Subchapter H. LABORATORY CERTIFICATION

Sec.



### § 109.801. Certification requirement.

A laboratory shall be [~~certified~~ ]ACCREDITED under this [~~subchapter~~] 25 PA. CODE CHAPTER 252 (RELATING TO LABORATORY ACCREDITATION) to perform analyses acceptable to the Department for the purposes of ascertaining drinking water quality and demonstrating compliance with monitoring requirements established in Subchapter C (relating to monitoring requirements).

[~~(1) The drinking water quality parameters for which general monitoring is prescribed under Subchapter C are divided into the certification categories of microbiological contaminants, inorganic chemicals, organic chemicals and radionuclides. The categories are further divided into subcategories.~~

~~(2) A laboratory may apply for and obtain certification in one or more of the certification categories or subcategories. The laboratory shall demonstrate competence to analyze all parameters in the category or subcategory for which certification is sought.~~

~~(3) A parameter of drinking water quality for which no MCL, MRDL or monitoring requirement of general applicability has been established may be part of a certification subcategory.~~]

## § 109.802. Application and supporting documents.

RESERVED

[~~The owner of a laboratory in this Commonwealth who seeks certification for one or more of the certification categories described in § 109.803 (relating to fees), or who seeks to add a category shall apply to the Department for certification on forms approved by the Department. The applicant shall provide other relevant information requested by the Department.~~]

## § 109.803. Fees.

RESERVED

[~~(a) The application for certification shall be accompanied by the appropriate fee in accordance with the following schedule. The fee for one or more subcategories within a category is the same as the fee for the category. A check shall be payable to the "Commonwealth of Pennsylvania." A laboratory owned or operated by a State regulatory agency is exempted from this fee requirement, but shall apply for certification under this chapter.~~

| *Certification Category* | *Fee* |
|---|---|
| (1) Inorganic chemicals | $ 800 |
| (2) Organic chemicals | $1,000 |
| (3) Inorganic and organic chemicals | $1,350 |
| (4) Microbiological contaminants | $ 800 |
| (5) Radionuclides | $1,300 |

(b) In addition to the appropriate fee, out-of-State laboratories shall reimburse the Department for out-of-State travel related expenses necessitated by the certification.]

## § 109.804. Laboratory inspections.

RESERVED

[The laboratory will undergo an initial inspection conducted by the Department or its agent as part of the certification procedure. A certified laboratory will be reinspected at least once every 3 years by the Department or its designee. Additional inspections may be required at the discretion of the Department. Owners and operators of laboratories shall make an effort to aid inspectors in scheduling and conducting inspections of laboratories.]

## § 109.805. Certification procedure.

RESERVED

[(a) After the Department receives a completed application accompanied by the applicable fee under § 109.803 (relating to fees), the Department may schedule an onsite inspection of the laboratory.

(b) The laboratory shall successfully complete at least one set of proficiency test samples required by the Department for the parameters in the category for which certification is sought. Acceptable tolerances of analyses of proficiency test evaluation samples shall be as stated by the EPA in 40 CFR Part 141 (relating to national primary drinking water regulations) or the "National Standards For Water Proficiency Testing, Criteria Document." For parameters not included in either document the acceptance limits shall be those established by the Department.

(c) The Department may grant administrative approval to a currently certified laboratory which has submitted a complete

~~application for renewal of an existing certification, and the appropriate fee, and has successfully completed a performance sample for a previously uncertified subcategory before final certification is issued for that new subcategory. Analyses performed by a laboratory with administrative approval satisfy the requirements of this chapter. The Department may revoke an administrative approval at any time for just cause.~~

~~(d) The laboratory shall conspicuously display an administrative approval or certification issued to the laboratory by the Department under this subchapter.~~

~~(e) In addition to terms and conditions in the certification issued to a laboratory, the certified laboratory shall fulfill the following requirements to maintain certification:~~

~~(1) The laboratory shall notify the Department within 30 days of major changes in personnel, personnel assignments, equipment and facilities which affect accredited procedures. The Department may require additional information or proof of continued capability to perform the certified category of analyses. For the purposes of this subsection, personnel include laboratory supervisors and trained, experienced analysts.~~

~~(2) The laboratory shall have a satisfactory onsite inspection at least once every 3 years.~~

~~(3) The laboratory shall successfully complete at least one set of proficiency test samples required by the Department at least once every 12 months.~~

~~(4) The laboratory shall submit results of test measurements or analyses performed by the laboratory under this chapter in accordance with § 109.810 (relating to reporting and notification requirements).~~]

## § 109.806. Standards for certification.

RESERVED

~~[The certification will be based upon compliance with Departmental guidelines and the minimum criteria contained in the most current edition of the *Manual for the Certification of Laboratories Analyzing Drinking Water* published by the EPA. The evaluation for certification will include, but is not limited to, consideration of facilities, personnel,~~

~~equipment, methodology, quality assurance, performance, recordkeeping, reporting and notification.~~]

## § 109.807. Disposition of application for certification.

RESERVED

[~~The Department will consider the application, results of inspections and the performance evaluation samples, and other information relevant to the capability of the laboratory to reliably perform the analyses for which certification is sought. For the certification category included in the application, the Department will either issue a certification or administrative approval or will deny certification and provide the applicant with a written explanation of the basis for the denial. A certification or administrative approval is valid for 1 year from the date of issuance, unless otherwise indicated on the certificate.~~]

## § 109.808. Renewal of certification.

RESERVED

[~~Applications for renewals of certification shall be submitted annually to the Department at least 60 days prior to the expiration of the laboratory's certification. Applications shall be made under § 109.805 (relating to certification procedure) and shall be accompanied by the applicable fee listed in § 109.803 (relating to fees).~~]

## § 109.809. Revocation of certification.

RESERVED

[~~Certification may be revoked for due cause, including, but not limited to, the following:~~

~~(1) Violation of a condition of the certification.~~

~~(2) Violation of a statute, this title or an order of the Department or its agent.~~

~~(3) Misrepresentation made to the Department or its agent.~~

~~(4) Falsifying analyses, selectively reporting data or engaging in other unethical or fraudulent practices.~~

~~(5) Failure to notify the Department under § 109.805(e)(1) (relating to certification procedure) of substantial change in personnel, facilities or equipment.~~

~~(6) Failure to participate in the analysis of a set of performance evaluation samples or arrange for timely onsite laboratory inspection at the designated intervals.~~

~~(7) Unacceptable performance evaluation sample results in two consecutive series of tests for the same parameter, which will result in decertification for that category until the laboratory analyzes at least one performance evaluation sample with acceptable results and submits an explanation for the previous unsatisfactory performance.~~

~~(8) Analysis of performance evaluation samples by personnel other than the analysts associated with the routine analysis of monitoring samples in the laboratory.~~]

## § 109.810. Reporting and notification requirements.

(a) A laboratory [~~certified~~ ]ACCREDITED under [~~this subchapter~~]25 PA CODE CHAPTER 252 (RELATING TO LABORATORY ACCREDITATION) shall submit to the Department, on forms provided by the Department, the results of test measurements or analyses performed by the laboratory under this chapter. Unless a different reporting period is specified in this chapter, these results shall be reported within either the first 10 days following the month in which the result is determined or the first 10 days following the end of the required monitoring period as stipulated by the Department, whichever is shorter.

(b) A laboratory [~~certified~~ ]ACCREDITED under [~~this subchapter~~]CHAPTER 252 shall whenever an MCL, MRDL or a treatment technique performance requirement under § 109.202 (relating to State MCLs, MRDLs and treatment technique requirements) is violated, or a sample result requires the collection of check samples under § 109.301 (relating to general monitoring requirements):

(1) Notify the public water supplier by telephone within 1 hour of the laboratory's determination. If the supplier cannot be reached within that time, notify the Department by telephone within 2 hours of the determination. If it is necessary for the laboratory to contact the Department after the Department's routine business hours, the laboratory shall contact the appropriate Department regional office's after-hours emergency response telephone number and provide information regarding the occurrence, the name of a contact person and the telephone number where that individual may be reached in the event further information is

needed. If the Department's appropriate emergency number cannot be reached, the laboratory shall notify the appropriate Department regional office by telephone within 1 hour of the beginning of the next business day. Each certified laboratory shall be responsible for the following:

(i) Obtaining and then maintaining the Department's current after-hours emergency response telephone numbers for each applicable regional office.

(ii) Establishing or updating a standard operating procedure by November 8, 2002, and at least annually thereafter to provide the information needed to report the occurrences to the Department. The information regarding the public water system shall include, but is not limited to, the PWSID number of the system, the system's name, the contaminant involved in the occurrence, the level of the contaminant found, where the sample was collected, the dates and times that the sample was collected and analyzed, the name and identification number of the certified laboratory, the name and telephone number of a contact person at the laboratory and what steps the laboratory took to contact the public water system before calling the Department.

(2) Notify the appropriate Department district office in writing within 24 hours of the determination. For the purpose of determining compliance with this requirement, the postmark, if the notice is mailed, or the date the notice is received by the Department, whichever is earlier, will be used. Upon approval by the Department, the notice may be made electronically to the Department as long as the information is received within the 24-hour deadline.

~~[(c) A laboratory certified under this subchapter shall notify the Department within 48 hours of termination of the laboratory certification from the EPA or another agency with primary enforcement responsibility.~~

~~(d) A laboratory shall notify the public water supplier served by the laboratory within 48 hours of the following:~~

~~(1) A failure to renew or Department denial of renewal of existing certification for a category of certification.~~

~~(2) Revocation of certification by the Department under this subchapter.]~~

# Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

# ARTICLE VI. GENERAL HEALTH AND SAFETY

# CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION

**Subchap.**



## Subchapter A. GENERAL PROVISIONS

Sec.



### § 252.1. Definitions.

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

*Acceptance criteria*--Specified limits placed on a measurement, quality control sample or process.

*Accreditation*--A determination by the Department that an environmental laboratory is capable of performing one or more classes of testing or analysis of environmental samples in accordance with the act and this chapter.

*Accreditation-by-rule*--Accreditation which an environmental laboratory is deemed to have for the fields of accreditation identified in § 252.6 (relating to accreditation-by-rule) upon compliance with that section.

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

*Act*--27 Pa.C.S. §§ 4101--4113 (relating to environmental laboratory accreditation).

*Analysis day*--A continuous 24-hour period during which testing or analysis of environmental samples is performed.

*Analyst*--An individual who performs the analytical methods and associated techniques and who is responsible for applying the required laboratory practices and quality controls to meet the required level of quality.

*Analyte*--The component, compound, element or isotope to be identified or quantified using a test or analysis.

*Batch*--Environmental samples that are prepared or analyzed together using the same procedures, personnel, lots of reagents and standards.

*Batch, analytical*--A batch composed of prepared environmental samples that are analyzed together as a group. An analytical batch may contain samples originating from various environmental matrices and can exceed 20 samples.

*Batch, preparation*--A batch composed of 1 to 20 environmental samples of the same matrix with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours.

*Calibration verification standard*--A standard used to confirm the validity of a previously performed initial calibration of a measurement process.

*Certificate of accreditation*--A document issued by the Department certifying that an environmental laboratory has met standards for accreditation.

*Commonwealth agency*--An agency that is a Commonwealth agency as that term is defined under 62 Pa.C.S. § 103 (relating to definitions.)

~~[*Confirmation*--Verification of the identity of an analyte through the use of a test or analysis using a different scientific principle from the original test or analysis.]~~

*Deficiency*--A deviation from acceptable procedures or practices.

*Detection limit*--The lowest concentration or amount of the target analyte that can be identified, measured and reported with confidence that the analyte concentration is not zero.

*Drinking water*--Any aqueous sample that has been collected for the purposes of demonstrating compliance with the Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1--721.17) or is from a potable or potential potable water source.

*ECp--Effective concentration percent*--The concentration that affects the test variable at p percent from the control value.

*Environmental laboratory*--A facility engaged in the testing or analysis of environmental samples.

*Environmental sample*--A solid, liquid, gas or other specimen taken for the purpose of testing or analysis as required by an environmental statute.

*Environmental statute*--A statute administered by the Department relating to the protection of the environment or of public health, safety and welfare.

*Facility*--A sole proprietor, partnership, corporation, association, institution, cooperative enterprise, municipal authority, political subdivision, Federal government or agency, state institution or agency or other legal entity which is recognized by law as the subject of rights and duties.

*Field of accreditation*--A combination of matrix; method or technology, or both; and analyte or analyte group for which an environmental laboratory may be accredited. Examples are:

(i) Nonpotable water; GC/MS, US EPA Method 625; benzo(a)pyrene.

(ii) Drinking water; ICP, US EPA Method 200.7; magnesium.

(iii) Drinking water; GC/MS, US EPA Method 524.2; total trihalomethanes.

*Holding time*--The maximum elapsed time from sample collection to initiation of testing or analysis.

*ICp*--Inhibition concentration percent--The concentration that inhibits the test variable at p percent from the control value.

*Industrial wastewater treatment facility*--Any facility that treats industrial waste or pollution, but not sewage, as those terms are defined in The Clean Streams Law (35 P. S. §§ 691.1--691.1001).

*Initial calibration*--Determination by measurement or comparison with a standard of known concentration the correct value or response of each scale reading on a meter, instrument or other device. Comparison of a measurement standard or instrument with another standard or instrument to report or eliminate by adjustment any variation in the accuracy of the item being compared.

*Initial demonstration of capability*--A procedure to establish the ability of an analyst, technical staff member or work cell to generate data of acceptable accuracy and precision.

*LCp*--Lethal concentration percent--The concentration that is lethal to p percent of the test organisms from the control organisms.

*Laboratory control sample*--A sample of a controlled matrix known to be free of the analyte of interest, to which a known and verified concentration of analyte has been added and that is taken through all preparation and analytical steps in the method.

*Laboratory management*--

(i) The individuals responsible for the overall operation, all personnel and the physical plant of an environmental laboratory.

(ii) The term includes the laboratory supervisor.

*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.**

*Laboratory supervisor*--A technical supervisor of an environmental laboratory who supervises laboratory procedures and reporting of **ANALYTICAL** data.

*Linear range*--The range of concentrations over which the instrument response is directly proportional to the analyte concentration.

*MCL--Maximum Contaminant Level*--The maximum permissible level of a contaminant in water which is delivered to a user of a public water system, and includes the primary and secondary MCLs established under the Safe Drinking Water Act (42 U.S.C.A. §§ 300f--300j-10) and MCLs adopted under the Pennsylvania Safe Drinking Water Act and the regulations promulgated thereunder.

*Matrix* or *matrices*--The media of an environmental sample that includes drinking water, nonpotable water, and solid and chemical materials.

*Matrix spike*--A sample prepared by adding a known mass of target analyte to a specified amount of environmental sample **AND THAT IS TAKEN THROUGH ALL PREPARATION AND ANALYTICAL STEPS IN THE METHOD**.

*Method*--The scientific technique used to perform testing or analysis on an environmental sample.

*Method blank*--A sample of a known matrix, similar to the associated samples, and known to be free of the analyte of interest **AND THAT IS TAKEN THROUGH ALL PREPARATION AND ANALYTICAL STEPS IN THE METHOD**.

*Mobile laboratory*--

(i) A portable enclosed structure within which testing or analysis of environmental samples occurs.

(ii) Examples include trailers, vans and skid-mounted structures configured to house environmental testing equipment and personnel.

*NELAC*--National Environmental Laboratory Accreditation Conference.

*NELAP*--National Environmental Laboratory Accreditation Program.

*NELAP accrediting authority*--An accrediting authority that has been recognized as meeting the requirements of the NELAC standards and has the authority to grant NELAP accreditation.

*NIST*--The National Institute of Standards and Technology of the United States Department of Commerce's Technology Administration.

*NOAEC*--No observed adverse effect concentration.

*NOEC*--No observed effect concentration.

*Negative culture control*--An organism selected to demonstrate that the medium does not support the growth of nontarget organisms or does not demonstrate the typical positive reaction of the target organisms.

*Nonpotable water*--Any aqueous sample excluded from the definition of drinking water matrix. The term includes wastewater, ambient water, surface water, groundwater, effluents, water treatment chemicals and toxicity characteristic leaching procedure or other extracts.

*Positive culture control*--An organism selected to demonstrate that the medium can support the growth of the target organisms and that the medium produces the specified or expected reaction to the target organism.

*Primary accreditation*--Accreditation received from the Department that is not based upon accreditation from another accrediting authority.

*Proficiency test study*--A sample or group of samples, the composition of which is unknown to the environmental laboratory and the analyst.

*Promulgated method*--A protocol for testing or analysis of a specific analyte that is approved for use by a State or Federal regulation.

*Quality manual*--A document stating, or making reference to, the policies, objectives, principles, responsibilities, accountability, implementation plans, methods, operating procedures or other documents of an environmental laboratory for ensuring the quality of its testing and analysis.

*Quantitation limit*--The minimum concentration or activity of the component, compound, element or isotope that can be reported with a specified degree of confidence. Typically it is the concentration that produces a signal ten standard deviations above the reagent water blank signal.

*Range of quantitation*--The concentration range between which an environmental laboratory reports results quantitatively which is defined by a low concentration standard and a high concentration standard.

*Reagent water*--Water with no detectable concentration of the component, compound, element or isotope to be analyzed and that is free of substances that interfere with the method. Reagent water may be prepared by distillation, ion exchange, adsorption, reverse osmosis or a combination thereof.

~~[*Relative standard deviation*--The coefficient of variation expressed as a percentage.]~~

*Revocation*--Removal by the Department of one or more fields of accreditation from an environmental laboratory.

*Sample duplicate*--Replicate aliquots of the same sample taken through the entire analytical procedure.

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

*Solid and chemical materials*--Soils, sediments, sludges, solid waste, drill cuttings, overburden, minerals, coal ash, and products and by-products of an industrial process that result in a matrix that is not otherwise defined.

*Solid waste*--Any waste, including, but not limited to, municipal, residual or hazardous wastes, including solid, liquid, semisolid or contained gaseous materials as that term is defined in the Solid Waste Management Act (35 P. S. §§ 6018.101--6018.1003).

*SPIKE*--A KNOWN AND VERIFIED MASS OR ACTIVITY OF THE TARGET ANALYTE OF INTEREST ADDED TO REAGENT WATER OR ENVIRONMENTAL SAMPLE IN ORDER TO DETERMINE RECOVERY EFFICIENCY OR FOR OTHER QUALITY CONTROL PURPOSES.

*Standard operating procedure*--A written document that provides detailed instructions for the performance of all aspects of test, analysis, operation or action.

*SURROGATE*--A SUBSTANCE WITH PROPERTIES SIMILAR TO THE ANALYTE OF INTEREST. A SURROGATE IS UNLIKELY TO BE FOUND IN AN ENVIRONMENTAL SAMPLE. A SURROGATE IS ADDED TO AN ENVIRONMENTAL SAMPLE PRIOR TO ALL PREPARATION AND ANALYTICAL STEPS IN THE METHOD FOR QUALITY CONTROL PURPOSES.

*Suspension*--The temporary removal by the Department of one or more fields of accreditation from an environmental laboratory for a period not to exceed 6 months.

*Technical staff*--Employees of an environmental laboratory that perform any portion of testing or analysis of environmental samples, including the analysts of the environmental laboratory.

*Test*--A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

*Wastewater*--A substance that contains the waste products or excrement or other discharge from the bodies of human beings or animals and noxious or deleterious substances being harmful or inimical to the public health, or to animal or aquatic life, or to the use of water for domestic water supply or for recreation, or which constitutes pollution under The Clean Streams Law.

*Wastewater facility*--A facility that operates a system designed to collect, convey or treat wastewater and from which effluent is discharged into waters of this Commonwealth.

*Work area*--The areas in an environmental laboratory necessary for testing and analysis and related activities. These areas include sample receipt area, sample storage area, chemical and waste storage area, data handling area and analytical areas.

*Work cell*--A defined group of analysts that together perform testing or analysis of environmental samples.

## § 252.2. Purpose.

The purpose of this chapter is to protect public health, safety, welfare and the environment by ensuring the accuracy, precision and reliability of data generated by environmental laboratories by establishing an accreditation program for environmental laboratories.

## § 252.3. Scope.

(a) *Environmental statutes.* This chapter applies to facilities that test or analyze environmental samples in the matrices listed in subsection (b) for the purpose of complying with following environmental statutes:

(1) The Oil and Gas Act (58 P. S. §§ 601.101--601.605).

(2) The Clean Streams Law (35 P. S. §§ 691.1--691.1001).

(3) The Hazardous Sites Cleanup Act (35 P. S. §§ 6020.101--6020.1305).

(4) The Land Recycling and Environmental Remediation Standards Act (35 P. S. §§ 6026.101--6026.908).

(5) The Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1--721.17).

(6) The Solid Waste Management Act (35 P. S. §§ 6018.101--6018.1003).

(7) The Storage Tank and Spill Prevention Act (35 P. S. §§ 6021.101--6021.2104).

(8) The Pennsylvania Bituminous Coal Mine Act (52 P. S. §§ 701-101--701-706).

(9) The Surface Mining Conservation and Reclamation Act (52 P. S. §§ 1396.1--1369.31).

(10) The Coal Refuse Disposal Control Act (52 P. S. §§ 30.51--30.206).

(11) The Bituminous Mine Subsidence and Land [~~Conversion~~ ]CONSERVATION Act (52 P. S. §§ 1406.1--1406.21).

(12) The Noncoal Surface Mining Conservation and Reclamation Act (52 P. S. §§ 3001--3326).

(b) *Matrix.* The following matrices are included:

(1) Drinking water.

(2) Nonpotable water.

(3) Solid and chemical materials.

(c) *Exclusions.* The following testing and analysis is specifically excluded from the requirements of this chapter:

(1) Corrosion protection system testing or testing of a storage tank system for tightness or structural soundness under Chapter 245 (relating to the Administration of the Storage Tank and Spill Prevention Program.)

(2) Routine release detection monitoring under §§ 245.442--245.445, 245.543 and 245.613.

(3) Analyses to determine the acceptability of soils for protective, daily, intermediate and final cover material, subbase, clay liner, clay cap, attenuating soil base and liner system construction material under Chapters 260--270 (relating to hazardous waste), Chapters 271--285 (relating to municipal waste) and Chapters 287--299 (relating to residual waste.)

(4) Testing or analysis of the physical, chemical, mechanical and thermal properties of liners, liner systems, leachate detection zones and barriers under Chapters 260--270, 271--285 and 287--299.

## § 252.4. General requirements.

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

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

(c) BY (EDITOR'S NOTE: THE BLANK REFERS TO A DATE 6 MONTHS AFTER THE EFFECTIVE DATE OF THIS CHAPTER), AN ENVIRONMENTAL LABORATORY TESTING OR ANALYZING ENVIRONMENTAL SAMPLES WITHIN A MATRIX IDENTIFIED IN § 252.3 (RELATING TO SCOPE) AND IN ORDER TO COMPLY WITH A STATUTE LISTED IN § 252.3 SHALL APPLY TO THE DEPARTMENT FOR ACCREDITATION IN ACCORDANCE WITH SUBCHAPTER B. 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 (EDITOR'S NOTE: THE BLANK REFERS TO A DATE 6 MONTHS AFTER THE EFFECTIVE DATE OF THIS CHAPTER), 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

(EDITOR'S NOTE: THE BLANK REFERS TO A DATE 6 MONTHS AFTER THE EFFECTIVE DATE OF THIS CHAPTER).

## § 252.5. NELAP equivalency.

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

(b) An environmental laboratory seeking NELAP accreditation shall:

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

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

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

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

(D) AN ENVIRONMENTAL LABORATORY RECEIVING NELAP ACCREDITATION FROM THE DEPARTMENT MAY ONLY TEST OR ANALYZE ENVIRONMENTAL SAMPLES WITHIN THE FIELDS OF ACCREDITATION AUTHORIZED BY THE ACCREDITATION RECEIVED FROM THE DEPARTMENT.

## § 252.6. Accreditation-by-rule.

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

(1) [~~When required by State or Federal laws, regulations, an order or permit conditions, the~~]THE environmental laboratory [~~shall~~] performS the testing or analysis in conformance with [ ~~promulgated methods and guidelines established by the Department~~ ] APPLICABLE STATE OR FEDERAL LAWS, REGULATIONS, PROMULGATED METHODS, ORDERS AND PERMIT CONDITIONS.

(2) 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** [~~guidelines governing quality control established by the Department~~].

(3) 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) Records pertaining to the testing or analysis of environmental samples are retained onsite and in accordance with § 252.[~~707~~]**706** (relating to recordkeeping). Records shall be made available to the Department upon request.

(5) 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.

(b) *Inappropriate activity.* The Department may require an environmental laboratory deemed to have accreditation-by-rule to apply for, and obtain, environmental laboratory accreditation under Subchapter B (relating to application, fees and supporting documents), or take other appropriate action, when the environmental laboratory is not in compliance with the conditions of accreditation-by-rule or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment of this Commonwealth.

(c) **TESTING AND ANALYSIS OF SAMPLES FROM** *Public water suppliers.* An environmental laboratory using an individual meeting the requirements specified in § 109.704 (relating to operator certification) and in compliance with subsections (a) and (b) will be deemed to be accredited under this chapter to perform **ONLY** those measurements identified in [~~Chapter 109, Subchapter C (relating to monitoring requirements)~~]**§ 109.304 (c) (RELATING TO ANALYTICAL REQUIREMENTS)** as measurements that may be performed by a person meeting the requirements of § 109.704.

(d) *Industrial wastewater treatment facility laboratory.* An environmental laboratory operated by an industrial wastewater treatment facility in compliance with subsections (a) and (b) will be deemed to be accredited under this chapter to perform testing or analysis not mandated by the Department and those tests identified in subsection (f).

(e) *Wastewater facility laboratory.* An environmental laboratory operated by a wastewater facility in compliance with subsections (a) and (b) will be deemed to be accredited under this chapter to perform testing or analysis not mandated by the Department and those tests identified in subsection (f).

(f) *Other testing and analysis.* With the exception of environmental laboratories **TESTING OR ANALYZING ENVIRONMENTAL SAMPLES IN ORDER TO COMPLY WITH THE PENNSYLVANIA SAFE DRINKING WATER ACT (35 P. S. §§ 721.1--721.17),** ~~[identified in subsection (e),~~ ] an environmental laboratory in compliance with subsections (a) and (b) will be deemed accredited under this chapter for the following tests or analyses:

(1) Alkalinity.

(2) Carbon dioxide ($CO_2$).

(3) Color.

(4) Conductivity.

(5) Dissolved oxygen.

(6) Field radioactivity using hand held survey instruments.

(7) Flash point and total halogen determination on waste oil by a waste oil transporter or waste oil transfer facility as required by § 298.44 (relating to rebuttable presumption for waste oil and flash point screening).

(8) Flow.

(9) Foam.

(10) Hardness.

(11) Odor.

(12) Oxidation reduction potential.

(13) Paint filter test.

(14) pH.

(15) Residual disinfectant concentration.

(16) Settleable solids.

(17) Sheen.

(18) Sludge volume index.

(19) Specific gravity.

(20) Sulfite.

(21) Taste.

(22) Temperature.

(23) Turbidity.

(24) Vapor analysis using hand held survey instruments.

(25) Volatile acids in wastewater AND SLUDGE.

(g) *Exclusion from requirements.* An environmental laboratory deemed to be accredited under this section is not required to meet any other requirements in this chapter.

## Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

Sec.



### § 252.201. Application and supporting documents.

(a) An environmental laboratory seeking accreditation for one or more fields of accreditation within a matrix described in § 252.3 (relating to scope) or that seeks to add a field of accreditation, shall apply to the Department for accreditation in writing on forms provided by the

Department. The applicant shall provide other relevant material requested by the Department.

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

(c) Environmental laboratories maintained on separate premises shall maintain distinct accreditation. Separate accreditation is not required for environmental laboratories in different buildings on the same or adjoining grounds, provided the laboratories are operated under the same management.

(d) Separate accreditation is required for a mobile laboratory.

## § 252.202. Application for transfer of laboratory accreditation.

(a) The new owner of an accredited environmental laboratory shall notify the Department in writing within 10 calendar days following a change in laboratory ownership. Within 30 calendar days following the change in laboratory ownership, an accredited environmental laboratory shall do the following:

(1) Submit an ownership transfer application, indicating any changes in the equipment, methodology and staffing.

(2) Pay the application fee for ownership transfer.

(3) Agree to correct any violations that exist at the time of the sale or transfer in accordance with a schedule that is acceptable to the Department.

(b) Open or pending enforcement actions will be transferred with the accreditation.

(c) Failure to comply with this section will cause the previous accreditation to expire.

(d) An environmental laboratory may operate under the previous accreditation until the Department makes a final decision on the transfer application. If the Department denies the transfer application, the environmental laboratory is no longer accredited and the new owner shall submit an application under § 252.201 (relating to application and supporting documents).

## § 252.203. Accreditation renewal.

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

**(b) AN APPLICATION FOR ACCREDITATION RENEWAL SHALL INCLUDE THE APPROPRIATE APPLICATION FEE IN ACCORDANCE WITH § 252.204 (RELATING TO FEES.)**

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

## § 252.204. Fees.

(a) The appropriate fee in accordance with the following schedule shall accompany [~~the~~ ]AN application for accreditation, RENEWAL OF ACCREDITATION, CHANGE OF OWNERSHIP, OR ADDITION OF FIELDS OF ACCREDITATION. [~~The Department may establish a list of equivalent methods that will be considered a single method with regard to fees.~~ ]A check must be payable to "Commonwealth of Pennsylvania." The fees [~~effective through December 31, 2008,~~ ]are as follows:

| [~~Category~~ | ~~Fee~~ |
|---|---|
| ~~Application fee--initial and renewal~~ | ~~$700~~ |
| ~~Application fee--ownership transfer~~ | ~~$150~~ |
| ~~Application fee--addition of fields of accreditation~~ | ~~$150~~ |
| ~~Basic nonpotable water category (Fecal coliform--bacteria, BOD, CBOD, residue, nitrate, ammonia, total nitrogen, phosphorus)~~ | ~~$750~~ |
| ~~Basic drinking water category (Total coliform--bacteria, fecal coliform bacteria, heterotropic--bacteria, nitrate, nitrite, fluoride, cyanide)~~ | ~~$700~~ |
| ~~Asbestos category~~ | ~~$500~~ |
| ~~Microbiology--basic, first method (includes 1--method each for total coliform, fecal coliform, E.coli, and heterotropic bacteria)~~ | ~~$300~~ |
| ~~Microbiology--basic, each additional method~~ | ~~$100~~ |
| ~~Microbiology--nonbasic each method~~ | ~~$250~~ |
| ~~Maximum fee for microbiology category~~ | ~~$1,000~~ |
| ~~Trace metal category, first method~~ | ~~$350~~ |

| | |
|---|---|
| ~~Trace metal category each additional method~~ | ~~$150~~ |
| ~~Maximum fee for trace metal category~~ | ~~$1,200~~ |
| ~~Inorganic nonmetal category, first method~~ | ~~$350~~ |
| ~~Inorganic nonmetal category, each additional method~~ | ~~$100~~ |
| ~~Maximum fee for inorganic nonmetal category~~ | ~~$2,500~~ |
| ~~Gas chromatography volatiles category, first method~~ | ~~$400~~ |
| ~~Gas chromatography volatiles category, each additional method~~ | ~~$100~~ |
| ~~Maximum fee for gas chromatography volatiles category~~ | ~~$1,000~~ |
| ~~Gas chromatography/mass spectrometry volatiles category, first method~~ | ~~$450~~ |
| ~~Gas chromatography/mass spectrometry volatiles category, each additional method~~ | ~~$150~~ |
| ~~Maximum fee for gas chromatography/mass spectrometry volatiles category~~ | ~~$1,000~~ |
| ~~Gas chromatography extractable category, each method~~ | ~~$400~~ |
| ~~Maximum fee for gas chromatography extractable category~~ | ~~$3,000~~ |
| ~~Gas chromatography/mass spectrometry extractable category, first method~~ | ~~$500~~ |
| ~~Gas chromatography/mass spectrometry extractable category, each additional method~~ | ~~$250~~ |
| ~~Maximum fee for gas chromatography/mass spectrometry extractable category~~ | ~~$2,000~~ |
| ~~Other organic including liquid chromatography, each method~~ | ~~$350~~ |
| ~~Maximum fee for other organic category~~ | ~~$2,000~~ |
| ~~Dioxin category, each method~~ | ~~$500~~ |
| ~~Radiochemical category, first method~~ | ~~$500~~ |
| ~~Radiochemical category, each additional method~~ | ~~$250~~ |
| ~~Maximum fee for radiochemical category~~ | ~~$1,500~~ |
| ~~Whole effluent toxicity testing category~~ | ~~$500]~~ |
| 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 COLIFORM BACTERIA, BOD, CBOD, NITRATE, AMMONIA, TOTAL NITROGEN, TOTAL KJELDAHL NITROGEN, NITRITE, PHOSPHORUS, AND 1 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 & 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 |

(b) 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 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 [~~The fees imposed under subsection (a) will be increased every 3 years beginning January 1, 2009. The initial fee increase will be by the percentage, if any, by which the Consumer Price Index for the calendar year 2008 exceeds the Consumer Price Index for the calendar year 2005. Subsequent fee increases shall be by the percentage, if any, by which the Consumer Price Index for the current calendar year exceeds the Consumer Price Index for the calendar year of the previous fee increase. For the purposes of this subsection:~~

~~(1) The Consumer Price Index for any calendar year is the average of the Consumer Price Index for All Urban Consumers, published by the United States Department of Labor, as of the close of the 12 month period ending on June 30.~~

~~(2) The revision of the Consumer Price Index that is most consistent with the Consumer Price Index for calendar year 2005 shall be used.~~

~~(3) The Department will publish the revised fee table in the *Pennsylvania Bulletin* at least 90 days prior to the effective date of the revision.~~]

(c) An environmental laboratory owned or operated by a Commonwealth agency is exempt from this fee requirement, but shall apply for accreditation under this chapter.

(d) Fees are nonrefundable.

(e) In addition to the nonrefundable application fee, an out-of-State environmental laboratory shall reimburse the Department for the costs associated with onsite assessments necessitated by accreditation as specified § 252.206 (relating to out-of-State onsite reimbursement).

## § 252.205. Out-of-State laboratories.

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

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

(2) *Secondary accreditation.*

(i) The Department will recognize accreditation granted by a primary NELAP accrediting authority for the same fields of accreditation for which the Department is a primary NELAP accrediting authority.

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

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

(A) Submit a properly completed application on forms provided by the Department.

(B) Pay the appropriate fee.

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

(D) Submit a copy of all onsite assessment reports conducted by the primary accrediting authority 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.

(b) The Department may conduct an onsite assessment or require analysis of a proficiency test study by an out-of-State environmental laboratory seeking secondary accreditation for reasons which may include addressing complaints from the public **OR DEPARTMENT PERSONNEL**, [~~requests from Department personnel,~~ ]discrepancies with environmental sample results, onsite assessment deficiencies, frequent errors in reporting data to the Department and suspicions of fraud regarding data quality. If the Department determines that an onsite assessment is required, the environmental laboratory shall pay the Department's travel costs associated with the onsite assessment in accordance with § 252.206 (relating to out-of-State onsite reimbursement).

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

## § 252.206. Out-of-State onsite reimbursement.

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

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

(2) Meals and lodging.

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

[~~(4) The fee imposed under subsection (c) will be increased every 3 years beginning January 1, 2009. The initial fee increase will be by the percentage, if any, by which the Consumer Price Index for the calendar year 2008 exceeds the Consumer Price Index for the calendar year 2005. Subsequent fee increases will be by the percentage, if any, by which the Consumer Price Index for the current~~

~~calendar year exceeds the Consumer Price Index for the calendar year of the previous fee increase. For the purposes of this subsection:~~

~~(i) The Consumer Price Index for any calendar year is the average of the Consumer Price Index for All Urban Consumers, published by the United States Department of Labor, as of the close of the 12 month period ending on June 30.~~

~~(ii) The revision of the Consumer Price Index that is most consistent with the Consumer Price Index for calendar year 2005 will be used.~~

~~(iii) The Department will publish the revised fee table in the *Pennsylvania Bulletin* at least 90 days prior to the effective date of the revision.~~]

## § 252.207. EXPIRATION OF APPLICATION.

**AN ENVIRONMENTAL LABORATORY THAT FAILS TO MEET THE REQUIREMENTS FOR ACCREDITATION WITHIN 1 YEAR FROM THE DATE THE DEPARTMENT RECEIVES THE APPLICATION SHALL SUBMIT A NEW APPLICATION AND PAY THE APPROPRIATE FEE TO BECOME ACCREDITED UNDER THIS CHAPTER.**

## Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

Sec.



## § 252.301. Laboratory supervisor.

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

(b) 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) THE LABORATORY SUPERVISOR SHALL ENSURE THAT ALL RECORDS REQUIRED BY THIS CHAPTER ARE MAINTAINED.

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

([d]e) 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.

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

([f]g) 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 [~~15~~]16 consecutive calendar days. If this absence exceeds 30 consecutive calendar days, the environmental laboratory shall notify the Department in writing under § [~~252.709~~ ]252.708 (relating to reporting and notification requirements).

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

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

(2) The adequacy of supervision in each laboratory.

## § 252.302. Qualifications of the laboratory supervisor.

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

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

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

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

~~[(b) A laboratory supervisor of an environmental laboratory limited to the basic nonpotable water category or the basic drinking water category, shall have the following qualifications:~~

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

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

~~(c)~~ ](b)A laboratory supervisor of an environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall have the following qualifications:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**(g) NOTWITHSTANDING ANY OTHER PROVISION OF THIS SECTION, A LABORATORY SUPERVISOR OF AN ENVIRONMENTAL LABORATORY LIMITED TO THE BASIC NONPOTABLE WATER CATEGORY OR THE BASIC DRINKING WATER CATEGORY, SHALL HAVE THE FOLLOWING QUALIFICATIONS:**

**(1) AT LEAST 16-COLLEGE SEMESTER CREDIT HOURS IN CHEMISTRY, BIOCHEMISTRY, PHYSICS, ENVIRONMENTAL SCIENCE, BIOLOGY, MICROBIOLOGY, PHYSICAL SCIENCES OR ENGINEERING.**

**(2) AT LEAST 2 YEARS OF EXPERIENCE IN THE TESTING OR ANALYSIS OF ENVIRONMENTAL SAMPLES IN REPRESENTATIVE FIELDS OF ACCREDITATION FOR WHICH THE ENVIRONMENTAL LABORATORY SEEKS TO OBTAIN OR TO MAINTAIN ACCREDITATION.**

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

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

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

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

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

## § 252.303. Grandfathering provisions for laboratory supervisors.

(a) A person who does not meet the education credential requirements for a laboratory supervisor but possesses the requisite years of experience required by § 252.302 (relating to qualifications of the laboratory supervisor) shall qualify as laboratory supervisor subject to the following conditions:

(1) The person shall be a laboratory supervisor of the environmental laboratory on _____ ***(EDITOR'S NOTE:*** **THE BLANK REFERS TO THE EFFECTIVE DATE OF THIS CHAPTER) [~~the date the environmental laboratory becomes subject to accreditation~~].**

(2) The person shall have been a laboratory supervisor of the environmental laboratory for at least 12 months for the fields of accreditation for which the environmental laboratory is applying.

(b) A person will be approved as a laboratory supervisor only for those fields of accreditation for which the person has been laboratory supervisor of the environmental laboratory for at least 12 months.

(c) The Department may approve a person, qualified as a laboratory supervisor under this section, for additional fields of accreditation if the person has the appropriate knowledge, skills and abilities to perform and supervise the testing or analyses on environmental samples for the requested fields of accreditation.

(d) **QUALIFICATION AS A LABORATORY SUPERVISOR UNDER THIS SUBSECTION MAY NOT BE TRANSFERRED TO ANOTHER LABORATORY.**

## § 252.304. Personnel requirements.

(a) *General requirements for technical staff.*

(1) An environmental laboratory shall have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.

(2) Each member of the environmental laboratory technical staff shall be responsible for complying with quality assurance and quality control requirements that pertain to their organizational or technical function.

(3) Each environmental laboratory technical staff member shall have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance and quality control procedures and records management.

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

(1) Defining the minimal level of qualification, experience and skills necessary for all positions or work cells in the environmental laboratory.

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

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

(i) That each employee has read, understood and is using the latest version of the environmental laboratory's quality manual that relates to each employee's job responsibilities.

(ii) That each employee has read, understood and is using the latest versions of the environmental laboratory's standard operating procedures that relate to each employee's job responsibilities.

(iii) Participation in training courses or workshops on specific equipment, analytical techniques or laboratory procedures that relate to each employee's job responsibilities.

(iv) Participation in training courses in ethical and legal responsibilities including the potential liabilities for improper, unethical or illegal actions.

(v) That each employee has read, understood and acknowledged his personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.

(vi) An initial demonstration of capability for each method that relates to the employee's job responsibilities.

(vii) A demonstration of continued proficiency by at least one of the following every 12 months for each method that relates to the employee's job responsibilities:

(A) Another initial demonstration of capability.

(B) Acceptable performance of blind performance samples (single blind to the analyst).

(C) Successful analysis of blind proficiency test samples on a similar test method using the same technology (for example--GC/MS volatiles by purge and trap for EPA Methods 524.2, 624 or [~~5035/8260~~ ]5030/8260 would require documentation for only one of the test methods.)

(D) At least four consecutive laboratory control samples with acceptable levels of precision and accuracy.

(E) Analysis of at least ten authentic samples with results statistically indistinguishable from those obtained by another trained analyst. The

samples must include samples free of the analyte of interest and samples containing the analyte of interest at measurable concentrations.

[~~(4) Documenting analytical and operational activities of the laboratory.~~]

([~~5~~]4) Supervising personnel employed by the laboratory.

([~~6~~]5) Establishing and implementing procedures and processes for permitting departures from documented policies and procedures.

([~~7~~]6) Ensuring that sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored.

[ ~~(8) Documenting the quality of data reported by the laboratory.~~]

([~~9~~]7) Developing a proactive program for prevention and detection of improper, unethical, or illegal actions. Components of this program may include the following:

(i) Internal proficiency testing (single and double blind).

(ii) Postanalysis electronic data and magnetic tape audits or reviews.

(iii) Separate standard operating procedures identifying appropriate and inappropriate laboratory and instrument manipulation practices.

(c) An environmental laboratory shall maintain records on initial demonstrations of capability, demonstrations of continued proficiency, proficiency test samples for each laboratory method and the qualifications, training, skills and experience of the laboratory technical staff members.

## § 252.305. Physical facilities.

(a) An environmental laboratory shall have accommodations, work areas, energy sources, lighting, heating and ventilation necessary to assure proper performance of tests and analyses.

(b) The environment in which testing or analysis of environmental samples is undertaken may not adversely affect the results of the testing or analysis or the required accuracy of measurement.

(c) An environmental laboratory shall document its monitoring and control of environmental conditions where monitoring or control of environmental conditions is specified in a method or by regulation.

(d) There must be effective separation between neighboring work areas and between work areas and nonwork areas when the activities performed in the different areas are incompatible.

(e) Adequate measures shall be taken to ensure that contamination does not adversely affect data quality.

## § 252.306. Equipment, supplies and reference materials.

(a) An environmental laboratory shall be furnished with all items of equipment, including reference materials, required for the correct performance of tests or analyses for which accreditation is sought.

(b) An environmental laboratory shall maintain records of each item of equipment significant to the testing or analysis performed. These records must include documentation on the following:

(1) The name of the item of equipment.

(2) The manufacturer's name, type identification, and serial number or other unique identification.

(3) The date received and date placed in service (if available).

(4) The current location, when appropriate.

(5) If available, condition when received (for example, new, used or reconditioned).

(6) A copy of the manufacturer's instructions, where available.

(7) The dates and results of calibrations or verifications.

(8) The manufacturer's instructions, if available, or reference their location.

(9) The details of maintenance performed.

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

(c) An environmental laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

(d) Equipment shall be properly maintained, inspected and cleaned.

(e) Any item of equipment that has been subjected to overloading, mishandling, gives suspect results or has otherwise been shown to be defective, shall be taken out of service and clearly identified until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous testing or analysis.

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

(1) *Certified NIST-reference thermometer.*

(i) A certified NIST-reference thermometer must have appropriate graduations and a range that spans the requirements of the method.

(ii) The certified NIST-reference thermometer shall be recalibrated at least once every 5 years at the temperatures of use.

(iii) An environmental laboratory shall retain a certificate documenting traceability of the calibration to NIST standards.

(2) *Working thermometers.*

(i) Working thermometers must have appropriate graduations and a range that spans the requirements of the method.

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

(A) Glass and electronic thermometers and continuous recording devices shall be calibrated every 12 months at the temperature used.

(B) Dial thermometers shall be calibrated every 3 months at the temperature used. Dial thermometers that cannot be calibrated may not be used.

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

(D) Working thermometers shall be uniquely identified and labeled with the date of calibration and correction factor.

(iii) The fluid column in glass thermometers may not be separated.

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

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

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

(ii) An environmental laboratory shall retain a certificate documenting traceability of the calibration to ASTM standards.

(4) *Analytical or pan balances.*

(i) Analytical or pan balances must provide sufficient accuracy and sensitivity for the weighing needs of the method.

(ii) An environmental laboratory shall verify the calibration of [~~an analytical~~]A balance daily or before each use, whichever is less frequent.

[~~(iii) An environmental laboratory shall verify the calibration of a pan balance monthly or before each use, whichever is less frequent.~~]

([~~iv~~]iii) A reference weight that is damaged or corroded may not be used for calibration of balances.

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

([~~vi~~]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.

([~~vii~~]vi) A qualified person shall service and calibrate analytical balances at least once per year.

([~~viii~~]vii) Records of annual service shall be maintained and the service date shall be recorded on the balance.

(5) *pH meter.*

(i) A pH meter must be equipped with an appropriate electrode and have scale graduations and accuracy appropriate to the method.

(ii) An environmental laboratory shall utilize either a thermometer or a temperature sensor for automatic compensation to make corrections for pH measurements.

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

(A) With at least three standard buffers which are at least three pH units apart and which bracket the expected pH range of the samples.

(B) Use a pH 7.0 and either a pH 4.0 or 10.0 standard buffer; whichever range covers the desired pH range of use.

(iv) Aliquots of standard buffers may not be used for longer than 1 analysis day.

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

(6) *Conductivity meter.*

(i) A conductivity meter must have a probe of sufficient sensitivity for the method. The scale must have readability in appropriate units, for example micromhos or microsiemens per centimeter.

(ii) An in-line conductivity meter that cannot be calibrated may not be used.

(iii) An environmental laboratory shall calibrate the conductivity meter daily or before each use whichever is less frequent, by one of the following:

(A) With certified and traceable standard solutions within the range of interest.

(B) By determining the cell constant utilizing the method described in currently approved editions of Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005.)

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

(7) *Refrigeration equipment and freezers.*

(i) An environmental laboratory shall maintain one thermometer immersed in liquid (except electronic thermometers) to the appropriate immersion line for each refrigerator or freezer. The thermometer must be graduated in increments no larger than 1°C.

(ii) Calibration-corrected temperatures for each refrigerator and freezer shall be recorded once a day for each day in use for all laboratory activities. The date, refrigerator or freezer identification, calibration corrected temperature and initial of responsible individual shall be recorded.

(iii) Samples and standards shall be stored in separate refrigerators where the potential for cross-contamination exists.

(iv) Samples which require thermal preservation shall be stored at a temperature which is + 2°C of the specified preservation temperature unless method specific criteria exist. For samples with a storage temperature of 4°C, storage at a temperature of 0.5°C to 6°C is acceptable.

(v) Freezer temperatures must be less than 0°C.

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

(i) An environmental laboratory shall control and monitor the temperature of incubators, water baths and heating blocks 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 immersed in liquid (except electronic thermometers) to the appropriate immersion line. When used as an incubation unit for microbiology, a minimum of one working thermometer shall be on the top and bottom shelf of the use area in each incubator.

(iii) When used as an incubation unit for microbiology, a water bath must be equipped with a gable cover and a pump or paddles to circulate the water.

(iv) Calibration-corrected temperatures for each incubator, water bath or heating block 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 four hours. The incubator, water bath or heating block identification, date, time, calibration corrected temperature and the initials of the responsible individual shall be recorded.

(9) *Volumetric dispensing devices.* 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 method at least once every 3 months.

(10) *Graduated sample containers.* When graduation marks on clear glass or plastic funnels or sample bottles are used to measure sample volume, an environmental laboratory shall verify and document the accuracy of the volume of each lot or at least once per year, whichever is more frequent.

(11) [~~*Visual comparison devices.*~~ ]*SPECTROPHOTOMETER OR COLORIMETER* [~~Visual comparison devices~~ ]A SPECTROPHOMETER OR COLORIMETER must be calibrated according to the manufacturer's specifications or test methods. An environmental laboratory shall maintain records of the calibrations.

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

(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 stock and working standard 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.

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

## § 252.307. Methodology.

(a) An environmental laboratory shall follow the requirements for testing or analysis, sample collection, sample preservation and holding times specified in this section.

(b) An environmental laboratory shall select an analytical method for a specific test or analysis that meets the following criteria:

(1) The method is appropriate for the analyte and sample matrix.

(2) The method is required by, **OR CONSIDERED APPROPRIATE FOR USE UNDER,** applicable State or Federal regulations, a permit, an order, or is an approved alternate method under subsection (c).

(3) The method enables the laboratory to quantitate at required levels.

(c) When a method meeting the requirements of subsection (b) is not available, an environmental laboratory may apply to the Department to use alternate or experimental procedures.

(1) The Department will approve the use of alternate methodologies if the EPA has approved their use. An environmental laboratory shall submit a copy of the EPA's written approval for the use of the alternate method to the Department.

(2) The Department may allow alternate methods that use new or innovative technologies on a case-by-case basis.

(3) An environmental laboratory shall submit a request for use of new or innovative technology in writing to the Department. The request must include the reasons for proposing the method and the potential scope of use for the method.

(4) The Department will establish criteria for validating the method **THAT ARE BASED UPON THE ANALYTE TO BE TESTED**.

(5) Upon receipt of the method validation data that meets the established criteria, the Department will approve or deny the request within 90 days **AND INFORM THE LABORATORY OF THE BASIS OF ITS DECISION IN WRITING**. The evaluation for approval will include consideration of the demonstrated need for the new or innovative technology, reasons for using the method, performance of the method, method validation data and applicability of the method to the matrix.

(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:

(i) Identification of the method.

(ii) Effective date.

(iii) Scope, including applicable matrix or matrices.

(iv) Equipment and supplies.

(v) Reagents and standards.

(vi) Quality control.

(vii) Calibration and standardization.

(viii) Analytical procedure.

(ix) Calculations.

(x) Corrective actions or contingencies for handling out-of-control or unacceptable quality control data.

(xi) Reporting of results.

(2) The standard operating procedures may consist of copies of published or referenced test methods or standard operating procedures that have been written by the environmental laboratory. When modifications to the published or referenced method have been made by the laboratory or when the published or referenced method is ambiguous or provides insufficient detail, the changes or clarifications shall be clearly described.

(e) An environmental laboratory shall make copies of the standard operating procedures, the promulgated method, Department regulations and Department guidance pertaining to testing or analysis of environmental samples available to the technical staff.

(f) When an environmental laboratory collects a sample to be analyzed, the sample collection method required by applicable State and Federal laws, regulations or permit conditions shall be followed.

(g) An environmental laboratory shall follow the sample container, preservation procedures and holding times required by State and Federal regulations. If the sample container, preservation procedures and holding times are not required by State or Federal regulations, an environmental laboratory shall follow the sample container, sample preservation procedures and holding time established in the method.

(h) The range of quantitation and detection limit shall be determined for each analyte reported by an environmental laboratory in accordance with a method specified by the Department.

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

(j) 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 shall 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.

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

## Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

Sec.



### § 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.

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

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

(d) An environmental laboratory shall develop and maintain an ethics policy statement relevant to the employee's duties and responsibilities under the act. The laboratory shall have procedures for educating and training personnel in their ethical and legal responsibilities under the act.

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

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

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

(1) Sample identification, location, date and time of collection, collector's name, preservation type and sample type.

(2) Sample labeling.

(3) Use of appropriate containers and sample preservation method.

(4) Adherence to holding times specified in the regulation and when not specified by the regulation, adherence to the holding times specified by the method.

(5) Sufficient sample volume shall be available to perform the necessary testing and analysis, including any required quality control testing or analysis.

(6) Procedures to be used when samples show signs of damage, contamination or inadequate preservation.

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

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

(1) Identify the individuals responsible for assessing each quality control type.

(2) Identify the individuals responsible for initiating or recommending, or both, corrective actions.

(3) Define how the analyst shall treat the results of testing or analysis of environmental samples if the associated quality control measures fail to meet the requirements of the method.

(4) Specify how out-of-control situations and subsequent corrective actions are to be documented.

(5) Specify procedures for the laboratory supervisor to review corrective action reports.

(j) An environmental laboratory shall develop procedures for reporting results of testing or analysis of environmental samples.

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

(1) Internal quality control procedures using statistical techniques.

(2) Participation in proficiency testing, other interlaboratory comparisons, or round robin testing.

(3) Analysis of split samples by different laboratories.

(4) Use of certified reference materials or in-house quality control using secondary reference materials, or both.

(5) Replicate testing using the same or different test methods.

(6) Retesting of retained samples.

(7) Correlation of results for different but related analysis of a sample (for example, total phosphorus should be greater than or equal to orthophosphate).

(l) To the extent possible, results of testing or analysis of environmental samples shall be reported only if all quality control measures are acceptable. If a quality control 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) Policies, procedures, protocols and practices specified in this section must be in writing and be followed.

## § 252.402. Essential quality control requirements-chemistry.

(a) In addition to the requirements of § 252.401 (relating to basic requirements), laboratories performing testing or analysis of environmental samples in the area of chemistry shall comply with this section.

(b) When the method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

(c) Initial calibration requirements are as follows:

(1) An environmental laboratory shall follow the initial calibration requirements of the method.

(2) The results of testing or analysis of environmental samples shall be determined from an initial calibration and may not be determined from any continuing calibration verification, unless otherwise required by regulation, method or program.

(3) The details of the initial calibration procedures including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the laboratory's standard operating procedure.

(4) Raw data records shall be retained to permit reconstruction of the initial calibration.

(5) Initial calibrations shall be verified with a standard obtained from a second manufacturer or with a standard from the same manufacturer if the verification standard is documented by the manufacturer as prepared independently of the standard used during initial calibration.

(6) 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:

(i) A relative standard deviation of less than 20% for the calculated response factors.

(ii) A correlation coefficient (r) of 0.99 for a linear calibration curve.

(iii) A correlation coefficient (r) of 0.999 for a nonlinear calibration curve or as otherwise specified by the Department.

(2) If the initial calibration fails to meet established acceptance criteria, corrective action shall be performed and all associated environmental samples shall be reanalyzed after an acceptable initial calibration is obtained. If reanalysis of the environmental samples is not possible, a new environmental sample shall be collected.

(3) If the results of testing or analysis of environmental samples that are below the initial calibration range are reported, the results shall be reported with appropriate data qualifiers.

(4) If the results of testing or analysis of environmental samples are above the initial calibration range, the environmental sample shall be diluted and reanalyzed or the results reported with appropriate data qualifiers. Sample results within the established calibration range will not require data qualifiers.

(5) The lowest calibration standard may not be below the detection limit and may not be above the MCL.

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

(i) For an initial calibration covering a range up to 20 times the lowest quantitation level, a minimum of three calibration standards shall be used.

(ii) For an initial calibration covering a range from greater than 20 times and up to 50 times the lowest quantitation level, a minimum of four calibration standards shall be used.

(iii) For an initial calibration covering a range greater than 50 times and up to 100 times the lowest quantitation level, a minimum of five calibration standards shall be used.

(e) For a method that explicitly allows calibration using a single concentration of a standard, not including a blank or zero concentration standard, the initial calibration shall meet the requirements of this subsection.

(1) Prior to the testing or analysis of environmental samples, the linear range of the instrument shall be established by analyzing a series of standards, one of which shall be at the lowest quantitation level.

(2) An initial calibration using a single calibration standard and a zero point shall be performed at the beginning of each analysis day.

(3) A standard corresponding to the lowest quantitation level must be analyzed with each analytical batch and must meet the acceptance criteria established by the method. When there are no established criteria in the method, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

(4) If the results of testing or analysis of environmental samples that are below the lowest quantitation level verification standard, specified in paragraph (3), are to be reported, the results shall be reported with appropriate data qualifiers.

(5) If the results of testing or analysis of environmental samples produce a result above the associated single point standard, the environmental laboratory shall do one of the following:

(i) Analyze a standard at or above the sample concentration that meets established acceptance criteria to validate linearity.

(ii) Dilute the sample so that the result falls below the single point calibration concentration.

(iii) Report the data with an appropriate data qualifier.

(f) Calibration verification requirements are as follows:

(1) A calibration verification standard shall be analyzed at the beginning and end of each analysis day. For methods that use an internal standard, a calibration verification standard is not required at the end of the analysis day unless specified in the method, or State or Federal law or regulation.

(2) A calibration verification standard shall be analyzed after every ten samples, unless a different frequency is specified in the method.

(3) At a minimum, the concentration of the calibration verification standard shall be alternated between a low and a high level.

(i) The concentration of the low calibration verification standard shall be within the lower 20% of the calibration curve and not more than five times the lowest quantitation level.

(ii) The concentration of the high calibration verification standard shall be within the upper 20% of the calibration curve.

(4) Details of the calibration verification procedure including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the laboratory's standard operating procedure.

(5) Raw data records shall be retained to permit reconstruction of the calibration verification.

(6) Acceptance criteria for calibration verification standards in the method shall be followed. When there are no established criteria in the method, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

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

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

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

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

(g) Method blank requirements are as follows:

(1) A method blank shall be processed along with and under the same conditions as the associated environmental samples including all steps of the analytical procedure.

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

(3) A method blank shall consist of a matrix that is similar to the associated environmental samples and is free of the analytes of interest. When a matrix that is similar to the associated environmental samples that is free of the analytes of interest is not available, reagent water or an artificial or simulated matrix may be used.

(4) A method blank is considered contaminated if one of the following applies:

(i) The concentration of a target analyte in the method blank is at or above the reporting limit established by the method, by the laboratory or by regulation.

(ii) The contamination in the method blank otherwise affects the environmental sample results as described in the method or in individual project data quality objectives.

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

(6) To the extent possible, any environmental samples associated with a contaminated method blank shall be reprocessed for analysis. If a contaminated method blank is found to be out of control, and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the contaminated method blank shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers.

(h) Laboratory control sample requirements are as follows:

(1) A laboratory control sample shall be processed along with and under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure.

(2) The laboratory control sample shall 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.

(3) An environmental laboratory shall analyze a laboratory control sample at a minimum of one per preparation batch. When no separate preparation method is used, for example volatiles in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together with the same method, personnel and lots of reagents.

(4) All analyte concentrations in the laboratory control sample shall be within the calibration range of the method and at or below the maximum contaminant level.

(5) The components to be spiked into the laboratory control sample shall be as specified by the method or other regulatory requirement. In the absence of specified components, the environmental laboratory shall use the following:

(i) For those components that interfere with an accurate assessment, such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the laboratory control sample shall represent the chemistries and elution patterns of the components to be reported.

(ii) For methods with more than ten analytes, a representative number may be chosen. The analytes selected shall be representative of all chemistries and analytes reported and shall be chosen using the following criteria:

(A) Targeted components shall be included in the laboratory control sample over a 2-year period.

(B) For methods that include 1-10 components, the laboratory control sample must contain all components.

(C) For methods that include 11-20 components, the laboratory control sample must contain at least ten components or 80%, whichever is greater.

(D) For methods with more than 20 components, the laboratory control samples must contain at least 16 components.

(6) Each individual laboratory control sample 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 limits.

(7) Environmental samples associated with an out of control laboratory control sample shall be reprocessed and reanalyzed from the beginning of the method or the results reported with the appropriate data qualifiers.

(i) Sample duplicate requirements are as follows:

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

(j) Surrogate spike requirements are as follows:

(1) Surrogate compounds, when commercially available, shall be added to all samples, standards and blanks for all organic chromatography test methods.

(2) Surrogate compounds shall be chosen to represent the various chemistries of the target analytes in the method.

(3) The results of the surrogate spike shall be compared to the acceptance criteria published in the method. When there are no established acceptance criteria for surrogate recovery in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(4) For surrogate spike results outside established criteria, corrective action shall be documented and the data reported with appropriate data qualifiers.

(k) Detection limit requirements are as follows:

(1) A detection limit shall be determined by the protocol in the method or regulation. If the protocol for determining detection limits is not specified in the method or regulation, the environmental laboratory shall select a procedure that reflects instrument limitations and the intended application of the method.

(2) A detection limit study is not required for any component for which spiking solutions or quality control samples are not available, such as temperature. A detection limit study is not required for testing or analysis where the results are logarithmic, such as pH, or when the results are expressed as presence or absence.

(3) A detection limit shall be initially determined for the compounds of interest in each method in a matrix in which neither the target analyte nor interferences are at a concentration that would impact the results. The detection limit shall be determined in the matrix of interest.

(4) A detection limit shall be determined each time there is a change in the method that affects how the test is performed or that affects the sensitivity of the analysis.

(5) The sample processing steps of the method shall be included in the determination of the detection limit.

(6) Supporting data shall be retained to permit reconstruction of the detection limit study.

(7) An environmental laboratory shall have an established procedure to relate detection limits with quantitation limits.

(8) The method's lower limit of quantitation shall be established and shall be above the detection limit.

(l) When retention times are used for the identification of an analyte, an environmental laboratory shall develop and document acceptance criteria for retention time windows. The laboratory shall document acceptance criteria for mass spectral tuning

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

(a) In addition to the requirements of § 252.401 (relating to basic requirements), an environmental laboratory that measures the toxicity or bioaccumulation of contaminants, including testing of effluents, receiving waters, sediments, elutriates, leachates and soils shall comply with this section.

(b) When the method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

(c) An environmental laboratory that measures toxicity or bioaccumulation of contaminants shall comply with [~~guidance issued by the Department~~]**25 PA CODE CHAPTER 16 (RELATED TO WATER QUALITY TOXICS MANAGEMENT STRATEGY)** regarding counting of neonates, algae cells and weighing of fish for selected endpoints.

(d) Negative control requirements are as follows:

(1) In addition to the negative controls specified by the method, permit or regulation, additional negative controls shall be included when sample adjustments (for example, pH adjustments or dechlorination) or solvent carriers are used in the test.

(2) The results of the negative controls shall be compared to the acceptance criteria published in the method. When there are no established acceptance criteria for the negative control in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(3) The test acceptability criteria for negative controls as specified in the method must be achieved for both the reference toxicant and the environmental sample toxicity test.

(e) The requirements for reference toxicants are as follows:

(1) The environmental laboratory shall demonstrate the ability to obtain consistent results with reference toxicants before performing toxicity tests on environmental samples.

(i) Intralaboratory precision shall be determined by performing a minimum of five acceptable reference toxicant tests for each method and species using different batches of organisms and negative controls (water,

sediment or soil) before performing testing or analysis on environmental samples.

(ii) An environmental laboratory shall maintain control charts for the control performance and reference toxicant statistical endpoint (such as NOEC or ECp) and shall evaluate the intralaboratory variability with a specific reference toxicant for each method.

(iii) The results of the toxicant test shall be compared to the acceptance criteria published in the method. When there are no established acceptance criteria for the toxicant test in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(2) The following minimum frequency of reference toxicant testing shall be met:

(i) Each batch of test organisms obtained from an outside source, field collection or from laboratory spawning of field-collected species not amenable to routine laboratory culture shall be evaluated with a reference toxicant test of the same type as the environmental toxicity test within 7 days preceding the test or concurrently with the test.

(ii) Test organisms obtained from in-house laboratory cultures shall be tested with reference toxicant tests at least once each month for each method.

(iii) If a species produced by in-house laboratory cultures is used less than once per month, a reference toxicant test of the same type shall be performed with each environmental toxicity test.

(iv) When methods and species commonly used in the laboratory are only tested on a seasonal basis, reference toxicant tests shall be conducted each month the method is in use.

(3) Ongoing environmental laboratory performance shall be documented by maintaining laboratory quality control charts that meet the following requirements:

(i) For endpoints that are point estimates (ICp, ECp), control charts shall be constructed by plotting the cumulative geometric mean and the limits that consist of the upper and lower 95% confidence limits (+ 2 standard deviations).

(ii) For endpoints from hypothesis tests (NOEC, NOAEC), control charts shall be constructed by plotting the values directly and the control

limits shall consist of one concentration interval above and below the concentration representing central tendency or the mode.

(iii) After 20 data points are collected for a method and species, the control charts shall be maintained by using only the most recent 20 data points.

(iv) Test results that fall outside of control chart limits at a frequency of 5% or less shall be retested and confirmed before reporting and all results shall be documented in the report of the testing and analysis.

(v) The endpoint shall be compared to the acceptance criteria published in the method.

(vi) When there are no established acceptance criteria for the endpoint in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(vii) If the reference toxicant fails to meet acceptance criteria, the results of environmental toxicity tests conducted during the affected period shall be examined for defects and the test repeated using a different batch of organisms or the results shall be reported with appropriate data qualifiers.

(4) Reference toxicant tests conducted for a method and species must use the same reference toxicant, test concentrations, dilution water and data analysis method as the environmental toxicity tests for which the precision is being evaluated unless otherwise specified in the method.

(5) The test duration, dilution or control water, feeding, organism age, age range and density, test volumes, renewal frequency, water quality measurements, number of test concentrations, replicates and organisms per replicate must be the same as the environmental toxicity test. A dilution factor of greater than 0.5 shall be used for both acute and chronic tests.

(f) Sensitivity requirements are as follows:

(1) If the Dunnett's procedure or hypothesis test (NOEC, NOAEC) is used, the statistical minimum significant difference (SMSD) by species shall be calculated according to the formula specified by the method and reported with the test results. The SMSD must be estimated for nonnormal distribution or heterogeneous variances, or both.

(2) Confidence intervals for point estimates (LCp, ICp or ECp) shall be reported as a measure of the precision around the point estimate value.

(g) When required, the data shall be plotted in the form of a curve relating the dose of the chemical or concentration of sample to cumulative percentage of test organisms demonstrating a response, such as death.

(h) At least once every 30 days, an environmental laboratory shall verify and document that the reagent grade water meets the following criteria:

(1) Conductivity must be less than 0.1 μmhos/cm or resistance greater than 17 megohms at 25°C.

(2) pH must be between 5.5 to 7.5.

(3) Total residual chlorine must be nondetectable.

(i) Reagent water used for culturing and testing shall be analyzed for toxic metals and organics whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause can be identified.

(j) An environmental laboratory shall demonstrate that any analyte at a measured concentration or the reported detection limit does not exceed one tenth the expected chronic value for the most sensitive species tested or cultured.

(k) Air used for aeration of test solutions, dilution waters and cultures must be free of oil and fumes.

(l) The requirements for test organisms are as follows:

(1) An environmental laboratory shall positively identify test organisms to species on an annual basis. The taxonomic reference (citation and pages) and the names of the taxonomic experts shall be documented. When organisms are obtained from an outside source, an environmental laboratory shall obtain the information from the supplier.

(i) Organisms used for a test must be from the same source. When available, certified seeds shall be used for soil tests.

(ii) Organisms used in tests or as brood stock to produce neonate test organisms must appear healthy, show no signs of stress or disease and exhibit survival of greater than 90% during the 24-hour period immediately preceding use in tests.

(iii) An environmental laboratory shall document the health and culturing conditions of all organisms used for testing. The documentation

shall include culture conditions and observations of any stress, disease or mortality.

(iv) When organisms are obtained from an outside source, the laboratory shall obtain written documentation of the water quality parameters and biological observations for each lot of organisms received.

(v) An environmental laboratory shall record the water quality parameters and the biological observations when the organisms arrive at the environmental laboratory.

(vi) Supporting information such as hatch dates and times, times of brood releases and metrics (for example, chironomid head capsule width) shall be documented.

(vii) Organisms obtained from an outside source may not be from different batches.

(viii) The control population of *Ceriodaphnia* in chronic effluent or receiving water tests may not contain more than 10% males.

(ix) Test soils and sediments must be within the geochemical tolerance range of the test organism.

(2) The requirements for feeding of test organisms are as follows:

(i) For each new batch of laboratory-prepared food or lot of commercial food used by the environmental laboratory, the performance of organisms fed with the new food shall be compared with the performance of organisms fed with a food of known quality. The suitability of food used for culturing shall be determined using a measure that evaluates the effect of food quality on survival and growth or reproduction of each of the relevant test species.

(ii) Foods used only in chronic toxicity tests shall be evaluated using the reference toxicant employed in the environmental laboratory quality assurance program, and shall be compared with results of previous tests using a food of known quality.

(iii) In the case of algae, rotifers or other cultured foods, which are collected as a continuous batch, the quality of the food shall be assessed as described in subparagraphs (i) and (ii) each time new nutrient stocks are prepared, a new starter culture is employed or when a significant change in culture conditions occurs.

(iv) The environmental laboratory shall have written procedures for the statistical evaluation of food acceptability.

(v) Food used to culture organisms used in bioaccumulation tests shall be analyzed for the compounds to be measured in the bioaccumulation tests.

(m) Equipment requirements are as follows:

(1) If closed [~~refrigerator-sized~~ ]incubators are used, culturing and testing of organisms shall be separated to avoid loss of cultures due to cross-contamination.

(2) Temperature control equipment must be adequate to maintain the required test temperature. The average daily temperature of the test solutions shall be maintained within 1°C of the selected test temperature for the duration of the test. Temperature measurements shall be made at least once per 24-hour period. The test temperature for continuous-flow toxicity tests shall be monitored and recorded continuously.

(3) The test chambers used in a test must be identical.

(4) Materials used for test chambers and any material coming in contact with test samples, solutions, control water, sediment, soil or food must be nontoxic and cleaned according to the method. Materials may not add to nor reduce sample toxicity.

(5) Light intensity shall be maintained as specified in the method. Measurements shall be made and recorded at least once per 12 months.

(6) The photoperiod shall be maintained as specified in the method and be documented at least once every 90 days.

(7) For algal and plant tests, the light intensity shall be measured and recorded at the start of each test.

(n) The requirements for sample holding times and conditions are as follows:

(1) The sample holding time may not exceed 36 hours.

(2) The last use of the sample in renewal tests may not exceed 72 hours unless specifically approved by the Department.

(3) Samples shall be chilled to 4°C during or immediately after collection and held at that temperature until time of analysis.

(o) Chronic tests must have a minimum of four replicates per treatment.

(p) The requirements for testing conditions are as follows:

(1) Dissolved oxygen and pH in aquatic tests must be within acceptable ranges published in the method. When there are no established acceptance criteria in the method, the environmental laboratory shall establish internal criteria and document the method used to establish the acceptance limits.

(2) During aquatic chronic testing, dissolved oxygen and pH shall be measured daily in at least one replicate of each concentration.

(3) In static-renewal tests, dissolved oxygen shall be measured at both the beginning and end of each 24-hour exposure period.

(4) The pH shall be measured at the end of each exposure period after organism transfer.

(5) Minimal aeration may be provided to tests only if acceptable dissolved oxygen concentrations cannot be otherwise maintained or if specified by the method.

## § 252.404. Essential quality control requirement--microbiology.

(a) In addition to the requirements of § 252.401 (relating to basic requirements), environmental laboratories performing testing or analysis in the area of microbiology shall comply with this section.

(b) When the method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

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

(1) *Autoclave.*

(i) An environmental laboratory shall use autoclaves that meet specified temperature tolerances of the method. Pressure cookers may not be used.

(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) 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) 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) 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.

(vii) Required times for autoclaving items at 121°C are set forth in this subparagraph. The following items must be at temperature for the required amount of time. Except for membrane filters and pads and carbohydrate-containing media, indicated times are minimum times and may necessitate adjustment depending upon volumes, containers and loads. For autoclave runs that include membrane filters and pads and media, the total cycle time may not exceed 45 minutes. Autoclaved membrane filters and pads and media shall be removed immediately after completion of the autoclave cycle.

| | |
|---|---|
| (A) Membrane filters & pads | 10 minutes |
| (B) Carbohydrate-containing media | 12-15 minutes |
| (C) Contaminated test materials | 30 minutes |
| (D) Membrane filtration units | 15 minutes |
| (E) Sample containers | 15 minutes |
| (F) Individual glassware | 15 minutes |
| (G) Dilution water | 15 minutes |

(H) Rinse water 15-30 minutes

(viii) 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) 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) 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) 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) 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.*

(i) An environmental laboratory shall use appropriate sterile inoculating equipment.

(ii) Metal loops and needles must be made of nickel alloy or platinum.

(iii) Wooden applicator sticks must be sterilized using dry heat.

(iv) For oxidase tests, nickel alloy loops may not be used.

(5) *Membrane filtration equipment.*

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

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

(iii) Forceps must be blunt and smooth-tipped without corrugations on the inner sides of tips.

(iv) Membrane filters must meet the following requirements:

(A) Membrane filters must be made of cellulose ester, white, grid marked, 47 mm diameter and 0.45-μm pore size unless otherwise specified by the method.

(B) Membrane filters must be either purchased presterilized or autoclaved for ten minutes at 121°C before use. Membrane filters may not be brittle or distorted.

(C) Membrane filters must be approved (based upon manufacturer data from tests for toxicity, recovery, retention and absence of growth-promoting substances) for the specified analysis for which they are to be used.

(v) 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) *Culture dishes.*

(i) Culture dishes must be presterilized plastic or sterilizable glass and of appropriate size for the method.

(ii) Stainless steel canisters, aluminum canisters or a wrap of heavy aluminum foil or char-resistant paper, shall be used for autoclave sterilization of glass culture dishes.

(iii) Loose-lid culture dishes shall be incubated in a tight fitting container containing a moistened paper towel.

(iv) Opened packs of disposable culture dishes shall be resealed between use periods.

(7) *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) *Pipettes.*

(i) Pipettes must have legible markings and may not be chipped or etched.

(ii) Stainless steel canisters, aluminum canisters or a wrap of heavy aluminum foil or char-resistant paper shall be used for autoclave sterilization of pipettes.

(iii) Opened packs of disposable sterile pipettes shall be resealed between use periods.

(9) *Sample containers.*

(i) Sample containers must be sterile plastic bags or wide-mouth plastic or noncorrosive glass bottles with nonleaking ground glass stoppers or caps with nontoxic liners that can withstand repeated sterilization. Sample containers must be capable of holding sufficient volume of sample for all required tests while maintaining adequate air space for mixing.

(ii) Glass stoppers must be covered with aluminum foil or char-resistant paper for sterilization.

(iii) Glass and plastic bottles that have not been presterilized shall be sterilized by autoclaving. Glass bottles may be sterilized by dry heat. Empty containers shall be moistened with several drops of water prior to autoclaving.

(10) *Plastic and glassware washing procedure.*

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

(ii) Washed plastic and glassware shall be tested at least once each month for possible acid or alkaline residue by testing at least one piece of plastic and glassware with a suitable pH indicator such as 0.04% bromothymol blue. Records of pH tests shall be maintained.

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

(12) *Quanti-Tray™ Sealer.*

(i) An environmental laboratory shall perform a sealer check on each Quanti-Tray Sealer once a month by adding a dye to a water sample and performing the sealing procedure.

(ii) Records of the sealer check shall be maintained and include the sealer identification, date, results and initials of responsible individual. If dye is observed outside the wells, the Quanti-Tray Sealer may not be used.

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

(1) An environmental laboratory shall use reagent water in the preparation of media, solutions and buffers.

(2) An environmental laboratory shall demonstrate that reagent water meets the following criteria on a monthly basis or whenever maintenance is performed on the water treatment system or at startup after a period of nonuse longer than 1 month:

(i) Total chlorine residual must be less than 0.1 mg/L.

(ii) Conductivity must be less than 2.0 μmhos/cm or resistance greater than 0.5 megohms at 25°C.

(iii) Heterotrophic plate count must be less than 500 CFU/mL.

(3) An environmental laboratory shall demonstrate that reagent water meets the following criteria every 12 months:

(i) The individual concentration of lead, cadmium, chromium, copper, nickel and zinc must be less than 0.05 mg/L.

(ii) The total concentration of lead, cadmium, chromium, copper, nickel and zinc must be less than 0.1 mg/L.

(iii) Except as provided in subsection (c)(6), the bacteriological water quality test ratio must be between 0.8 and 3.0. The bacteriological water quality test shall be performed according to the currently approved editions of Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005).

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

(5) Results of the monthly and annual reagent water analysis shall be maintained and include the date, type of test, results and initials of responsible individual. Reagent water that does not meet the required criteria may not be used.

(6) The bacteriological water quality test need not be performed if the environmental laboratory can supply documentation to show that their laboratory pure water or reagent water meets the criteria, as specified in 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 or Type II reagent water.

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

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

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

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

(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:

(1) An environmental laboratory shall use dehydrated or commercially manufactured prepared media. Dehydrated media shall be stored in a cool, dry location. Caked or discolored dehydrated media shall be discarded.

(2) An environmental laboratory that 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) Media may not be reautoclaved.

(5) After sterilization, prepared media shall be stored and maintained as follows:

(i) Stored away from sources of direct light.

(ii) Prepared plates shall be stored in sealed plastic bags or containers.

(iii) Each bag, container or rack of broth or agar media shall be labeled with the date prepared or expiration date.

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

(v) Prepared liquid media shall be discarded if evaporation exceeds 10% of the original volume.

(vi) Poured agar plates and broth in tubes, bottles or flasks with loose-fitting closures shall be discarded if not used within 2 weeks of sterilization unless otherwise specified by the method.

(vii) Broth in tightly closed screw-cap tubes, bottles or flasks shall be discarded if not used within 3 months of sterilization unless otherwise specified by the method.

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

(1) A sterility blank shall be analyzed for each lot of pre-prepared, ready-to-use medium and for each batch of medium prepared in the laboratory prior to first use of the medium. Records shall be maintained and include media identification, date, results and initials of responsible individual. If sterility blank indicates contamination, the media may not be used.

(2) For each 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.

(3) For pour plate technique, sterility blanks of the medium shall be made by pouring at least one uninoculated plate for each lot of pre-prepared, 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.

(4) Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, presterilized containers with an appropriate nonselective growth media. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with an appropriate nonselective growth media. Results shall be maintained and include sample container identification, date, results and initials of responsible individual. If sample container sterility check indicates contamination, the affected sample container may not be used.

(5) A sterility blank shall be performed on each batch of dilution/rinse water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with an appropriate non-selective growth media. The concentration of media shall be single strength after addition of dilution water. Results shall be maintained and include dilution/rinse water identification, date, results, and initials of the responsible individual. If dilution/rinse water sterility check indicates contamination, the affected dilution water may not be used.

(6) At least one filter from each new lot of membrane filters shall be checked for sterility with an appropriate nonselective growth media. Results shall be maintained and include membrane filter identification, date, results and initials of the responsible individual. If the membrane filter sterility check indicates contamination, the affected membrane filters may not be used.

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

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

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

(4) Stock positive and negative culture controls shall be discarded upon the manufacturer's expiration date unless it is shown through appropriate biochemical and purity tests that the stock culture control has not been contaminated or altered.

(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.

## § 252.405. Essential quality control requirement--radiochemistry.

(a) In addition to the requirements of § 252.401 (relating to basic requirements), laboratories performing testing or analysis of environmental samples in the area of radiochemistry shall comply with this section.

(b) When the method selected by an environmental laboratory in accordance with § 252.307 (relating to methodology) contains more stringent requirements than the requirements of this section, the environmental laboratory shall follow the more stringent requirements contained in the method.

(c) The requirements for initial calibration are as follows:

(1) An environmental laboratory shall follow the initial calibration requirements of the method or regulation.

(2) Initial calibrations shall be performed using calibration standards that have the same general characteristics as the associated environmental samples, for example geometry, homogeneity and density.

(3) The initial calibration shall include, when applicable, determination of instrument background, efficiency, mass attenuation and energy calibration.

(4) The results of testing or analysis of environmental samples shall be determined from an initial calibration that is not more than 12 months old and may not be determined from any continuing calibration verification, unless otherwise required by regulation, method or program.

(5) The details of the initial calibration procedures including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the laboratory's standard operating procedures.

(6) Raw data records shall be retained to permit reconstruction of the initial calibration.

(d) The requirements for an instrument suitability verification are as follows:

(1) An instrument suitability verification standard shall be analyzed at the beginning of each analysis day, unless a higher frequency is required in the method or regulation.

(2) The instrument suitability verification standard shall be a check source that provides adequate counting statistics for a relatively short count time and is sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel.

(3) For alpha and gamma spectroscopy systems, the instrument suitability verification standard shall include determination of instrument counting efficiency, energy calibration and peak resolution.

(4) For gas-proportional and liquid scintillation counters, the instrument suitability verification standard shall include determination of instrument counting efficiency.

(5) For scintillation counters, the instrument suitability verification standard shall include determination of instrument counting efficiency.

(6) Details of the instrument suitability verification procedure including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the laboratory's standard operating procedures.

(7) Raw data records shall be retained to permit reconstruction of the instrument suitability verification.

(8) Acceptance criteria for instrument suitability verification standards in the method or regulation shall be followed. When there are no established criteria in the method, an environmental laboratory shall determine internal criteria and document the procedure used to establish the criteria.

(9) If an instrument suitability verification standard fails the acceptance criteria, an environmental laboratory shall initiate corrective actions.

(10) Environmental samples not bracketed by acceptable instrument suitability verification standards shall be reanalyzed.

(e) The requirements for an instrument background measurement are as follows:

(1) An instrument background check shall be analyzed every analysis day.

(2) Instrument background values shall be subtracted from the total measured activity in the determination of the sample activity.

(3) Each individual background check shall be compared to the acceptance criteria in the method or regulation. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the limits.

(4) Environmental samples associated with an out of control instrument background check shall be reprocessed and reanalyzed from the beginning of the method or the results reported with the appropriate data qualifiers.

(f) The requirements for a method blank are as follows:

(1) A method blank shall be processed along with and under the same conditions as the associated samples including all steps of the preparation and analytical procedure.

(2) A method blank shall be analyzed at a minimum of one per preparation batch. When no separate preparation method is used, such as gamma analysis in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together using the same method, personnel and lots of reagents.

(3) A method blank shall consist of a matrix that is similar to the associated environmental samples and is free of the isotopes of interest. When a matrix that is similar to the associated environmental samples that is free of the analytes of interest does not exist and cannot be prepared, reagent water or an artificial or simulated matrix may be used.

(4) When an environmental sample is analyzed by gamma spectrometry by placing the sample matrix into a calibrated counting geometry, the method blank shall consist of a similar counting geometry that is filled to a similar volume with reagent water to partially simulate gamma attenuation due to a sample matrix.

(5) The method blank result may not be subtracted from the sample results in the associated preparation or analytical batch unless permitted by the method or regulation.

(6) The method blank shall be prepared with similar aliquot size to that of the routine samples for analysis. The method blank result and acceptance criteria shall be calculated in a manner that compensates for sample results based upon differing aliquot size.

(7) If a contaminant is detected in the method blank, the source of contamination shall be investigated and measures shall be taken to minimize or eliminate the contamination. A method blank is considered contaminated if one of the following applies:

(i) The activity of a target isotope in the method blank is at or above the reporting limit established by the method or by regulation.

(ii) The contamination in the method blank otherwise affects the environmental sample results as described in the method, regulation or in individual project data quality objectives.

(8) Environmental samples associated with a contaminated method blank shall be reprocessed for analysis or the results reported with the appropriate data qualifiers.

(g) The requirements for a laboratory control sample are as follows:

(1) A laboratory control sample shall be processed along with and under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure.

(2) The laboratory control sample shall consist of a defined matrix containing known and verified activities of isotopes. When a matrix that is similar to the associated environmental samples that is free of the analytes

of interest is not available, reagent water or an artificial or simulated matrix may be used.

(3) A laboratory control sample shall be analyzed at a minimum of one per preparation batch. When no separate preparation method is used, such as gamma analysis in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together with the same method, personnel and lots of reagents.

(4) The activity of the laboratory control sample shall be within the calibration range of the method and one of the following

(i) Two to ten times the detection limit.

(ii) At an activity level comparable to that of the environmental samples being tested or analyzed, if the sample activities are expected to exceed ten times the detection limit.

(5) The standard used to prepare the laboratory control sample shall be from a source independent of the standards used for initial calibration.

(6) When a radiochemical method, other than gamma spectroscopy, has more than one reportable isotope, for example, plutonium, Pu 238 and Pu 239, using alpha spectrometry, only one of the isotopes shall be included in the laboratory control sample. When more than one isotope is present above the specified detection limit, each isotope shall be assessed against the acceptance criteria.

(7) When gamma spectrometry is used to identify and quantitate more than one isotope, the laboratory control sample shall contain isotopes that represent the low, for example americium-241, medium, for example cesium-137, and high, for example cobalt-60, energy range of the analyzed gamma spectra. The isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.

(8) Each individual laboratory control sample shall be compared to the acceptance criteria in the method or regulation. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the limits.

(9) Environmental samples associated with an out of control laboratory control sample shall be reprocessed and reanalyzed from the beginning of the method or the results reported with the appropriate data qualifiers.

(h) The requirements for sample duplicates are as follows:

(1) A sample duplicate shall be analyzed at a minimum of one per preparation batch. When no separate preparation method is used, for example gamma analysis 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) An environmental laboratory shall document the calculations used for determining the relative percent difference or other statistical method for evaluation of the sample duplicate pairs.

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

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

(i) Tracer requirements are as follows:

(1) For those methods that utilize a tracer or internal standard, each sample result shall have an associated tracer or internal standard recovery calculated and reported.

(2) The tracer or internal standard recovery shall be assessed against the acceptance criteria specified in the method or regulation. When there are no established criteria in the method or regulation, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

(3) For tracer or internal standard recovery outside established criteria, corrective action shall be documented and the data reported with appropriate data qualifiers.

(j) Carrier requirements are as follows:

(1) For those methods that utilize a carrier, each sample must have an associated carrier recovery calculated and reported.

(2) The carrier recovery for each sample shall be assessed against the acceptance criteria specified in the method or regulation. When there are no established criteria in the method or regulation, an environmental

laboratory must determine internal criteria and document the procedure used to establish the acceptance limits.

(3) For carrier recovery outside established criteria, corrective action shall be documented and the data reported with appropriate data qualifiers.

(k) The requirements for detection limits are as follows:

(1) A detection limit shall be determined by the protocol in the method or regulation. If the protocol for determining detection limits is not specified in the method or regulation, the environmental laboratory shall select a procedure that reflects instrument limitations and the intended application of the method.

(2) A detection limit shall be initially determined for the isotopes of interest in each method in a matrix in which neither the target isotope nor interferences are at a concentration that would impact the results. The detection limit shall be determined in the matrix of interest.

(3) A detection limit shall be determined each time there is a change in the method that affects how the test is performed or that affects the sensitivity of the analysis.

(4) The sample processing steps of the method shall be included in the determination of the detection limit.

(5) Supporting data shall be retained to permit reconstruction of the detection limit determination.

(6) An environmental laboratory shall have a written procedure to relate detection limits with quantitation limits.

(7) The method's lower limit of quantitation must be established and must be above the detection limit.

(l) Each result shall be reported with the associated measurement uncertainty. The procedures for determining the measurement uncertainty shall be documented and be consistent with the method and regulation.

## Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

Sec.

## § 252.501. Proficiency test study requirements.

(a) By _____ (*Editor's Note:* The blank refers to a date 30 days of the effective date of this chapter), the Department will publish a list IN THE *PENNSYLVANIA BULLETIN* of fields of accreditation for which proficiency test studies are available. The Department may update the list of available fields of accreditation by publishing a revised list of available proficiency test studies.

(b) An environmental laboratory shall participate in proficiency test studies, when available, as specified in subsection (a), for each field of accreditation for which the laboratory seeks to obtain or maintain accreditation.

(c) Within the 12 months prior to applying for initial accreditation under this chapter or during the approval process, an environmental laboratory shall successfully analyze at least one single blind, single concentration proficiency test study, when available, as specified in subsection (a), for each field of accreditation for which it seeks accreditation.

(d) An environmental laboratory accredited under this chapter shall successfully analyze at least one single blind, single concentration proficiency test study for each field of accreditation, when available, as specified in subsection (a), for which the laboratory is accredited at least once every 12 months.

(e) Proficiency test studies shall be purchased at the environmental laboratory's expense directly from suppliers approved by the Department as a proficiency test provider.

(f) An environmental laboratory shall ensure that all proficiency test study samples are managed, analyzed and reported in the same manner as real environmental samples and utilize the same staff, procedures, equipment, facilities, number of replicates and methods for the routine analysis of the analyte.

(g) An environmental laboratory may not send a proficiency test study, or a portion of a proficiency test study, to another laboratory for analysis for a field of accreditation for which it seeks accreditation or is accredited prior to the time the results of the study are released by the proficiency test study provider.

(h) An environmental laboratory may not knowingly analyze a proficiency test study, or a portion of a proficiency test study, for another environmental laboratory for which the sending environmental laboratory

seeks accreditation or is accredited prior to the time the results of the study are released by the proficiency test study provider.

(i) An environmental laboratory may not communicate with another environmental laboratory, including other laboratories under common ownership, concerning the proficiency test study prior to the time the results of the study are released by the proficiency test study provider.

(j) An environmental laboratory may not attempt to obtain the prepared value of a proficiency test study from the proficiency test study provider prior to the time the results of the study are released by the proficiency test study provider.

(k) If an environmental laboratory fails to successfully analyze a proficiency test study **FOR AN INDIVIDUAL FIELD OF ACCREDITATION**, it shall determine the cause for the failure and take any necessary corrective action. The laboratory shall document the investigation and corrective action.

(l) An environmental laboratory shall direct the proficiency test study provider to report the proficiency test study performance results directly to the Department at the same time that the provider reports the results to the environmental laboratory.

(m) An environmental laboratory shall maintain copies of all raw data associated with proficiency test studies for at least 5 years.

## Subchapter F. ONSITE ASSESSMENT REQUIREMENTS

Sec.



### § 252.601. Onsite assessment requirements.

(a) Prior to accrediting an environmental laboratory, the Department will perform an onsite assessment of the laboratory.

(b) Prior to granting accreditation for an additional field of accreditation to an environmental laboratory, the Department may perform an onsite assessment of the laboratory.

(c) The Department may conduct announced or unannounced onsite assessments of an environmental laboratory to ensure compliance with the conditions of accreditation, this chapter or orders issued by the Department.

(d) The Department will provide the environmental laboratory with an onsite assessment report documenting any deficiencies found by the Department.

(e) An environmental laboratory shall submit a corrective action report to the Department within 60 calendar days from receipt of an onsite assessment report from the Department where the Department has found deficiencies. The corrective action report shall document the corrective action taken by the laboratory to correct each deficiency.

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

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

(1) Purchase new equipment.

(2) Revise the quality manual.

(3) Replace significant laboratory personnel.

## Subchapter G. MISCELLANEOUS PROVISIONS

Sec.

252.[~~709~~]708. Reporting and notification requirements.

[~~§ 252.701. Expiration of application.~~

~~An environmental laboratory that fails to meet the requirements for accreditation within 1 year from the date the Department receives the application shall submit a new application and pay the appropriate fee to become accredited under this chapter.~~]

## § 252.[~~702~~]701. Denial of application.

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

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

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

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

(1) Falsifying analyses.

(2) [~~Selectively reporting data.~~]FAILURE TO COMPLY WITH THE REPORTING AND NOTIFICATION REQUIREMENTS AS SPECIFIED IN § 252.708 (RELATING TO REPORTING AND NOTIFICATION REQUIREMENTS).

(3) Making misrepresentations to the Department.

(4) Engaging in unethical or fraudulent practices.

(5) Analysis of proficiency test studies by personnel other than the analysts associated with the routine analysis of environmental samples in the laboratory.

(6) Failure to submit a complete application.

(7) Failure to pay required fees.

(8) Failure of laboratory staff to meet the personnel qualifications of education, training and experience.

(9) Failure to successfully analyze and report proficiency test studies as required by this chapter.

(10) Failure to respond to an onsite assessment report with a corrective action report within the required timeframes.

(11) Failure to submit an acceptable corrective action report in response to an onsite assessment within the required timeframes.

(12) Failure to implement the corrective actions detailed in the environmental laboratory's corrective action report within a time frame approved by the Department.

(13) Failure to implement a quality assurance program.

[~~(14) Failure to pass an onsite assessment.~~]

([~~15~~]14) Denial of entry to the Department during normal business hours for an onsite assessment.

([~~16~~]15) Violation of a statute, this chapter or an order of the Department.

([~~17~~]16) Failure to meet the requirements of this chapter.

## § 252.[~~703~~]702. Revocation.

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

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

(1) Failure to respond to an onsite assessment report with a corrective action report within the required timeframes.

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

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

(4) Failure of an environmental laboratory that has been suspended to correct all outstanding violations or deficiencies within 6 months of the effective date of the suspension.

(5) Failure to submit an acceptable corrective action report in response to an onsite assessment report within the required timeframes.

(6) Violation of a condition of accreditation.

(7) Violation of a statute, this chapter or an order of the Department.

(8) Falsifying analyses.

~~[(9) Selectively reporting data.]~~

([~~10~~]9) Making misrepresentations to the Department.

([~~11~~]10) Engaging in unethical or fraudulent practices.

([~~12~~]11) Analysis of proficiency test studies by personnel other than the analysts associated with the routine analysis of environmental samples in the laboratory.

([~~13~~]12) Failure to implement a quality assurance program.

([~~14~~]13) Failure to participate in the proficiency test study program as required by this chapter.

([~~15~~]14) Denial of entry to the Department during normal business hours for an onsite assessment.

([~~16~~]15) Failure to comply with the reporting and notification requirements as specified in § [~~252.709~~]252.708 (relating to reporting and notification requirements).

([~~17~~]16) Failure to employ staff that meets the personnel qualifications for education, training and experience.

([~~18~~]17) Failure to meet the requirements of this chapter.

(c) The environmental laboratory may continue to test or analyze environmental samples for those fields of accreditation not revoked.

(d) Within 72 hours of receiving notice of the revocation of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the revocation in writing of the revocation on a form approved by the Department.

## § 252.[~~704~~]703. Suspension.

(a) Denial of access to the Department during normal business hours will result in immediate suspension of accreditation for all fields of accreditation. Upon notice from the Department, the laboratory shall immediately cease testing or analysis of environmental samples.

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

(1) The Department finds that protection of the environment or the public health, safety or welfare requires emergency action.

(2) The environmental laboratory fails to successfully complete a proficiency test study within the previous 12 months.

(3) The environmental laboratory fails two consecutive proficiency test studies for a field of accreditation.

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

(1) Failure to comply with the reporting and notification requirements as specified in § 252.709 (relating to reporting and notification requirements).

(2) Failure to implement a quality assurance program.

(3) Failure to employ staff that meets the personnel qualifications for education, training and experience.

(d) A laboratory may continue to test or analyze environmental samples for those fields of accreditation not affected by the suspension.

(e) Within 72 hours of receiving notice of the suspension of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the suspension in writing of the suspension on a form approved by the Department.

## § 252.[~~705~~]704. Voluntary relinquishment.

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

(b) An environmental laboratory that voluntarily relinquishes its certificate of accreditation shall insure records are maintained in accordance with § 252.[~~707~~]706 (relating to recordkeeping).

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

## § 252.[~~706~~]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.

(2) Make accurate statements concerning their accreditation status.

(3) Not use their certificate of accreditation, accreditation status or the Department's logo to imply endorsement by the Department.

(b) Environmental laboratories using the Department's name, making reference to its accreditation status or using the Department's logo in catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials, shall:

(1) Distinguish between testing for which the laboratory is accredited and testing for which the laboratory is not accredited.

(2) Include the environmental laboratory's accreditation number.

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

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

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

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

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

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

## § 252.[~~707~~]706. Recordkeeping.

(a) An environmental laboratory shall maintain records in a 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.

**(c) ALL GENERATED DATA, EXCEPT DATA GENERATED BY AUTOMATED DATA COLLECTION SYSTEMS, SHALL BE RECORDED PROMPTLY AND LEGIBLY IN PERMANENT INK OR IN AN ELECTRONIC FORMAT. CHANGES TO RECORDS SHALL BE MADE SUCH THAT THE ORIGINAL ENTRY REMAINS VISIBLE. THE INDIVIDUAL MAKING THE CHANGE SHALL SIGN OR INITIAL AND DATE THE CORRECTION. THESE CRITERIA ALSO SHALL APPLY TO ELECTRONICALLY MAINTAINED RECORDS.**

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

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

## § 252.[~~708~~]707. Subcontracting.

(a) [~~**The subcontracted environmental laboratory shall be indicated on the final report.**~~]**AN ENVIRONMENTAL LABORATORY MAY NOT SUBCONTRACT TESTING OR ANALYSIS COVERED UNDER THIS CHAPTER TO AN ENVIRONMENTAL LABORATORY THAT IS NOT ACCREDITED AND IN COMPLIANCE WITH THIS CHAPTER.**

(b) [~~An environmental laboratory may not subcontract testing or analysis covered under this chapter to an environmental laboratory that is not accredited and in compliance with this chapter.~~]THE SUBCONTRACTED ENVIRONMENTAL LABORATORY SHALL BE INDICATED ON THE FINAL REPORT.

## § 252.[~~709~~]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.

(b) An environmental laboratory shall notify the Department, in writing, within 30 calendar days of A change[~~s~~] in laboratory supervisor[~~s, analysts, supervisor or analyst assignments, testing or analysis equipment and facilities which affect accredited fields of accreditation~~].

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

(d) AN ENVIRONMENTAL LABORATORY SHALL NOTIFY THE DEPARTMENT, IN WRITING, WITHIN 30 CALENDAR DAYS OF A CHANGE IN ANY ITEM CONTAINED ON THE APPLICATION FOR ACCREDITATION.

([~~d~~]e) 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.

([~~e~~]f) 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.

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

# ENVIRONMENTAL LABORATORY ACCREDITATION REGULATION
# COMMENT AND RESPONSE DOCUMENT

## List of Commentators

1. John Schmidt
   Chalfont-New Britain Twp Sewage Authority
   1645 Upper State Rd
   Doylestown, PA 18901

2. Louis D. D'Amico
   Executive Director
   Independent Oil & Gas Association of Pennsylvania
   Northridge Office Plaza II
   115 VIP Drive, Suite 110
   Wexford, PA 15090-7906

3. Rocco P. Marinaro
   Manager, Environmental Compliance
   Keystone Cement Company
   P.O. Box A
   Bath, PA 18014-0058

4. Peter T. Slack, P.E., DEE
   Government Relations Associate
   PA Municipal Authorities Association
   1000 North Front Street, Suite 401
   Wormleysburg, PA 17043

5. Gene Barr
   Vice President, Political and Regulatory Affairs
   Pennsylvania Chamber of Business and Industry
   417 Walnut Street
   Harrisburg, PA 17101-1902

6. Pam Witmer
   President, Pennsylvania Chemical Industry Council (PCIC)
   200 North Third Street, 10th Floor
   Harrisburg, PA 17101

7. Mr. Charles Mowbray
   Manager, Environmental Affairs
   FirstEnergy Corp.
   2800 Pottsville Pike
   P.O. Box 16001
   Reading, PA 19612-6001

8. J. Michael Love,
   President and CEO

Energy Association of Pennsylvania

9. Barbara Jordan, P.G.
   Senior Environmental Scientist
   Geological Services Corporation
   260 Executive Drive, Ste 500
   Cranberry Township, PA 16066

10. David S. Wildasin
    QA/QC Officer
    American Westech, Inc.
    4359 Linglestown Road
    Harrisburg, PA 17112

11. M. John Schon, P.E.
    Manager
    Butler Area Sewer Authority
    100 Litman Road, Butler, PA 16001-3256

12. Arthur E. Hall, P.E., DEE
    Director, Environmental Affairs
    Wheatland Tube Company
    One Council Avenue
    Wheatland, PA 16161

13. Rebecca Snyder
    Operations Manager
    Hart Resource Technologies
    P.O. Box 232
    Creekside, PA 15732

14. Douglas H. Sammak
    President
    American Analytical & Environmental Inc.
    738 Front Street
    Catasauqua, PA 18032

15. Joyce M. Fankulewski
    Director of Environmental Affairs
    Envirotrol, Inc.
    432 Green Street
    P.O. Box 61
    Sewickley, PA 15143-0061

16. Elton W. DeLong, Jr.
    Operations Manager

Pennsylvania Brine Treatment Inc.
5148 US 322
Franklin, PA 16323

17. Kevin B. Snyder
Environmental Specialist
Air Products and Chemicals, Inc.
7201 Hamilton Boulevard
Allentown, PA 18195-1501

18. Independent Regulatory Review Commission

19. Senator Mary Jo White, Chairman and
Senator Raphael J. Musto, Democratic Chairman
Senate Environmental Resources and Energy Committee
Room 168 State Capitol Building
Senate Box 203021
Harrisburg, PA 17120

20. Representative William F. Adolph, Jr., Majority Chairman and
Representative Camille "Bud" George, Democratic Chairman
House Environmental Resources and Energy Committee

## COMMENTS AND RESPONSES

General Comments—Data Quality

1. Comment: PADEP is to be commended for recognizing the lack of Federal laboratory accreditation standards for non-potable and solid and chemical materials and taking the necessary steps to ensure continued protection of the Commonwealth's environment by establishing consistent laboratory testing quality standards and requirements. (5) We support the need for regulations addressing environmental laboratory accreditation. (11)

Response: Thank you for this comment supporting our efforts.

2. Comment: The Department is to be applauded in its desire to improve the overall quality of laboratory data. (10)

Response: Thank you for this comment supporting our efforts.

3. Comment: The Department and the Laboratory Accreditation Advisory Committee are to be applauded for their efforts in developing this rulemaking and addressing stakeholder comments. (8)

Response: Thank you for this comment supporting our efforts.

Chapter Organization

4. Comment: Subchapter B. Application, Fees and Supporting Documentation: This subchapter focuses on the "process" for obtaining accreditation. It might be useful to relocate some of the provisions contained in Subchapter G, that deal with "process" matters (i.e. §§ 701-705) to Subchapter B for continuity purposes. (4)

Response: The Department agrees that §701 should be moved to Subchapter B. The remaining sections contain consequences of failure to meet the requirements that are contained in other subchapters of the regulation.

Composition of Advisory Committee

5. Comment: The LAAC bylaws should be modified to include "an environmental engineer *or professional geologist.*" This change might better represent the regulated community and/or the technical expertise available in the environmental consulting industry. (9)

Response: Thank you for the comment. The composition of the Laboratory Accreditation Advisory Committee is specified by § 4108 of the Act and does not include a professional geologist as a member. Amending the advisory committee bylaws or

seeking an amendment to the enabling legislation to change the composition of the committee is outside the scope of this process.

Scope

6. Comment: As presently drafted, does the testing of PCBs fall within this proposed rulemaking? (8)

Response: Yes, testing of PCBs fall within the scope of the proposed regulation, provided the testing is required by the Department under one of the statutes listed in the regulation.

7. Comment: §252.3(a)—Scope. While the Clean Air Act (CAA) and the Pennsylvania Air Pollution Control Act are not listed as one of the statues covered by Chapter 252, several of the statues listed in this section do cross-reference air permitting and regulatory requirements. The standard should also include specific exclusions for all sampling and monitoring of air emissions and air quality, including any sampling and analysis requirements covered by the Clean Air Act and Air Pollution Control Act, whether or not the air related requirements are referenced regulations or permits issued under environmental statures listed in 252.3(a). (5, 17 and 18)

Response: The regulation lists the specific statutes included in the scope of the regulation. This section is sufficiently clear that only those statutes listed are affected by this regulation. In contrast, specifically exempting the Clean Air Act or the Air Pollution Control act would create confusion. The Department administers other statutes related to the protection of the environment and of health, safety, and welfare of the Citizens of the Commonwealth that are not included within the scope of this regulation. New statutes may be enacted that will be administered by the Department. Listing an exemption for only 1 or 2 specific statutes could lead to questions concerning the applicability of the regulation to the other unlisted statues. The Department believes that additional clarifying language is not necessary in the regulation. The Department will add additional language to the Preamble further clarifying that facilities that test environmental samples in order to comply with the Clean Air Act or the Air Pollution Control Act do not need to be accredited to perform these tests..

8. Comment: Section 252.204(a) indicates a special fee regarding the asbestos category. Asbestos testing requirements are contained in the Federal Clean Air Act and Air Pollution Control Act, which are not covered in the scope of the regulation. Asbestos testing and the asbestos category should be clarified to specify what asbestos testing requirements under which applicable statutes listed in 252.3(a) are to be covered by this category. (5)

Response: Testing of samples for asbestos is required under the drinking water program and may also be required under programs other than the CAA program in the future. These qualifications and references to asbestos and airborne filters are for

completeness and not intended to add additional statutes to those covered by the regulations.

9. Comment: §252.3(a)—Scope. Industrial users subject to Federal pretreatment standards that discharge to an NPDES-permitted Publicly Owned Treatment Works appear to be specifically exempt from Pennsylvania lab accreditation requirements. This exemption should be specifically listed in Section 252.3(c) to ensure industries subject to Federal pretreatment standards within the Commonwealth do not unnecessarily expend resources attempting to comply with a non-applicable rule. (5 and 18)

Response: The regulation is applicable to testing or analysis required by the Department. Testing performed to satisfy only Federal requirements is outside the scope of the Act and could not be covered by the regulation. Additional clarifying language is not necessary in the regulation and might lead to confusion. The Department will add clarifying language to the Preamble.

Definitions

10. Comment: §252.1 Modify the definition "environmental laboratory" to limit the scope to commercial environmental laboratories. The additional requirements provide no benefit to non-commercial laboratories that are already performing testing in accordance with a Department issued permit. (15)

Response: The definition of environmental laboratory is identical to the definition found in the Act. The Department does not agree that limiting the scope of the regulations is consistent with the intent of the Act.

11. Comment: The term "confirmation" is defined in §252.1 but is not used.(18)

Response: The definition will be removed from the regulation.

12. Comment: The terms "MCL" "Matrix Spike" "Mobile Laboratory" and "Relative standard deviation are defined in §252.1, but each term is used only once. The EQB should review these definitions to determine whether it may be clearer to define them where they are used. (18)

Response: The definition for relative standard deviation will be removed because the term is used as it is commonly defined. Although used only once in the regulation, the Department believes that placing the definitions of MCL, Matrix Spike, and Mobile Laboratory within the body of the regulation would be confusing to most environmental laboratories.

13. Comment: "Surrogate spike" should be defined as it applies in §252.402—Essential quality control requirements for chemistry. (5)

Response: Definitions will be added for "surrogate" and for "spike".

14. Comment: "Final Report" should be defined as it applies in §252.708(a), "...indicated on the *final report*." (6)

Response: The Department does not believe that a definition is required. The terms are used with their plain meaning.

15. Comment: "Validation" should be defined as it applies to §252.307, "Published methods have been *validated*." Does this statement refer to a suitability study? (5)

Response: This sentence does not exist in the proposed regulation. Section 252.307(c) relates to approval of alternate method. Subparagraph (4) states "The Department will establish criteria for validating the method." However, validation is the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled, that is that the method is suitable for its intended use.

16. Comment: "Certified" should be defined as it applies to §252.301(b), "The laboratory supervisor shall *certify* that each test is accurate..." (5)

Response: The Department is using certify with its usual definition. Certify – to attest as true or as meeting a standard. *Webster's Ninth New Collegiate Dictionary* The requirement that the laboratory supervisor certify the accuracy of the test and data reported is consistent with the provision of the Act, section 4106 (c). The purpose of this requirement is to emphasize and clarify that the laboratory supervisor is ultimately responsible for the quality of the data reported by an environmental laboratory. One way that a laboratory supervisor could certify the accuracy of the test and data reported is by signing the final report. An environmental laboratory would be free to use another mechanism as long as the requirement is met.

17. Comment: §252.301(a) is unclear as to the meaning of "direct supervision." (5 and 18)

Response: Section 4106(c) of the Act requires "testing, analysis and reporting of data by an accredited laboratory shall be under the direct supervision of a laboratory supervisor." This section of the Act provides additional detail for the responsibilities of the laboratory supervisor. Section 252.301 of the regulations reflects these requirements. The laboratory supervisor is not required to be in the laboratory during all times that testing and analysis is being performed. A laboratory supervisor would be required to be available, be able to exercise appropriate control over the operations of the laboratory, and be responsible for the accuracy and validity of the data provided by the laboratory. The requirements are described in the Act, § 4106 (c), and the proposed regulations, Subchapter C, especially 252.301 and 252.304. Should multiple environmental laboratories wish to use the same individual as the laboratory supervisor,

each laboratory would need to demonstrate the adequacy of the supervision as required by Section 252.301 (g).

18. Comment: The definition of environmental sample in §252.1 should not include "gas" as a possible sample type. Gas is not listed as an applicable sample matrix, yet it is included in the definition of an environmental sample. (5)

Response: The definition of environmental sample is the definition from the Act and it would not be appropriate to modify the definition.

19. Comment: "Failure" should be defined as it applies in §252.501(k), "If an environmental laboratory *fails* to successfully analyze a proficiency test study" For example, if a laboratory tests 25 parameters in a PT study, and 24 are acceptable, is this considered a failure? (8 and 18)

Response: Yes, it would be considered a failure for a single field of accreditation. A failure for one field of accreditation may not adversely affect other fields of accreditation. Noted exceptions are in the case of related parameters, such as total trihalomethanes in drinking water where failure for a proficiency test study for total trihalomethes is prescribed by the US EPA. The Department will clarify the meaning of this section by adding "for an individual field of accreditation" to this sentence.

20. Comment: Definition of "Laboratory Supervisor" does not include the term "analytical" as used in 27 Pa. C.S. § 4102. (18)

Response: The definition has been changed in the final regulation to be consistent with the Act.

21. Comment: The definition of "laboratory notebook" should include a reference to more modern technology. The term "notebook" implies a bound paper book used for record keeping. Most laboratories have converted all calibration records onto a personal computer. (6)

Response: A clarifying sentence has been added to the definition of laboratory notebook. Additional clarification will also be included in the record keeping section, §252.707(proposed regulation) and §252.706(final regulation) regarding the types of records that must be retained.

Interim Accreditation and Time of Application for Accreditation

22. Comment: An interim accreditation clause should be added to allow the opportunity to make necessary changes in preparation of the new rulemaking. The regulations should include a clause in Section 252.6 that accredits all regulated laboratories by-rule until a future date, by which all affected laboratories will have to meet the requirements of this rulemaking. The Act provides for interim accreditation for laboratories that apply within 6 months of the date the regulations become final. Why

wasn't this provision included in the regulations? How will laboratories be notified of the requirement to become accredited? (6 and 18)

Response: The Department will change § 252.4 to reflect the requirements of Section 4107 of the Act, which provides that a laboratory that submits an application within 6 months of the effective date of the regulation will be granted interim authorization to continue operations until the Department takes a final action on the application. The Department will send information concerning the accreditation requirements to all registered environmental laboratories. Additionally, the laboratory accreditation regulations will be publicized in the Department's website. The Department has already begun a statewide compliance assistance effort for laboratories that are affected by this regulation.

23. Comment: The standard does not require the Department to complete initial on-site assessments within a specified amount of time. Section 252.601(a) requires an environmental laboratory to receive an on-site assessment before receiving accreditation. Laboratories should be permitted to operate under its standard operating procedures until the Department can complete an assessment. In addition, a time limit should be placed on the requirement to complete an on-site assessment, because if a laboratory has to wait an indefinite period of time prior to accreditation, it will adversely affect their financial stability. (6)

Response: The Department will change § 252.4 to reflect the requirements of Section 4107 of the Act, which provides that a laboratory that submits an application within 6 months of the effective date of the regulation will be granted interim authorization to continue operations until the Department takes a final action on the application. Because the interim authorization continues until the Department takes a final action, the laboratory would not be adversely affected.

Following the initial 6-month grace period for submission of an application, an on-site will be required to assure that new laboratories meet the requirements of these regulations. Applications from new laboratories are processed in the order received and will be processed as expeditiously as possible.

24. Comment: § 252.201 Application and supporting documents: There is no reference to the statutory requirement for environmental laboratories to apply for accreditation within six months of promulgation of the final regulations. We suggest that this be identified somewhere in the final rulemaking package. (4)

Response: The Department will change § 252.4 to reflect the requirements of Section 4107 of the Act, which provides that a laboratory that submits an application within 6 months of the effective date of the regulation will be granted interim authorization to continue operations until the Department takes a final action on the application.

Accreditation-By-Rule

25. Comment: Section 252.6(f) lists specific tests that raise the question about whether they fall under the regulation if air monitoring is excluded. For example, is carbon dioxide and vapor analyses with handheld instruments intended to refer to air monitoring, or monitoring of some other media, such as volatile compounds in soils? (5)

Response: These tests are included under accreditation-by-rule because monitoring of these compounds is required by, or applicable under, some of the statutes listed in the scope section. These tests were therefore listed under the accreditation-by-rule section to eliminate any possible questions concerning whether an environmental laboratory that performs these tests would need to formally apply for accreditation.

26. Comment: Because in-house laboratories are often NPDES permitted and are required to report measurements for BOD, COD, TDS, and TSS, they would be required to seek accreditation under Chapter 252. These parameters should be included in accreditation-by-rule under Section 252.6(f). (6 and 12)

Response: Because of the significance of these parameters in assessing environmental quality and because of the technical skills necessary to perform these tests correctly, these tests were not included under accreditation-by-rule. Differentiating between in house and commercial laboratories is not appropriate. The purpose of these regulations is to improve the quality of data for any testing or analysis of environmental samples that is required by the Department. Because these data are essential for making decisions that affect the environment and the public health, safety and welfare of the citizens of the Commonwealth, the Department believes these tests should not be included under the accreditation-by-rule provision. The Department does not agree that the location of the testing nor the firm or individual performing the testing should be the basis for inclusion under the regulations.

27. Comment: Environmental consulting firms that do limited field-testing should either be exempted from the requirements of this rulemaking or considered accredited-by-rule. Much of the testing performed by these firms is completed in the field using test kits, portable gas chromatograms or X-ray fluorescence units, which are rented for short periods. None of these analyses is complicated, and would never be confused with work of an environmental laboratory. Although a portable gas chromatograph is a handheld survey instrument, instruments like x-ray fluorescence units, field chemical test kits for various parameters, and field test kits using such techniques as immunoassays are clearly not included in this list. The list needs to be expanded for consultants to continue to perform these types of tests in the field. These tests should be listed under the accreditation-by-rule section of 252.6. (6 and 18)

Response: The purpose of these regulations is to improve the quality of data for any testing or analysis of environmental samples that is required by the Department. Because these data are essential for making decisions that affect the environment and

the public health, safety and welfare of the citizens of the Commonwealth, the Department believes these tests should not be included under the accreditation-by-rule provision. The Department does not agree that the location of the testing nor the firm or individual performing the testing should be the basis for inclusion under the regulations.

28. Comment: Include a process in the regulations for obtaining a variance from the regulations. Specifically, include a provision that laboratories that perform routine testing as part of a RCRA Waste Analysis Plan and MCAT Feedstream Analysis Plan be able to apply for a variance, especially facilities where SOP's are Department approved. (3)

Response: Review of the laboratory's written standard operating procedure is only one indicator that a laboratory is producing good quality data. A more thorough evaluation is necessary to insure that a laboratory is producing adequate quality data and is in conformance with all of the requirements of the laboratory accreditation regulation, the promulgated method, and all other applicable federal and State regulations. The accreditation process includes other aspects of data evaluation and an on-site review of the laboratory, which include, but is not limited to, consideration of facilities, personnel, equipment, methodology, quality assurance, record keeping, and performance. The Department does not believe that providing a mechanism for a variance is appropriate for inclusion in the regulation.

29. Comment: The accreditation-by-rule section should be more flexible and should be amended to accept individual cases where the intent of the law is being followed. Specifically add to the accreditation-by-rule parameters tests (chloride and total suspended solids) that are performed in-house by trained personnel. These in-house testing procedures have been adopted and approved by the DEP Bureau of Oil and Gas management, however the tests that are performed are not listed in the accreditation-by-rule exemption. These tests should be added to the exemption for the following reasons: (1)The analyses have already been approved by DEP and have been in place for several years with no adverse effect, (2)The analyses are specific to the industry and can't be performed accurately by outside independent laboratories, (3)The analyses are only used for compliance of that particular facility. No analyses are performed for outside companies or individuals, (4)The analyses meet several of the criteria outlined in the proposed rulemaking for accreditation-by-rule exemption. (2, 13, 15, 16, and 18)

Response: Because of the significance of these parameters in assessing environmental quality and because of the technical skills necessary to perform these tests correctly, these tests were not included under accreditation-by-rule. The purpose of this regulation is to improve the quality of data for any testing or analysis of environmental samples that is required by the Department. Because these data are essential for making decisions that affect the environment and the public health, safety and welfare of the citizens of the Commonwealth, accreditation of the facilities performing this type of testing is appropriate. The Department does not agree that the location of the testing nor the firm or individual performing the testing should be the basis for inclusion under the accreditation-by-rule regulations.

30. Comment: Major NPDES dischargers are already required to participate in the USEPA's annual Discharge Monitoring Report-Quality Assurance (DMRQA) Study. As long as an in-house lab (one that only performs analyses for its own facility's permit requirements) successfully performs the analytical procedures under the DMRQA program, it should be deemed accredited-by-rule. (5, 12, and 18)

Response: Successful performance on one Proficiency Test Sample per year (e.g. a DMRQA Study) is only one indicator that a laboratory is producing good quality data. A more thorough evaluation is necessary to insure that a laboratory is producing adequate quality data and is in conformance with all of the requirements of the laboratory accreditation regulation, the promulgated method, and all other applicable federal and State regulations. The accreditation process includes other aspects of data evaluation and an on-site review of the laboratory, which include, but is not limited to, consideration of facilities, personnel, equipment, methodology, quality assurance, record keeping, and performance.

31. Comment: The preamble's explanation of how the analytical parameters were selected for accreditation-by-rule appears to offer no meaningful rationale for the selections. For example, why should a test with a short allowable holding time be less preferable for consideration than a test that is less sensitive to holding times? Why would non-instrumented tests be better than those using instruments that are calibrated? Why would one offer accreditation by rule for tests involving sample that "cannot be transferred/transported without degradation" but deny accreditation for tests involving samples that degrade with transportation? (5 and 18)

Response: The preamble indicated that to be considered for accreditation by rule the test would need to meet one of the criteria listed. The LAAC agreed to these criteria following an extensive discussion of the merits of the proposed items. Tests proposed for inclusion under accreditation-by-rule were then evaluated against these criteria, especially with regard to the impact that an improperly performed test would have on the environment or the public health, safety and welfare. Short holding times, sample degradation during transport and non-instrumented tests were factors for consideration for inclusion of a particular test or analysis under accreditation-by-rule, provided mistakes in testing would not necessarily result in a significant threat of harm to the environment. The Department, in conjunction with the LAAC, subsequently selected the accreditation-by-rule parameters in the proposed regulation.

32. Comment: The proposed rulemaking does not extend far enough in its consideration of in-house laboratories, including small in-house laboratories maintained by private companies. It was never the intent of Act 90 to open in-house laboratories to the possibility of requiring accreditation through accreditation-by-rule. An exemption should be instituted for all in-house laboratories that perform simple quality assurance or backup testing rather than using the data to maintain compliance with an environmental permit or regulation. The regulations should specifically identify

additional testing parameters for small in-house laboratories for inclusion under accreditation-by-rule. (6, 13, 16)

Response: The regulation is only applicable to testing or analysis required by the Department. Testing performed only for quality assurance testing (or any testing that is not required to comply with a statue administered by the Department) would not be included in the scope of the Act nor would it be covered by the regulation.

33. Comment: The Safe Drinking Water Act regulations allow facilities that test drinking water for phosphates to be eligible for accreditation-by-rule. All in-house laboratories that test for phosphates should also be permitted to attain accreditation-by-rule when testing non-potable water or solid and chemical materials. (6)

Response: The testing of phosphates in non-potable water is more difficult that the testing of phosphate in drinking water because of the complexity of the matrix. The Department does not agree that testing of phosphate in non-potable water or in solid and chemical materials should be included under accreditation-by-rule.

34. Comment: The accreditation-by-rule provision is strongly supported because it will allow the small, on-site, laboratories to comply with the requirements of the proposed rule at a level that is commensurate with the tests and analyses that are authorized by this accreditation. (7, 9, 13, and 17)

Response: Thank you; this is one of the ways in the regulation where the Department has attempted to address the unique needs of small, in-house and municipal laboratories.

35. Comment: There is strong support for the provision that accredited-by-rule laboratories be exempt from all other requirements in proposed Chapter 252. (7)

Response: A laboratory that is accredited-by-rule need only comply with the requirements of the accreditation-by-rule section and any requirements of the Act. A laboratory that is accredited by rule must be registered and have paid the one-time registration fee of $50. A laboratory that is accredited by rule is not required to pay any additional fee for accreditation. Section 252.6(a)(4) requires the laboratory to retain records pursuant to §252.707.

36. Comment: §252.6(d) states that those tests not mandated by Department statue are accredited-by-rule. These regulations should not refer to tests and analysis not mandated by the PA-DEP. The scope of this regulation is to regulate only those tests mandated by specific environmental statues. (5 and 18)

Response: Discussion with individuals, advisory committees and other groups affected by this regulation indicated a need to clarify applicability of this regulation to this type of testing. In particular, testing for certain parameters may not be required by the Department. However if such a test is conducted, the results must be reported.

Laboratories were concerned that they would be required to be accredited to perform these types of tests. Requests were made to emphasize this point in the regulation. This section was added for additional clarification.

37. Comment: Expand Section 252.6 (f), accreditation-by-rule, to include all analyses and tests performed by an in-house laboratory that are required by state or federal laws, regulations, an order, or permit conditions. (3 and 18)

Response: The Department strongly disagrees with this comment. The exclusion, as suggested, would exempt in-house laboratories from accreditation requirements. The Department does not believe exclusion of these laboratories was the intent of the Act. The purpose of this regulation is to improve the quality of data for any testing or analysis of environmental samples that is required by the Department. Because these data are essential for making decisions that affect the environment and the public health, safety and welfare of the citizens of the Commonwealth, accreditation of the facilities performing this type of testing is appropriate. The Department does not agree that the location of the testing nor the firm or individual performing the testing should be the basis for inclusion under the accreditation-by-rule regulations.

38. Comment: Subsection 252.6(c) outlines the provision to grant accreditation-by-rule to public water suppliers, and appears to grant accreditation for the full range of drinking water parameters listed in Ch. 109, in contrast to a very limited number of parameters for wastewater laboratories. We understand that this is not the intent and suggest clarifying this in the final rulemaking. (4)

Response: The Department will revise the wording to §252.6(c) to clarify the meaning and intent of this section.

39. Comment: The accreditation-by-rule §252.6 should be rewritten. The language of the section should reflect the intention of the regulations rather than writing a list "in stone" of parameters that may be analyzed. The section should reflect the criteria used to determine how a parameter could be deemed accredited under accreditation-by-rule. The language can then include those tests that the Department deems unacceptable, for instance, total residue, biochemical oxygen demand, and fecal coliforms. The permitted list will most certainly change as comments are considered. This will allow for the changes in guidance. (9)

Response: The regulation revision process will be used to make revisions to the list of tests or analysis that are included under the accreditation-by-rules section, §252.6. The change process would include discussion with the LAAC and publication of the proposed additions in the *Pennsylvania Bulletin*.

40. Comment: Of the 25 parameters listed in §252.6(f), accreditation-by-rule, only pH, dissolved oxygen, and residual disinfectant concentration typically appear on an industrial wastewater treatment facility's discharge permit. As a result, virtually no industrial wastewater treatment facility's on-site laboratory would be eligible for

accreditation-by-rule. Most industrial wastewater facilities are required to test for TSS, iron, zinc, lead, oil and grease, and pH to demonstrate compliance with their NPDES discharge permit. This accreditation would then cost $3250 initially and $2550 annually thereafter. This does not include the material and labor costs for performing the required QA/QC procedures (estimated cost: $20,000), training personnel and maintaining voluminous records. (5 and 12)

Response: Because of the significance of these parameters in assessing environmental quality and because of the technical skills necessary to perform these tests correctly, these tests were not included under accreditation-by-rule. The purpose of this regulation is to improve the quality of data for any testing or analysis of environmental samples that is required by the Department. Because these data are essential for making decisions that affect the environment and the public health, safety and welfare of the citizens of the Commonwealth, accreditation of the facilities performing this type of testing is appropriate.

After reviewing the comments regarding the fees and their structure, the Department reexamined the fee structure and will be implementing some cost saving measures, including the use of newly developed database technology. As a result, the Department made changes to the fee structure. These changes include: charging a fee per category per matrix, thus eliminating the individual method charges; different fees for an initial application fee and a renewal application fee; reducing the fees for both basic drinking water and non-potable water categories; and adding categories that are combinations of several categories. All changes make fees more responsive to the unique needs of small, in-house environmental laboratories.

Based upon the revised fee schedule, the initial fee for the testing listed would be $2200 and the renewal fee would be $2100. The laboratory would be required to successfully complete one proficiency test sample per year at an estimated cost of $150. The annual total direct costs would then be approximately $2250.

If the on-site laboratory is currently performing these tests using methods from *Standard Methods for the Examination of Water and Wastewater*, essentially all of the quality control required by the regulation should be current routine laboratory practice. Therefore, the Department would expect that any additional cost associated with performing the required QA/QC procedures would be minimal and be far less than the commentator's estimate of $20,000. The laboratory will need to meet the record keeping requirements required in these regulations but these should not result in excessive cost or time for the laboratory. Requiring that an environmental laboratory maintain records for 5 years helps to ensure that historical records will be available to reconstruct important and vital environmental data. Reviewing records of testing and analysis is an important component of an on-site evaluation of an environmental laboratory. The laboratory may need to develop a quality manual. The Department is providing compliance assistance to laboratories on the preparation of a quality manual. The Department believes that a small laboratory, with the Department's planned compliance assistance efforts, could develop a quality manual with minimal cost.

41. Comment: 252.6 (a) (1) and (2) requires conformance with guidelines established by the Department. What are these guidelines and where can they be found? (18)

Response: The wording in the regulation will be changed to require conformance to state and Federal regulation.

Mobile Laboratories

42. Comment: The requirement for separate accreditation for mobile laboratories convolutes the field testing process. Requiring mobile laboratories, even when affiliated with an established environmental laboratory and established for a very limited time, that will perform testing such as hazard characterization or sample composting with subsequent samples being sent to a permanent laboratory, should not be required to obtain separate accreditation. The accreditation process would take longer than the actual fieldwork would require. (6 and 18)

Response: Separate accreditation is required because a mobile laboratory would be expected to be operated independently of any associated fixed facility and under a different quality manual and standard operating procedures. A mobile laboratory would not be required to apply for accreditation for each site or testing location. Accreditation of a mobile laboratory would include any methods or procedures for which it has demonstrated compliance with the requirements of Chapter 252. The Department does not think the regulation will be too burdensome for mobile laboratories.

43. Comment: If one entity owns several mobile laboratories that perform the same testing will the mobile laboratories be accredited as a group? Must mobile laboratories maintain a laboratory supervisor for each mobile laboratory? (18)

Response: Each laboratory would be considered as a separate environmental laboratory and would be required to maintain separate accreditation. Even though the mobile laboratories are owned or operated by the same entity, they may be performing testing and analysis at geographically separate locations. A single individual could serve as the laboratory supervisor for more than one mobile laboratory provided the requirements of §252.301(g) are met.

Fees

44. Comment: As printed in the Pennsylvania Bulletin, paragraph (4) of §252.206 refers to subsection (c). Was the intent to reference the fee in Paragraph (3)? (18)

Response: Yes, that was the intent, however the section has been removed.

45. Comment: § 252.204 Fees: We suggest adding the parameters TKN (total kjeldahl nitrogen) and Nitrite to the non-potable water category in § 204(a) to avoid potential confusion in implementing this provision. (4)

Response: Thank you for the suggestion. These 2 parameters will be added to the non-potable water category

46. Comment: The annual fees and proficiency test costs are prohibitive. The proposal is responsive to the needs of small laboratories, but does nothing to help medium-sized laboratories. Large laboratories may benefit from the maximums in the fee categories; however, this does nothing to benefit medium laboratories. Up to $25,000/year for annual fees and PTs may cause financial strains on medium-size laboratories. (10)

Response: After reviewing the comments regarding the fees and their structure, the Department reexamined the fee structure. As a result of some recently implemented and planned cost saving measures, including the use of newly developed database technology, the Department was able to make some changes to the fee structure. These changes include: charging a fee per category per matrix, thus eliminating the individual method charges; different fees for an initial application fee and a renewal application fee; reducing the fees for both basic drinking water and non-potable water categories; and adding categories that are combinations of several categories. All changes make fees more responsive to the unique needs of small, in-house environmental laboratories.

The Act requires that the fees be sufficient to pay the department's cost of implementing and administering the accreditation program. 27 Pa C.S. §4104(6). Based upon the Department's experience with the drinking water laboratory accreditation program, the cost of an accreditation program are related to the complexity of the analytical method and to the number of methods for which a laboratory is seeking accreditation. The fee structure distributes the costs accordingly. The number of samples analyzed by the laboratory does not affect the time required by Department staff to perform on-site evaluations, review proficiency test results, and perform other activities that are required for determining the accreditation status of a laboratory.

47. Comment: The Consumer Price Index escalator is a circumvention of the regulatory process. Linking fee increases to the changes in the CPI does not allow for consideration of actual program costs to determine the fee charged to the regulated community. The escalator does not account for any future changes in the scope of the accreditation program. The establishment and change of fees is a fundamental regulatory step. The purpose of the regulatory review process is to avoid unchallenged or hurried decision-making. The change of fees should be subject to full public disclosure. This language regarding an automatic escalator should be removed from the proposed rulemaking. (5, 6, 11, 18, 19, and 20)

Response: The language increasing fees based upon CPI increases has been removed. However, the Act requires the Department to establish fees in an amount sufficient to recover the Department's costs to implement and administer the

accreditation program. Therefore, the Department will regularly evaluate its costs to administer the accreditation program and, if necessary, revise the accreditation fees through future rulemakings.

48. Comment: The fee structure heavily favors larger environmental laboratories, and disadvantages smaller and specialty laboratories. A laboratory that receives a large amount of income by offering all categories of testing will easily reach the maximum fee they can pay, approximately $19,000. However, a smaller laboratory that specializes in specific categories of testing will end up paying a larger proportion of their income in accreditation fees. The fee structure should be reconsidered with the perspective of smaller laboratories firmly in mind. The fee schedule should be based upon the number of tests conducted by the environmental laboratory. (6, 14, 18, and 19)

Response: After reviewing the comments regarding the fees and their structure, the Department reexamined the fee structure. As a result of some recently implemented and planned cost saving measures, including the use of newly developed database technology, the Department was able to make some changes to the fee structure. These changes include: charging a fee per category per matrix, thus eliminating the individual method charges; different fees for an initial application fee and a renewal application fee; reducing the fees for both basic drinking water and non-potable water categories; and adding categories that are combinations of several categories. All changes make fees more responsive to the unique needs of small, in-house environmental laboratories.

The Act requires that the fees be sufficient to pay the department's cost of implementing and administering the accreditation program. 27 Pa C.S. §4104(6). Based upon the Department's experience with the drinking water laboratory accreditation program, the cost of an accreditation program are related to the complexity of the analytical method and to the number of methods for which a laboratory is seeking accreditation. The fee structure distributes the costs accordingly. The number of samples analyzed by the laboratory does not affect the time required by Department staff to perform the on-site evaluation, review proficiency test results, and perform other activities that are required for determining the accreditation status of a laboratory.

49. Comment: The proposed fee structure will be burdensome to the operation of a small laboratory. A fee schedule for small non-commercial laboratories should be considerably less that that for commercial or "for-hire" laboratories. (3, 12, and 18)

Response: After reviewing the comments regarding the fees and their structure, the Department reexamined the fee structure. As a result of some recently implemented and planned cost saving measures, including the use of newly developed database technology, the Department was able to make some changes to the fee structure. These changes include: charging a fee per category per matrix, thus eliminating the individual method charges; different fees for an initial application fee and a renewal application fee; reducing the fees for both basic drinking water and non-potable water

categories; and adding categories that are combinations of several categories. All changes make fees more responsive to the unique needs of small, in-house environmental laboratories.

The Act requires that the fees be sufficient to pay the department's cost of implementing and administering the accreditation program. 27 Pa C.S. §4104(6). Based upon the Department's experience with the drinking water laboratory accreditation program, the cost of an accreditation program are related to the complexity of the analytical method and to the number of methods for which a laboratory is seeking accreditation. The fee structure distributes the costs accordingly. The number of samples analyzed by the laboratory does not affect the time required by Department staff to perform the on-site evaluation, review proficiency test results, and perform other activities that are required for determining the accreditation status of a laboratory.

50. Comment: There should be a fee for accreditation renewal along with the fee for initial accreditation. If fees are a true representation of the accreditation process, then the renewal fee should be lower than the initial accreditation fee. (6 and 18)

Response: After reviewing the comments regarding the fees and their structure, the Department reexamined the fee structure. As a result of some recently implemented and planned cost saving measures, including the use of newly developed database technology, the Department was able to reduce the renewal application fee by $100.00.

However, a significant cost of the accreditation program is the cost of performing an on-site assessment. The Department expects to conduct on-site evaluations on a 2-year cycle. The Department explored the option of having one fee when an on-site is required and a different fee when an on-site is not required. A higher amount would be required each year the laboratory is required to have an on-site assessment. The Laboratory Accreditation Advisory Committee did not favor this option. The proposed fee structure averages the costs over the full 2-year cycle.

51. Comment: With regard to the specific analytical fee categories, these should be described in more detail in DEP guidance documents. (4)

Response: After reviewing the comments regarding the fees and their structure, the Department reexamined the fee structure. The revised fee categories more clearly describe the parameters that are included within each category.

Out-of-State Laboratories

52. Comment: The costs identified in §252.206 include "travel time" at a rate of $50/hour. This "travel time" should be clarified to mean actual commuting time, not overnight hours spent in a hotel before or after the on-site assessment. (7 and 18)

Response: Clarification that travel time only includes time spent traveling from the home office to the location of the out-of-State laboratory and does not include time spent in a hotel will be provided in the preamble.

53. Comment: Department Personnel should not be permitted to request on-site assessments for out-of-state laboratories, as allowed by §252.205(b). This may be construed as a potential conflict of interest if the requesting party would also be conducting the assessment. Department personnel should have to show cause to request an on-site assessment. (6)

Response: The Laboratory Accreditation Program operates independently of other Departmental programs and therefore the requesting party would not be the individual conducting the assessment. However, for clarity, the phrase "requests from Department personnel" will be removed and §252.205(b) will be revised to clarify the original intent that on-site assessments may be conducted in response to complaints by Department personnel.

54. Comment: It is not necessary for the Department to assess laboratories that are reciprocally accredited by other states or NELAP. If the Department is willing to accept reciprocal accreditation for an environmental laboratory located in another state, the Department concedes that the state's laboratory accreditation rule is similar to Pennsylvania's rule. If this is true, an assessment from an out-of-state official should be sufficient to maintain accreditation in another state. The same should also be true for laboratories that are accredited by NELAP and inspected by NELAC. Out-of-state laboratories that are accredited either by their home state or by NELAP should be permitted to reciprocate their home state assessment instead of being required to receive a Pennsylvania inspection. An out of state laboratory that is not accredited by its home state or does not meet Pennsylvania standards for reciprocal accreditation should receive assessments from the Department. (6)

Response: Out-of-State laboratories that receive accreditation by mutual recognition, including through recognition of NELAP accreditation, are not subject to routine on-site evaluations. Accreditation is based upon the accreditation status granted by the laboratory's primary accrediting state. An out-of-State laboratory would only be subject to an on-site evaluation for cause, as described in § 252.205(b).

55. Comment: Laboratories that apply for secondary NELAP accreditation from Pennsylvania should not have to pay accreditation fees. The Department should recognize out-of-State NELAP accreditation without an associated burdensome application process. Remove the conditions of §252.205a(2)iii. (5 and 15)

Response: It is neither the Department's desire nor intent to discourage out-of-State laboratories from doing business in Pennsylvania. The fee structure is designed to provide an equal opportunity for Pennsylvania based laboratories and for out-of-State laboratories. If the total of the fees for accreditation of an out-of-State laboratory plus the fee for accreditation from the state granting the out-of-State laboratory primary

accreditation were lower than the fees paid by a comparable Pennsylvania based laboratory, the out-of-State laboratory would have a competitive advantage. In addition, Pennsylvania laboratories would be further disadvantaged because all other NELAP accrediting authorities charge identical fees for primary and secondary NELAP accreditation.

56. Comment: Particular flexibility is needed when there is no PA accredited laboratory that can perform a required test, specifically when there is a need for timely analysis. A provision should be included to allow for a variance for an out-of-State laboratory from the accreditation process if there is no Pennsylvania accredited laboratory that performs the required analysis. (5)

Response: It is neither the Department's desire nor intent to discourage out-of-State laboratories from doing business in Pennsylvania. The Act states that a laboratory meeting Pennsylvania accreditation standards may perform any required testing and analysis. The regulations and the accreditation program are designed to assure that the tests and analyses are performed according to the minimum documentation, quality control and method requirements, and that the laboratory's procedures have been reviewed to assure these requirements are being met. Note that out-of-State laboratories may be granted accreditation by recognition of accreditation granted by other state accreditation programs that are substantially equivalent to the Pennsylvania laboratory accreditation program. Accreditation that is granted by recognition of another state's accreditation can usually occur within 30 days of the receipt of a completed application. The Department does not believe that including a provision for a variance for out-of-State laboratories is consistent with the intent of the Act.

57. Comment: The Department should consider reciprocating other laboratory accreditation programs other than NELAP. There may come a time in the future when a laboratory accreditation program similar to NELAP, such as the American Association for Laboratory Accreditation may emerge as an alternative to NELAP. In order to account for this possibility, the rulemaking should include language giving the Department the ability to recognize reciprocal accreditation when granted by a program with guidelines similar to those of the Commonwealth. (6, 15, 18, and 19)

Response: Section 4104 (1) of the Act limits the recognition of other accreditation programs to Federal or State accreditation programs. Additionally, the National Environmental Laboratory Accreditation Conference Standard requires that an accrediting authority be a state or federal agency. The regulation as proposed conforms to both the NELAC Standard and the Act.

The Department did include a provision, §252.205(a)(2)(ii), in the regulation to recognize accreditation granted by another state accrediting authority. This provision will allow the Department to recognize another specific broad-based Federal or State accreditation program, should it come into existence.

58. Comment: How does the Department plan to evaluate other accreditation programs that meet the statutory criteria? (18)

Response: The Department will consider the following items to determine if a state accreditation program is substantially equivalent to the requirements of the regulation (§252.205(a)(2)(ii)): frequency and rigor of on-site evaluation; requirements for corrective action for deficiencies identified during the on-site evaluation; qualification requirements for laboratory supervisor and other laboratory personnel; proficiency test requirements; authority to deny, revoke, or suspend accreditation; record keeping requirements; quality manual requirements; and other quality control requirements. In accord with § 4104 (1) of the Act, recognition of other accreditation programs will be limited to Federal or State accreditation programs.

59. Comment: The fee structure will limit the marketplace by discouraging out-of-state laboratories from becoming accredited in Pennsylvania. §252.205(b) proposes that out-of-state laboratories must pay travel expenses including lodging and travel time and salaries of assessors. Sometimes PA laboratories do not test for some of the required parameters necessary for a waste disposal characterization. Requiring an out-of-state laboratory to pay these fees for very infrequent and specialized testing would be a very large inconvenience and not cost effective. This marketplace exclusion will increase costs of environmental testing of participating laboratories and limit the number of firms Pennsylvania businesses can potentially choose, if the out of state laboratories reject Pennsylvania samples due to the fees of accreditation to perform testing. There should be a flat fee established to cover part of the cost associated with an on-site visit to an out-of-state laboratory. (5 and 6)

Response: It is neither the Department's desire nor intent to discourage out-of-State laboratories from doing business in Pennsylvania. The fee structure is designed to provide an equal opportunity for Pennsylvania based laboratories and for out-of-State laboratories. If the total of the fee for Pennsylvania's accreditation of an out-of-State laboratory plus the fee for accreditation from the state granting the out-of-State laboratory primary accreditation were lower than the fees paid by a comparable Pennsylvania based laboratory, the out-of-State laboratory would have a competitive advantage. The Act, 27 Pa C.S. §4104(6), requires that the fees be sufficient to pay the department's cost of implementing and administering the accreditation program. Should an out-of-state laboratory not pay all of the costs associated with accrediting that laboratory, the program would be required to recoup these costs. The result would be higher costs for Pennsylvania based laboratories.

60. Comment: The provision for out-of-State laboratories allows facilities that are required to use an accredited laboratory to continue to use a laboratory located outside the Commonwealth. The commentator supports the provision providing for accreditation of out-of-State laboratories. (7)

Response: Thank you for your comment in support of this provision.

Laboratory Supervisor

61. Comment: §252.301(b) requires the laboratory supervisor to certify the accuracy of the test and data reported. A provision should be included to allow for peer review, rather than supervisor certification, as long as the appropriate quality assurance measures are in place. (5)

Response: The requirement that the laboratory supervisor certify the accuracy of the test and data reported is consistent with the provision of the Act, section 4106 (c). The purpose of this requirement is to emphasize and clarify that the laboratory supervisor is ultimately responsible for the quality of the data reported by an environmental laboratory. One way that a laboratory supervisor could certify the accuracy of the test and data reported is by signing the final report. An environmental laboratory would be free to use another mechanism as long as the requirement is met.

62. Comment: During the Laboratory Accreditation Advisory Committee (LAAC) meetings, it was stressed that the laboratory supervision and management is responsible for the capability of the analysts, the quality of the results, and the reliability of the equipment, then why is it necessary to notify the Department of any changes other than the laboratory supervision and management? (8)

Response: The Department will modify the notification requirements and only require notification of changes to information provided on the application for accreditation.

63. Comment: When an absence of more than 15 days occurs for the laboratory supervisor, the laboratory should be able to distribute various components of the laboratory supervisor's duties to multiple staff members. Would a director or superior to the laboratory supervisor satisfy this requirement? (8 and 18)

Response: Yes, provided the individuals meet the requirements of a laboratory supervisor for the laboratory.

64. Comment: With regard to §252.301(f), the requirement to notify the Department of a newly designated supervisor when an absence of the regular supervisor occurs for more than 15 calendar days would necessitate notification when a supervisor takes a two-week vacation. Fifteen calendar days is exceeded by a two-week vacation period (including the initial and final weekends). We recommend restating using a 23-day period. (8 and 18)

Response: The regulation requires designation of an alternate laboratory supervisor for absences greater than 15 days but does not require that the Department be notified unless the absence is greater than 30 days. An absence of a laboratory supervisor for greater than 15 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 does not believe that designation of an alternate supervisor imposes an

unreasonable burden on a laboratory. To accommodate the possible scenario described above, the Department will change the regulation to read greater than 16 days, 6 weekend days plus 10 weekdays.

65. Comment: §252.709(b) requires notification of any change in supervisor, analysts, or supervisor/analysts assignments, or testing or analysis equipment and facilities that "affect accredited fields of accreditation." This notification requirement is overly burdensome. Given that a list of personnel, their assignments, and equipment is not required at the time of application, requiring repeated notifications as to changes in personnel or equipment would be meaningless. Especially since new equipment could be interpreted as glassware, thermometers, and probes. (5, 6, 8, 11 and 18)

Response: The Department will modify the notification requirements and only require notification of changes to information provided on the application for accreditation.

66. Comment: § 252.301 Laboratory supervisor: Under § 301(f), if the laboratory has more than one designated supervisor, must the laboratory still appoint a temporary supervisor for a >15 day absence and notify the Department of a >30 day absence of one of the supervisors? This would seem to be unnecessary. (4)

Response: The laboratory would need to notify the Department of an extended, greater than 30 days, absence of a supervisor. The extended absence of a supervisor, even if there are multiple supervisors, could adversely affect the laboratory's ability to produce data of appropriate quality. The laboratory could designate other supervisors within the laboratory to perform the duties and responsibilities of the absent supervisor. The designated supervisor must meet the qualifications of a laboratory supervisor for the area of the laboratory being supervised. This would be particularly applicable for a large complex laboratory that may have specialized areas requiring specific qualifications for a laboratory supervisor.

67. Comment: § 252.302 Qualifications of the laboratory supervisor: We suggest some clarification relative to the sequence of presentation of these requirements. Under the "basic non-potable water" and "basic drinking water" categories, that are covered under subsection 302(b), a laboratory supervisor could be supervising both "chemical" and "microbiological" analyses, which are the subject of more rigorous qualification provisions contained in (a) and (d). However, the qualifications in (b) are sandwiched among the other, more rigorous, qualification subsections. Perhaps (b) should be relocated just prior to (h), and some "notwithstanding" language added for further clarification. (4)

Response: The Department will rearrange the sections for better clarity.

68. Comment: In § 303(a)(1), we suggest clarifying that the date that "the environmental laboratory becomes subject to accreditation" is not the date that the Laboratory Accreditation Act was enacted (April 2, 2002), but "6 months after the EQB establishes the requirement by regulation," as stated in the Act (27 Pa.C.S.A. §

4107(b)). In other words, the person must have been a supervisor for at least 12 months by a date 6 months after the date that the regulations are finally adopted, not by April 2002. (4)

Response: The Department agrees with the commentator that the date the Laboratory Accreditation Act was enacted in not the appropriate date. However, the date that the laboratory becomes subject to accreditation is the date the regulation is published as a final regulation in the *Pennsylvania Bulletin*. Appropriate wording will be added to this section.

69. Comment: § 252.303 Grandfathering provisions for laboratory supervisors: The preamble to the proposed rulemaking states that approval under this provision is limited to the current facility and may not be transferred to a different environmental laboratory, but this is not stated as such in the regulation. To avoid confusion, we suggest either deleting this statement from the preamble or adding corresponding language to the regulation. (4)

Response: The Department agrees with the commentator and appropriate wording will be added to § 252.303.

70. Comment: The grandfather provision only allows a Certified Operator to act temporarily as a laboratory supervisor until the laboratory supervisor sub-classification becomes available. Continue to allow a Certified Operator that is in responsible charge to act as the laboratory supervisor. (1)

Response: A laboratory supervisor who has been deemed qualified under the grandfather provision will not need to meet any additional requirements. Therefore, certified operators who meet the laboratory supervisor grandfather provision could continue to act as the laboratory supervisor. The requirements for laboratory supervisor listed in §252.302 are not applicable to a supervisor that has been deemed qualified under the grandfather provision.

71. Comment: The PA-DEP does not currently have a laboratory supervisor requirement for operator certification. The Department should develop the certification before the Department requires this certification in regulations. (5, 11 and 18)

Response: 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 submitted for consideration in the near future. There was no reason to postpone inclusion of this section. The section addresses the concerns of certified operators about being able to meet the formal educational requirements contained elsewhere in the regulations. Certified operators who meet the laboratory supervisor grandfather provision can continue to act as the laboratory supervisor.

72. Comment: §252.302 allows certified operators to act as laboratory supervisors. This subsection should be consistent with the Operator Certification Act and it should

note that Industrial Wastewater facilities do not need to meet that requirement. This puts industrial sites at a disadvantage because the PA-DEP does not require certification of industrial wastewater facility operators. Many members' facilities do not require college education for operators for supervisory positions. More years of experience should be comparable to some level of college education. According to PA's Operator Certification Plan, one college course is equivalent to one and a half month's experience. We believe that substituting additional experience in lieu of college credits would provide additional flexibility without jeopardizing data. (5)

Response: The Department does not agree that the requirements for a laboratory supervisor put an industrial wastewater facility at a disadvantage nor do they impose an undue burden on these laboratories. Alternate qualifications for a laboratory supervisor of an environmental laboratory performing the testing listed in the basic wastewater category are contained in §252.302(b) of the proposed regulation. The required college credits provide the scientific background to understand the technical and quality control requirements of the methods and the regulation.

Personnel Requirements and Training

73. Comment: §252.304(a)(1) How will a laboratory know when it has sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions? How will a laboratory know when it has satisfied this requirement? How will the requirement be enforced? (18)

Response: A laboratory will have sufficient trained personnel when it is able to meet all quality control, documentation and reporting requirements of the regulation and the promulgated method. The Department will review the practices and procedures of the laboratory for conformance with the requirements of the regulation. Failure to analyze samples within required holding times, failure to maintain documentation, failure to perform required quality control, and failure to follow method requirements would be evidence of lack of sufficient trained personnel.

74. Comment: §252.304(b) (4) and (8) Requirements for documentation are vague. Both should be expanded to describe what documentation is required. (18)

Response: Other areas of the regulation contain more specific provisions that address the intent of §252.304(b)(8). The Department will remove the section from the final regulation. Section 252.304(b)(4) will be reworded to indicate that laboratory management is responsible for ensuring that all records required by this regulation are maintained.

75. Comment: Training courses in ethical and legal responsibilities are unnecessary because the responsibilities of laboratory personnel are more clearly expressed in writing. Section 252.304(b)(3)(v) requires management to ensure that all technical staff have read, understood and acknowledged their ethical and legal responsibilities, which

is sufficient for the purposes of this rulemaking. Therefore, section 252.304(b)(3)(iv) should be deleted. (6)

Response: The Department does not agree that training in ethical and legal responsibilities is unnecessary for all laboratory personnel. A training session provides a formal opportunity for discussion of the issues and resolution of questions.

76. Comment: With respect to §252.304(b)(3)(iv), defining the scope of ethical training is hard to define or discern. The regulation should be clarified to require training concerning an ethics policy statement developed by the lab to govern laboratory operations. (5)

Response: Guidance and information on training on ethics polices and practices will be provided as part of the Department's compliance assistance efforts..

77. Comment: The required training described in §§252.304(b)(3)(iii) is not clear regarding what types and how often these training courses or workshops are required. (5)

Response: Because of the number and diversity of equipment, methods, and techniques available to an environmental laboratory, it would be virtually impossible to include a comprehensive listing of the training that is appropriate for each situation. Laboratory management is responsible for determining appropriate training for each individual. This section requires that participation in appropriate training is documented.

78. Comment: The language, "quality of data reported by the laboratory" in §252.304(b)(8) is vague. This section should be made clearer regarding the quality of data that is to be summarized, recorded, and documented. (5)

Response: Other sections of the regulation list specific documentation requirements. The type and detail of the documentation is dependant on the analyses performed by the laboratory. Prescribing specific documentation in regulation would be overly burdensome. By not imposing unnecessary documentation requirements on laboratories is one example of the way the regulation is responsive to the needs of small, municipal, and in-house laboratories. Other areas of the regulation contain more specific provisions that address the intent of §252.304(b)(8). The Department will remove the section from the final regulation.

79. Comment: The requirements in §252.304(b)(3)(vii) go beyond the required quarterly QC samples and annual PTs. Requiring each member to be retested for proficiency in each method that a lab performs would be arduous. Repeated proficiency testing should only be required when there is a change in instrumentation or method. (5, 11 and 18)

Response: The Department strongly believes that demonstrating continued proficiency at least once every 12 months is a reasonable minimum. The analysts must only

demonstrate continued proficiency for those tests he or she performs. This demonstration does not require analysis of purchased proficiency test samples. Options are provided that can easily be met by an individual that routinely performs a particular test or analysis. Specifically, the provision allowing for the use of four consecutive laboratory control samples would not add cost to the laboratory. Analyses of the laboratory control samples are necessary to meet other method and Chapter 252 requirements.

80. Comment: The language, "documenting analytical and operational activities of the laboratory" in §252.304(b)(4) is particularly vague. The type of documentation required should be substantially clarified. (5)

Response: Other sections of the regulation list specific documentation requirements. The type and detail of the documentation is dependant on the analyses performed by the laboratory. Prescribing specific documentation in regulation would be overly burdensome. By not imposing unnecessary documentation requirements on laboratories is one example of the way the regulation is responsive to the needs of small, municipal, and in-house laboratories. Section 252.304(b)(4) will be reworded to indicate that laboratory management is responsible for ensuring that all records required by this regulation are maintained.

Equipment

81. Comment: The reference to "visual comparison devices" is confusing and vague. The Department should either amend the definition of visual comparison device or provide examples. (6 and 18)

Response: The term will be replaced with spectrophometer or colorimeter.

82. Comment: §252.306(f)(2)(iv) states that working thermometers that vary from more than 1.0 degree Celsius from the reference thermometer may not be used. The standard outlined in the U.S/Pharmacopoeia (USP) allows for a difference of 2.0 degrees Celsius. (5)

Response: The requirement in the regulation is consistent with the requirements of the US EPA *Manual for the Certification of Laboratories Analyzing Drinking Water*, 5th Edition, January 2005. It is not appropriate to allow wider variation for other environmental measurements.

83. Comment: The requirements under Section 252.306 for equipment calibration are excessively specific. The constant calibration and measurement of laboratory equipment is an unmanageable requirement that is equally difficult to enforce. This section does not take specialty equipment and new technologies that may only be used by certain laboratories into consideration. The Department should draft a simpler requirement stating that a laboratory must document that any instrument used in the

testing process is in good working condition and has been calibrated within a set timetable. (6 and 18)

Response: Specific requirements for some commonly used equipment are included to eliminate the need for guidance documents and eliminate questions of interpretation. Small laboratories also requested that all requirements be included in a single document for ease of use. The requirements in the regulation are very similar to the requirements contained in the *US EPA Manual for the Certification of Laboratories Analyzing Drinking Water*, 5th Edition, January 2005, and in *Standard Methods for the Examination of Water and Wastewater*. The Department has been determining compliance with these requirements, or similar requirements from earlier versions of the same documents, as a routine part of the current Drinking Water Laboratory Certification Program since 1984. The Department believes the requirements are both understandable and enforceable.

84. Comment: §252.306(f)(4)(vii) The section requires a qualified person to service and calibrate analytical balances. Who is considered a qualified person? (18)

Response: A qualified person is a person that has been trained to service and calibrate an analytical balance. Service companies employ individuals who are specifically trained in servicing and calibrating analytical balances.

Methodology

85. Comment: The EPA does not approve methods for testing that fall under a Performance Based Measurement System (PBMS). Section 252.307(b) requires the laboratory to comply with applicable State or Federal regulations when selecting an appropriate method. Although EPA does publish methods for environmental testing, several of the EPA methods employ PBMS, and issue interpretable guidelines instead of methods. Section 252.307(b) should be amended to reflect this. (6 and 18)

Response: The purpose of the Laboratory Accreditation Program is not to determine which tests or methods are acceptable for use in a regulated program, but to ensure that when a test or methodology is specified, the laboratory analyzes the sample properly. Other programs within the Department or the US EPA are usually responsible for the promulgation of methods and guidelines. Wording will be added to Section 252.307(b)(2) to address situations where the requirement is to use a method that is considered appropriate for use.

86. Comment: The prescriptive nature of determining analytical methods exceeds some of the requirements of federal regulation. The EPA Office of Solid Waste has implemented a Performance-Based Measurement System (PBMS) for all analytical measurements conducted in support of the Resource Conservation and Recovery Act. The requirement of laboratories to comply with available DEP methods denies a laboratory the flexibility to select a method that is most appropriate for that particular sample. It greatly limits the ability of laboratories to implement new and emerging

technologies to meet mandated reporting requirements. The Department should amend any sections referring to methodology to allow laboratories flexibility in determining the most appropriate methodology available to them through Performance Based Measurement System (PBMS). In addition, the prescriptive nature of determining methods violates the requirements of Executive Order 1996-1, which prohibits Pennsylvania's regulations from exceeding Federal Standards without a compelling reason. (6 and 18)

Response: The regulation does not violate the requirements of Executive Order 1996-1 because the Laboratory Accreditation Program does not determine or specify which tests or methods are acceptable for use in a regulated program. Other programs within the Department or the US EPA are responsible for the promulgation of methods and guidelines limiting the use of methods. No additional limitations on the acceptable use of methods are contained in this regulation. The purpose of the Laboratory Accreditation Program is to ensure that when a test or methodology is specified, the environmental laboratory analyzes the sample properly. Wording will be added to Section 252.307(b)(2) to address situations that require use of a method considered appropriate for use.

87. Comment: §252.307 (c) How will a laboratory apply for permission to use an alternative or experimental procedure? How will a laboratory appeal a decision under this subsection? What process will the Department use to establish criteria for validating a method? How will laboratories be notified of the Department's decision? (18)

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 various formats that are appropriate for the test method and analyte. The method for validation of an alternate or experimental procedure is dependant upon the analyte. The Department will utilize the USEPA Guidelines, e.g. *Protocol for EPA Approval of Alternate Test Procedures for Organic and Inorganic Analytes in Wastewater and Drinking Water* (EPA 821-B-98-002, March 1999), where available and when appropriate. A decision to allow or disallow an alternative or experimental procedure would be appealed to the Environmental Hearing Board. The Department will notify the laboratory by mail of its decision.

Records and Recordkeeping

88. Comment: Most NPDES permits require maintenance of records for three years. Chapter 252 requires these same records be maintained for a minimum of five years. On-site captive laboratories should be allowed to follow the record keeping requirements of the permit for which the tests are made. (5, 11, 12, and 18)

Response: The Department believes the maintenance of historical laboratory records is essential to data integrity. Requiring that an environmental laboratory maintain records for 5 years helps to insure that historical records will be available to reconstruct

important and vital environmental data. Under some regulations, for example the drinking water program, the permit holder is only required to retain a summary of the results.

89. Comment: There is no need for in-house captive laboratories to have a written procedure to transfer and assure maintenance of records if there is a change in ownership. Normally, the former permittee for whom the tests were conducted (the seller) must retain the records covering their period of operation. (5 and 18)

Response: The Department believes the maintenance of historical laboratory records is essential to data integrity. Requiring that an environmental laboratory maintain records for 5 years helps to insure that historical records will be available to reconstruct important and vital environmental data. Under some regulations, for example the drinking water program, the permit holder is only required to retain a summary of the results.

The procedure for the transfer of laboratory records may reference or be linked to the plan for transfer and maintenance of records of the parent facility in the event of a sale or closure. The plan could include transferring the records to the new owner or the seller retaining the responsibility for the maintenance of the records.

90. Comment: In sections 252.6(a)(4) and 252.707(d), there is no need for in-house captive laboratories to have a written procedure to transfer and assure maintenance of records if there is a change in ownership. Normally, the laboratory would not transfer ownership unless the power plant that supports it transferred ownership, so the record transfer would occur as part of a larger agreement of sale. The power plant laboratory would cease operation if the power plant closed, so there would be no need to maintain or transfer records. We suggest 252.6(a)(4) be amended to read:

> "(4)Records pertaining to the testing or analysis of environmental samples are retained onsite and in accordance with 252.707 (relating to record keeping). Records shall be made available to the Department upon request. *The written plan required in 252.707(d) is not required by an environmental laboratory, accredited by rule, that operates solely in support of the facility of which it is part and is under the same management of the facility it supports."* (7 and 18)

Response: The Department believes the maintenance of historical laboratory records is essential to data integrity. Requiring that an environmental laboratory maintain records for 5 years helps to insure that historical records will be available to reconstruct important and vital environmental data. Under some regulations, for example the drinking water program, the permit holder is only required to retain a summary of the results.

The procedure for the transfer of laboratory records may reference or be linked to the plan for transfer and maintenance of records of the parent facility in the event of a sale or closure. The plan could include transferring the records to the new owner or the seller retaining the responsibility for the maintenance of the records. The plan would

also need to assure that the records are maintained even if the facility closed or ceased operation.

Work Cells

91. Comment: Modify the definition of a work cell to indicate that a work cell may consist of a single individual. (3 and 6)

Response: A work cell, by definition, would never consist only of a single individual. A work cell is a defined group of analysts that together perform testing or analysis of environmental samples. No single analyst performs the entire sample preparation and analytical method alone when working as part of a work cell. An individual analyst (person who performs all analytical steps, including sample preparation, quality control, and analysis) would be required to demonstrate capability as an individual without the aid of any other laboratory personnel and would not be considered a work cell..

92. Comment: The regulations should be amended to allow new analysts to demonstrate capability on an individual level, without the assistance of the other members of a work cell. (6)

Response: A work cell is used when several members of the laboratory staff participate in an analysis that has multiple steps and no single analyst performs the entire analysis on his or her own. In a work cell, each member of the work cell has specifically defined responsibilities that are part of an integrated process. Therefore, the new member must demonstrate his/her ability to perform their specific part of the method in conjunction with the other work cell members. If an individual were part of a work cell, it would be impossible for an individual to demonstrate capability alone without the other members of a work cell.

93. Comment: The requirement for a work cell to demonstrate capability upon addition of new member is unreliable. Section 252.307(j)(7)(ii) says that when a work cell changes, the new work cell must demonstrate capability. This means that a veteran analyst may have to complete several capability demonstrations, and can do so without input from the new analyst. This does nothing to demonstrate the abilities of a new analyst. (6)

Response: A work cell is used when several members of the laboratory staff participate in an analysis that has multiple steps and no single analyst performs the entire analysis on his or her own. In a work cell, each member of the work cell has specifically defined responsibilities that are part of an integrated process. Therefore, the new member must demonstrate his/her ability to perform their specific part of the method in conjunction with the other work cell members. A veteran analyst may have already demonstrated capability for their specific function within one work cell; however, this analyst has never demonstrated their ability to perform their specific function in conjunction with the new analyst, i.e. new work cell. The abilities of the new analyst must be demonstrated in his/her specific function within the analysis, where the remainder of the group performs

other portions of the analytical procedure. Thereby, not only demonstrating the capabilities of the new analyst, but also the capabilities of the newly defined work cell to work together to obtain acceptable results. This does not result in the performance of superfluous capability demonstrations for the veteran analyst, since §252.307(j)(7)(ii) states that the work cell shall demonstrate capability by means of acceptable quality control performance checks on four consecutive batches. Therefore, the laboratory should be able to work the consecutive quality control checks into their regular sample load.

94. Comment: The requirement for initial capability demonstration if a work cell cannot achieve acceptable quality control performance checks in four consecutive batches after addition of a new analyst is unreliable and excessive. The inability to achieve acceptable results may have very little to do with the new analyst or the work cell in general. Laboratories should be given the ability to determine the qualifications of their own analysts. (6)

Response: The entire analytical process is part of the demonstration of capability. Should the demonstration fail due to factors not associated with the new analyst, the laboratory personnel must then determine what went wrong. This is a valid part of demonstrating that the analytical procedure is in control and that the new analyst has the capability to perform the assigned test.

Chemistry Quality Control Requirements

95. Comment: §252.401 (i)(4) What constitutes an "out-of-control" situation? (18)

Response: The Department does not believe that an additional clarification for the term "out-of-control" is required. This term is well understood by environmental laboratory personnel. An out-of-control situation is identified as any situation that does not conform to the requirements and/or expectations of the analytical method, regulation, or Chapter 252 requirements. Examples would include, but not be limited to, failed quality control, failed calibration curve, and retention time shifts outside established retention time windows.

96. Comment: Evaluation criteria for the control sample, duplicate sample, and surrogate spike would be better served through historical laboratory data. According to subsections 252.402(h-j), the evaluation criteria for the chemistry quality control requirements must meet those specified in the reference method. A more accurate measurement of the accuracy of the laboratory would be to use recovery and relative percent difference criteria based on the historical laboratory data, which takes the laboratory standard operating procedure and its implementation into account. (6)

Response: The regulation as proposed does allow for the use of historical laboratory data to generate acceptance limits provided that the limits are at least as stringent as the promulgated method requirements. Allowing wider or less stringent limits would decrease the quality of the data generated by a laboratory.

97. Comment: Language regarding initial calibration for the chemistry essential quality control requirements is unclear. Section 252.402(c)(6) requires the laboratory to report any results not bracketed by the initial calibration standards with appropriate qualifiers. Results from testing are typically bracketed by an initial calibration (ICAL) and a continuing calibration verification (CCV). According to the wording of this subsection, analysis of the ICAL standards may be able to be analyzed on separate days. We recommend that the language be clarified in this section. (6)

Response: The Department, in conjunction with the LAAC, developed the language in the section. The Department believes that the language as written is understandable by environmental laboratory personnel and does not need additional clarification.

98. Comment: The detailed procedures and requirements contained in the draft regulations do not satisfactorily distinguish non-profit and municipal laboratories from the commercial "for-profit" laboratories. The quality control samples listed in Section 252.402 are required at least once per analysis day, no matter how few samples are analyzed. The regulations should be changed to allow a total number of samples to be analyzed no matter how much time passes between analyses before the quality control samples are required. For municipal laboratories, QA/QC sample frequencies should be defined in terms of a minimum of one per "X" number of samples analyzed. (11)

Response: The goal of the rulemaking is to assure the quality of the data that is used to make environmental decisions and thus better protect the environment and the health, safety and welfare of the citizens of this Commonwealth. During the drafting of the rulemaking only items that are essential for the production of good quality data were included. These items were determined to be applicable regardless of the size of the laboratory or the number of samples analyzed by the laboratory.

99. Comment: To ensure quality control reliability for section 252.402(k), language should be added requiring that a Method Detection Limit (MDL) study be performed annually. (6)

Response: A method detection limit study is only required by some of the programs included in this regulation. To impose a requirement to perform a method detection limit study annually would be an unnecessary and potentially burdensome requirement. The regulation does include a requirement for a demonstration of continued proficiency on an annual basis, §252.304 (b)(3).

<u>Toxicity Testing Quality Control Requirements</u>

100. Comment: §252.403 (c) The regulations should cross reference the guidance document regarding the counting of neonates, algae cells and weighing of fish for selected endpoints. The regulation should cross reference the guidance document. (18)

Response: This section will be revised to include a reference to the applicable State regulation.

101. Comment: §252.403 (m) To improve clarity, the size requirements for an incubator should be clearer, such as a measurement in cubic feet. (18)

Response: To clarify this section, the term "refrigerator-sized" will be deleted as the requirement is applicable to any closed incubator.

Microbiology Quality Control Requirements

102. Comment: The word "are" should be inserted between "areas" and "as" in §252.404(d). (18)

Response: The appropriate change will be made.

103. Comment: Language regarding the function properties of an autoclave and hot air oven is unclear. §§252.404(c)(1) and (2) require laboratories to establish autoclaves and hot air ovens function properties and performance, suggesting that heat distribution is one of the properties. It is unclear what measurement the Department requires. Please clarify the rulemaking. (6)

Response: Including required specific testing would make the regulation more prescriptive and limit the options available to laboratories for the use of newer or advanced technology. One method for demonstrating proper functioning of an autoclave or hot air oven would be the following:

Prior to first use laboratories are to determine the functional properties of the unit. Laboratories are to conduct performance studies including temperature distribution for each cycle and load configuration to be used. For example, the maximum temperature thermometer is placed in different areas of the unit (e.g. one adjacent to temperature control and one removed from temperature control) to show equivalent temperature throughout with special attention being paid to large loads. For cycles containing liquids (especially large volumes) the maximum temperature thermometer or biological indicator is to be placed in the autoclave or oven in liquid in a container during the processing of a full load to demonstrate that sterilization parameters are distributed throughout the chamber.

Radiochemistry Quality Control

104. Comment: §252.405 (d)(8) states "Acceptance criteria for instrument suitability verification standards in the method or regulation shall be followed." Are there any situations where the method or regulation would differ? (18)

Response: Yes, there may be situations where the regulations impose different, and more stringent requirements, than the method. For example, the USEPA drinking water program often establishes very specific quality control requirements in regulation that

exceed the requirements of the promulgated method. In that instance, the Federal program regulation requirements would take precedence.

Proficiency Testing

105. Comment: §252.501 (a) This subsection states the Department will publish a list of fields of accreditation for which proficiency test studies are available. Where and how often will these lists be published? The regulation should state where an environmental laboratory can find an updated list of proficiency test studies for fields of accreditation. (18)

Response: The Department will publish an initial list and any future revisions in the *Pennsylvania Bulletin*, in Department guidance documents describing the environmental laboratory accreditation program, and on the Departments website. The regulation will be revised to indicate that the list will be published in the *Pennsylvania Bulletin*.

Miscellaneous Provisions

106. Comment: Subsections 702(b)(2) and 703(b)(9) refer to "selectively reporting data." We assume it refers to intentionally failing to disclose some data so as to create an inaccurate record. In any event, the terminology is sufficiently vague so as to create the potential for misinterpretation on the part of laboratories and Department staff, and we suggest that an effort be made to further define this terminology and how it fits into the context of denial of accreditation. (4)

Response: The proposed language came directly from the current drinking water regulations, 25 PA Code § 109.809(4). For consistency, selectively reporting data will be eliminated in §252.703(b)(9) and replaced in §252.701(b)(2) with the wording in §252.703 "Failure to comply with the reporting and notification requirements as specified in § 252.709 (relating to reporting and notification requirements)."

107. Comment: Section 252.708 concerning subcontracting should be clarified. §252.708(a) states, "the subcontracted laboratory shall be indicated on the final report." The reference to "the" subcontracted laboratory suggests a specific laboratory, when none was previously referenced. (6)

Response: For better clarity, paragraphs (a) and (b) will be switched.

108. Comment: § 702 Denial of application. Subsection 702(b)(14) provides that an application can be denied for "failure to pass an on-site evaluation." However, the rules for on-site evaluations provide a mechanism to cure any failings. Thus, theoretically, a lab could "fail" an inspection, provide the corrective action, and be denied accreditation for the initial failure. We suggest clarifying this subsection to reflect that denial for "failure to pass an on-site inspection" would also require failure to cure the deficiency as provided in Subchapter F. Alternatively, (14) could possibly be removed since the situation is essentially covered in Subsections 252.702(a)(2) and (b)(10). (4)

Response: The Department will remove this subsection. Other areas of the regulations adequately address the Department's concerns with regard to on-site assessments and implementation of the required corrective action.

109. Comment: §§ 702(b)(15), 703(b)(15) and 704(a) provide for rescission of accreditation for denial of access to DEP inspectors (in fact § 704(a) mandates suspension for this). However, circumstances may justify denial of access in certain situations, such as an ongoing on-site emergency situation requiring limited access for safety purposes. It may be worthwhile to qualify these provisions to include the phrase "without good cause." (4)

Response: The Act provides that denial of access shall result in the immediate suspension of any accreditation of the laboratory. (27 Pa. C.S. §4109 (c). This provision is consistent with the Act and is included to reinforce the requirements of the Act.

Coordination with Other Regulations

110. Comment: The Regulatory Analysis Form states that laboratory certification requirements found in Subchapter H of 25 Pa. Code Chapter 109 will be deleted and moved to this regulatory package. The proposed rulemaking does not include deletion of Chapter 109 requirements. (18)

Response: It has clearly been the intent of the Department that this regulation would replace and supercede the provisions of Subchapter H of 25 Pa Code Chapter 109, that describe the requirements of the laboratory certification. Appropriate changes to Chapter 109 are included in the final rulemaking package. The Department is also proposing similar changes to Chapter 78 to avoid any potential conflict or confusion.

Pennsylvania Department of Environmental Protection

**Rachel Carson State Office Building**
**P.O. Box 2063**
**Harrisburg, PA 17105-2063**
October 26, 2005

**Policy Office** 717-783-8727

Kim Kaufman, Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown #2
333 Market Street
Harrisburg, PA 17120

Re: Final Rulemaking – Environmental Laboratory Accreditation Regulations 25 Pa. Code, Chapter 252 (#7-392)

Dear Mr. Kaufman:

Pursuant to Section 5.1(a) of the Regulatory Review Act, enclosed is a copy of a final-form regulation for review by the Commission. The Environmental Quality Board (EQB) approved this final-form rulemaking on August 16, 2005.

This final rulemaking is an entirely new set of regulations promulgated to implement Act 90-2002 (Environmental Laboratory Accreditation Act). In addition, it transfers the current Safe Drinking Water laboratory accreditation program and the current Oil and Gas laboratory accreditation program to Chapter 252. The regulations include specific application procedures, fees, and standards for accreditation.

The proposed regulations were adopted by the EQB on August 17, 2004, and published in the *Pennsylvania Bulletin* on January 22, 2005 with a 30-day public comment period. Comments were received from 20 commentators including the Independent Regulatory Review Commission (IRRC), and the Senate and House Environmental Resources and Energy Committees. The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in development of the draft regulations. Additionally, the LAAC and the Certification Program Advisory Committee (CPAC) met jointly on January 23, 2004 to discuss several key concepts associated with the proposed draft regulations. The final-form regulations and the comment and response document were presented to the CPAC, the State Board for Certification of Water and Wastewater Systems Operators, and the Technical Assistance Center for Small Water Systems in June 2005. The LAAC reviewed the draft final Comment and Response document and the draft final regulations on June 1, 2005 and supported moving the regulations forward to the EQB.

Comments on the fees and fee structure from commentators and LAAC members indicated that the proposed fee structure was difficult to understand and that the fees favored (depending upon the commentator) large, mid-size or small laboratories. This clarity concern has been addressed in final regulation. Several commentators opposed linking automatic fee adjustments to the Consumer Price Index (CPI). The CPI link is not included in the final regulations. Rather, the Department will evaluate the fees at least every three years to insure that they continue to cover the Department's cost of administering the program. If there is a disparity between fees and costs, the Department will recommend changes to the EQB through a proposed rulemaking.

Several comments were received about the accreditation-by-rule provision or the definition of environmental laboratory. Most of these comments were requests for inclusion of specific tests or analysis under the accreditation-by-rule section or exclusion of a group of laboratories from the regulations entirely. Also, several commentators indicated that the regulations would discourage out-of-State laboratories from doing business in Pennsylvania or raise costs to Pennsylvania based businesses. Several commentators thought that the proposed regulations did not adequately address the unique needs of small businesses, municipalities, municipal authorities and in-house laboratories. All the comments have been addressed in the comment/response document, and some revisions to the rulemaking were made in response to the comments.

The Department will provide assistance as necessary to facilitate the Commission's review of this final-form regulation under Section 5.1(e) of the Regulatory Review Act. This review is tentatively scheduled for December 1, 2005. Please contact me if you would like additional information.

Sincerely,

Marjorie L. Hughes

Marjorie L. Hughes
Regulatory Coordinator

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT**

| | |
|---|---|
| I.D. NUMBER: | 7-392 |
| SUBJECT: | Environmental Laboratory Accreditation |
| AGENCY: | DEPARTMENT OF ENVIRONMENTAL PROTECTION |

#2454

**TYPE OF REGULATION**

Proposed Regulation

X 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

**FILING OF REGULATION**

| DATE | SIGNATURE | DESIGNATION |
|---|---|---|
| 10/26 | | HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY |
| 10/26 | | |
| 10.26 | | |
| 10/26 | | SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY |
| | | |
| 10/26 | | INDEPENDENT REGULATORY REVIEW COMMISSION |
| | | ATTORNEY GENERAL (for Final Omitted only) |
| | | LEGISLATIVE REFERENCE BUREAU (for Proposed only) |

October 24, 2005