Regulatory Analysis Form

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INDEPENDENT REGULATORY REVIEW COMMISSION

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(1) Agency
Environmental Protection

(2) Agency Number:
Identification Number: 7-495

IRRC Number: 3157

(3) PA Code Cite: 25 *Pa. Code* Chapter 252

(4) Short Title: Environmental Laboratory Accreditation Regulation

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

Primary Contact: Laura Edinger, 717.873.8727, ledinger@pa.gov
Secondary Contact: Jessica Shirley, 717.783.8727, jesshirley@pa.gov

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

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

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

This proposed rulemaking amends the Environmental Laboratory Accreditation Regulation, 25 Pa. Code Chapter 252. The majority of the proposed changes encompass clarifying the current regulatory language, removing overly restrictive and cost prohibitive language, and adding several additional requirements that the current regulations lack. Additionally, the fee assessment outlined in the regulation does not adequately fund the Laboratory Accreditation Program as mandated by the Environmental Laboratory Accreditation Act (Act 90 of 2002, 27 Pa C.S. §§ 4101 et seq). The rulemaking offers amendments to the following areas of the laboratory accreditation regulations: (a) Fee Structure, (b) Definitions, (c) NELAP Equivalency, (d) Quality Assurance/Quality Control Procedures, (e) Analytical Procedures, (f) Record Keeping Procedures, and (g) Notification Requirements.

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

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

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

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

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

The Environmental Laboratory Accreditation Regulations set forth the requirements that laboratories must meet in order to become accredited to perform testing for 12 environmental statutes administered by the Commonwealth. While completing ongoing rounds of laboratory assessments under the Chapter 252 regulation, which became effective on April 10, 2010, the Laboratory Accreditation Program discovered various portions of the regulations that could benefit from clarification. Numerous laboratories continue to be noncompliant due, in part, to a misunderstanding of some of the regulations. Also proposed to be added are several necessary requirements that will improve the quality of the data and ensure consistent application of the current requirements. These proposed changes to the regulation will benefit the entire regulated community and ensure that the laboratories generate high-quality, reliable, and well-documented environmental testing data for compliance with Department regulations.

The Department also discovered various portions of the regulation where the rules are overly restrictive and cost prohibitive to the regulated community. These proposed changes to the regulation will benefit the entire regulated community. Specifically, the requirements for inorganic non-metals and microbiology laboratory supervisors were changed to require less analytical testing experience to qualify as a laboratory supervisor. The Department removed the requirement for "onsite" assessments as a continuing monitor for laboratory performance, which will allow the Department to explore other cost-saving and technological advances. The Department also added several provisions to suspend a laboratory's accreditation instead of revocation of accreditation, thus allowing the Department more flexibility in enforcement of the regulation.

The Environmental Laboratory Accreditation Act requires that the Department establish and collect fees in an amount sufficient to pay the Department's costs of implementing and administering the accreditation program. The new fee structure accounts for the number of laboratories currently seeking accreditation, the size of the laboratory's scope of accreditation, and the amount of time and cost associated with administering the accreditation program. In 2014, the Laboratory Accreditation Program began providing accreditation services for cryptosporidium, which imposes additional costs not recovered by the fees promulgated in 2010. The proposed fee structure separates the basic microbiology category from complex microbiology and assesses two different fees based on the complexity of the accreditation activities.

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

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

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

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

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

No

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in the development on drafts of the proposed regulations. The LAAC membership is made up of one representative from a municipal authority, a commercial environmental laboratory, an industrial environmental laboratory, an academic laboratory, a small environmental laboratory, an environmental engineer, a member of an association of community water supply systems, a member of an association of wastewater systems, a member with technical expertise in testing and analysis of environmental samples, and two members of the general public.

The LAAC held public meetings on December 11, 2014, March 11, 2015, June 24, 2015, September 30, 2015, and December 2, 2015 to review the Department's proposed drafts of the Chapter 252 regulations. The LAAC and other members of the public provided invaluable advice and insight to the Department during these meetings. The Department considered all comments and agreed to the majority of the recommendations made by the LAAC. On December 2, 2015, the LAAC voted unanimously to recommend that the draft Chapter 252 amendments be submitted to the EQB for consideration.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

The types and number of entities that will be affected by the regulation are limited to those currently regulated by 25 Pa. Code Chapter 252. This proposed rulemaking does not expand the current scope of the Chapter 252 regulations. Those persons, businesses, small businesses, and organizations that may be affected by the proposed regulations include any individual, corporation, institution, or group that applies for environmental laboratory accreditation and seeks to analyze environmental samples for compliance with one or more of the 12 statutes listed in the 25 Pa. Code 252.3(a). The laboratories affected by these proposed regulations will be required to amend their current standard operating procedures and practices to meet the new regulations and they will be required to pay the new fees. Laboratories accredited in the basic microbiology category and inorganic non-metals will find it easier to hire a qualified laboratory supervisor because the experience requirements have been reduced from two years to one year of experience.

A review of the USA Small Business Size Regulations under 13 CFR Chapter 1, Part 121 provides a standard for determining what constitutes a small business. The small size standard for an environmental laboratory is annual receipts of not more than $15 million.

The Environmental Laboratory Accreditation Act and Chapter 252 regulations do not contain any requirements for the submission of financial records. The Department has no way to estimate annual receipts. The Department has historically classified environmental laboratories based on the scope of the laboratory's accreditation. There are three classifications; small laboratories and publicly owned treatment works (POTW), medium laboratories, and large laboratories. Small laboratories and POTWs perform testing in microbiology and/or basic inorganic non-metals, medium laboratories perform testing in microbiology, inorganic non-metals, trace metals, and sometimes volatile organic compounds; large laboratories perform testing for the same tests as medium laboratories and in addition to semi-volatile organic compounds, and/or radiochemistry.

(16) List the persons, groups or entities, including small businesses, which will be required to comply with the regulation. Approximate the number that will be required to comply.

The Department currently has approximately 450 accredited laboratories that will be required to comply with these proposed regulations. The Department estimates that the majority of these 450 accredited laboratories are considered small businesses for financial purposes. Based on the Program's designation of small, medium, and large laboratories based on scope of analytical testing, there are approximately 300 small laboratories, 80 medium laboratories and 70 large laboratories.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The impact of these regulations is minimal with regard social impact. The fees proposed in the regulations will have a financial impact on the regulated laboratories and will require the laboratories to pay increased annual fees. The proposed fees will ensure that the program will recover the operating costs. The other proposed changes in the regulation will ensure that the minimum requirements are met for the testing and analysis of environmental samples that are used by the Department to make compliance decisions. The Department must ensure that it receives reliable testing results for which it will make compliance decisions that impact the public health and the environment. The Department also proposes to remove overly restrictive and cost prohibitive requirements where appropriate. The minimum standard for all environmental laboratories generating compliance data for the Department is reflected in these regulations.

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

The regulations are the minimum standard for ensuring that the Department receives reliable testing results for which it will make compliance decisions that impact the public health and the environment. The minimum standard for all environmental laboratories generating compliance data for the Department is reflected in these regulations. The proposed fees ensure that the program will recover the operating costs. Failure to implement these changes will violate section 4104(6) of the Act which requires the Program to require a fee in an amount sufficient to pay the Department's costs of implementing and administering the accreditation program.

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

Additional legal, accounting, or consulting procedures will not be required. The fees associated with the regulatory requirements are an annual application fee that laboratories will be required to pay. The direct costs for compliance will be payment of the required fees. These costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. The annual renewal application fees will range from $1,300 to $18,000. The cost savings will occur when the Department is able to use technology to perform assessments and reduce the amount of travel time and onsite time for the laboratories. A clearly written standard that includes specific requirements for accreditation will benefit the laboratories by reducing non-compliance and reducing the costs associated with corrective action.

To equally distribute the costs of the accreditation program based on the workload associated with the two accreditation types (State and NELAP), the renewal fee for State accreditation is proposed to be increased by $200/year while the renewal fee for NELAP applicants is proposed to be increased by $750/year. The costs and amount of time associated with accrediting NELAP laboratories is more than double that of a laboratory accredited in the State program. The proposed fees for small laboratories seeking accreditation for basic

drinking water or basic non-potable water will increase by $300. Laboratories seeking accreditation for these two categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories. The proposed fees for medium to large accredited laboratories are likely to increase by approximately 20-30% depending on the requested scope of accreditation. The Department is required to set fees in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program.

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

The proposed rulemaking contains a fee structure that is responsive to the needs of small laboratories; publicly owned treatment works laboratories fall into this category. Categories of testing are included for basic drinking water parameters and for basic wastewater parameters as a group. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. The fees for the laboratories accredited in these categories would increase by $300 per year over the current fees and the majority of the accredited laboratories fall into these categories. The fees assessed to a small environmental laboratory would be increased from an annual fee of $1250 to an annual fee of $1550.

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

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

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

This proposed rulemaking will require no changes to the legal, accounting, or consulting procedures for the regulated community. There are no additional reporting, paperwork, forms or reports that are required to be submitted or developed for the regulated community. The regulation does include some additional recordkeeping requirements for documentation of observations made in the laboratory for microbiology incubation units, pH meters, analytical balances, volumetric dispensing devices, and sample receiving documentation. These requirements are minimal and will not result in significant implementation costs.

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

	Current FY Year 14/15	FY+1 Year 15/16	FY+2 Year 16/17	FY+3 Year 17/18	FY+4 Year 18/19	FY+5 Year 19/20
SAVINGS:	$	$	$	$	$	$
Regulated Community	0.00	0.00	0.00	0.00	0.00	0.00
Local Government	0.00	0.00	0.00	0.00	0.00	0.00
State Government	0.00	0.00	0.00	0.00	0.00	0.00

Total Savings	0.00	0.00	0.00	0.00	0.00	0.00
COSTS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	0.00	0.00	100,000.00	250,000.00	250,000.00	250,000.00
Local Government	0.00	0.00	0.00	0.00	0.00	0.00
State Government	0.00	0.00	0.00	0.00	0.00	0.00
Total Costs	0.00	0.00	100,000.00	250,000.00	250,000.00	250,000.00
REVENUE LOSSES:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	0.00	0.00	0.00	0.00	0.00	0.00
Local Government	0.00	0.00	0.00	0.00	0.00	0.00
State Government	0.00	0.00	0.00	0.00	0.00	0.00
Total Revenue Losses	0.00	0.00	0.00	0.00	0.00	0.00

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY-3 (12/13)	FY-2 (13/14)	FY-1 (14/15)	Current FY (15/16)
Laboratory Accreditation	$1,539,844.84	$1,606,203.61	$1,585,868.40	$1,675,044.00

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.

Of the approximately 450 regulated laboratories that fall under this regulation, the Department estimates that the majority of these 450 accredited laboratories are considered small businesses for financial purposes. Based on the Program's designation of small, medium, and large laboratories based on scope of analytical testing, there are approximately 300 small laboratories, 80 medium laboratories and 70 large laboratories.

(b) The projected reporting, recordkeeping, and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.

The majority of the regulated community is small businesses. The Laboratory Accreditation Advisory Committee membership is heavily weighted with representatives from small businesses or small regulated entities. The actual costs associated with the additional recordkeeping and other administrative costs for compliance with the proposed regulation are minimal. The majority of the new language includes clarifications to current requirements or items that will require additional items to be recorded during testing processes that are already being performed. No additional professional skills are necessary for these regulations.

(c) A statement of probable effect on impacted small businesses.

The probable effect on small businesses will most likely be limited to the fee increase. The proposed fees for the smallest regulated laboratories will be increased by approximately $300. The medium to large laboratories will see an increase of between 20-30% based on the type of accreditation sought and the laboratory's requested scope of accreditation.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

The proposed rulemaking is not intrusive with regard to the actual changes proposed to the current regulations. The significant costs associated with the proposed rulemaking are associated with the fee changes. The fees determined based on the costs associated with implementing the accreditation program, and assessed based on the amount of time the program spends to accredit a particular scope of accreditation. The fees were discussed openly during several advisory committee meetings where the public was able to express its concerns. During these discussions, the Department explained that the costs of operating the program must be distributed appropriately throughout the applicant laboratories and that the costs must be appropriate to the size of the laboratory. The fees are representative of the Department's efforts to minimize the cost to small publicly owned laboratories and its effort to ensure that no one group has an unfair competitive advantage or disadvantage.

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

The proposed 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. These groupings include the tests usually performed by the smaller drinking water and wastewater facilities. The fees for the laboratories accredited in these categories increase by only $300 and the majority of the accredited laboratories fall into these categories.

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

There are no effective regulatory alternatives.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

(a) The establishment of less stringent compliance or reporting requirements for small businesses.

(b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

(c) The consolidation or simplification of compliance or reporting requirements for small businesses.

(d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation.

(e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

(a) – (e) The majority of the regulated community affected by this regulation is small businesses. The Laboratory Accreditation Advisory Committee membership is heavily weighted with representatives from small businesses or small regulated entities and provided the Department with invaluable insight and advice during the development of this proposed rulemaking. The proposed regulations include many reductions in current requirements and clarifications to requirements that will make the regulation more easily understood. Small businesses will not find it difficult to come into compliance with the regulation and will not require an alternate deadline for compliance. The regulation does not require submission of reports to the Department. The

regulation does not include design or operational standards. The regulations are the minimum standard for ensuring that the Department receives reliable testing results for which it will make compliance decisions that impact the public health and the environment. The minimum standard for all environmental laboratories generating compliance data for the Department is reflected in these regulations.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

Data was not the basis for this regulation.

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

A. The date by which the agency must receive public comments: Quarter 3, 2016

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

C. The expected date of promulgation of the proposed regulation as a final-form regulation: Quarter 2, 2017

D. The expected effective date of the final-form regulation: Quarter 2, 2017

E. The date by which compliance with the final-form regulation will be required: Quarter 2, 2017

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

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

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

BUREAU OF LABORATORIES:
LABORATORY ACCREDITATION PROGRAM FEES
3-YEAR REGULATORY FEE AND PROGRAM COST ANALYSIS REPORT
TO THE ENVIRONMENTAL QUALITY BOARD

STATEMENT OF PURPOSE

The Environmental Laboratory Accreditation Act requires that accreditation fees cover the cost of the operation of the laboratory accreditation program. Chapter 252 requires that DEP review the adequacy of this fee every three years. The primary changes to the existing fees included in the proposal are: new fees for the complicated microbiology that require significant expertise, training, and oversight by program personnel and an overall fee increase for all laboratories based on increased program costs for implementation and operation of the program. Proposed fee increases were determined through an evaluation of the amount of time that DEP staff expend during the accreditation of a typical laboratory; the number of laboratories that seek accreditation, and the disparity in current program income to program costs. Small laboratories and publicly owned treatment facilities were given additional consideration. Under this proposed fee increase, the smaller Basic Non-Potable Water and Basic Drinking Water laboratories would experience a $300 increase per year while medium to large accredited laboratories might experience an increase of between 20-30%. The intent is to cover the Department's current and projected costs to administer the program through FY 2019/2020. This proposal would result in an additional $170,000 in fees and potentially impact 450 commercial laboratories.

Small and publicly owned laboratories include approximately 300 wastewater/drinking water/industrial laboratories and 90 medium sized state and National Environmental Laboratory Accreditation Program (NELAP) accredited laboratories. The 300 laboratories would experience approximately a 19% increase and the 80 medium sized state and NELAP accredited laboratories would experience an approximate 20-25% increase in fees. The large commercial facilities, including approximately 70 large commercial state and NELAP accredited laboratories, would experience up to a 30% increase.

BACKGROUND: The environmental laboratory accreditation fees were originally promulgated through final rulemaking on January 28, 2006 and then updated through a final rulemaking on April 10, 2010. The fees support the implementation of the Environmental Laboratory Accreditation Act (ELAA) through application and compliance activities. The 2010 fee schedule was finalized in response to the § 252.204(b) requirement to amend fees for laboratory accreditation to address any disparity between the program income generated by the accreditation fees and the program costs. The fee calculations were based on the workload analysis for managing staffing, and salary rates from 2009. When the fees were proposed in 2010, the total program costs were about $1,500,000, with projections of $1,600,000 through FY14/15.

The Laboratory Accreditation Program ("LAP") implements ELAA through the review of accreditation applications for a variety of public facilities and commercial and non-commercial environmental laboratories. This ranges from small water and wastewater treatment facilities that perform their own compliance monitoring to large commercial environmental laboratories that perform environmental testing activities for DEP-permitted facilities and other entities to demonstrate compliance with a permit, order, regulation, or statute. Accreditation certificates are issued on an annual basis and laboratories may request amendments to their accredited testing activities on an as-needed basis. The LAP performs on-site and off-site assessments of the applicant laboratories at least once every three years and on an as-needed or as-requested basis. The accreditation activities performed by the LAP are conducted in accordance with 25 Pa. Code Chapter 252.

BUREAU OF LABORATORIES:
LABORATORY ACCREDITATION PROGRAM FEES
3-YEAR REGULATORY FEE AND PROGRAM COST ANALYSIS REPORT
TO THE ENVIRONMENTAL QUALITY BOARD

PROGRAM COST ANALYSIS:
Note: the fee collections values include revenue from civil penalties, accreditation fees, and out-of-state travel reimbursement.

Fiscal Year	FEE COLLECTIONS	PROGRAM COSTS
FY-2 (12-13)	$1,631,009.42	$1,539,844.84
FY-1 (13-14)	$1,658,783.55	$1,606,203.61
FY-0 (14-15)	$1,519,882.97	$1,585,868.40*
FY+1 (15-16)	$1,550,000.00 (est)	$1,675,044.00 (projected)
FY+2 (16-17)	$1,550,000.00 (est)	$1,708.545.00 (projected)
FY+3 (17-18)	$1,800,000.00 (est)	$1,742,716.00 (projected)

*Program Costs for FY 2014-2015 reflect a 6-month vacancy of a Chemist 2 laboratory accreditation officer.

TREND ANALYSIS: The current fee structure was established to cover the anticipated costs of the accreditation program through FY2013-2014. Based on the actual revenue, the LAP's costs are projected to continue to be covered through FY2015-2016. The actual revenue for the program has not been generated solely from the accreditation fees. The LAP has experience an increase in non-compliance from several commercial and non-commercial laboratories which generated some revenue from civil penalties that resulted in the LAP being able to cover its costs without requiring a regulatory fee increase. However, in the calendar year 2014, the LAP experienced a significant decrease in the number of NELAP laboratories seeking secondary accreditation. This resulted in approximately a $200,000.00 decrease in actual accreditation fees versus anticipated accreditation fees for FY2014-2015. Secondary NELAP accreditations pay fees at the same rate as primary accreditations, however, the program incurs less expense for processing these applications and the actual accreditation activities undertaken by the LAP are less for secondary NELAP applicants. The loss of secondary NELAP applicants results in very little reduction in workload but a large reduction in revenue.

Without an adjustment to the fee schedule, the gap between the fees and program costs will continue to grow, as costs will increase and revenue will remain flat or reduce. Revenue from fees is expected to remain consistent with the amount from FY 2014-2015. Cost increases are due to personnel costs. It is also likely that additional costs will be incurred due to the increased enforcement actions that the program continues to experience with non-compliant laboratories. However, these costs should be offset by civil penalties. Efficiencies are being planned by developing an electronic application system to allow laboratories to submit applications via the web and thereby reduce the amount of manual data entry required by program staff. The program is also developing an electronic proficiency testing processing system that will reduce the amount of manual data entry and evaluation that the program staff undertake.

Review of expenses reveals that most of the costs are incurred for personnel. The cost of salary, benefits, and travel reimbursement make up the majority of the cost of the program.

ADVISORY COMMITTEE REVIEW: The Department worked collaboratively with the Laboratory Accreditation Advisory Committee (LAAC) to develop a proposed amended fee schedule. LAAC was created by the Environmental Laboratory Accreditation Act of 2002 and provides technical advice to the Department for laboratory accreditation and other environmental laboratory issues. The Department first presented the proposed accreditation fees to the LAAC on December 11, 2014 and an amended fee schedule on June 24, 2015. The Department presented a summary of the accreditation costs compared to the anticipated revenue at the September 30 and December 2, 2015 LAAC meetings.

RECOMMENDATION AND COMMENT: It is recommended that fees be increased to cover the program costs. The Department, in collaboration with the LAAC, has been working to develop a proposed rulemaking to update fees and to amend other regulatory language included in Chapter 252.

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FACE SHEET
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WITH THE LEGISLATIVE REFERENCE BUREAU

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

By: Amy M. Elliott
(Deputy Attorney General)

JUL 20 2016
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. 7-495

DATE OF ADOPTION MAY 17, 2016

BY John Quigley

TITLE JOHN QUIGLEY
CHAIRMAN

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

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

BY Marisa A. D. Lehr

DATE OF APPROVAL 5/25/2016

(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 PROPOSED RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Environmental Laboratory Accreditation

25 *Pa. Code*, Chapter 252

Notice of Proposed Rulemaking
Department of Environmental Protection
Environmental Quality Board
25 Pa. Code Ch. 252
Environmental Laboratory Accreditation

The Environmental Quality Board (Board) proposes to amend 25 Pa. Code Chapter 252 (relating to environmental laboratory accreditation). The proposal clarifies existing requirements, removes or amends overly restrictive and cost prohibitive requirements, and proposes additional requirements necessary for laboratory accreditation. The proposal also revises the current fee structure found at 25 Pa. Code § 252.204.

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

A. Effective Date

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

B. Contact Persons

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

C. Statutory Authority

This proposed rulemaking is being made under the authority of § 4103 (a) of the Act of June 29, 2002 (P.L. 596, No. 90) (dealing with Environmental Laboratory Accreditation) (Title 27 Pa. C.S. §§ 4101 – 4113) (the Act), which directs the Department to establish an accreditation program for environmental laboratories, § 4104 which directs the Department to establish, administer and enforce an environmental laboratory accreditation program which shall include the standards necessary for a State certification program, § 4105, delegating the Board the power to adopt the regulations of the Department to implement the Act, and § 1920-A of The Administrative Code of 1929 (71 P.S. §510-20), authorizing and directing the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. Background and Purpose

The regulations governing environmental laboratory accreditation at 25 Pa. Code Chapter 252 became effective on January 28, 2006 and were amended on April 10, 2010. While completing ongoing rounds of laboratory assessments under these regulations, the Laboratory Accreditation Program ("Program") discovered various provisions that are unclear or where the rules are lacking sufficient detail to ensure full compliance with the regulatory requirements or where the standards were overly restrictive and cost prohibitive. The Program also determined that several necessary standards for accreditation were lacking. The Scope of the regulation remains unchanged.

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

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

E. Summary of Regulatory Requirements

Federal regulations exist for the certification of the analysis of drinking water samples but no federal regulations exist for the accreditation of the analysis of non-potable water (wastewater) or solid and chemical materials. This proposal is more stringent than the federal requirements for laboratory accreditation but not more stringent than the current Environmental Laboratory Accreditation regulations. The proposed rule does not expand the Department's oversight or regulatory authority over environmental testing laboratories.

Federal regulations cover the testing and analysis of samples from public drinking water suppliers. The federal drinking water laboratory certification program consists of requiring the use of federally promulgated methods for testing and analysis and recommended laboratory practices. Some of the requirements listed in these regulations are more stringent than the federal standards for the certification of environmental laboratories performing testing or

analysis on samples from public drinking water suppliers because the federal standards offer recommendations or guidance that are mandated in this regulation.

There are no federal standards or regulations for accreditation of environmental laboratory testing for non-potable water (wastewater) and solid and chemical materials. The federal regulations do mandate specific test methods and performance of the testing laboratories, but do not mandate that the laboratories seek and obtain accreditation. Because there is no federally mandated accreditation program for environmental laboratories testing non-potable water (wastewater) and solid and chemical materials and the federal certification program for testing of potable water consists mostly of recommended practices, most of these regulations are more stringent than the federal program. 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.

An effective laboratory accreditation program is a proactive measure to protect the public health and the environment and to help ensure that the results used to make critical decisions about the public health and environment obtained using Department and USEPA approved procedures and that the data are of known and documented quality. In recent years, the Program has observed an increase in the number and severity of violations committed by commercial environmental laboratories. These violations directly impact the quality of the data used for compliance decisions in the Commonwealth. The Program continues to investigate, enforce, and penalize these non-compliant laboratories based on the Act and its regulations. Non-regulation would result in a system that does not ensure the procedures that produce the overwhelming majority of data used for environmental decisions in the Commonwealth are being performed accurately. Without periodic in-depth on-site and off-site laboratory assessments, the Department cannot have confidence in the data submitted.

Subchapter A.

§§ 252.1 and 252.5. The definitions and NELAP Equivalency sections are proposed to be changed to correctly state that the Department offers and grants "NELAP" accreditation.

§ 252.4. Laboratories reporting analytical testing results for any of the 12 statutes listed in subsection (a) is proposed to be included among the types of laboratories which fall within the scope of the regulations. Currently, only laboratories which test or analyze environmental samples fall within the scope of the regulations.

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

§ 252.6. The Accreditation-by-Rule ("ABR") section is proposed to be amended to specify that all laboratories performing testing or analysis for compliance testing or reporting results of compliance testing must meet the requirements of this section and that laboratories are deemed to be accredited-by-rule if, among other things, they only report the ABR parameters listed in subsections (c) and (f).

Subchapter B.

§ 252.201. Subsection (a) is proposed to be amended by removing the term "in writing." The requirement to apply to the Department for accreditation "in writing" was removed and the phrase "in the format specified by the Department" was added to allow for advances in technology and submission of electronic applications.

§ 252.203. Subsection (a) is proposed to be amended by removing the term "in writing." The requirement to apply to the Department for accreditation "in writing" was removed and the phrase "in the format specified by the Department" was added to allow for advances in technology and submission of electronic applications. Subsection (d) is proposed to be added to require laboratories to provided notification to each affected customer of an expiration of the certificate of accreditation within 48 hours of the expiration.

§ 252.204. Subsection (a) is proposed to be amended to allow applicant laboratories to pay the accreditation fees via credit card when such a time exists that the Department can accept credit card payments. The laboratories choosing to pay via credit card will be required to pay all service charges or administrative fees in addition to the accreditation fees established by this regulation.

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

In order to appropriately distribute the cost of the implementation of the Laboratory Accreditation Program, the fee structure is proposed to be amended to reflect the costs associated with implementation of the Program.

§ 252.205. Subsection (a)(2)(i) is proposed to be amended to add clarification that laboratories seeking secondary NELAP accreditation must meet the requirements of § 252.5 (relating to NELAP equivalency).

§ 252.206. The rate for reimbursement of out-of-State travel for assessors is proposed to be changed from $50 to $75 per hour.

Subchapter C.

§ 252.301. Subsection (h) is proposed to be amended to specify that the laboratory must designate a DEP-approved temporary laboratory supervisor if the primary laboratory supervisor is absent. The proposed regulation also changes the number of days that a laboratory supervisor may be absent from 16 to 21.

§ 252.302. Terminology is proposed to be added to subsections (a) and (b) to better explain the current requirements for laboratory supervisors at laboratories accredited to perform organics, trace metals, and inorganic non-metals analyses. The education and experience requirements for organics and trace metals analyses remains unchanged while the experience requirements for laboratory supervisors supervising inorganic non-metals, basic microbiology, basic drinking water, basic non-potable water, and supervisors approved through the operator certification program are proposed to be reduced from two years to one year.

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

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

The operator certification exam for laboratory supervisors became available in July 2015, as such; subsection (h) allowing two years of testing experience to substitute for the laboratory supervisor sub-classification for operator certification is no longer applicable and is proposed to be removed and replaced with a minimum requirement of one year of analytical testing experience.

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

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

The U.S. Environmental Protection Agency (EPA) granted the Department primacy for the certification of cryptosporidium in 2014. EPA mandates specific experience requirements for

analysts performing testing of cryptosporidium that are not listed in the Chapter 252 regulation. Accordingly, subsection (m) is proposed to be added to specify that if any method, regulation, or program requires more stringent qualifications than those listed in § 252.302, then those requirements must be met.

§ 252.304. Subparagraphs (b)(3)(vi) and (vii) which relate to initial and ongoing demonstration of capability requirements, are proposed to be amended to include additional detail regarding the concentration at which to prepare the four aliquots of the analyte. The proposal also clarifies that the analyses of the 4 aliquots must be analyzed consecutively but can occur on one or multiple days and provides additional clarification to explain how to evaluate the final results.

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

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

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

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

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

Subchapter D

§ 252.401. During public meetings with the LAAC procedures for handling environmental samples outlined in subsection (f) were repeatedly discussed and comments regarding the Department's proposals and expectations were received. It was suggested that additional detail is needed to more fully explain how and when samples must be checked and how the documentation of these checks must be maintained. The existing regulation does not specify when the checks must be made, only that the environmental laboratory is responsible for these checks and that the laboratory must ensure that each check is appropriate to determine the validity of the test and that the checks must be recorded. The requirement to verify and document the condition of the samples by the environmental laboratory is proposed to be clarified to explain that both chemical and thermal preservation must be checked for all samples, that sample pH for all samples is analyzed for chemistry; that whole effluent toxicity and radiochemistry fields of accreditation must be checked for all samples; and that samples must be checked for residual chlorine if the requested test will be negatively impacted by the presence of chlorine. A requirement to include the identification of the individual receiving the sample at the laboratory is proposed to be added.

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

for tests with short holding times, a unique test report identifier or code, and requirements for amendments to test reports.

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

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

This section is proposed to be amended to add standards necessary for the quality control protocols mandated by Chapter 252 where the approved methods do not include acceptance criteria requirements. Many analytical methods do not include specific acceptance criteria for one or more required quality control elements for which the Chapter 252 regulations mandate. A proposed amendment to paragraph (f)(6) provides that when a method exists that does not include minimum acceptance criteria for one or more quality control measures the environmental laboratory must use the acceptance criteria established in an equivalent method. An equivalent method would be one where the same or similar analyte is analyzed using the same or similar methodology/technology. For example, a laboratory is using a spectrophotometric method for the analysis of nitrate that does not have acceptance criteria for the LCS recovery, such as Standard Methods 4500-NO3 E. EPA 353.2 is also a spectrophotometric method for the analysis of nitrate and the LCS recovery for the LCS is 90-110% of the true value. The laboratory would use the 90-100% recovery limits for the evaluation of the LCS when analyzed by SM 4500-NO3 E. The proposed regulation also provides specific information regarding how to develop acceptance criteria for quality control measures when no equivalent method is available.

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

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

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

Subchapter E.

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

Subchapter F.

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

Subchapter G.

Editorial changes are being proposed throughout this subchapter, including removal of the term "onsite", as explained above. Subsections 252.702(d), 252.703(e), and 252.704(c) are proposed to be amended to state that the laboratory may notify the customers of a revocation or suspension in a manner approved by the Department instead of on a form approved by the department. It is proposed to add failure to maintain test instruments, equipment, supplies, and reference materials meeting the specifications required to produce valid analytical results as grounds for denial, suspension, and revocation of accreditation in §§ 252.701(b)(17), 252.702(b)(18), and 252.703(c)(7). Failure to manage PT study results in accordance with § 252.501 is proposed to be added as a cause for revocation and suspension of accreditation in §§ 252.702(b)(11) and 252.703(b)(8). Three additional reasons for suspension of accreditation are proposed in § 252.703(c), including failure to submit an acceptable corrective action report, failure to correct deficiencies from an onsite assessment, and failure to implement corrective action. This would provide the Department greater flexibility in enforcement of the Act and the implementing

regulations. Currently, the Department's only option in response to a violation of these provisions is revocation of accreditation.

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

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

§ 252.708. These regulations incorporate the reporting and notification requirements for the Safe Drinking Water regulations, 25 Pa Code Chapter 109, by reference. In the 2010 revision of Chapter 252, subsection (a) incorrectly included "microbiological" as a type of test that could be reviewed within 24 hours of acquisition of sample results and radiochemistry was missing from this section. These proposed regulations remove "microbiological" from paragraph (a)(2) and add radiochemical to paragraph (a)(3). Three additional paragraphs are proposed to be added to subsection (a) to provide that microbiological results must be read within 30 minutes of the end of the incubation, laboratory control samples must be analyzed at or below the MCL, and a clarification that only those analytical results that meet all method, regulatory, and permit requirements for sample collection, preservation, holding time, sample analysis, and quality control performance may be reported to the Drinking Water Environmental Reporting (DWELR) system unless the Department specifically approves the results to be reported.

F. Benefits, Costs, and Compliance

Benefits

The most significant benefit of these proposed regulations will be the benefit of a clear, concise, and improved regulation for the regulated community. The proposed amendments will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories. All laboratories, particularly small laboratories, will benefit from allowing a laboratory supervisor to be absent for up to 21 days, rather than the current 16 days, and be replaced by a qualified staff member without requiring a DEP-approval for that replacement. Several of the laboratory supervisor areas of experience qualifications were reduced from two years to one year. The proposed rulemaking removes the requirement for the Department to conduct "on-site" assessments, thus allowing the Department to explore and utilize advances in technology to perform off-site assessments which can substantially reduce overall costs to the Program and the regulated laboratories.

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

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

Compliance Costs

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

The renewal fee for State accreditation is proposed to be increased by $200 per year while the renewal fee for NELAP applicants is proposed to be increased by $750 per year. The proposed renewal application fees will increase for all laboratories at a rate of approximately 28%. Each laboratory is also responsible for paying the appropriate category fee associated with its requested scope of accreditation, such as microbiology, trace metals, volatile organics, etc. The total accreditation fee for each laboratory is the renewal application fee plus each appropriate category fee. Each proposed category fee was increased by between $100-200 depending on the complexity of each category. The proposed fees for medium to large accredited laboratories are likely to increase by approximately 20-30% depending on the requested scope of accreditation. The proposed regulations contain a fee structure that is responsive to the needs of small laboratories. Specifically, increased category costs for smaller laboratories will be minimal as the fees for the Basic Non-Potable Water and Basic Drinking Water fee categories are proposed to increase by $300. The current annual fee paid by these environmental laboratories is $1250.00, and the proposed fee change would result in an annual fee of $1550.00. Laboratories seeking accreditation for these two categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories. In addition, the proposed fee structure includes changes including separation of the microbiology category into "basic" and "complex" to ensure that laboratories that are performing the more complex testing, which requires additional staff time and oversight, cover the costs of the accreditation.

Indirect costs will be related to the individual laboratory's implementation of the new requirements. Many in the regulated community are already in compliance with the additional requirements itemized in the proposed rulemaking and will not incur any additional costs for

implementation. Others will be required to update or develop standard operating procedures and update recordkeeping procedures.

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

Compliance Assistance Plan

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

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

Paperwork Requirements

The proposed regulations do not include any additional forms, reports, or other paperwork to be submitted.

G. Pollution Prevention

Not applicable.

H. Sunset Review

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

I. *Regulatory Review*

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

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

J. *Public Comments*

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

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

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

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

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

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

PATRICK McDONNELL,
Acting Chairperson

CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION

Subchapter A. GENERAL PROVISIONS

Sec.

§ 252.1. Definitions.

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

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§ 252.4. General requirements.

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

§ 252.5. NELAP[/TNI] equivalency.

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(b) An environmental laboratory seeking NELAP accreditation shall:

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

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

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

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

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

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

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§ 252.6. Accreditation-by-rule.

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

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

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Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

Sec.

§ 252.201. Application and supporting documents.

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

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§ 252.203. Accreditation renewal.

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

* * * * *

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

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

§ 252.204. Fees.

(a) The appropriate fee in accordance with the following schedule must accompany an application for accreditation, renewal of accreditation, change of ownership, change in administrative information, addition of fields of accreditation, or supplemental onsite assessment. A check must be payable to ''Commonwealth of Pennsylvania.'' **When the Department is able to accept credit card payments, an environmental laboratory may make payment via credit card and shall pay to the Commonwealth all service charges or other administrative fees in addition to the accreditation fees.** The fees are as follows:

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

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

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

*****

§ 252.205. Out-of-State laboratories.

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

*****

(2) *Secondary accreditation.*

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

*****

§ 252.206. Out-of-State onsite reimbursement.

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

*****

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

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

Sec.

§ 252.301. Laboratory supervisor.

*****

(h) An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor **and who is approved by the Department as described in subsection (a)** to temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding **[16] 21** consecutive calendar days. If this temporary absence exceeds 30 consecutive calendar days, the environmental laboratory shall notify the Department in writing under § 252.708 (relating to reporting and notification requirements).

*****

§ 252.302. Qualifications of the laboratory supervisor.

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

*****

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

*****

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

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

*****

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

*****

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

*****

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

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

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

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

*****

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

*****

(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:

*****

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

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

*****

(3) **[Until 12 months after a certificate under the Water and Wastewater Systems Operators' Certification Act for laboratory supervisor in the appropriate water or wastewater subclassification becomes available from the Department, 2 years of experience performing testing or analysis of environmental samples using the methods and procedures currently in use by the environmental laboratory may be substituted for a laboratory supervisory certificate] At least 1 year of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.**

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

(j) A laboratory supervisor of an environmental laboratory engaged in whole effluent toxicity analysis shall have the following qualifications:

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

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

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

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

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

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

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

§ 252.304. Personnel requirements.

*****

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

*****

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

*****

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

*****

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

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

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

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

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

*****

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

*****

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

*****

§ 252.306. Equipment, supplies and reference materials.

*****

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

*****

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

*****

(4) *Analytical or pan balances.*

*****

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

*****

(5) *pH meter.*

*****

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

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

*****

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

*****

(7) *Refrigeration equipment and freezers.*

*****

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

*****

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

*****

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

(9) *Volumetric dispensing devices.*

(i) Except for Class A glassware **and glass microliter syringes**, **[mechanical]**volumetric dispensing devices, including**, but not limited to, graduated cylinders, pipettes, and** burettes, **[autopipetors and dilutors]**, must be of sufficient sensitivity for the application **and the environmental laboratory shall verify and document the accuracy of the volume of use for each lot or at least once per year whichever is more frequent**. Delivery volumes of mechanical volumetric dispensing devices **such as mechanical pipettes, autopipetors, and dilutors** shall be checked at least once every 3 months.

*****

(10) *Graduated sample containers.*

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

*****

(g) An environmental laboratory shall maintain records for all reference materials, reagents**, laboratory supplies that are essential to obtain analytical results** and support services utilized by the laboratory for testing or analysis.

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

*****

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

*****

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

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

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

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

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

* * * * *

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

(j) The laboratory shall perform temperature distribution studies for incubators that are used as incubation units for microbiology.

(1) The laboratory shall perform a temperature distribution study for each incubator prior to first use, after repair and every three (3) years by the following procedure:

(i) The laboratory shall develop a procedure to determine the temperature distribution and fluctuations within its incubator(s). The laboratory shall take into account the size of the incubator (height, width, and depth), number of shelves, and type of incubator when developing the procedure to perform the temperature distribution study.

(ii) At a minimum, the laboratory shall monitor and record the temperature of each shelf.

(iii) Incubators that do not maintain constant temperatures within the acceptable temperature range for the application may not be used. The laboratory may establish

procedures to limit incubator use to specific shelves or areas of the incubator that can be verified to maintain acceptable temperature fluctuations.

§ 252.307. Methodology

* * * * *

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

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

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

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

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

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

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

(v) Field blank requirements.

(vi) Holding time.

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

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

Sec.

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

§ 252.401. Basic requirements.

*****

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

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

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

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

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

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

*****

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

*****

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

*****

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

*****

(15) An identification of subcontracted units.

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

(17) An identification of amendments to the test report. The laboratory shall uniquely identify all amendments to a test report, and the amended report shall be issued in the form of a further document, data transfer, or completely new test report, which includes the statement, "Amended" or "Revised" and includes the identification of the unique laboratory code that meets the requirements of paragraph (16).

*****

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

(o) The environmental laboratory shall clearly identify any opinions and interpretations as such on test reports. When test reports include opinions and interpretations, the laboratory shall include an explanation for the basis upon which the opinions and interpretations have been made.

§ 252.402. Essential quality control requirements—chemistry.

*****

(c) Initial calibration requirements are as follows:

*****

(4) Raw data records shall be retained to permit reconstruction of the initial calibration, **including, but not limited to, identification or reference to the reagents, standards, and supplies used, date(s) of analysis, instrument identification, results of the initial calibration, calibration criteria, and analyst identification**.

*****

(f) Calibration verification requirements are as follows:

*****

(6) Acceptance criteria for calibration verification standards in the method shall be followed. When there are no established criteria in the method, an environmental laboratory shall **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Stree NW, Washington, D.C. 20005) to** determine internal criteria and document the procedure used to establish the acceptance limits.

*****

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

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

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

(g) Method blank requirements are as follows:

*****

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

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

([6]7) To the extent possible, any environmental samples associated with a contaminated method blank shall be reprocessed for analysis. If a contaminated method blank is found to be out of control, and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the contaminated method blank shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers.

(h) Laboratory control sample requirements are as follows:

*****

(6) Each individual laboratory control sample must be compared to the acceptance criteria in the method. When there are no established criteria in the method, an environmental laboratory shall **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005) to** determine internal criteria and document the procedure used to establish the limits.

(7) Raw data records shall be retained to permit reconstruction of the laboratory control sample.

([7]**8**) Environmental samples associated with an out of control laboratory control sample must be reprocessed and reanalyzed from the beginning of the method or the results reported with the appropriate data qualifiers.

(i) Sample duplicate requirements are as follows:

*****

(4) Each duplicate relative percent difference shall be compared to the acceptance criteria in the method. When there are no established criteria in the method, an environmental laboratory shall **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005) to** determine internal criteria and document the procedure used to establish the acceptance limits.

*****

(j) Surrogate spike requirements are as follows:

*****

(3) The results of the surrogate spike shall be compared to the acceptance criteria published in the method. When there are no established acceptance criteria for surrogate recovery in the method, the environmental laboratory shall **use the acceptance criteria described in an equivalent method for the same type of analysis. When an equivalent method is not available, the laboratory shall establish control charts in accordance with Standard Methods for the Examination of Water and Wastewater (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005) to** establish internal criteria and document the method used to establish the acceptance limits.

*****

§ 252.404. Essential quality control requirement—microbiology.

*****

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

(1) *Autoclave.*

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

*****

(9) *Plastic and glassware washing procedure.*

*****

(ii) Washed plastic and glassware shall be tested at least once each month for possible acid or alkaline residue by testing at least one piece of plastic and glassware with a suitable pH indicator such as 0.04% bromothymol blue. Records of pH tests shall be maintained **and include the date, results, and identification of the responsible individual**.

*****

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

*****

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

(7) The heterotrophic plate count and bacteriological water quality test ratio analyses described in paragraphs (2) and (3) must be performed by an environmental laboratory accredited under this chapter for the appropriate field(s) of accreditation.

*****

(f) The requirements for media are as follows:

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

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

*****

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

(1) A sterility blank shall be analyzed for each lot of preprepared, ready-to-use medium and for each batch of medium prepared in the laboratory prior to first use of the medium. Records shall be maintained and include media identification, date **and time of the start and end of incubation**, results and initials of responsible **[individual] individual(s)**. If sterility blank indicates contamination, the media may not be used.

(i) For chromogenic/fluorogenic media, add single-strength media to sterile DI water and incubate at the appropriate temperature and time.

(ii) For all other media, incubate uninoculated, single-strength at the appropriate temperature and time.

(2) For each reusable membrane filtration unit used during a filtration series, the laboratory shall prepare at least one sterility blank at the beginning and at the end of the series. A series is considered ended when more than 30 minutes elapses between filtrations. The laboratory shall insert a sterility blank after every 10 samples filtered through each membrane **[filration] filtration** unit or sanitize filtration units by UV light after each sample filtration in addition to the regular rinsing procedure. Records of sterility blank results must be maintained **in the same manner as the associated sample and include the date and time of the start and end of the incubation, results, and initials of the responsible individual(s)**. If sterility blanks indicate contamination, the laboratory must treat each affected sample according to program requirements.

*****

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

(5) A sterility blank shall be performed on each batch of dilution/rinse water prepared in the laboratory and on each batch of preprepared, ready-to-use dilution water with an appropriate non-selective growth media. The concentration of media shall be single strength after addition of dilution water. Results shall be maintained and include dilution/rinse water identification, date **and time of the start and end of incubation**, results and initials of responsible **[individual] individual(s),** results, and initials of the responsible individual. If dilution/rinse water sterility check indicates contamination, the affected dilution water may not be used.

(6) At least one filter from each new lot of membrane filters shall be checked for sterility with an appropriate nonselective growth media. Results shall be maintained and include membrane filter identification, date **and time of the start and end of incubation**, results and initials of the responsible **[individual] individual(s)**. If the membrane filter sterility check indicates contamination, the affected membrane filters may not be used.

(7) Sterility checks on *Quanti-Tray*™ sample trays shall be performed on at least one sample tray for each lot of purchased, presterilized sample tray with an appropriate non-selective growth media. Results shall be maintained and include sample tray identification, date and time of the start and end of incubation, results and initials of the responsible individual(s). If the sample tray sterility check indicates contamination, the affected lot of sample trays may not be used.

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

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

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

*****

(4) Stock positive and negative culture controls shall be discarded upon the manufacturer's expiration date unless **[it is shown through appropriate biochemical and purity tests]reevaluated and validated by a procedure approved by the Department** that **demonstrates that** the stock culture control has not been contaminated or altered.

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

*****

(i) For test methods that specify colony counts, duplicate counts shall be performed monthly on one positive sample for each month that the test is performed. If the laboratory has two or more

analysts, each analyst shall count typical colonies on the same plate. Counts may not differ by more than 10%. In an environmental laboratory with only one analyst, the analyst shall count the same plate twice. Counts may not differ by more than 5%.

(j) All quality control checks, including but not limited to, sterility checks and positive and negative controls shall be conducted after the laboratory receives the material or supply and before or during first use. These checks must be performed by an environmental laboratory accredited under this chapter and utilizing the same supplies, reagents, and media to be used during laboratory analysis of environmental samples. Certificates of Analysis from a manufacturer may not be used to demonstrate compliance with the requirements of this subsection.

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

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

§ 252.501. Proficiency test study requirements.

*****

(o) An environmental laboratory shall evaluate and report the analytical result of each proficiency test study sample to the proficiency test reporting limit for each field of accreditation, when available, as outlined in subsection (a).

(p) The Department will invalidate any proficiency test study result that is not handled, managed, analyzed, or reported in accordance with this section.

Subchapter F. [ONSITE] ASSESSMENT REQUIREMENTS

§ 252.601. [Onsite assessment] Assessment requirements.

*****

(d) The Department will provide the environmental laboratory with an **[onsite]** assessment report documenting any deficiencies found by the Department. **The Department may deny, suspend, or revoke an environmental laboratory's accreditation in accordance with subchapter G (relating to miscellaneous provisions) before issuing the assessment report or during the corrective action process.**

(e) An environmental laboratory shall submit a corrective action report to the Department within 60 calendar days from receipt of an **[onsite]** assessment report from the Department where the Department has found deficiencies. The corrective action report shall **[document the corrective action taken by the laboratory to correct each deficiency.]:**

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

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

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

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

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

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

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

*****

Subchapter G. MISCELLANEOUS PROVISIONS

Sec.

§ 252.701. Denial of application.

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

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

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

*****

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

(11) Failure to submit an acceptable corrective action report in response to an **[onsite]** assessment **report** within the required time frames.

*****

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

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

§ 252.702. Revocation.

*****

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

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

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

(3) Failure to implement corrective action **[related to] to correct** violations or deficiencies found during an **[onsite]** assessment.

(4) Failure of an environmental laboratory that has been suspended to correct all outstanding violations or deficiencies within 6 months of the effective date of the suspension.

(5) Failure to submit an acceptable corrective action report in response to an **[onsite]** assessment report within the required timeframes.

*****

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

*****

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

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

(c) The environmental laboratory may continue to test or analyze environmental samples for those fields of accreditation not revoked.

(d) Within 72 hours of receiving notice of the revocation of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the revocation in writing of the revocation **[on a form] in a manner** approved by the Department.

§ 252.703. Suspension

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

(1) Failure to comply with the reporting and notification requirements **[as specified in § 252.708 (relating to reporting and notification requirements)]**.

(2) Failure to implement a quality assurance program.

(3) Failure to employ staff that meets the personnel qualifications for education, training and experience **[as specified in § 252.302 (relating to qualifications of the laboratory supervisor)]**.

(4) Failure to submit an acceptable corrective action report in response to an assessment report within the required timeframes.

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

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

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

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

(d) A laboratory may continue to test or analyze environmental samples for those fields of accreditation not affected by the suspension.

(e) Within 72 hours of receiving notice of the suspension of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the suspension in writing of the suspension **[on a form]** **in a manner** approved by the Department.

§ 252.704. Voluntary relinquishment.

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

§ 252.705. Use of accreditation.

*****

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

*****

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

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

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

§ 252.706. Recordkeeping.

*****

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

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

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

(3) Instrument identification.

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

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

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

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

(8) Manual calculations.

(9) Test results.

(c) All **[generated data] records**, except **[data] records** generated by automated **[data]** collection systems, shall be recorded promptly and legibly in permanent ink or in an electronic format. **[Changes to records shall be made so that the original entry remains visible. The individual making the change shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.]**

(1) The individual generating the record shall be identified by initials or signature and the individual making the observation shall be identified by initials or signature, if different from the individual generating the record.

(2) Changes to records shall be made so that the original entry remains visible. The individual making the change shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.

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

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§ 252.708. Reporting and notification requirements.

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

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

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

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

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

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

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

*****

pennsylvania
DEPARTMENT OF ENVIRONMENTAL
PROTECTION

July 29, 2016

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

Re: Proposed Rulemaking: Environmental Laboratory Accreditation (#7-495)

Dear Mr. Sumner:

Pursuant to Section 5(a) of the Regulatory Review Act, please find enclosed a copy of a proposed regulation for review and comment by the Independent Regulatory Review Commission (Commission). This proposal is scheduled for publication in the *Pennsylvania Bulletin* on August 20, 2016 with a 30-day public comment period. The Environmental Quality Board (EQB) adopted this proposal on May 17, 2016.

The environmental laboratory accreditation regulations in 25 Pa. Code Chapter 252 set forth the requirements that laboratories must meet to be accredited to perform testing for 12 environmental statutes. This proposed rulemaking aims to add valuable and necessary standards for laboratory accreditation; to clarify existing requirements to allow the regulated community to more easily understand and comply with the regulations; to remove unnecessary or cost prohibitive requirements; and to amend the current fee structure in order to adequately fund the Laboratory Accreditation Program, as mandated by the Environmental Laboratory Accreditation Act.

The current fee structure does not ensure that the costs of administering the accreditation program are covered by the fees collected from the accredited laboratories. The proposed fee structure accounts for the number of laboratories currently seeking accreditation, the size of the laboratory's scope of accreditation, and the amount of time and cost associated with administering the accreditation program.

Other amendments include clarifications of current requirements such as: performing temperature distribution studies for microbiology incubators; developing sample collection and handling procedures/instructions for sample collectors; verifying and documenting the condition of the sample upon receipt; explaining that the Department of Environmental Protection (DEP) will not accept proficiency test study results that are not performed in accordance with Chapter 252 requirements; and DEP's authority to suspend, revoke, or deny accreditation based on non-compliance found during an on-site assessment.

The proposed regulation removes or amends several overly restrictive or cost prohibitive requirements, such as: reducing the amount of hands-on analytical experience necessary for a laboratory supervisor for basic microbiology and inorganic non-metals; allowing college semester credit hours in health physics and chemistry instead of limiting credits in chemistry for radiochemistry laboratory supervisors; allowing DEP to develop procedures and practices to conduct laboratory assessments offsite and use other technological advances instead of requiring all assessments to occur onsite at the laboratory; and allowing DEP to suspend a laboratory's

accreditation or violations relating to assessment requirements instead of requiring revocation of the laboratory's accreditation.

Finally, the proposed rule adds additional sections to the National Environmental Laboratory Accreditation Program (NELAP) equivalency portion of section 252.5 to ensure that all laboratories generating compliance data for DEP are doing so under the same requirements; specifically, the requirements for sample collection, acceptance, and handling.

Those impacted 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 for compliance with 12 enumerated environmental statutes. Approximately 5,000 laboratories are regulated by Chapter 252, but approximately 450 entities would be required to change procedures.

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in development of the draft proposed regulations. LAAC held public meetings on December 11, 2014, March 11, 2015, June 24, 2015, September 30, 2015, and December 2, 2015, to review the proposed drafts of these regulations. LAAC and other members of the public provided feedback to DEP during these meetings. All recommendations were considered and the majority of these recommendations were incorporated into the draft proposed regulation. On December 2, 2015, LAAC voted unanimously to recommend that the draft proposal move forward for EQB consideration.

The Department will provide the Commission with the assistance required to facilitate a thorough review of this proposal. Section 5(g) of the Regulatory Review Act provides that the Commission may, within 30 days of the close of the comment period, convey to the agency its comments, recommendations and objections to the proposed regulation. The Department will consider any comments, recommendations or suggestions made by the Commission, as well as the Committees and public commentators, prior to final adoption of this rulemaking.

Please contact me by e-mail at ledinger@pa.gov or by telephone at 717.783.8727 if you have any questions or need additional information.

Sincerely,

Laura Edinger
Regulatory Coordinator

Enclosures

0120-FM-PO0011 6/2015

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
POLICY OFFICE

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7-495 Environmental Laboratory Accreditation

SUBJECT:

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

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

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FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
7/29/16	John Engrich	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative John Maher
7/29/16	Jamie Bauter	Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative Greg Vitali
7/29/16	Patricia Zelenus	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Gene Yaw
7/29/16		Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator John Yudichak
7/29/16	Stephen F. Hoffman	INDEPENDENT REGULATORY REVIEW COMMISSION David Sumner
		ATTORNEY GENERAL (for Final Omitted only)
7-29-16	Leah M. Brown	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

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		Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
		Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
		Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
		Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
		INDEPENDENT REGULATORY REVIEW COMMISSION
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