

<h1>Regulatory Analysis Form</h1> <p>(Completed by Promulgating Agency)</p> <p>(All Comments submitted on this regulation will appear on IRRC's website)</p>		<p>INDEPENDENT REGULATORY REVIEW COMMISSION</p>	
<p>(1) Agency</p> <p>Department of Environmental Protection</p>		<p>IRRC Number:</p>	
<p>(2) Agency Number: 7</p> <p>Identification Number: 578</p>			
<p>(3) PA Code Cite: 25 Pa. Code Chapter 252</p>			
<p>(4) Short Title: Environmental Laboratory Accreditation Fees</p>			
<p>(5) Agency Contacts (List Telephone Number and Email Address):</p> <p>Primary Contact: Laura Griffin, 717-772-3277, laurgriffi@pa.gov Secondary Contact: Lauren Imgrund, 717-783-8727, limgrund@pa.gov</p>			
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input checked="" type="checkbox"/> Proposed Regulation <input type="checkbox"/> Final Regulation <input type="checkbox"/> Final Omitted Regulation</p>		<p><input type="checkbox"/> Emergency Certification Regulation; <input type="checkbox"/> Certification by the Governor <input type="checkbox"/> Certification by the Attorney General</p>	
<p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p>The Environmental Laboratory Accreditation Program (Program) accredits analytical laboratories to ensure capacity for quality testing of environmental samples under environmental statutes for the Commonwealth. Every three years, the Program must compile a fee report reviewing Program costs and revenues, which includes an analysis of the projected costs for the next three years. The current fee report indicates that the Program costs are expected to exceed projected fee revenue for the Program this fiscal year. This proposed rulemaking would increase the current fees to ensure they cover the costs required to continue the operation of the Program.</p>			
<p>(8) State the statutory authority for the regulation. Include specific statutory citation.</p> <p>This proposed rulemaking is authorized under the Commonwealth's Environmental Laboratory Accreditation Act (ELAA), 27 Pa.C.S. §§ 4104 and 4105, (relating to powers and duties; and powers and duties of Environmental Quality Board) and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20), authorizing and directing the Environmental Quality Board (Board) to adopt regulations necessary for the proper performance of the work of the Department.</p>			
<p>(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.</p> <p>Yes, the regulation is required by State law. Section 4104(6) of the ELAA requires "a fee for the processing of an application for a certificate of accreditation, including the issuance, renewal,</p>			

modification or other action relating to the certificate, in an amount sufficient to pay the department's cost of implementing and administering the accreditation program.” The ELAA’s implementing regulations, found at 25 Pa. Code Chapter 252, require the Department to evaluate “any disparity between the program income generated by the fees and program costs,” at least every three years and “recommend regulatory changes to the fees” to address the disparity. 25 Pa. Code § 252.204(b).

(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 ELAA requires the Board to establish and collect fees in an amount sufficient to pay the Department’s costs of implementing and administering an accreditation program. The new fee structure in this proposed rulemaking accounts for amount of time and cost associated with administering the Program.

The Environmental Laboratory Accreditation regulations set the requirements that laboratories must meet to become accredited to perform testing for twelve environmental statutes administered by the Commonwealth. In turn, the continuing activities of the Program support the protection of environmental and public health related to these twelve statutes.

(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.

No provisions are more stringent than federal standards.

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

It is difficult to compare laboratory accreditation fees across states as each state has its own unique set of required testing according to their environmental statutes and a wide variety of fee determination protocols exist among states. Many states do not list exact fees in their laboratory accreditation regulations or manuals. Some only issue an invoice with costs after applicants submit their accreditation requests. Some states (like New York) determine the fees annually based on the accreditation program’s previous year’s income.

The most common laboratories accredited by the Program are small commercial laboratories, drinking water systems and wastewater systems that perform a common series of testing covered in the Basic Non-Potable Water and Basic Drinking Water categories. The proposed fee increase would result in an annual state renewal accreditation cost of \$2,000 and \$1,850, respectively, for these laboratories.

Available data from regional states (New Jersey, Ohio, and Virginia), who appear to fund their programs in a manner similar to Pennsylvania, indicate that accreditation fees for laboratories performing the same testing categories ranged from \$1,680 to \$3,550. Therefore, the proposed fee increases as a result of this rulemaking are in line with comparable states and are not expected to impact 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.

The regulation will not affect any other Commonwealth regulations.

(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 feedback on the draft proposed regulation. 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 Department presented the draft proposed fee increases to the LAAC during its public meeting on November 19, 2024. The feedback provided during the meeting included the suggestion of rounding the increased fees to nearest \$50, which has been incorporated into the regulation. Members also suggested a change to the fee schedule to create a separate category for emerging new technologies such as PFAS testing and recommended the LAP evaluate the current testing packages for drinking water and non-potable water analytes to determine if the fees are appropriate in relation to other types of analytes. The Department informed the members that the Program does not have the data needed to support these proposed changes yet and would need to gather additional information and analysis to potentially include these suggestions in a future rulemaking.

(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 would be affected by the regulation are limited to those currently regulated by 25 Pa. Code Chapter 252. 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 25 Pa. Code § 252.3(a).

The Department has historically classified environmental laboratories based on the scope of the laboratory’s accreditation. There are three classifications: small laboratories, which include small commercial laboratories, public drinking water systems and wastewater systems; medium laboratories; and large laboratories. Small laboratories 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, plus semi-volatile organic compounds and/or radiochemistry. The current breakdown of small, medium and large laboratories is listed in the following table:

ACCREDITED ENTITIES	
Small Laboratories	
I. Small Laboratories (not drinking water or wastewater) (< 25 analytes)	69
II. Public Drinking Water Systems	
a. Local government owned	29
b. Privately owned	19
III. Public Wastewater Systems	
a. Local government owned	103
b. Privately owned	4
Total	224
Medium Laboratories (26-500 analytes)	
I. Local government owned	2
II. Privately owned	60
Total	62
Large Laboratories (> 500 analytes)	52
State Government Laboratories	2

The costs of the rulemaking vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. Laboratories that request National Environmental Laboratory Accreditation Program (NELAP) accreditation and pay fees to the Program (currently 117 laboratories) would increase by \$950 for the initial application fee and \$750 for the annual renewal fee. The fees for laboratories that choose State accreditation (typically between 200-300 laboratories) would increase by \$400 for the initial application fee and \$200 for the annual renewal fee. Laboratories would also pay an approximately 27% higher fee (rounded to the nearest \$50 increment) for each additional field of accreditation testing category they select.

The 2017 revision of the Program's fee structure included only minimal fee increases for accreditation in Basic Non-Potable Water and Basic Drinking Water categories versus fee increases for other testing categories offered by the Program. Laboratories seeking accreditation for these two categories represent the majority of applicant laboratories as well as the smallest laboratories in the regulated community, which is why the previous fee adjustment instituted a more equitable fee structure for the small laboratories. The fees for these small laboratories (currently 224 laboratories) would increase by \$250 for the Basic Non-Potable Water category and \$200 for the Basic Drinking Water category.

This regulation proposes to increase fees for the entire regulated community by approximately \$460,000, based on the current number of accredited laboratories and their current fields of accreditation testing.

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

There are currently 338 laboratories accredited by the Program that will be required to comply with these proposed regulations and pay increased fees. (There are two state government-owned laboratories that are exempt from paying accreditation fees. See the response to Question 21.) The Department estimates that the majority of these accredited laboratories are considered small businesses for financial purposes. Based on the Program's designation of small, medium, and large laboratories that would pay accreditation fees, there are currently 224 small laboratories, 62 medium laboratories and 52 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.

This regulation proposes to increase fees by 27% for the entire regulated community accredited to State or NELAP standards by approximately \$460,000, based on the current number of accredited laboratories and their current fields of accreditation testing. This increase is in line with an inflation rate of 3% per year since the last year that the Program's fees were increased (2017).

The proposed fee increase is needed to provide adequate funding for the Department's Program to continue to provide oversight of accredited laboratories to comply with the requirements of ELAA. The Department would benefit from the proposed rulemaking by having the needed revenue to cover the costs of the Program mandated by the ELAA. The public would benefit from the proposed rulemaking as the Program continues to ensure that laboratory data generated from environmental regulatory samples are of high accuracy and quality to inform decision makers in protecting the environmental and public health of the state.

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

The proposed increased fees would allow the Department to maintain the Program at current levels of operation. This includes enabling the Department to continue to fund personnel and cover operational costs, including travel to laboratories for assessments, required assessor trainings, rent and maintenance of leased building office space, office expenditures, and IT consulting and services. The Program's fees have not increased since 2017, but the costs to implement the Program have risen steadily each year. The regulation's proposed fee increase ensures that the Program may recover its operating costs as required by section 4104(6) of the ELAA and the Department has the resources to continue 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.

The costs of the regulation for individual laboratories would vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. The fees for non-state government laboratories that request NELAP accreditation (currently 117 laboratories) would increase by \$950 for the initial application fee and \$750 for the annual renewal fee. The fees for laboratories that choose State accreditation (currently 222 laboratories) would increase by \$400 for the initial application fee and \$200

for the annual renewal fee. Laboratories would also pay a 27% higher fee for each additional field of accreditation testing category they select.

The regulated community includes municipal drinking water systems and wastewater systems that comprise a large portion of the Program's clients. However, these facilities are owned by local governments, so please see the response to Question 20 for details on how they are impacted.

There are also two state government laboratories that are exempt from paying accreditation fees. Please see the response to Question 21 for further details.

Small, medium, and large non-public laboratories would incur a range of cost increases based on the number and type of categories they choose for accreditation. It is estimated that these regulated laboratories would incur a total increase in accreditation costs of approximately \$399,250. This cost is derived from the total projected Program costs increase of \$460,000 minus the costs to local governments identified in the response to Question 20.

Additional legal, accounting, or consulting procedures would not be required.

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

Under this proposed regulation, the local governments with accredited laboratories would pay higher accreditation fees. These laboratories are primarily accredited to analyze samples for a municipal drinking water system or wastewater system. The fees would increase by approximately 27%.

All local government-owned systems would pay a \$200 increase for their State accreditation renewal, from \$700 to \$900.

In addition, drinking water systems seeking accreditation for the Basic Drinking Water category would pay a \$200 increase, from \$750 to \$950. Wastewater systems seeking accreditation for the Basic Non-Potable Water category would pay a \$250 increase, from \$850 to \$1,100.

Currently, 132 laboratories owned by local governments are expected to renew their State accreditation and either the Basic Drinking Water category or Basic Non-Potable Water category. These laboratories each would see an increase in total accreditation fees of \$400 or \$450, respectively.

- Drinking Water Systems: $29 \times \$400 = \$11,600$
- Wastewater Systems: $103 \times \$450 = \$46,350$

Additionally, there are two, local government small laboratories with various accredited categories.

- Local Government Small Laboratories: increase of \$2,800

Therefore, the total increase in accreditation costs to local governments would be around \$60,750.

Additional legal, accounting, or consulting procedures would not be required.

(21) Provide a specific estimate of the costs and/or savings to the *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.

There are no expected costs or savings to state government from this regulation. While the ELAA requires the Department to establish fees at a level that covers the cost of administering the Program, the two Commonwealth agencies that have accredited laboratories are exempt from paying the accreditation fees, under § 252.204(c).

(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 regulation would require no changes to the legal, accounting, or consulting procedures for the regulated community.

(22a) Are forms required for implementation of the regulation?

There are no additional reporting, paperwork, forms, or reports that are required to be submitted or developed for the regulated community.

(22b) If forms are required for implementation of the regulation, attach copies of the forms here. If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.

Not applicable.

(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 2024-25	FY +1 2025-26	FY +2 2026-27	FY +3 2027-28	FY +4 2028-29	FY +5 2029-30
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	399,250	399,250	399,250	399,250
Local Government	0	0	60,750	60,750	60,750	60,750
State Government	0	0	0	0	0	0
Total Costs	0	0	460,000	460,000	460,000	460,000

REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

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

Program	FY -3 2021-22	FY -2 2022-23	FY -1 2023-24	Current FY 2024-25
Laboratory Accreditation	\$869,339*	\$1,311,938	\$1,416,437**	\$1,207,244**

*Please see the attached fee report for an explanation of the Program costs for FY 2021-22.

**Figures have been updated since the fee report was finalized in mid-2024.

(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.

The majority of the 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 currently 224 small laboratories that would be impacted.

(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 proposed regulation does not impose any new reporting or recordkeeping requirements. No additional administrative costs or professional skills are necessary for compliance with the proposed regulation.

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

The probable effect on small businesses is the proposed fee increase of approximately 27-30%, based on the type of accreditation sought and the laboratory's requested scope of accreditation. (At the suggestion of LAAC, the proposed fees are rounded to the nearest \$50 to simplify payment calculation. Therefore, some fee increases are slightly greater than 27% due to rounding up.) The fees for the smallest regulated laboratories would be increased by approximately \$400-450/year, which includes the \$200 increase for the State accreditation renewal fee and either the \$200 or \$250 increase for the basic drinking water fee or basic non-potable water fee, respectively.

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

The fees must cover the costs associated with implementing the Program and are assessed based on the amount of time the Program spends to accredit a particular scope of accreditation. No other alternative exists.

(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.

No special provisions have been developed because the increased fees are necessary to cover the cost of the Program, as required by the ELAA. In the last rulemaking to increase Program fees, finalized in 2017 (47 Pa.B. 4085), the Department sought to more equitably distribute the costs of the Program based on the workload associated with the two accreditation types (State and NELAP). As the costs and amount of time associated with accrediting NELAP laboratories is more than double that of a smaller laboratory that is typically accredited in the State program, the renewal fee for State accreditation in 2017 was only increased by \$200/year while the renewal fee for NELAP applicants was increased by \$750/year. The current proposed rulemaking maintains this equitable cost ratio established in the last rulemaking.

(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 performance standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

(a) – (e) Small businesses would not find it difficult to come into compliance with the regulation and would 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. Although there are no exemptions for small businesses proposed in this rulemaking, the previous fee rulemaking in 2017 instituted a fee structure that more equitably distributed the costs to implement the program. This resulted in smaller increases in fees for categories that small commercial laboratories, drinking water systems and wastewater systems sought accreditation for, as discussed in the response to Question 25.

(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 is the basis for this proposed rulemaking. The Department prepared the “Three-Year Regulatory Fee and Program Cost Analysis Report” (report) in the spring of 2024 to summarize the Department’s fee collections and Program costs by functional area for the fiscal years since the last fee increase in 2017 and the next three projected years. The conclusion of this fee report is that the Program fee structure requires an increase to cover Program costs. A copy of the report is attached and the report also is available on the Board’s website here:

https://files.dep.state.pa.us/PublicParticipation/Public%20Participation%20Center/PubPartCenterPortalFiles/Environmental%20Quality%20Board/2024/Sept_10_2024/02_Lab%20Accreditation_Fee%20report_Final.pdf.

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

- | | |
|---|---|
| A. The length of the public comment period: | <u>30 days</u> |
| B. The date or dates on which any public meetings or hearings will be held: | <u>None Scheduled</u> |
| C. The expected date of delivery of the final-form regulation: | <u>Quarter 3, 2026</u> |
| D. The expected effective date of the final-form regulation: | <u>Upon publication</u>
<u>in the <i>Pennsylvania Bulletin</i></u> |
| E. The expected date by which compliance with the final-form regulation will be required: | <u>Upon publication</u>
<u>in the <i>Pennsylvania Bulletin</i></u> |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <u>Not applicable</u> |

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

Section 252.204(b) requires that the Department review the accreditation fees at least once every three years and recommend to the Board any regulatory changes to the fee schedule if needed.