Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency
Environmental Protection

(2) Agency Number:
Identification Number:

IRRC Number**:**

(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):

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(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 <u>specific</u> 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.