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: 7-495

IRRC Number**: 3157**

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

(4) Short Title: Environmental Laboratory Accreditation

(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 final-form rulemaking amends the Environmental Laboratory Accreditation Regulations, 25 Pa. Code Chapter 252. The majority of the changes include clarifying the current regulatory language, removing overly restrictive and cost-prohibitive language, and adding necessary requirements that the current regulations lack. Additionally, the fee schedule included in the existing regulation does not adequately fund the Laboratory Accreditation Program as mandated by 27 Pa.C.S.§ 4104(6) (Environmental Laboratory Accreditation). The final-form rulemaking offers amendments to the following areas of the laboratory accreditation regulations: (a) Fee Structure, (b) Definitions, (c) National Environmental Laboratory Accreditation Program (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.

27 Pa.C.S. § 4105(a) (dealing with Environmental Laboratory Accreditation)

(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. The Department has also added several provisions that will improve the quality of the data and ensure consistent application of the current requirements. These amendments 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 regulations where the rules were overly restrictive and cost-prohibitive to the regulated community. These changes to the regulations will also benefit the entire regulated community. Specifically, the requirements for inorganic non-metals, basic non-potable water, and basic 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 allow for the suspensions of a laboratory's accreditation instead of revocation of accreditation, thus allowing the Department more flexibility in enforcing the regulations.

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 revised fee structure included in this final-form rulemaking 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 covered by the fees promulgated in 2010. The revised 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 requires the use of promulgated methods for testing and analysis and includes recommended laboratory practices.

It should be noted that this final-form rulemaking is more stringent than the federal requirements for laboratory accreditation but <u>not</u> more stringent than the current Environmental Laboratory Accreditation Regulation. The final 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 requires the use of promulgated methods for testing and analysis and recommended laboratory practices. Some of the requirements included in the final-form regulations are more stringent than the federal standards. The federal standards for the accreditation of environmental laboratories performing testing or analysis on samples from public drinking water suppliers offer recommendations but not firm requirements. Those recommendations are included as requirements in this final-form rulemaking.

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 final 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 proactive in ensuring that the data used to make critical decisions about the environment are of known and documented quality. In recent years, the Laboratory Accreditation Program (Program) has observed an increase in the number and severity of violations committed by some commercial environmental laboratories. These violations directly impact the quality of the data used for compliance decisions in the Commonwealth. The Program continues to investigate and take enforcement action against these non-compliant laboratories based on the Environmental Laboratory Accreditation Act and its regulations. Regulation is necessary to ensure that the laboratories' practices and procedures that produce the overwhelming majority of data used for environmental decisions in the Commonwealth are being performed accurately.

(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 amendments are in line with those of other states. This regulation will not adversely affect Pennsylvania's ability to compete with other states. The current accreditation regulation mandates that any environmental laboratory performing compliance testing for one of the 12 statutes listed in § 252.3 (relating to scope) apply for and obtain accreditation with the Department. The amendments to this regulation amend citations to the 12 statutes listed in the Scope upon original promulgation in 2006, but does not add new statutes to the requirement for accredited testing. All laboratories performing compliance testing for any of these 12 statutes, whether physically located in the boarders of the Commonwealth or outside of those boarders are required to pay the same applications fees and meet the same accreditation requirements.

49 out of 50 states have obtained primacy from the U.S. Environmental Protection Agency (EPA) for the certification of drinking water testing laboratories. Wyoming is the only state that does not have primacy for drinking water certification, and the EPA oversees and certifies the laboratories performing drinking water compliance testing for Wyoming. The states that participate in the National Environmental Laboratory Accreditation Program (NELAP) each require environmental laboratories seeking accreditation in drinking water, non-potable water, and solids to obtain accreditation in order to perform compliance testing for their states. The NELAP states include: New Hampshire, New York,

Virginia, New Jersey, Pennsylvania, Florida, Illinois, Minnesota, Louisiana, Texas, Kansas, Utah, and Oregon.

Washington, South Carolina, California, Colorado, Oklahoma, Alabama, Wisconsin, Michigan, Ohio, Indiana, Kentucky, Georgia, West Virginia, Ohio, Connecticut, Massachusetts, Arizona, and Vermont all operate independent laboratory accreditation programs that either accept NELAP accreditation in lieu of their own state accreditation or require their own state accreditation for drinking water and non-drinking water parameters. Many states require accreditation for testing of air samples, while the Department does not require accreditation for air testing.

(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, 71 P.S. § 745.3)

The Laboratory Accreditation Advisory Committee (LAAC) provided technical assistance in the development on drafts of the proposed and final-form 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 and met again on December 7, 2016 to discuss the public comments and the Department's proposal for final-form rulemaking. The LAAC and members of the public in attendance provided invaluable advice and insight to the Department during these meetings. The Department considered all comments and concurred with the majority of the recommendations made by the LAAC. The Department also agreed with many of the comments provided by the public during the public comment period. On December 7, 2016, the LAAC voted unanimously to recommend that the final-form 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 final-form 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 final-form 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 laboratories affected by these regulations will be required to amend their current standard operating procedures and

practices to comply with the new regulations and they will be required to pay the new fees. Laboratories accredited in the basic microbiology category, basic non-potable water, 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. However, 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 in addition to semi-volatile organic compounds, and/or radiochemistry.

The final-form rulemaking 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 written notification to the Department. Several of the laboratory supervisor areas of experience qualifications were reduced from two years to one year. The final-form 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 amendments will ensure that all laboratories performing testing or analysis of compliance samples for the Department are meeting the same minimum standard.

Costs of the final-form rulemaking 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 increased by $200 per year while the renewal fee for NELAP applicants is increased by $750 per year. The renewal application fees increase for all laboratories at a rate of approximately 30%.

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 category fee was increased by between $100-200 depending on the complexity of each category. The fees for medium to large accredited laboratories are likely to increase by approximately 20-30% depending on the requested scope of accreditation.

The final-form regulations include a fee structure that is responsive to the needs of small laboratories. Specifically, increased accreditation costs for smaller laboratories will be minimal as the fees for the

Basic Non-Potable Water and Basic Drinking Water fee categories increase by $300. The current annual fee paid by these environmental laboratories is $1250.00, and the fee change will 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 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 final 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.

(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.

The Department estimates approximately 450 accredited laboratories will be required to comply with these 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 to social impact. The final-form rulemaking will have a financial impact on the regulated laboratories and will require the laboratories to pay increased annual application fees. The fees will ensure that the program will cover the operating costs. The other changes included in the final-form rulemaking 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. Also, the final-form rulemaking removes overly restrictive and cost-prohibitive requirements where appropriate. The minimum standard for all environmental laboratories generating compliance data for the Department is reflected in this final-form rulemaking.

(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 from 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 revised fee schedule ensures that the program will cover the operating costs. Failure to implement these changes will violate section 4104(6) of the Act

which requires the Program to require a fee structure in an amount sufficient to pay the Department's costs of implementing and administering the accreditation program.

The most significant benefit of this final-form rulemaking is the clear, concise, and improved regulation for the regulated community. The final-form rulemaking will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories.

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

Please also see the answer to Question 15.

(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 are increased by $200/year while the renewal fee for NELAP applicants are 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 general renewal fees will increase for all laboratories at a rate of approximately 30%. The accreditation fees for small laboratories seeking accreditation for basic drinking water or basic non-potable water will increase by $300/year. Laboratories seeking accreditation for these two categories represent the majority of the applicant laboratories as well as the smallest of the regulated laboratories. The accreditation fees for medium to large accredited laboratories are increased by approximately 20-30% depending on the requested scope of accreditation. Fees are required to be set 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 the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The final-form rulemaking contains a fee structure that is responsive to the needs of small laboratories; with publicly owned treatment works laboratories falling 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 will increase by only $300 over the current fees and the majority of the accredited laboratories fall into these categories. The fees assessed to a small environmental laboratory would thus 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 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.

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 final-form rulemaking will require no changes to the legal, accounting, or consulting procedures for the regulated community. There are no additional reporting requirements, 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, analytical balances, volumetric dispensing devices, and sample receiving documentation. These requirements are minimal and will not result in significant implementation costs.

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

The Department requires submission of application forms for laboratory registration, initial and renewal applications, laboratory supervisor approvals, and changes in ownership, administrative information, and quality assurance officer.

(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.**

The attached forms are as follows:

Environmental Laboratory Registration Application

Application for Environmental Laboratory Accreditation

- Part 1 – Initial/Renewal Application
- Part 2 – Methodology Requests
- Part 3 – Add/Change Laboratory Supervisor
- Part 4 – Add Field of Accreditation
- Part 5 – Changes to Laboratory Information

It should be noted that no additional forms are needed for compliance with the amendments included in this final-form rulemaking. All forms provided as attachments are in use currently by the regulated community.

(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 2016/17	FY +1 2017/18	FY +2 2018/19	FY +3 2019/20	FY +4 2020/21	FY +5 2021/22
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:	0.00	0.00	0.00	0.00	0.00	0.00
Regulated Community	0.00	$300,000	$400,00	$400,000	$400,000	$400,000
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	$300,000	$400,00	$400,000	$400,000	$400,000
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 (13/14)	FY -2 (14/15)	FY -1 (15/16)	Current FY (16/17)
Laboratory Accreditation	$1,606,203.61	$1,585,868.40	$1,689,858.89	$1,040,637.96

(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 final-form rulemaking 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 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 final-form rulemaking is not intrusive with regard to the actual changes to the current regulations. The costs of the final-form rulemaking are associated with the fee changes. The fees were 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 advisory committee 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. Finally, the fees were presented as part of the proposed rulemaking and open for public comment for 30 days. The Department did not receive any negative comments from the public regarding the proposed fees or in presenting the final regulation to the LAAC.

(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 final-form rulemaking contains a fee structure that is responsive to the needs of small laboratories. Categories of testing are included for basic drinking water parameters and for basic wastewater parameters as a group. 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/year 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 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) 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 final-form rulemaking. The final-form 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 final -form rulemaking and will not require an alternate deadline for compliance. The final-form regulations do not require submission of reports to the Department. The final-form regulations do not include design or operational standards. The final-form 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 final-form regulations.

The proposed rulemaking included a provision for checking and documenting the pH of every sample container entering the laboratory. During the public comment period and the LAAC meetings, the Department received comments regarding the negative financial impact this requirement would have on the laboratories. The Department included this provision at the recommendation of the Safe Drinking Water (SDW) Program and the EPA's instruction that an improperly collected sample is invalid and cannot be used for compliance purposes. Through discussions with the regulated community, the Department agreed to limit the pH testing requirement to those samples that require a specific pH by method, regulation, or permit, and all SDW compliance samples. Thus ensuring the protection of the public health but reducing the financial burden for non-drinking water samples. The regulated community participating in the public meeting were amenable to this solution.

(28) If data is the basis for this regulation, please provide a description of the data, explain <u>in detail</u> 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 length of the public comment period: 30 days

B. The date or dates on which any public meetings or hearings will be held: None

C. The expected date of delivery of the final-form regulation: Quarter 2, 2017

D. The expected effective date of the final-form regulation: Quarter 3, 2017

E. The expected date by which compliance with the final-form regulation will be required: Upon Publication

F. The expected 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.