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

Preamble

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

This proposal was adopted by the Board at its meeting of _____.

A. Effective Date

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

B. Contact Persons

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

C. Statutory Authority

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

D. Background and Purpose

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

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

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

E. Summary of Regulatory Requirements

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

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

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

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

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

Subchapter A.

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

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

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

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

Subchapter B.

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

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

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

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

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

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

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

Subchapter C.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subchapter D

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

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

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

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

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

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

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

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

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

Subchapter E.

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

Subchapter F.

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

Subchapter G.

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

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

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

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

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

F. Benefits, Costs, and Compliance

Benefits

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

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

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

Compliance Costs

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

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

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

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

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

Compliance Assistance Plan

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

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

Paperwork Requirements

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

G. Pollution Prevention

Not applicable.

H. Sunset Review

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

I. Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on _____, the Department submitted a copy of these proposed amendments to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed regulatory analysis

form prepared by the Department. A copy of this material is available to the public upon request.

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

J. Public Comments

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

Comments including the submission of a one-page summary of comments may be submitted to the Board online, by e-mail, by mail or express mail as follows. If an acknowledgement of comments submitted online or by e-mail is not received by the sender within 2 working days, the comments should be retransmitted to the Board to ensure receipt. Comments submitted by facsimile will not be accepted.

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

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

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

JOHN QUIGLEY,
Chairperson