ENVIRONMENTAL LABORATORY ACCREDITATION REGULATIONS (25 PA CODE CHAPTER 252)

3-YEAR REGULATORY FEE AND PROGRAM COST ANALYSIS REPORT TO THE ENVIRONMENTAL QUALITY BOARD

BACKGROUND:

The regulations governing environmental laboratory accreditation at 25 Pa. Code Chapter 252 became effective on January 28, 2006. While completing the first round of laboratory assessments under these regulations, the Laboratory Accreditation Program discovered various provisions that are unclear or where the rules are overly restrictive and cost prohibitive to the regulated community. The Laboratory Accreditation Program also determined that several necessary standards for accreditation were missing.

Section 4104(6) of the Act of June 29, 2002 (P.L. 596, No. 90) (dealing with Environmental Laboratory Accreditation) (27 Pa C.S. §§ 4101 – 4113) authorizes the Department to "require a fee for the processing of an application, including the issuance, renewal, modification or other action relating to the certificate, in an amount sufficient to pay the department's cost of implementing and administering the accreditation program." The Department is required to set fees in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program. These fees are intended to reflect the costs of implementing and administering the environmental laboratory accreditation program to the environmental laboratories.

The current fees are in accordance with the following schedule and must accompany an application for accreditation, renewal of accreditation, change of ownership, or addition of fields of accreditation. The fees are as follows:

CATEGORY

Application FeeInitial Application Application Fee—Renewal Application Application FeeOwnership Transfer Application FeeAddition Of Fields Of Accreditation	\$600 \$500 \$150 \$250
Basic Drinking Water Category (1 Method For Each Of The Following: Total Coliform Bacteria, Fecal Coliform Bacteria, <i>E-Coli</i> Bacteria, Heterotropic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide)	\$600
AsbestosDrinking Water MicrobiologyDrinking Water Trace Metal CategoryDrinking Water Inorganic Nonmetal CategoryDrinking Water Trace Metal And Inorganic Nonmetal CategoryDrinking Water Volatile Organic ChemicalsDrinking Water Extractable And Semivolatile Organic ChemicalsDrinking Water DioxinDrinking Water Radiochemical CategoryDrinking Water	\$350 \$450 \$450 \$500 \$800 \$500 \$750 \$600 \$700

CATEGORY

CATEGORY	FEE
Basic Nonpotable Water Category (1 Method For Each Of The Following: Fecal Coliform Bacteria, Bod, Cbod, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, And 1 Method For Each Type Of Residue)	\$700
AsbestosNonpotable Water MicrobiologyNonpotable Water Trace Metal CategoryNonpotable Water Inorganic Nonmetal CategoryNonpotable Water Trace Metal And Inorganic Nonmetal CategoryNonpotable Water Volatile Organic ChemicalsNonpotable Water Extractable And Semivolatile Organic ChemicalsNonpotable Water DioxinNonpotable Water Radiochemical CategoryNonpotable Water Whole Effluent Toxicity Testing Category	\$350 \$400 \$450 \$550 \$900 \$500 \$950 \$600 \$600
MicrobiologyDrinking Water & Nonpotable Water Trace Metal CategoryDrinking Water & Nonpotable Water Inorganic Nonmetal CategoryDrinking Water & Nonpotable Water Trace Metal And Inorganic Nonmetal CategoryDrinking Water & Nonpotable Water Volatile Organic ChemicalsDrinking Water & Nonpotable Water Extractable And Semivolatile Organic ChemicalsDrinking Water & Nonpotable Water	\$750 \$800 \$1,000 \$1,550 \$900 \$1,650
DioxinDrinking Water & Nonpotable Water Radiochemical CategoryDrinking Water & Nonpotable Water	\$1,050 \$1,050
AsbestosSolid And Chemical Materials MicrobiologySolid And Chemical Materials Trace Metal CategorySolid And Chemical Materials Inorganic Nonmetal CategorySolid And Chemical Materials Volatile Organic ChemicalsSolid And Chemical Materials Extractable And Semivolatile Organic ChemicalsSolid And Chemical Materials DioxinSolid And Chemical Materials Radiochemical CategorySolid And Chemical Materials	\$350 \$450 \$450 \$550 \$550 \$1,200 \$600 \$600

PROPOSED FEE STRUCTURE:

The current Chapter 252 regulations outline fees based on specific matrices; Drinking Water (DW), Non-Potable Water (NPW), and Solid and Chemical Materials (SCM). The regulations require that a laboratory pay a fee for an accreditation category in a specific matrix. The regulatory fee structure also provides for a reduced fee if a laboratory performs testing in both DW and NPW; however, a similar reduced fee is not currently provided to laboratories performing testing of samples in NPW+SCM or DW+SCM. Additionally, the current fee structure allows for various options to calculate the laboratory's fee. These various options have resulted in confusion among laboratories when calculating their fees. Many laboratories submit more money than required which results in additional paperwork and staff hours to issue refunds.

The Chapter 252 fees must cover the cost of administering the accreditation program. The current fee structure has inadvertently introduced added costs by requiring the Department to expend resources to issue numerous refunds. Finally, the amount of work required by the Department to accredit an environmental laboratory is not dependent on the matrix in which it performs its analytical testing. Because of these issues, the Laboratory Accreditation Program (LAP) decided to re-structure the fees.

The current fee structure provides for accreditation options in the following matrices: DW; NPW; DW+NPW; and SCM. Within these matrices are various analytical category fee options. The applicant laboratory pays the analytical category fee appropriate to the chosen matrix.

The proposed fee structure provides for accreditation options in the following fields: First Matrix; Second Matrix; and Third Matrix.

The analytical category fee options within these matrices are the same as those in the current fee structure. Each analytical fee category in each subsequent matrix is less expensive than the previous matrix. The proposed fee structure allows for a laboratory performing NPW and SCM testing to receive a reduced fee, which is currently not offered in the current fee structure.

The cost of each analytical fee category was increased in a manner that reflects the number of FTEs required to accredit an environmental laboratory for the particular analytical category requested. Most analytical category fees increased by approximately \$50-100, however, the Extractable and Semi-Volatile Organic Chemicals category fee increased by \$750. This increase is necessary due to the number of analytical methods included in this category. The original fee assessed to this analytical category was unreasonably low when accounting for the volume of test methods included in this category and the amount of time required to accredit a laboratory in this category.

The proposed fee structure also includes several new categories, including a NELAP accreditation fee and a supplemental on-site assessment fee. These fees were added because the cost of accrediting an environmental laboratory in the NELAP Program incurs additional costs not associated with the Chapter 252 accreditation requirements. The current fee structure requires a State accredited laboratory to pay the same fee as a NELAP accredited laboratory. The supplemental on-site assessment fee was added because the fees associated with accreditation assume participation in an on-site evaluation approximately every 2.5 years. Laboratories frequently apply to add fields of accreditation to their current scope of accreditation that necessitates an on-site evaluation. It is only reasonable that a laboratory requesting a field of accreditation that necessitates an on-site evaluation should be responsible for paying for the evaluation rather than factoring additional on-site evaluation costs into the annual accreditation fees for all laboratories.

The proposed fees would be in accordance with the following schedule and must accompany an application for accreditation, renewal of accreditation, change of ownership and change in administrative information addition of fields of accreditation. The fees are as follows:

CATEGORY	FEE
Application Fee – Initial Application for State Accreditation	\$750
Application Fee – Renewal Application for State Accreditation	\$500
Application Fee – Ownership Transfer or Change in Administrative Information	\$150
Application Fee – Initial Application for NELAP/TNI Accreditation	\$2,500

Application Fee – Renewal Application for NELAP/TNI Accreditation	\$2,000
Application Fee – Addition of Field of Accreditation	\$250
Application Fee – Supplemental On-Site Assessment	\$500
Basic Drinking Water Category – includes 1 method for each of the following: Total Coliform Bacteria, Fecal Coliform Bacteria, <i>E. coli</i> Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	\$650
Basic Non-potable Water Category – includes 1 method for each of the following: Fecal Coliform Bacteria, BOD, CBOD, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, and 1 method for each type of residue including % Solids for land-applied biosolids	\$750
Asbestos—first matrix	\$400
Microbiology—first matrix	\$500
Trace Metal Category—first matrix	\$550
Inorganic Non-metal Category—first matrix	\$600
Volatile Organic Chemicals —first matrix	\$650
Extractable and Semi-volatile Organic Chemicals—first matrix	\$1,500
Dioxin—first matrix	\$650
Radiochemical Category—first matrix	\$750
Whole Effluent Toxicity Testing—first matrix	\$700
Asbestos—second matrix	\$350
Microbiology—second matrix	\$450
Trace Metal Category—second matrix	\$500
Inorganic Non-metal Category—second matrix	\$550
Volatile Organic Chemicals—second matrix	\$600
Extractable and Semi-volatile Organic Chemicals—second matrix	\$1,400
Dioxin—second matrix	\$600
Radiochemical Category—second matrix	\$700
Asbestos—third matrix	\$300
Microbiology—third matrix	\$400
Trace Metal Category—third matrix	\$450
Inorganic Non-metal Category—third matrix	\$500
Volatile Organic Chemicals—third matrix	\$550
Extractable and Semi-volatile Organic Chemicals—third matrix	\$1,300
Dioxin—third matrix	\$550
Radiochemical Category—third matrix	\$650

For the environmental laboratories required to maintain accreditation in accordance with the Chapter 252 regulation, the costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. The annual application fees will range from \$900 to \$15,000. The Department believes that the increased accreditation fees will not result in prohibitive cost increases for any environmental laboratory.

ANALYSIS:

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 Laboratory Accreditation 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 were not sufficient to recover the Department's costs to implement the program. These proposed regulations provide a new fee structure to cover the costs of the Laboratory Accreditation Program, including increases in salaries for union covered employees, benefits and operational expenses (including travel, training, equipment costs, office supplies, and information technology support). Please see Appendix 1 for a listing of specific staff activities supported by the fees associated with the laboratory accreditation program.

The figures below set forth the costs that are associated with the activities of the Laboratory Accreditation Program from fiscal year 2007 to fiscal year 2012. The annual 4% increase in program costs from fiscal years 2009 through 2012 is representative of the anticipated increases in personnel and operational costs.

PROGRAM COSTS:

	FY 2007-08	FY 2008-09	FY 2009-10	FY 2010-11	FY 2011-12	FY 2012-13
Program Cost:	\$1,170,605	\$1,314,605	\$1,350,000	\$1,460,000	\$1,580,000	\$1,690,000

The figures indicated in the table below include the projected revenue for the program, assuming the effectuation of the proposed fee increase. Fiscal years 2010, 2011 and 2012 are anticipated to be the first full three years in which the proposed fees would be collected. It is anticipated that the revenue collected through the proposed fee increase will cover program costs.

ANTICIPATED FEE COLLECTIONS:

	FY 2007-08	FY 2008-09	FY 2009-10	FY 2010-11	FY 2011-12	FY 2012-13
Fee Collection:	\$880,000	\$1,260,000	\$1,300,000	\$1,300,000	\$1,600,000	\$1,600,000

RECOMMENDATION AND COMMENT:

The Department recommends the Environmental Quality Board's approval of the proposed regulations, including the proposed fee structure. The proposed rulemaking contains a fee structure that is responsive to the needs of small laboratories. The different testing procedures for basic drinking water parameters and for basic wastewater parameters have been grouped together. Additional tests were added to the basic wastewater parameter group in response to comments received by the Laboratory Accreditation Advisory Committee. 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 \$50 per year and the majority of the accredited laboratories fall into these categories. The fees assessed to these smallest of environmental laboratories will increase from an annual fee of \$1200 to an annual fee of \$1250. The average fee for a medium environmental laboratory will increase from \$3,700 to \$4,900 and the increase for a large accredited environmental laboratory will increase from \$8,100 to \$10,600. A NELAP accreditation for any lab would be an additional \$2,000. The estimated cost of the Laboratory Accreditation Program for 2011/2012 fiscal year is \$1,580,000 and the projected revenue for the first full year is \$1,600,000. Thus the projected amount collected in revenue covers the estimated cost of the 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 and the LAAC ensured that the interests, concerns, and needs of the regulated community were considered and implemented as appropriate. The LAAC met throughout 2008 to review and comment on the draft Chapter 252 amendments presented by the Department. On December 1, 2008, the LAAC unanimously voted to recommend the Chapter 252 amendments for presentation to the Board.

APPENDIX 1

Examples of environmental laboratory accreditation program activities supported by the fees associated with laboratory accreditation program include the following:

- Assessment of Applicant Laboratories—Includes performing on-site evaluations, writing
 assessment reports, reviewing corrective action reports submitted by the laboratory, and
 updating a laboratory's accreditation status resulting from the completed on-site
 evaluation. A laboratory on-site evaluation includes the evaluation of laboratory's
 facilities, equipment, methodologies, quality control practices, and personnel.
- Application Review—Includes review of a laboratory's application for accreditation, evaluation of appropriate fee payment, updating a laboratory's scope of accreditation based on their application requests, and issuing a new certificate of accreditation. Review of a laboratory's application for accreditation includes the review and evaluation of laboratory supervisors for compliance with Chapter 252 requirements.
- 3. Review and Approval of Proficiency Testing (PT) Results—Includes review of a laboratory's current scope of accreditation, review of the laboratory's history of pass and fail rates in past PT studies, changes to a laboratory's accreditation status based on the laboratory's performance on PT studies, or lack thereof.
- 4. Provide Technical Assistance to Applicant Laboratories Required by 27 Pa C.S. § 4104

 (7)—Includes responding to phone calls, e-mails, and other correspondence from applicant laboratories within approved timeframes. The Laboratory Accreditation staff also attend meetings and training sessions offered to applicant laboratories and interpret the State, National, and EPA rules and regulations that apply to applicant laboratories when guidance is requested.
- 5. Maintain Approval as a NELAP Accreditation Body—Includes review and approval by The NELAC Institute (TNI), maintenance of the Laboratory Accreditation Program's quality system, a requirement for biennial on-site assessments of NELAP accredited laboratories, a requirement for annual training of all Laboratory Accreditation Program staff, participation in TNI committees and attendance at the biannual face-to-face meetings.