

# "Externalization" of EPA'S Water Laboratory Performance Evaluation Programs

Options Paper

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"EXTERNALIZATION" OF EPA'S  
WATER LABORATORY PERFORMANCE  
EVALUATION PROGRAMS

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## TABLE OF CONTENTS

ACRONYMS .....	ii
INTRODUCTION .....	1
BACKGROUND .....	1
Assumptions Used in Evaluating Potential Options .....	2
Implementation Issues and Assumptions .....	3
Consistency Within a Multiple Provider System .....	5
Role of Stakeholders .....	5
Relationship of NELAC to the Redesigned Program .....	5
Process and Criteria for Developing and Selecting Options .....	6
Organization of the Options Paper .....	8
Definition of Terms .....	9
DESCRIPTIONS OF OPTIONS .....	13
Option 1: EPA Oversees PE Study Providers .....	14
Option 2: NIST Oversees PE Study Providers .....	21
Option 3: States Oversee Private Sector PE Study Providers .....	30
Option 4: Private Sector Third Party Oversees PE Study Providers .....	38
Option 5: EPA-designated Third Party Oversees National Program .....	46
Option 6: No EPA Involvement in Water PE Studies .....	54
Option 7: No National Accreditation/Oversight of PE Study Providers .....	60
Option 8: EPA Oversees One or More Government or Non-profit PE Study Providers .....	66
APPENDIX A EPA Requirements for National Consistency Among Multiple PE Study Providers .....	A-1
APPENDIX B Table of Performance Evaluation Externalization Responsibilities Under Each Option .....	B-1

## ACRONYMS

A2LA	American Association for Laboratory Accreditation
AA	Assistant Administrator
ANSI	American National Standards Institute
CWA	Clean Water Act
DW	Drinking Water
DMRQA	Discharge Monitoring Report Quality Assurance
ELAB	Environmental Laboratory Advisory Board
EMMC	Environmental Monitoring Management Council
EMMP	Environmental Monitoring Management Program
EPA	Environmental Protection Agency
FACA	Federal Advisory Committee Act
FTE	Full Time Equivalents
IAG	Interagency Agreement
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
NERL-CI	National Exposure Research Laboratory - Cincinnati
NIST	National Institute of Science and Technology
NSF	National Science Foundation
NVLAP	National Voluntary Laboratory Accreditation Program
NY	New York
ORD	Office of Research and Development
OW	Office of Water
PE	Performance Evaluation
QA	Quality Assurance
SDWA	Safe Drinking Water Act
SSA	Standards Setting Authority

# EXTERNALIZATION OF EPA's WATER LABORATORY PERFORMANCE EVALUATION PROGRAMS

## INTRODUCTION

EPA is reevaluating the Federal role in the implementation of the Water Performance Evaluation (PE) Study Program in light of current funding limitations as well as the Agency's inability to create a dedicated fund for any fees collected under the existing user fee authority. In May of 1994, EPA's Assistant Administrators for Water, Research and Development, and Enforcement and Compliance Assurance instructed staff in the Office of Water (OW) and the Office of Research and Development (ORD) to establish a Water Laboratory PE Redesign Work Group. They charged the Work Group with: (a) streamlining the current operation; and (b) redesigning the current program to make it more effective and to address gaps in coverage, and completing a scheme to make the study self-supporting. The Water Laboratory PE Redesign Work Group was formed in August 1994 and first met in September 1994. The Work Group consists of approximately 35 members from OW, ORD, OECA, and the Regional Environmental Services/Sciences Divisions. In addition, several States have been invited to provide input during the development of options for all three charges. **This paper outlines the options under consideration by the Work Group for making the studies self supporting and highlights the Agency's role in Water Laboratory PE Studies under each option.**

## BACKGROUND

Since the 1970s, the Agency has been conducting laboratory performance evaluation (PE) studies to support the various water programs administered by the States and EPA under Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA). The PE studies involve preparing solutions of known concentrations of analytes, sending the samples to participating laboratories for analysis, and scoring the results against performance criteria that are statistically or empirically based to determine whether the laboratory has demonstrated acceptable performance. PE studies are a valuable indicator of a laboratory's competency to analyze water samples. The PE studies also serve as one component of EPA's overall program for assuring the quality of the environmental measurements conducted to implement both the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA).

In total, EPA conducts three PE study programs to support nationwide implementation of water programs:

*Water Supply (WS) study program*, which includes chemistry, microbiology, and radiochemistry PE studies, supports implementation of the Safe Drinking Water Act. Under the Safe Drinking Water Act, laboratory certification programs are administered primarily by States (although, in limited instances, by EPA). Although participation in the WS study is not federally compelled,

many State drinking water laboratory certification programs rely on the WS PE study program to provide a critical element for laboratory certification.

*Water Pollution (WP) study program*, which includes chemistry PE studies, tests laboratories' abilities to analyze for common surface water quality pollutant parameters and supports 25 to 30 State wastewater and other environmental laboratory certification programs. Many States conduct laboratory accreditation programs in support of the National Pollutant Discharge Elimination System (NPDES) permitting program under the Clean Water Act. Participation in the WP is not federally compelled, however, many States require laboratories to participate in the WP study as a basis for accreditation under State laws.

*Discharge Monitoring Report Quality Assurance (DMRQA) study program*, which includes inorganic chemistry and whole effluent toxicity (WET) PE studies, is used as one tool for ensuring the quality of monitoring data submitted by National Pollutant Discharge Elimination System (NPDES) permittees. Regions and States use the results to identify laboratories that may need follow-up inspections. Historically, EPA administered the DMRQA studies *through* NPDES "major" permittees, who would transmit the DMRQA test samples to the laboratories who conducted compliance monitoring for such permittees. Starting in FY 1996, the DMRQA program is structured slightly differently. Now, the NPDES permittee instructs the laboratory that conducts compliance monitoring for the permittee to request the samples they need from EPA. EPA, in turn, sends PE samples directly to the NPDES laboratory. NPDES permittees are required to participate in the DMRQA study under the authority of Clean Water Act section 308. Thus, though laboratories are not directly required to participate, participation is effectively or indirectly required by market forces.

The PE studies are sent to over 9000 laboratories and NPDES permittees annually at a cost to EPA of \$2.5 million in extramural resources and approximately 15 Office of Research and Development FTEs and approximately 8 to 10 Regional FTEs. Ensuring an adequate source of funding for these studies has been a concern of the Agency for nearly a decade. As a first step in implementing cost savings measures for the PE studies, later this year, the Office of Research and Development is conducting a combined WP and DMRQA study. This combined study will result in a projected annual program savings of approximately \$0.3 to 0.5 million. Additional cost reductions are necessary however, in order to ensure continuation of the studies.

### **Assumptions Used in Evaluating Potential Options**

Various assumptions were made at the outset of the process to develop alternative funding options for the Water PE Study Program. These assumptions were based on the charge to the Work Group by senior Agency managers, current Agency policies, legal restrictions, and other important concerns identified by the Work Group. The assumptions are:

- The redesigned program must ensure high standards, credibility with the public and private sectors, consistent national standards, and responsiveness to the needs of the

regulatory, regulated, and laboratory support communities. In order to ensure these conditions are met, **the Work Group assumed that EPA must retain significant leadership responsibility in the standards setting process selected for the program.**

- EPA will not have the resources to continue to produce and distribute PE study kits free of charge (e.g., the status quo will not continue). Under the redesigned program, organizations external to EPA will produce the water PE studies and participants in both the public and private sectors will have to pay to participate in studies.
- All options addressed by the options analysis must be within the scope of EPA's statutory authorities.
- Every effort will be made to implement the redesigned program as soon as possible. Regardless of the option selected, the redesigned program must be implemented no later than Fiscal Year 2000.
- At least a two year lead time will be provided to the states in order to give them sufficient time to implement any necessary statutory, regulatory and budgetary changes, based on past written assurances from ORD management.
- EPA has tried and has not been able to obtain fee retention authority for this program from Congress and therefore, having EPA collect fees from the states and/or private sector to pay for the operation of the program cannot be considered as an option in the foreseeable future.
- EPA will not provide funding or "seed money" to any non-government organization for purposes of establishing the program.
- In order to encourage endorsement by all EPA Offices, EPA Regions, and the States, the option development and selection process will be coordinated with the EMMC and National Environmental Laboratory Accreditation Conference (NELAC).

### **Implementation Issues and Assumptions**

Because of the large number of stakeholder groups involved (i.e., EPA, the states, participating commercial and government laboratories, commercial vendors, the regulated community, and others), implementation of the redesigned program will require considerable attention to identifying and addressing the implementation concerns of the states and private sector. As a first step toward ensuring that implementation issues are identified from as many perspectives as possible, the Work Group agreed that steps would be taken to obtain input through several efforts such as formal notice and comment procedures, a public meeting, dialogues with various stakeholder groups, and extensive review of the options paper by EPA regional and state program representatives. The Work Group is also working directly with

representatives from the National Institute of Standards and Technology (NIST) to ascertain whether NIST will be able to assist with a redesigned program. In addition, the Work Group chairs have developed a process for coordinating the efforts of the National Environmental Laboratory Accreditation Conference (NELAC) Proficiency Testing Committee with the Water Laboratory PE Redesign Work Group to ensure that these two efforts remain as consistent as possible and maintain compatible schedules to the extent practical.

The Work Group agreed to four assumptions regarding implementation, which apply to all options presented in this paper. These assumptions are:

- **The redesigned program will not result in any significant changes to existing EPA regulatory requirements or compliance monitoring programs.** The regulatory requirement to successfully complete at least one PE study per year in order to maintain laboratory certification under the Safe Drinking Water Act will remain in place, for example. EPA will also retain the requirement that all major NPDES permit holders participate in one DMRQA study each year.
- **Authorities delegated to the states under the Clean Water Act and the Safe Drinking Water Act and related federal regulatory provisions also will not change in any substantive way as a result of the redesigned program.** For example, under the current SDWA regulations (40 CFR 141, *et seq.*), certified drinking water laboratories are required to obtain an appropriate PE study from EPA (i.e., the Office of Research and Development in Cincinnati, OH) or from the state in which they maintain or seek certification. This requirement can be interpreted to mean that laboratories can obtain a study directly from the State or from a provider designated by the accrediting body in the state in which they maintain or seek certification. Under this existing system, states have the authority to require that their laboratories participate in the EPA studies or to designate an alternate source for PE studies. This aspect of the program will not change as a result of the redesign.
- **EPA and the states will receive all of the information needed to fulfill the requirements of regulatory, compliance monitoring, and laboratory certification programs under the redesigned program.** Consequently, any approved PE study provider, whether a government organization or a commercial entity, will provide reports to EPA and the states sufficient to meet program needs. At a minimum, such reports will include all information currently provided to the EPA Regions and the states under the existing program.
- **In order to facilitate reporting, electronic methods of transmission utilizing standardized data formats will be developed and implemented to the maximum extent possible.**



## **Consistency Within a Multiple Provider System**

All of the options presented in this paper include the use of a system involving multiple providers of PE studies. Under such a system, multiple providers would conduct the PE studies according to established standards in an effort to meet and better serve the needs of the different PE programs as well as reduce EPA costs for the studies. The Work Group recognized that moving from the current single-supplier system to a system involving multiple providers will introduce concerns regarding consistency in PE studies. Consequently, the Chairperson of the Work Group requested several members to convene a committee to examine the issue of achieving national consistency in a multiple provider system and to identify the critical elements required to achieve an acceptable level of consistency. The draft report generated by this committee, *"EPA Requirements for National Consistency Among Multiple PE Study Providers,"* is presented as Appendix A to this document.

## **Role of Stakeholders**

The Work Group recognizes that the Water PE Study program and redesign effort have important roles in other on-going Agency and external efforts related to environmental monitoring and quality assurance. In particular, efforts undertaken by EPA's Environmental Monitoring Management Committee (EMMC) regarding the establishment of a performance-based system for analytical methods, national environmental laboratory accreditation, and integration of EPA's analytical methods all relate to the water PE study program. Consequently, EPA has and will continue to coordinate its effort to re-configure the water PE study program with these other related activities to ensure that no duplication of efforts occurs and to ensure that the outcomes of these efforts reflect consistent monitoring policy.

The Work Group also recognizes that working with external stakeholders such as the States, NPDES permit holders, drinking water suppliers, private laboratories, PE study providers, and State/Trade Associations will be key in the decision making process. Consequently, the Office of Water is taking steps to ensure that stakeholder groups have an opportunity to comment on the redesign options. This summer, OW will hold a public meeting in Washington, D.C., for the purpose of taking comment on the ten options presented in this paper. In addition, OW will undertake additional outreach efforts such as use of conference calls, small discussion groups, and electronic bulletin boards. The intent is to provide external stakeholders an opportunity to discuss the options under consideration and mutually determine the best way to address any concerns prior to selecting a preferred option.

## **Relationship of NELAC to the Redesigned Program**

One of the Work Group's goals is to have a program that is suitable for inclusion in the National Environmental Laboratory Accreditation Conference (NELAC). NELAC serves as national standards-setting body for environmental laboratory accreditation. The members of

NELAC—state and federal regulatory and non-regulatory programs having environmental laboratory oversight, certification, or accreditation functions plus the private sector in a nonvoting role—come together to develop consensus standards through the NELAC committee structure and at two annual meetings. Participants agree to adopt the NELAC consensus standards for use in their own programs in order to achieve a uniform national program in which environmental testing laboratories will be able to receive one annual accreditation that is accepted nationwide. As part of this uniform national laboratory accreditation program, NELAC intends to develop standards for a proficiency testing program that addresses all fields of testing, including drinking water and wastewater.

The intent of the NELAC standards setting process is to ensure that the needs of EPA and state regulatory programs are satisfied in the context of a uniform national laboratory accreditation program. The EPA recognizes that using NELAC processes as an important part of EPA's Water PE Study Redesign options will enable states, environmental testing laboratories and PE study providers to give input into the evaluation and selection process early enough in the process to have a significant impact on the direction of the Water PE Study redesign effort. It is hoped that a mutual effort will minimize the impact of the redesigned Water PE Study program on the states and lead to participation in the new Water PE Study program by all states so that the NELAC goal of a uniform national laboratory accreditation program can be achieved. Consequently, as stated previously, the Work Group chairs have developed a process for coordinating the efforts of the NELAC Proficiency Testing Committee with the Redesign Work Group to ensure that these two efforts remain as consistent as possible and maintain compatible schedules to the extent practical.

### **Process and Criteria for Developing and Selecting Options**

Initially, the Water Laboratory PE Redesign Work Group defined a comprehensive set of options that included the full range of scenarios from bringing the program in house (conducting all activities using EPA facilities, equipment and staff) to establishing a private sector program in which EPA has no role. The Work Group assessed several options that had a single provider manufacturing and distributing all the PE samples. A single provider rather than multiple providers has the major benefit of assuring that all study participants are treated exactly the same. The work group initially believed that an ideal candidate for a single provider would (1) be an entity of the Federal government and (2) be capable of charging for PE samples. The National Institute of Standards and Technology (NIST) met these requirements. Accordingly, in-depth discussions were held with NIST personnel to determine whether it could take over this role from the EPA. After much consideration, NIST management decided that such a role was not compatible with the NIST mission and this scenario was eliminated as an option.

The remaining eight options involve transferring all or some component of the PE study program to organizations other than EPA (see Table 1). They will be evaluated against seven evaluation criteria. Wherever possible, quantitative scores will be used to indicate both rank order and absolute difference between options. Whenever quantitative evaluations can not be

made, but one option can be said to be better than another with respect to a specific factor, options will be rank ordered only. The seven evaluation criteria are as follows:

### **Criterion #1: Legal Considerations**

Each option would be evaluated to determine whether EPA has the necessary authority to implement the option under existing legal authorities. Options which may require statutory amendment or enactment would generally be not favored.

### **Criterion #2: National Consistency**

Each option would be evaluated against the following measures for the degree to which:

- a. Participating laboratories are evaluated on similar bases and subjected to the same standards;
- b. The probability of a laboratory "passing" a particular study is independent of the PE study supplier;
- c. A common measure can be applied to all data received from participating laboratories regardless of PE study sample supplier;
- d. To the extent applicable under the option considered, data from different PE study suppliers could be combined into a national data base; and
- e. Water PE Samples used by the participating laboratories would be of equal "challenge," irrespective of PE study supplier.

### **Criterion #3: Quality of PE Studies**

Each option would be evaluated relative to the ease with which the homogeneity, accuracy and stability of the samples can be monitored.

### **Criterion #4: Cost to EPA**

Each option would be evaluated with respect to its costs to EPA in terms of both personnel and costs. Options which costs less to government agencies would generally be preferred.

### **Criterion #5: Adverse Impact on States**

Each option would be evaluated to determine the budgetary, statutory, regulatory, programmatic and other impacts that they would have on participating States. Options would be evaluated for the costs and problems the States might incur under each option. Options with substantial adverse impacts on the States would be not favored.

### **Criterion #6: Cost of Program to Laboratory Community**

Each option would be evaluated for its implementation cost to participating laboratories. Lower cost options would be favored. One "cost" that we have not been able to quantify—interstate reciprocity—would be important to EPA decision making. Any option that would require a laboratory desiring to do business in more than one State to participate in multiple PE studies (or bear higher participation fees) would be less favored compared to an option where the costs of multi-state operations are low.

### **Criterion #7: Implementation Timetable**

Each option would be evaluated relative to how long it would take to be implemented. Options which can be implemented faster would be considered more favorably.

### **Organization of the Options Paper**

The remainder of this paper presents a description and evaluation of each of the remaining seven options. The discussion of each option consists of the following components:

- A summary table that describes the responsibilities of the Standards Setting Authority, the PE Study Provider Accreditation Body, and the PE Study Provider(s);
- A brief narrative summary of each option;
- A time line that identifies the key steps in implementation of the option and the estimated date of completion for each step;
- A summary table providing estimated costs to all stakeholder groups; and
- A summary of key factors affecting the ranking of each option, by evaluation criterion.

## Definition of Terms

In reviewing the administration of existing EPA PE study programs and developing various options for future administration, the Work Group defined its terms to identify the various roles of actors in the implementation of the programs. Currently, the primary actors in PE studies include EPA, permittees and laboratories, and in many instances, participating States. EPA currently oversees contractor preparation and distribution of samples directly to the laboratories. Results are returned to EPA, either directly by the laboratory, or, for DMRQA, by the permittee. For the purpose of evaluating different options to transfer portions of the PE Study programs to other entities, the Work Group identified the various components of the PE Study program and the different roles currently played by EPA. The definitions below identify different components and roles that might be transferred to an entity other than EPA. In defining these terms, the Work Group has made certain assumptions about the different components that might be transferred to other entities. Those assumptions are also explained.

**Environmental Testing Laboratories:** Any public or private sector laboratory that participates in approved laboratory performance evaluation programs in order to: obtain or maintain certification/accreditation under EPA or State water programs, meet DMRQA requirements, or fulfill internal quality assurance or training requirements.

**PE Study Providers:** Organizations that supply PE study samples to environmental testing laboratories.

**PE Study Provider Accreditation Body:** Organization authorized to evaluate PE Study Providers using national standards and to accredit those PE Study Providers that meet the standards.

**Standards Setting Authority:** Organization responsible for determining the operation of the particular national water program (concerned with laboratory capacity), for setting the national standards for water PE studies and establishing national standards applicable to PE Study Providers.

**National Standards for Water PE Studies:** Nationally-applicable standards which establishes for the Water PE studies:

- Analytes to be included in each of the studies;
- Concentration ranges for each analyte in the PE samples for each type of study; and
- Scoring/evaluation criteria to be used in evaluating the data to determine acceptable performance.

Ideally, national standards for Water PE Studies would be reviewed and published periodically (at least annually) and would incorporate the specific regulatory and non-regulatory requirements of the water programs. Depending on the administration option selected, such standards might be published in the *Federal Register* as a notice, or as a guidance document, or both. If the administration option selected involves EPA in standard setting, EPA would attempt to use technical standards developed or adopted by voluntary consensus standards bodies, consistent with section 12(d) of the National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, § 12(d), 110 Stat. 783 (to be codified at 15 U.S.C. § 272 note).

**National Standards for Accreditation of Water PE Study Providers:** Technical performance standards that establish the minimum level of performance to be achieved by a PE Study Provider as a condition of accreditation. Accreditation standards might include, at a minimum, technical standards for:

- Procedures necessary to ensure that each study is a fair and representative test;
- Adequacy of PE manufacturing facilities and equipment, including criteria describing adequate manufacturing and analytical testing components;
- Minimum required qualifications and experience of the personnel involved in all aspects of PE study design, manufacture, distribution, data evaluation, reporting, and data storage/retrieval;
- Adequacy of quality systems used by PE Study Suppliers to ensure the quality of PE studies; and
- Any other aspects of PE studies deemed necessary to ensure the consistency and quality of PE studies.

Ideally, national accreditation standards would be performance-based and would not reflect a highly prescriptive approach to PE study development and production. For example, accreditation standards might specify the components of an adequate quality system for PE study design, manufacture, and distribution. Accreditation standards might require that accredited PE Study Providers develop and maintain standard operating procedures for the various aspects of their processes, but would not specify the exact procedures to be used.

National accreditation standards might be published in the *Federal Register*, as a guidance document, or both. Such standards would be reviewed and revised periodically, as deemed necessary by the Standard Setting Authority. If the administration option selected involves EPA in standard setting for accreditation, EPA would attempt to use technical standards developed or adopted by voluntary consensus standards bodies, consistent with section 12(d) of the National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, § 12(d), 110 Stat. 783 (to be codified at 15 U.S.C. § 272 note).

**Primary Reference Standards:** Analyte-specific standards that could be developed, for example, by the National Institute for Standards and Technology (NIST), an organization within the U.S. Department of Commerce, and used by all accredited PE Study Providers to ensure the traceability of PE materials. Properly prepared PE materials would have analyte concentrations with true values that are directly traceable to the primary reference standards.

### **PE Study Management Options**

In developing options for consideration, EPA envisioned that an efficient Water PE Study program would consist of three core functions: (1) national standard setting for PE studies, (2) designation (selection and/or approval) of organizations to manufacture PE materials and administer PE studies, and (3) actual production and administration of the PE studies. Each of the options considered by EPA reflect permutations of these three core functions—variations on which organization(s) or type of organization(s) would fulfill the three functions.

Using these core functions, the EPA developed 8 different options for consideration. These 8 options reflect a range of possibilities. The options, however, are not exhaustive. The options do, however, represent the range of reasonable options available to EPA.

The options considered by the Work Group are summarized in the section of this document entitled "Descriptions of Options" and in Table 1. The organization(s) responsible for specific activities of performance evaluation study program functions under each of the eight options being considered are presented in Appendix B of this document.

**Table 1. Summary of Options Considered**

<b>Option Number</b>	<b>Standards Setting Authority</b>	<b>PE Study Provider Accreditation Body</b>	<b>PE Study Provider</b>	<b>Cost to EPA for this Option (\$K)*</b>	<b>Approximate Time Needed to Implement This Option</b>
1	EPA	EPA	Private Sector\States	*	2 yrs.
2	EPA	NIST	Private Sector\States	*	1 yr, 9 mo.
3	EPA	States	Private Sector\States	*	4 yrs.
4	EPA	3rd Party	Private Sector\States	*	3 yrs.
5	3rd Party	3rd Party	Private Sector/States	*	3 yrs.
6	None	States/3rd Party	Private Sector/States	*	2 yrs.
7	EPA	None	Private Sector\States	*	2 yrs.
8	EPA	EPA	Gov't.\ Non-profit	*	2 yrs.

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\* To be added, pending information collection and analysis.



## **DESCRIPTIONS OF OPTIONS**

**Roles and Responsibilities  
Detailed Fact Sheets  
Implementation Plans,  
Costs, and Timetables**

**Option 1: EPA Oversees PE Study Providers**

**Roles and Responsibilities**

<b>Option 1: EPA Oversees PE Study Providers</b>		
<b>STANDARDS SETTING AUTHORITY</b>	<b>PE STUDY PROVIDER ACCREDITATION BODY</b>	<b>PE STUDY PROVIDERS</b>
<p><b>EPA would:</b></p> <ul style="list-style-type: none"> <li>- Set national standards for PE studies</li> <li>- Set national standards for accreditation of PE Study Providers</li> </ul>	<p><b>EPA would:</b></p> <ul style="list-style-type: none"> <li>- Accredite PE Study Suppliers</li> <li>- Oversee PE Study Supplier performance through on-site assessments and ampule verification</li> <li>- Design and maintain the national data base</li> </ul>	<p><b>Interested states and private sector suppliers would:</b></p> <ul style="list-style-type: none"> <li>- Manufacture and distribute PE studies</li> <li>- Score results and report to EPA and the states</li> <li>- Maintain accreditation and cooperate in EPA oversight activities</li> </ul>

## **Option 1: EPA Oversees PE Study Providers**

### **Summary**

#### **Standard Setting Authority**

EPA would serve as the Standards Setting Authority and as the PE Study Provider Accreditation Body. EPA staff would establish the national standards and standards for accrediting PE Study Providers. This activity would be closely coordinated with NELAC initially and could be transferred to NELAC eventually once national consensus standards are available for water laboratory PE Studies. Accreditation standards would be based on current regulations, policies, and practices applicable to the WS, WP, and DMRQA studies.

#### **PE Study Provider Accreditation Body**

EPA would also serve as the PE Study Provider Accreditation Body and would design a national accreditation program, determine which PE Study Providers should be accredited, and conduct periodic compliance monitoring activities (such as on-site audits and proficiency testing through ampule verification). EPA would publish a list of accredited PE Study Providers at least annually.

EPA would also continue to maintain a national data base. The purpose is to enable EPA to evaluate performance of the PE Study Providers, laboratory performance, and method effectiveness and make changes as necessary.

#### **PE Study Providers**

The private sector and interested States would assume the responsibility for conducting water PE studies. The PE Study Providers would: produce the PE materials; distribute the PE studies to participating laboratories; analyze client lab measurement data; determine acceptance limits according to procedures established by EPA; and report results (in the appropriate format and detail) to the participating laboratories, the organization accrediting the laboratory or requiring the laboratory to participate, and to EPA.

Laboratories desiring to participate in PE studies following EPA standards use a PE study provider on the EPA list. The laboratories pay a participation fee to their PE study provider.

OPTION 1 TIME TABLE	
COMPLETION DATE	ACTIVITY OR MILESTONE
December 1, 1996*	<b>Announcement of Final Decision:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN announcing option selected
April 1, 1997	<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish
October 1, 1997	<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures; publish
April 1, 1998	<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution ** <b>Complete National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement
October 31, 1998	<b>Implement Initial Studies:</b> Design studies; develop study plan; announce study; manufacture materials; verify materials; distribute materials; receive and process results; report †

\* Assumes final option selection occurs by October 1, 1996.

\*\* Assumes that EPA will require 60 days to complete each accreditation and a total of 15 vendors will be accredited.

† Assumes each vendor will require 60 days to distribute first study after receipt of accreditation. Vendors will begin designing and producing their initial studies as they are notified of accreditation. All vendors should receive accreditation by August 31, 1998.

OPTION 1 SUMMARY OF ESTIMATED COSTS				
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)			
	EPA	STATES	PROVIDERS	LABS
<u>Initial Costs</u>				
<b>Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN	0.25 FTE \$25K	N/A	N/A	N/A
<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish	0.25 FTE \$40K	N/A	N/A	N/A
<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures	0.25 FTE \$50K	N/A	N/A	N/A
<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution	1.5 FTE \$150K	N/A	N/A	N/A
<b>Obtain Accreditation:</b> Prepare and submit application; participate in on-site assessment; respond to requests for additional information	N/A	NELAC	ELAB	N/A
<b>Initial Studies:</b> Design studies; develop study plan; announce study; manufacture materials; verify materials; distribute materials; receive and process results; report	N/A	NELAC	ELAB	N/A
<b>National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement	EID	N/A	N/A	N/A

OPTION 1 SUMMARY OF ESTIMATED COSTS				
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)			
	EPA	STATES	PROVIDERS	LABS
<u>Routine Costs</u>				
<b>Update National Standards:</b> Identify issues; develop changes and revise standards; facilitate EPA review/concurrence; publish	0.25 FTE \$30K	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation Program:</b> Conduct re-accreditation; take revocation actions as needed; conduct routine communications; accredit new PE Study Providers; make changes to procedures/checklists/reports consistent with updated standards; conduct ampule verification program	EID	N/A	N/A	N/A
<b>Conduct Studies:</b> Design studies; announce; manufacture and distribute materials, receive and process results; report	N/A	NELAC	All costs recovered thru fees	N/A
<b>Maintain PE Study Provider Accreditation:</b> Participate in annual on-site assessment; provide information as required; participate in QA/ampule verification program	N/A	NELAC	ELAB	N/A
<b>Participate in Studies:</b> Select PE Study Provider(s); analyze materials; prepare results reports	N/A	N/A	N/A	ELAB
<b>National Data Base:</b> Conduct data entry/verification; make modifications consistent with updated standards as needed; make improvements/corrections as needed; develop routine reports; monitor status and trends	EID	N/A	N/A	N/A

**Abbreviations**

N/A Not applicable. No significant costs incurred by this stakeholder group for this activity.

EID Estimate in development (by ORD or OW).

ELAB Environmental Laboratory Advisory Board (ELAB) will assist with estimate.

NELAC States choosing to serve as PE Study Providers will incur some costs. NELAC is assisting in estimating potential costs.

**Option 1: EPA Oversees PE Study Providers**

**Evaluation**

The principal advantage of this option is that it is less disruptive and costly for the states than other options. Its chief disadvantage is that EPA lacks direct statutory authority to accredit PE study providers.

**SCORE**

\_\_\_\_\_ Legal Concerns

EPA lacks direct statutory authority to accredit PE study providers.

EPA could not compel the states to use the national program. State participation likely would be achieved eventually on a voluntary basis through NELAC. Current participation is voluntary and is based on State interest in using the EPA studies.

Process for approving PE study providers could be subject to claims that EPA is interfering with private sector competition.

\_\_\_\_\_ National Consistency

Depends on specificity of the national standards and resources available for EPA oversight of PE study providers.

\_\_\_\_\_ Quality of PE Studies

Depends on availability of EPA resources for conducting on-site audits and a sample verification program.

\_\_\_\_\_ Cost to EPA

PE study design, manufacturing, distribution, and data management/scoring functions would be supported with user fees.

EPA resources would be needed for standard setting (initial standards development and annual review/revision/updating), oversight of PE study providers, data base development and maintenance, and reporting of scores to states/regions.

\_\_\_\_\_ Impact on States

Implementation schedule allows ample time for states to obtain necessary budget appropriations or make statutory/regulatory changes.

State expenditures should be limited to purchasing PE studies for certification of State laboratories. States need not incur oversight costs for monitoring the performance of PE study providers.

Any states that serve as PE study providers would be subject to EPA oversight/accreditation.

\_\_\_\_\_ Cost of Program to Laboratory Community

Laboratories would pay market prices for participating in PE studies.

EPA would have no leverage for ensuring that small laboratories are offered affordable studies of limited scope. PE providers will determine whether specialized materials and studies can be offered based on profitability.

Only a portion of total program costs would be passed on to regulated community; EPA would retain responsibility for costs of oversight and standards development/maintenance.

\_\_\_\_\_ Implementation Timetable

Requires approximately 2 years to implement following final selection (Time Table assumes decision October 1, 1996).

\_\_\_\_\_ TOTAL FOR OPTION 1



**Option 2: NIST Oversees PE Study Providers**

**Roles and Responsibilities**

<b>Option 2: NIST Oversees PE Study Providers</b>		
<b>STANDARDS SETTING AUTHORITY</b>	<b>PE STUDY PROVIDER ACCREDITATION BODY</b>	<b>PE STUDY PROVIDERS</b>
<p><b>EPA would:</b></p> <ul style="list-style-type: none"> <li>- Set national standards for PE studies</li> <li>- Set national standards for accreditation of PE Study Providers</li> <li>- Enter into a Memorandum of Agreement with NIST</li> <li>- Work closely with NIST to ensure that the studies meet EPA's needs</li> <li>- Conduct an annual review of the NIST program</li> </ul>	<p><b>NIST would:</b></p> <ul style="list-style-type: none"> <li>- Accredit PE Study Suppliers</li> <li>- Oversee PE Study Supplier performance through on-site assessments and ampule verification</li> <li>- Design and maintain the national data base</li> <li>- Produce and distribute primary reference standards</li> </ul>	<p><b>Interested states and private sector suppliers would:</b></p> <ul style="list-style-type: none"> <li>- Manufacture and distribute PE studies</li> <li>- Score results and report to EPA, NIST and the states</li> <li>- Maintain accreditation and cooperate in NIST oversight activities</li> </ul>

## **Option 2: NIST Oversees PE Study Providers**

### **Summary**

#### **Standard Setting Authority**

EPA would be the Standards Setting Authority for the Water PE Study program. EPA would work with NIST to establish the operational and technical standards to be used for accrediting private sector and State PE Study Providers. NIST would be responsible for publishing the accreditation standards. Both standards setting functions would be closely coordinated with NELAC.

#### **PE Study Provider Accreditation Body**

NIST's NVLAP would serve as the PE Study Provider Accreditation Body. NIST would oversee compliance with the national standards through annual on-site audits and validation of the quality of PE studies developed by the private sector and States. NIST would collect a fee from participating PE Study Providers to cover their accreditation costs. NIST would maintain a national data base, accessible to EPA staff which would enable NIST and EPA to evaluate PE Study Providers' performance, laboratory performance, and method effectiveness. NIST would also develop primary reference standards which would be distributed to all accredited PE Study Providers.

#### **PE Study Providers**

The private sector and interested States would assume responsibility for conducting Water PE Studies. The PE Study Providers would: produce the PE materials; distribute the PE studies to participating laboratories; analyze client lab measurement data; determine acceptance limits according to procedures established by EPA; and report results (in the appropriate format and detail) to the participating laboratories, the organization accrediting the laboratory or requiring the laboratory to participate, and to NIST. The report to NIST would provide a summary of how the laboratories have varied and how they have performed relative to EPA's performance criteria. The PE Study Providers would prepare and characterize each batch of samples within a study according to approved protocols involving value assignment against NIST-provided primary reference standards. PE Study Providers would pay a fee to NIST for their accreditation.

Laboratories desiring to participate in the Water PE Studies employing EPA/NIST standards would have to pay a participation fee to the private sector or State PE Study Providers.

OPTION 2 TIME TABLE	
COMPLETION DATE	ACTIVITY OR MILESTONE
December 1, 1996*	<b>Final Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN (EPA)
April 1, 1997	<b>Establish EPA/NIST MOU:</b> Prepare draft agreement; facilitate internal EPA and NIST reviews; revise/finalize/execute (EPA & NIST) <b>Develop Process for Annual Review of NIST Studies:</b> Develop review process; facilitate internal EPA review/approval and NIST review (EPA & NIST)
May 1, 1997	<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish in <i>Federal Register</i> (EPA)
October 1, 1997	<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures (NIST) <b>Complete National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement (NIST)
January 1, 1998	<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution **
July 1, 1998	<b>Complete Initial Studies:</b> Design studies; develop study plan; announce study; manufacture materials; verify materials; distribute materials; receive and process results; report (NIST) †
Beginning March 1, 1998	<b>Generate and Distribute Standard Reference Materials:</b> Develop production plan and schedule; obtain equipment and materials; produce and package; conduct quality control and quality assurance; distribute to PE Study Providers

\* Assumes final option selection occurs by October 1, 1996.

\*\* Date NIST will begin accepting applications for accreditation. Assumes that NIST will require 60 days to complete each accreditation.

† Assumes each state or vendor will require 60 days to distribute first study after receipt of accreditation.

OPTION 2 SUMMARY OF ESTIMATED COSTS					
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)				
	EPA	NIST	STATES	PROVIDERS	LABS
<u>Initial Costs</u>					
<b>Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN	0.25 FTE \$25K	N/A	N/A	N/A	N/A
<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish	0.25 FTE \$40K	N/A	N/A	N/A	N/A
<b>Establish EPA/NIST MOU:</b> Prepare draft agreement; facilitate internal EPA and NIST reviews; revise/finalize/execute	0.1 FTE	0.1 FTE	N/A	N/A	N/A
<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures	0.1 FTE	0.25 FTE \$50K	N/A	N/A	N/A
<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution	N/A	1.5 FTE \$150K	N/A	N/A	N/A
<b>Obtain Accreditation:</b> Prepare and submit application; participate in on-site assessment; respond to requests for additional information	N/A	N/A	NELAC	ELAB	N/A
<b>Generate and Distribute Standard Reference Materials:</b> Develop production plan and schedule; obtain equipment and materials; produce and package; conduct quality control and quality assurance; distribute to PE Study Providers	\$3 M	Costs recovered from EPA	N/A	N/A	N/A

OPTION 2 SUMMARY OF ESTIMATED COSTS					
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)				
	EPA	NIST	STATES	PROVIDERS	LABS
<u>Initial Costs, cont.</u>					
<b>National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement	N/A	EID	N/A	N/A	N/A
<b>Initial Studies:</b> Design studies; develop study plan; announce study; obtain standard reference materials; manufacture materials; verify materials; distribute materials; receive and process results; report	N/A	N/A	NELAC	ELAB NIST	N/A
<u>Routine Costs</u>					
<b>Update National Standards:</b> Identify issues; develop changes and revise standards; facilitate EPA review/concurrence; publish	0.25 FTE \$30K	0.1 FTE	N/A	N/A	N/A
<b>Review/Update EPA/NIST MOU:</b> Conduct annual program review; agree on changes required; prepare draft revised MOU; facilitate internal EPA and NIST reviews; revise/finalize/execute	0.1 FTE	0.1 FTE	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation Program:</b> Conduct re-accreditation; take revocation actions as needed; conduct routine communications; accredit new PE Study Providers; make changes to procedures/checklists/reports consistent with updated standards; conduct ampule verification program	N/A	EID	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation:</b> Meet annual reporting requirements; participate in ampule verification program; cooperate in annual on-site assessment	N/A	N/A	NELAC	ELAB	N/A

OPTION 2 SUMMARY OF ESTIMATED COSTS					
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)				
	EPA	NIST	STATES	PROVIDERS	LABS
<u>Routine Costs, cont.</u>					
<b>Produce Standard Reference Materials:</b> Manufacture materials to maintain stock; maintain ordering/shipping/billing systems	N/A	Costs recovered from EPA and PE Providers	N/A	N/A	N/A
<b>Conduct Studies:</b> Design studies; announce; manufacture and distribute materials, receive and process results; report	N/A	N/A	NELAC	All costs recovered thru fees	N/A
<b>Participate in Studies:</b> Select PE Study Provider(s); analyze materials; prepare results reports	N/A	N/A	N/A	N/A	ELAB
<b>National Data Base:</b> Conduct data entry/verification; make modifications consistent with updated standards as needed; make improvements/corrections as needed; develop routine reports; monitor status and trends	N/A	EID	N/A	N/A	N/A

**Abbreviations**

N/A Not applicable. No significant costs incurred by this stakeholder group for this activity.

EID Estimate in development (by ORD or OW).

ELAB Environmental Laboratory Advisory Board (ELAB) will assist with estimate.

NIST Estimate to be supplied by the National Institute of Standards and Technology.

## **Option 2: NIST Oversees PE Study Providers**

### **Evaluation**

This option would achieve a high level of national consistency, provided that the states are willing to participate. However, those states that have their own PE study programs would likely object to paying NIST for accreditation. This option has the further advantage that it would make a large portion of the program self-supporting and it therefore minimizes the continuing costs of the program to EPA. Initially, EPA would have to provide \$3 million to NIST for start-up, or find other federal partners and/or private sector partners willing to help capitalize the NIST program as well as pay for that portion of the program NIST has not assumed during the first three years.

### **SCORE**

#### Legal Concerns

Avoids the issue of whether EPA has direct statutory authority to accredit PE study providers.

EPA could not compel the states to use the national program. State participation likely would be achieved eventually on a voluntary basis through NELAC. Current participation is voluntary and is based on State interest in using the EPA studies.

Process for approving PE study providers could be subject to claims that EPA and NIST are interfering with private sector competition.

#### National Consistency

Depends on specificity of the national standards and resources available for EPA oversight of NIST program.

An acceptable level of consistency is likely to be achievable.

#### Quality of PE Studies

Use of NIST primary reference standards for traceability ensures that all providers are using analytes from a single, documented source. This could reduce the likelihood of errors.

EPA could work with NIST to establish a quality system that meets EPA's standards.

\_\_\_\_\_ Cost to EPA

NIST estimates that it would need one-time funding of \$3 million from EPA to develop NIST primary reference standards for use by accredited PE study providers.

EPA resources would be needed for standard setting (initial standards development and annual review/revision/updating), negotiating an interagency agreement with NIST (initially and annually), and oversight of the NIST program.

Program for accrediting and overseeing PE study providers would be self-supported using fees paid by PE study providers to NIST.

PE study manufacturing, distribution, data base maintenance, and scoring functions would be supported with user fees paid by laboratories to accredited PE study providers.

\_\_\_\_\_ Impact on States

Implementation schedule allows ample time for states to obtain necessary budget appropriations or make statutory/regulatory changes.

State expenditures should be limited to purchasing PE studies for certification of State laboratories. States need not incur oversight costs for monitoring the performance of PE study providers.

Any states that serve as PE study providers would be subject to NIST oversight/accreditation. This might be objectionable to the states.

\_\_\_\_\_ Cost of Program to Laboratory Community

Laboratories would pay market prices for participating in PE studies.

EPA and NIST would have no leverage for ensuring that small laboratories are offered affordable studies of limited scope. PE providers will determine whether specialized materials and studies can be offered based on profitability.

Private sector PE providers would pay costs of accreditation/oversight, with the exception of the initial \$3 million investment for developing benchmark standards.



\_\_\_\_\_ Implementation Timetable

Requires approximately 1 year and 9 months to implement.

\_\_\_\_\_ TOTAL FOR OPTION 2

**Option 3: States Oversee Private Sector PE Study Providers**

**Roles and Responsibilities**

<b>Option 3: States Oversee Private Sector PE Study Providers</b>		
<b>STANDARDS SETTING AUTHORITY</b>	<b>PE STUDY PROVIDER ACCREDITATION BODY</b>	<b>PE STUDY PROVIDER</b>
<p><b>EPA would:</b></p> <ul style="list-style-type: none"> <li>- Set national standards for PE studies</li> <li>- Set national standards for accreditation of PE Study Providers</li> <li>- Implement a program for approving state PE Study Provider accreditation programs</li> <li>- Design and maintain the national data base</li> </ul>	<p><b>States would:</b></p> <ul style="list-style-type: none"> <li>- Accredit PE Study Suppliers</li> <li>- Oversee PE Study Supplier performance through on-site assessments and ampule verification</li> </ul>	<p><b>Interested states and private sector suppliers would:</b></p> <ul style="list-style-type: none"> <li>- Manufacture and distribute PE studies</li> <li>- Score results and report to EPA and the states</li> <li>- Maintain accreditation and cooperate in state oversight activities</li> </ul>

### **Option 3: States Oversee Private Sector PE Study Providers**

#### **Summary**

#### **Standard Setting Authority**

EPA would serve as the Standards Setting Authority for the Water PE Study program and would maintain the national data base. EPA would also design and implement a program for overseeing State PE Study Provider accreditation programs consistent with the national standards. This activity would be closely coordinated with NELAC.

#### **PE Study Provider Accreditation Body**

The States would serve as PE Study Provider Accreditation Bodies. The States would establish individual programs for accrediting private sector PE Study Providers, individually or collectively through NELAC. The States would each determine the authorized PE Study Providers in their States. The States would also oversee compliance with the national standards through periodic on-site audits and ampule verification programs. Alternatively, any State could choose to serve as the PE Study Provider for all laboratories that it certifies or accredits.

#### **PE Study Providers**

The private sector and interested States would conduct the Water PE Studies. The PE Study Providers would produce the PE materials; distribute the PE studies to participating laboratories; analyze client lab measurement data; determine acceptance limits according to procedures established by EPA; and report results (in the appropriate format and detail) to the participating laboratories and EPA. Those states able to retain fees would charge PE Study Providers for accreditation.

Environmental testing laboratories would use any PE Study Provider approved by the laboratory accrediting authority in the State where they are operating. Laboratories desiring to participate in the Water PE Studies would have to pay a participation fee to the private sector or State PE Study Providers.

OPTION 3 TIME TABLE	
COMPLETION DATE	ACTIVITY OR MILESTONE
December 1, 1996*	<b>Announcement of Final Decision:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN announcing option selected
April 1, 1997	<b>Develop State PE Provider Program Oversight Process:</b> Develop criteria and review process; facilitate internal EPA review and concurrence; coordinate with states
May 1, 1997	<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish
October 1, 1998**	<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures (STATES) <b>Complete National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement (EPA)
October 1, 1999	<b>Complete State Program Approvals:</b> Review required documentation; conduct on-site assessments; make initial determination; negotiate necessary changes with states; issue final approvals <b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution (STATES)
May 1, 2000†	<b>Complete Initial Studies:</b> Design studies; develop study plan; announce study; manufacture materials; verify materials; distribute materials; receive and process results; report

\* Assumes final option selection occurs by October 1, 1996.

\*\* Allows states 2 years, from decision date of October 1, 1996, to make any necessary statutory, regulatory, and budgetary changes.

† Estimated date when all accredited vendors will complete their initial studies. Some may occur sooner.

OPTION 3 SUMMARY OF ESTIMATED COSTS				
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)			
	EPA	STATES	PROVIDERS	LABS
<u>Initial Costs</u>				
<b>Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN	0.25 FTE \$25K	N/A	N/A	N/A
<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish	0.25 FTE \$40K	N/A	N/A	N/A
<b>Design PE Study Provider Oversight Program:</b> Determine type of program needed; design documentation and review procedures needed; design/develop information management and tracking system; develop revocation/appeals process; design communication procedures	N/A	NELAC	N/A	N/A
<b>Implement PE Study Oversight Program:</b> Receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution	N/A	NELAC	N/A	N/A
<b>Obtain Accreditation:</b> Prepare and submit application; participate in on-site assessment; respond to requests for additional information	N/A	N/A	ELAB	N/A
<b>Initial Studies:</b> Design studies; develop study plan; announce study; obtain standard reference materials; manufacture materials; verify materials; distribute materials; receive and process results; report	N/A	N/A	ELAB	N/A
<b>Design State Oversight Program:</b> Define critical program elements; develop review protocol; establish review schedule; coordinate with states	0.25 FTE \$50K	NELAC	N/A	N/A
<b>National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement	EID	N/A	N/A	N/A

OPTION 3 SUMMARY OF ESTIMATED COSTS				
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)			
	EPA	STATES	PROVIDERS	LABS
<u>Routine Costs</u>				
<b>Update National Standards:</b> Identify issues; develop changes and revise standards; facilitate EPA review/concurrence; publish	0.25 FTE \$30 K	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation Program:</b> Conduct re-accreditation; take revocation actions as needed; conduct routine communications; accredit new PE Study Providers; make changes to procedures/checklists/reports consistent with updated standards	N/A	NELAC	N/A	N/A
<b>Maintain PE Study Provider Accreditation:</b> Meet annual reporting requirements; participate in ampule verification program; cooperate in annual on-site assessment	N/A	N/A	ELAB	N/A
<b>Conduct Studies:</b> Design studies; announce; manufacture and distribute materials, receive and process results; report	N/A	NELAC	All costs recovered thru fees	N/A
<b>Participate in Studies:</b> Select PE Study Provider(s); analyze materials; prepare results reports	N/A	N/A	N/A	ELAB
<b>Conduct State Oversight Program:</b> Conduct state program reviews; generate reports; conduct follow-up activities as needed; negotiate changes with states as needed	0.25 FTE \$30K	NELAC	N/A	N/A
<b>National Data Base:</b> Conduct data entry/verification; make modifications consistent with updated standards as needed; make improvements/corrections as needed; develop routine reports; monitor status and trends	EID	N/A	N/A	N/A

**Abbreviations**

N/A Not applicable. No significant costs incurred by this stakeholder group for this activity.

EID Estimate in development (by ORD or OW).

ELAB Environmental Laboratory Advisory Board (ELAB) will assist with estimate.

NIST Estimate to be supplied by the National Institute of Standards and Technology.

### Option 3: States Oversee Private Sector PE Study Providers

#### Evaluation

The chief advantage of this option is that most of the costs of the program are transferred to the industry or states, causing EPA's costs to be minimized. Since the states would have the option of designing their own single or multiple source program, there is high potential for variability in state programs, which would impact negatively on national consistency and could cause laboratories and PE providers to need multiple accreditation.

#### SCORE

##### \_\_\_\_\_ Legal Concerns

Avoids issue of whether EPA has direct statutory authority to accredit PE study providers or direct the states to use specific sources for PE studies.

EPA could not compel the states to use the national program. State participation likely would be achieved eventually on a voluntary basis through NELAC. Current participation is voluntary based on State interest in using the EPA studies.

##### \_\_\_\_\_ National Consistency

Depends on:

Specificity of national standards;  
Availability of EPA resources to oversee states; and  
States' abilities to establish effective accreditation and oversight programs.

Likely to be a high degree of variability based on experience in other programs.

##### \_\_\_\_\_ Quality of PE Studies

Large number of oversight organizations (states) and PE study providers increases probability of errors and complexity of quality assurance.

##### \_\_\_\_\_ Cost to EPA

PE study design, manufacturing, distribution, and data management/scoring functions would be supported with user fees paid by laboratories to PE study providers.

Accreditation and oversight of PE study providers would be supported by user fees paid to the states by private sector PE study providers, where possible, or supported with state resources.

EPA resources would be needed for standard setting (initial standards development and annual review/revision/updating), oversight of state programs, and data base development and maintenance.

#### Impact on States

Implementation schedule allows ample time for states to obtain necessary budget appropriations or make statutory/regulatory changes.

States would need to provide resources to support the accreditation and oversight program for PE study providers. Some states may be able to charge an accreditation fee to make the program self-supporting. Others may not be able to obtain the statutory authority to charge fees. For those states, this would be the most expensive option.

Any state that serves as a PE study provider would not need to make any changes, except those necessary to ensure compliance with the national standards.

Not clear whether the states would be willing to establish reciprocal agreements. If not, PE study providers would have to obtain approval from every state in which they conduct business.

#### Cost of Program to Laboratory Community

Laboratories would pay market prices for participating in PE studies.

Private sector PE study providers would support state accreditation/oversight programs with user fees in some states.

EPA would have no leverage for ensuring that small laboratories are offered affordable studies of limited scope. PE providers will determine whether specialized materials and studies can be offered based on profitability.

Without reciprocity among the states, PE study providers would have to obtain multiple accreditation. Even with reciprocity, PE study providers might have to pay licensing or other fees to every state in which they do business.



\_\_\_\_\_ Implementation Timetable

Requires approximately 4 years to implement.

\_\_\_\_\_ TOTAL FOR OPTION 3

**Option 4: Private Sector Third Party Oversees PE Study Providers**

**Roles and Responsibilities**

<b>Option 4: Private Sector Third Party Oversees PE Study Providers</b>		
<b>STANDARDS SETTING AUTHORITY</b>	<b>PE STUDY PROVIDER ACCREDITATION BODY</b>	<b>PE STUDY PROVIDERS</b>
<p><b>EPA would:</b></p> <ul style="list-style-type: none"> <li>- Set national standards for PE studies</li> <li>- Set criteria for selection of third party PE Study Accrediting Bodies</li> <li>- Set national standards for accreditation of PE Study Providers</li> <li>- Implement a program to oversee the PE Study Provider Accrediting Bodies</li> <li>- Design and maintain the national data base</li> </ul>	<p><b>Interested states and qualified third parties would:</b></p> <ul style="list-style-type: none"> <li>- Accredit PE Study Suppliers</li> <li>- Oversee PE Study Supplier performance through on-site assessments and ampule verification</li> </ul>	<p><b>Interested states and private sector suppliers would:</b></p> <ul style="list-style-type: none"> <li>- Manufacture and distribute PE studies</li> <li>- Score results and report to EPA and the states</li> <li>- Maintain accreditation and cooperate in EPA oversight activities</li> </ul>

## **Option 4: Private Sector Third Party Oversees PE Study Providers**

### **Summary**

#### **Standard Setting Authority**

EPA would serve as the Standards Setting Authority for the Water PE Studies. EPA would set the national standards; set technical performance standards for accrediting PE Study Providers; set standards for selecting qualified accrediting bodies; and select and oversee PE Study Provider accrediting bodies. All of these functions would be closely coordinated with NELAC and could be transferred to NELAC once they have developed consensus water laboratory PE study standards. EPA would also maintain the national data base.

#### **PE Study Provider Accreditation Body**

One or more third party would serve as the Water PE Study Provider Accreditation Body. The Water PE Study Provider Accreditation Body(ies) would oversee compliance with the EPA standards through annual on-site audits and ampule verification programs. The Water PE Study Provider Accreditation Body(ies) would collect a fee from participating PE Study Providers to cover their accreditation and for ongoing reaccreditation costs.

#### **PE Study Providers**

The private sector and interested States would conduct the Water PE Studies. The PE Study providers would: produce the PE materials; distribute the PE studies to participating laboratories; analyze client lab measurement data; determine acceptance limits according to EPA-established procedures; and report results (in the appropriate format and detail) to the participating laboratories, the organization accrediting the laboratory or requiring the laboratory to participate, and the PE Study Provider Accreditation Body. The report to the PE Study Provider Accreditation Body would provide a summary of how the laboratories have varied and how they have performed relative to EPA's performance criteria.

Environmental Testing Laboratories would use any accredited PE Study Provider or the State, where States choose to be the provider. Laboratories desiring to participate in the Water PE Studies employing EPA Standards would have to pay a participation fee to the PE Study Provider.

OPTION 4 TIME TABLE	
COMPLETION DATE	ACTIVITY OR MILESTONE
December 1, 1996*	<b>Announcement of Final Decision:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN announcing option selected
April 1, 1997	<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish <b>Design PE Study Provider Accreditation Body Qualification Program:</b> Develop application process; develop documentation and communication processes; design necessary support systems (information management and tracking); design review procedures; obtain required EPA approvals
July 1, 1997	<b>Publish Notice of Accreditation Body Qualification Program:</b> Prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN
January 31, 1998	<b>Implement PE Study Provider Accreditation Body Qualification Program:</b> receive applications; conduct reviews, make selections
September 1, 1998	<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures (3rd Parties) <b>Complete National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement
January 1, 1999	<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution
October 1, 1999	<b>Complete Initial Studies:</b> Design studies; develop study plan; announce study; manufacture materials; verify materials; distribute materials; receive and process results; report

\* Assumes final option selection occurs by October 1, 1996.

OPTION 4 SUMMARY OF ESTIMATED COSTS					
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)				
	EPA	3RD PARTIES	STATES	PROVIDERS	LABS
<u>Initial Costs</u>					
<b>Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN	0.25 FTE \$25K	N/A	N/A	N/A	N/A
<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish	0.25 FTE \$40K	N/A	N/A	N/A	N/A
<b>Design and Implement PE Study Provider Accreditation Body Qualification Program:</b> Develop application process; develop documentation and communication processes; design necessary support systems (information management and tracking); design review procedures; obtain required EPA approvals; conduct reviews; make selections	0.25 FTE \$30K	N/A	N/A	N/A	N/A
<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures	N/A	ELAB	N/A	N/A	N/A
<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution	N/A	ELAB	N/A	N/A	N/A
<b>Obtain Accreditation:</b> Prepare and submit application; participate in on-site assessment; respond to requests for additional information	N/A	ELAB	NELAC	ELAB	N/A
<b>Initial Studies:</b> Design studies; develop study plan; announce study; obtain standard reference materials; manufacture materials; verify materials; distribute materials; receive and process results; report	N/A	N/A	NELAC	ELAB	N/A
<b>National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement	N/A	EID	N/A	N/A	N/A

OPTION 4 SUMMARY OF ESTIMATED COSTS					
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)				
	EPA	3RD PARTIES	STATES	PROVIDERS	LABS
<u>Routine Costs</u>					
<b>Update National Standards:</b> Identify issues; develop changes and revise standards; facilitate EPA review/concurrence; publish	0.25 FTE \$30K	N/A	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation Program:</b> Conduct re-accreditation; take revocation actions as needed; conduct routine communications; accredit new PE Study Providers; make changes to procedures/checklists/reports consistent with updated standards; conduct ampule verification program	N/A	ELAB	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation:</b> Meet annual reporting requirements; participate in ampule verification program; cooperate in annual on-site assessment	N/A	N/A	NELAC	ELAB	N/A
<b>Conduct Studies:</b> Design studies; announce; manufacture and distribute materials, receive and process results; report	N/A	N/A	NELAC	All costs recovered thru fees	N/A
<b>Participate in Studies:</b> Select PE Study Provider(s); analyze materials; prepare results reports	N/A	N/A	N/A	N/A	ELAB
<b>National Data Base:</b> Conduct data entry/verification; make modifications consistent with updated standards as needed; make improvements/corrections as needed; develop routine reports; monitor status and trends	N/A	EID	N/A	N/A	N/A

**Abbreviations**

N/A Not applicable. No significant costs incurred by this stakeholder group for this activity.

EID Estimate in development (by ORD or OW).

ELAB Environmental Laboratory Advisory Board (ELAB) will assist with estimate.

NIST Estimate to be supplied by the National Institute of Standards and Technology.

#### **Option 4: Private Sector Third Party Oversees PE Study Providers**

##### **Evaluation**

Under this option, many aspects of the program would become self-supporting and EPA's costs would be significantly reduced. The states may object to the use of a third party to oversee PE study providers.

##### **SCORE**

###### Legal Concerns

Avoids issue of whether EPA has direct statutory authority to accredit PE study providers.

EPA could not compel the states to use the national program. State participation likely would be achieved eventually on a voluntary basis through NELAC. Current participation is voluntary based on State interest in using the EPA studies.

Process for approving PE study providers could be subject to claims that EPA is interfering with private sector competition.

Process for approving PE study providers could be subject to claims that EPA is interfering with private sector competition.

Process for selecting and overseeing the third-party oversight organization would be subject to claims regarding potential conflicts of interest.

###### National Consistency

Level of consistency would depend on:

Specificity of the national standards;

Quality of EPA's oversight program;

States' willingness to participate.

\_\_\_\_\_ Quality of PE Studies

Use of multiple providers increases probability of error.

Oversight program should not be resource-limited. EPA could work with the third party to design a quality system that meets EPA standards.

\_\_\_\_\_ Cost to EPA

Almost all aspects of the program would be supported with user fees:

Laboratories would pay fees to PE study providers to support manufacturing, distribution, and data management/scoring functions.

PE providers would pay fees to the third-party accreditor to support accreditation and oversight.

EPA resources would be needed for standard setting (initial standards development and annual review/revision/updating), selection and oversight of the third-party accreditor, and data base development and maintenance.

\_\_\_\_\_ Impact on States

Implementation schedule allows ample time for states to obtain necessary budget appropriations or make statutory/regulatory changes.

Any state that serves as a PE study provider under the program would need to be accredited by the third-party. States have already voiced a strong objection to this type of program through NELAC and other NELAC-related discussions.

\_\_\_\_\_ Cost of Program to Laboratory Community

Laboratories would pay market prices for participating in PE studies.

Private sector PE study providers would support the third-party accreditation/oversight program through user fees.



EPA would have no leverage for ensuring that small laboratories are offered affordable studies of limited scope. PE providers will determine whether specialized materials and studies can be offered based on profitability.

If states establish their own programs instead of participating in the national program, PE study providers may have to obtain multiple accreditation or pay licensing or other fees to every state in which they do business.

\_\_\_\_\_ Implementation Timetable

Requires approximately 3 years to implement.

\_\_\_\_\_ TOTAL FOR OPTION 4

**Option 5: EPA-designated Third Party Oversees National Program**

**Roles and Responsibilities**

<b>Option 5: EPA-designated Third Party Oversees National Program</b>		
<b>STANDARDS SETTING AUTHORITY</b>	<b>PE STUDY PROVIDER ACCREDITATION BODY</b>	<b>PE STUDY PROVIDERS</b>
<p><b>Third Party selected by EPA</b> would:</p> <ul style="list-style-type: none"> <li>- Set national standards for PE studies</li> <li>- Set national guidance for PE Study Provider performance</li> </ul>	<p><b>Interested states and qualified third parties</b> would:</p> <ul style="list-style-type: none"> <li>- Accredit PE Study Suppliers</li> <li>- Oversee PE Study Supplier performance through on-site assessments and ampule verification</li> </ul>	<p><b>Interested states and private sector suppliers</b> would:</p> <ul style="list-style-type: none"> <li>- Manufacture and distribute PE studies</li> <li>- Score results and report to EPA and the states</li> <li>- Maintain accreditation and cooperate in EPA oversight activities</li> </ul>

## **Option 5: EPA-designated Third Party Oversees National Program**

### **Summary**

This is essentially a completely privatized program which would use a process similar to the one employed to privatize the Drinking Water Additives Program.

### **Standard Setting Authority**

EPA would establish competitive process for selecting an organization to act as a Standard Setting Authority (SAA); publish the process in the Commerce Business Daily/Federal Register; and encourage non-profit, third-party standard organizations to respond. An appropriate group of EPA staff (Headquarters and Regional staff from OW, OECA, ORD and OGC) would grade the proposals and select the SSA.

The selected SAA would develop consensus industry standards for PE samples/studies. EPA would be a participant in this process. Current EPA standards and/or forthcoming NELAC draft standards may serve as the model for the industry to develop the consensus industry standards for PE samples/studies.

### **PE Study Provider Accreditation Body**

The SSA may assume the role of the Water PE Study Provider Accreditation Body or may select/contract with other third party organizations to certify private sector and State PE study providers. The Water PE Study Provider Accreditation Body(ies) would oversee compliance with the consensus industry standards through annual on-site audits and ampule verification. The Water PE Study Provider Accreditation Body or the SSA would maintain a national data base. The Water PE Study Provider Accreditation Body(ies) would collect a fee from participating PE Study Providers to cover their accreditation and for ongoing reaccreditation costs.

### **PE Study Providers**

The private sector and interested States conduct the Water PE Studies. The PE Study providers: produce the PE materials; distribute the PE studies to participating laboratories; analyzes client lab measurement data; determine acceptance limits according to procedures established by the SSA; and report results (in the appropriate format and detail) to the participating laboratories, the organization accrediting the laboratory or requiring the laboratory to participate, and the PE Study Accrediting Body and/or the SSA. The report to the PE Study

Provider Accreditation Body provides a summary of how the laboratories have varied and how they have performed relative to the SSA's performance criteria.

Environmental Testing Laboratories use any accredited PE Study Provider. Laboratories desiring to participate in the Water PE Studies would have to pay a participation fee to the PE Study Provider.

OPTION 5 TIME TABLE	
COMPLETION DATE	ACTIVITY OR MILESTONE
December 1, 1996*	<b>Announcement of Final Decision:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN announcing option selected
April 1, 1997	<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate industry/government consensus building process; revise/finalize standards; publish <b>Design Third Party Selection Process:</b> Develop application process; develop documentation and communication processes; design review procedures; obtain required EPA approvals
July 1, 1997	<b>Publish Notice of Third Party Selection Process:</b> Prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN
January 31, 1998	<b>Implement Third Party Selection Process:</b> Receive applications; conduct reviews; make selection
September 1, 1998	<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures (3rd Party) <b>Complete National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement (3rd Party)
January 1, 1999	<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution **
October 1, 1999	<b>Complete Initial Studies:</b> Design studies; develop study plan; announce study; manufacture materials; verify materials; distribute materials; receive and process results; report

\* Assumes final option selection occurs by October 1, 1996.

\*\* Assumes each state or vendor will require 60 days to distribute first study after receipt of accreditation.

OPTION 5 SUMMARY OF ESTIMATED COSTS					
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)				
	EPA	3RD PARTY	STATES	PROVIDERS	LABS
<u>Initial Costs</u>					
<b>Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN	0.25 FTE \$25K	N/A	N/A	N/A	N/A
<b>Design and Implement Third Party Selection Process:</b> Develop application process; develop documentation and communication processes; design review procedures; obtain required EPA approvals; conduct reviews; make selection	0.10 FTE	N/A	N/A	N/A	N/A
<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate industry/government consensus building process; revise/finalize standards; publish	N/A	ELAB	N/A	N/A	N/A
<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures	N/A	ELAB	N/A	N/A	N/A
<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution	N/A	ELAB	N/A	N/A	N/A
<b>Obtain Accreditation:</b> Prepare and submit application; participate in on-site assessment; respond to requests for additional information	N/A	ELAB	NELAC	ELAB	N/A
<b>Initial Studies:</b> Design studies; develop study plan; announce study; obtain standard reference materials; manufacture materials; verify materials; distribute materials; receive and process results; report	N/A	N/A	NELAC	ELAB	N/A
<b>National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement	N/A	EID	N/A	N/A	N/A

OPTION 5 SUMMARY OF ESTIMATED COSTS					
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)				
	EPA	3RD PARTY	STATES	PROVIDERS	LABS
<u>Routine Costs</u>					
<b>Update National Standards:</b> Identify issues; develop changes and revise standards; facilitate EPA review/concurrence; publish	0.25 FTE \$30K	N/A	N/A	N/A	N/A
<b>Oversee Third Party:</b> Conduct annual program review; determine changes needed; report; negotiate changes	0.1 FTE	ELAB	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation Program:</b> Conduct re-accreditations; take revocation actions as needed; conduct routine communications; accredit new PE Study Providers; make changes to procedures/checklists/reports consistent with updated standards; conduct ampule verification program	N/A	ELAB	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation:</b> Meet annual reporting requirements; participate in ampule verification program; cooperate in annual on-site assessment	N/A	N/A	NELAC	ELAB	N/A
<b>Conduct Studies:</b> Design studies; announce; manufacture and distribute materials, receive and process results; report	N/A	N/A	NELAC	All costs recovered thru fees	N/A
<b>Participate in Studies:</b> Select PE Study Provider(s); analyze materials; prepare results reports	N/A	N/A	N/A	N/A	ELAB
<b>National Data Base:</b> Conduct data entry/verification; make modifications consistent with updated standards as needed; make improvements/corrections as needed; develop routine reports; monitor status and trends	N/A	EID	N/A	N/A	N/A

**Abbreviations**

- N/A Not applicable. No significant costs incurred by this stakeholder group for this activity.
- EID Estimate in development (by ORD or OW).
- ELAB Environmental Laboratory Advisory Board (ELAB) will assist with estimate.
- NIST Estimate to be supplied by the National Institute of Standards and Technology.

## **Option 5: EPA-designated Third Party Oversees National Program**

### **Evaluation**

This option was eliminated because with no EPA involvement in standard setting, there is a strong potential for national consistency and quality to fall below acceptable levels.

#### Legal Concerns

Drinking Water Additives Program establishes precedent.

EPA could not compel the states to use the national program. State participation likely would be achieved eventually on a voluntary basis through NELAC. Current participation is voluntary based on State interest in using the EPA studies.

Process for approving PE study providers could be subject to claims that EPA is interfering with private sector competition.

Process for selecting the third party oversight organization would be subject to claims regarding potential conflicts of interest.

#### National Consistency

Level of consistency would depend on:

- Specificity of the national standards;
- Quality of the national accreditation/oversight program for PE study providers;
- States' willingness to participate.

#### Quality of PE studies

National quality assurance program would be supported by user fees and should not be resource-limited.

Does not ensure that quality assurance program will meet EPA standards.

#### Cost to EPA

All aspects of the program would be supported with user fees:



Laboratories would pay fees to PE study providers to support manufacturing, distribution, and data management/scoring functions.

PE providers would pay fees to the third-party to support development of national standards, accreditation, and oversight.

EPA resources would be needed for selecting a third party, announcing the change in the program, and participating in the standard-setting process.

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Impact on States

Implementation schedule allows time for states to obtain necessary budget appropriations or make statutory/regulatory changes.

Any state that serves as a PE study provider under the program would need to be accredited by the third-party. States have already voiced a strong objection to this type of program through NELAC and other NELAC-related discussions.

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Economic Impact

Laboratories would pay market prices for participating in PE studies.

Private sector PE study providers would support the third-party standard setting and accreditation/oversight programs through user fees.

EPA would have no leverage for ensuring that small laboratories are offered affordable studies of limited scope. PE providers will determine whether specialized materials and studies can be offered based on profitability.

If states establish their own programs instead of participating in the national program, PE study providers may have to obtain multiple accreditations or pay licensing or other fees to every state in which they do business.

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Implementation Timetable

Requires approximately 3 years.

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TOTAL FOR OPTION 5

**Option 6: No EPA Involvement in Water PE Studies**

**Roles and Responsibilities**

<b>Option 6: No EPA Involvement in Water PE Studies</b>		
<b>STANDARDS SETTING AUTHORITY</b>	<b>PE STUDY PROVIDER ACCREDITATION BODY</b>	<b>PE STUDY PROVIDERS</b>
<p><b>EPA</b> would:</p> <ul style="list-style-type: none"> <li>- Set national guidance for PE studies</li> </ul>	<p><b>Interested states and third parties</b> would:</p> <ul style="list-style-type: none"> <li>- Accredit PE Study Suppliers</li> <li>- Oversee PE Study Supplier performance</li> </ul>	<p><b>Interested states and private sector suppliers</b> would:</p> <ul style="list-style-type: none"> <li>- Manufacture and distribute PE studies</li> <li>- Score results and report to the states</li> </ul>

**Option 6: No EPA Involvement in Water PE Studies**

**Summary**

This is a completely privatized program. EPA would notify the States and the public of its intention to discontinue the Water PE Studies and publish the national standards. On the preannounced date, EPA would discontinue its PE Studies. EPA would no longer maintain a national data base.

**Standard Setting Authority**

There would be no single Standard Setting Authority. States could structure their own PE Study programs, if they thought one was necessary, and manage them to meet regulatory requirements.

**PE Study Providers**

States would direct their laboratories to one or more private sector or State PE Study Providers. It would be up to each individual State to decide who would: produce the PE materials; validate the PE Study materials; distribute the PE studies to participating laboratories; analyze client laboratory measurement data; determine acceptance limits in accordance with State-specified procedures; and report results. It would also be up to each individual State to determine if they need a data base. The States could also organize and conduct a cooperative national program through NELAC.

Environmental Testing Laboratories would use PE Study Provider(s) accepted in the State where they do business. Laboratories would pay a participation fee directly to the State or PE Study Provider.

OPTION 6 TIME TABLE	
COMPLETION DATE	ACTIVITY OR MILESTONE
December 1, 1996*	<b>Announcement of Final Decision:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN announcing option selected
April 1, 1997	<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish
October 1, 1998**	<b>Initial Studies:</b> Design studies; develop study plan; announce study; obtain standard reference materials; manufacture materials; verify materials; distribute materials; receive and process results; report

\* Assumes final option selection by October 1, 1996.

\*\* Allows states 2 years to make necessary statutory, regulatory, or budgetary changes.

OPTION 6 SUMMARY OF ESTIMATED COSTS					
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)				
	EPA	3RD PARTY	STATES	PROVIDERS	LABS
<u>Initial Costs</u>					
<b>Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN	0.25 FTE \$25K	N/A	N/A	N/A	N/A
<b>National Standards for Studies:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish	N/A	ELAB	N/A	N/A	N/A
<b>Obtain Accreditation:</b> Prepare and submit application; participate in on-site assessment; respond to requests for additional information	N/A	N/A	NELAC	ELAB	N/A
<b>Initial Studies:</b> Design studies; develop study plan; announce study; obtain standard reference materials; manufacture materials; verify materials; distribute materials; receive and process results; report	N/A	N/A	NELAC	ELAB	N/A
<u>Routine Costs</u>					
<b>Update National Standards:</b> Identify issues; develop changes and revise standards; facilitate EPA review/concurrence; publish	N/A	ELAB	N/A	N/A	N/A
<b>Conduct Studies:</b> Design studies; announce; manufacture and distribute materials, receive and process results; report	N/A	N/A	NELAC	All costs recovered thru fees	N/A
<b>Participate in Studies:</b> Select PE Study Provider(s); analyze materials; prepare results reports	N/A	N/A	N/A	N/A	ELAB

**Abbreviations**

N/A Not applicable. No significant costs incurred by this stakeholder group for this activity.

EID Estimate in development (by ORD or OW).

ELAB Environmental Laboratory Advisory Board (ELAB) will assist with estimate.

NIST Estimate to be supplied by the National Institute of Standards and Technology.

**Option 6: No EPA Involvement in Water PE Studies**

**Evaluation**

This option has an even greater potential than Option 7 to result in national consistency and quality falling below acceptable levels.

\_\_\_\_\_ Legal Concerns

None.

\_\_\_\_\_ National Consistency

There would be no controls to ensure national consistency.

Market forces (i.e., competitiveness) should weed out the bad performers.

\_\_\_\_\_ Quality of PE Studies

No national quality assurance program. Market forces (i.e., competitiveness) would eliminate bad performers.

\_\_\_\_\_ Legal Concerns

None.

\_\_\_\_\_ National Consistency

There would be no controls to ensure national consistency.

Market forces (i.e., competitiveness) should weed out the bad performers.

\_\_\_\_\_ Quality of PE Studies

No national quality assurance program. Market forces (i.e., competitiveness) would eliminate bad performers.

\_\_\_\_\_ Cost to EPA

Only minimal EPA resources would be needed for announcing the decision.

\_\_\_\_\_ Impact on States

Implementation schedule allows ample time for states to obtain necessary budget appropriations or make statutory/regulatory changes.

States would have to decide whether to establish their own multiple or single-source programs.

Uniformity in state programs could only be achieved on a voluntary basis through NELAC.

\_\_\_\_\_ Cost to Laboratory Community

Impact would vary from state to state. PE study providers may be subject to participating in numerous, highly variable state programs, which is likely to be costly.

\_\_\_\_\_ Implementation Timetable

Requires approximately 2 years to implement.

\_\_\_\_\_ TOTAL FOR OPTION 6

**Option 7: No National Accreditation/Oversight of PE Study Providers**

**Roles and Responsibilities**

<b>Option 7: No National Accreditation/Oversight of PE Study Providers</b>		
<b>STANDARDS SETTING AUTHORITY</b>	<b>PE STUDY PROVIDER ACCREDITATION BODY</b>	<b>PE STUDY PROVIDERS</b>
<p><b>EPA would:</b></p> <ul style="list-style-type: none"> <li>- Set national standards for PE studies</li> <li>- Set national guidance for PE Study Provider performance</li> <li>- Design and maintain the national data base</li> </ul>	<p>None.</p>	<p><b>Interested states and private sector suppliers would:</b></p> <ul style="list-style-type: none"> <li>- Manufacture and distribute PE studies</li> <li>- Score results and report to EPA and the states</li> </ul>



## **Option 7: No National Accreditation/Oversight of PE Study Providers**

### **Summary**

#### **Standard Setting Authority**

EPA would serve as the Standard Setting Authority for the Water PE Study Program. EPA would publish the national standards and performance standards for PE Study Providers as guidance. EPA would also maintain a national data base in order to monitor the effectiveness of PE studies.

#### **PE Study Providers**

Any private sector company authorized by the laboratory accreditation body in the state they are operating or state entity would be eligible to provide PE studies to participating environmental testing laboratories. The market place would police itself, i.e., the PE material suppliers (private sector companies) through trade associations, such as, the Certified Reference Material Manufacturing Association (CRMMA) would develop criteria/protocols to which PE manufacturers would adhere voluntarily, in order to maintain their competitive market share. The PE customers i.e., participating PE study laboratories and regional/state regulators, would determine which PE study providers were providing quality products that met their needs.

The private sector and interested States would assume responsibility for conducting Water PE Studies. The PE Study Providers produce the PE materials; distribute the PE studies to participating laboratories; analyze client lab measurement data; determine acceptance limits according to EPA guidance; and report results (in the appropriate format and detail) to the participating laboratories, the organization accrediting/certifying the laboratory or requiring the laboratory to participate, and to EPA. The report to EPA provides analyte true values, participating laboratories reported values and an evaluation of how the laboratories have performed relative to EPA's performance criteria.

Laboratories desiring to participate in PE studies would purchase the appropriate PE samples from the provider of his/her choice, declare up-front that the PE samples are for official evaluation, and pay a participation fee to a PE study provider.

OPTION 7 TIME TABLE	
COMPLETION DATE	ACTIVITY OR MILESTONE
December 1, 1996*	<b>Announcement of Final Decision:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN announcing option selected
April 1, 1997	<b>National Standards for Studies:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish  <b>Complete National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement
October 1, 1998**	<b>Initial Studies:</b> Design studies; develop study plan; announce study; obtain standard reference materials; manufacture materials; verify materials; distribute materials; receive and process results; report

\* Assumes final option selection occurs by October 1, 1996.

\*\* Allows states 2 years to make necessary statutory, regulatory, or budgetary changes. Initial studies could begin as soon as the summer of 1997.

OPTION 7 SUMMARY OF ESTIMATED COSTS				
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)			
	EPA	STATES	PROVIDERS	LABS
<u>Initial Costs</u>				
<b>Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN	0.25 FTE \$25K	N/A	N/A	N/A
<b>National Standards for Studies:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish	0.25 FTE \$30K	N/A	N/A	N/A
<b>Initial Studies:</b> Design studies; develop study plan; announce study; obtain standard reference materials; manufacture materials; verify materials; distribute materials; receive and process results; report	N/A	NELAC	ELAB	N/A
<b>National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement	EID	N/A	N/A	N/A
<u>Routine Costs</u>				
<b>Update National Standards:</b> Identify issues; develop changes and revise standards; facilitate EPA review/concurrence; publish	0.25 FTE \$30K	N/A	N/A	N/A
<b>Conduct Studies:</b> Design studies; announce; manufacture and distribute materials, receive and process results; report	N/A	NELAC	All costs recovered thru fees	N/A
<b>Participate in Studies:</b> Select PE Study Provider(s); analyze materials; prepare results reports	N/A	N/A	N/A	ELAB
<b>National Data Base:</b> Conduct data entry/verification; make modifications consistent with updated standards as needed; make improvements/corrections as needed; develop routine reports; monitor status and trends	EID	N/A	N/A	N/A

**Abbreviations**

N/A Not applicable. No significant costs incurred by this stakeholder group for this activity.

EID Estimate in development (by ORD or OW).

ELAB Environmental Laboratory Advisory Board (ELAB) will assist with estimate.

NIST Estimate to be supplied by the National Institute of Standards and Technology.

**Option 7: No National Accreditation/Oversight of PE Study Providers**

**Evaluation**

Under this option, EPA would achieve a significant cost savings. As in Option 5, however, there could be high variability among state programs, which would reduce national consistency and cause the industry to be subject to multiple, redundant PE Study Provider accreditation.

**SCORE**

\_\_\_\_\_ Legal Concerns

None.

\_\_\_\_\_ National Consistency

National standards would be the only controls on consistency and quality of PE materials.

Market forces (i.e., competitiveness) should eliminate bad performers.

\_\_\_\_\_ Quality of PE Studies

No national quality assurance for PE studies. Market forces (i.e., competitiveness) should eliminate bad performers.

\_\_\_\_\_ Cost to EPA

PE study design, manufacturing, and distribution would be supported through user fees paid by laboratories.

No costs associated with oversight of PE study providers.

EPA resources would be needed for standard setting (initial standards development and annual review/revision/updating), and data base development and maintenance.

\_\_\_\_\_ Impact on States

Implementation schedule allows ample time for states to obtain necessary budget appropriations or make statutory/regulatory changes.

States would have to decide whether to establish their own multiple or single-source programs.

Uniformity among state programs could likely be achieved eventually on a voluntary basis through NELAC.

\_\_\_\_\_ Cost of Program to Laboratory Community

Impact would vary from state to state. PE study providers may be subject to participating in numerous, highly variable state programs, which is likely to be costly.

\_\_\_\_\_ Implementation Timetable

Requires approximately 2 years to implement.

\_\_\_\_\_ TOTAL FOR OPTION 7

**Option 8: EPA Oversees One or More Government or Non-profit PE Study Providers**

**Roles and Responsibilities**

<b>Option 8: EPA Oversees One or More Government or Non-profit PE Study Providers</b>		
<b>STANDARDS SETTING AUTHORITY</b>	<b>PE STUDY PROVIDER ACCREDITATION BODY</b>	<b>PE STUDY PROVIDERS</b>
<p><b>EPA would:</b></p> <ul style="list-style-type: none"> <li>- Set national standards for PE studies</li> <li>- Set national standards for accreditation of PE Study Providers</li> <li>- Implement a program for overseeing PE Study Provider Accreditation Bodies</li> <li>- Design and maintain the national data base</li> </ul>	<p><b>EPA would:</b></p> <ul style="list-style-type: none"> <li>- Accredit PE Study Suppliers</li> <li>- Oversee PE Study Supplier performance through on-site assessments and ampule verification</li> </ul>	<p><b>Interested states, Federal government, and non-profit suppliers would:</b></p> <ul style="list-style-type: none"> <li>- Manufacture and distribute PE studies</li> <li>- Score results and report to EPA and the states</li> <li>- Maintain accreditation and cooperate in EPA oversight activities</li> </ul>

**Option 8: EPA Oversees One or More Government or Non-profit PE Study Providers**

**Summary**

**Standard Setting Authority**

EPA would serve as the Standards Setting Authority and as the PE Study Provider Accreditation Body. EPA would set the national standards; set technical performance standards for PE Study Providers. EPA would maintain the national data base. All of EPA's functions would be closely coordinated with NELAC.

**PE Study Provider Accreditation Body**

EPA would also serve as the PE Study Provider Accreditation Body and would design a national accreditation program, determine which PE Study Providers should be accredited, and conduct periodic compliance monitoring activities (such as on-site audits and ampule verification). EPA would publish a list of accredited PE Study Providers at least annually.

**PE Study Providers**

One or more neutral, government, or non-profit entities serve as the Water PE Study Providers. The study providers would conduct the Water PE Studies. The PE Study Providers would produce the PE materials; distribute the PE studies to participating laboratories; analyze client lab measurement data; determine acceptance limits according to EPA procedures; and report results (in the appropriate format and detail) to the participating laboratories, the organization accrediting the laboratory or requiring the laboratory to participate, and to EPA.

Environmental Testing Laboratories use the authorized PE Study Provider(s). Laboratories would have to pay a participation fee to their PE Study Provider.

OPTION 8 TIME TABLE	
COMPLETION DATE	ACTIVITY OR MILESTONE
December 1, 1996*	<b>Announcement of Final Decision:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN announcing option selected
April 1, 1997	<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish
October 1, 1997	<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures
April 1, 1998	<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution ** <b>Complete National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement
October 31, 1998	<b>Complete Initial Studies:</b> Design studies; develop study plan; announce study; manufacture materials; verify materials; distribute materials; receive and process results; report †

\* Assumes final option selection occurs by October 1, 1996.

\*\* Assumes that EPA will require 60 days to complete each accreditation and a total of 3 organizations will be accredited simultaneously.

† Assumes each vendor will require 60 days to distribute first study after receipt of accreditation. All vendors should receive accreditation by August 31, 1998.



OPTION 8 SUMMARY OF ESTIMATED COSTS				
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)			
	EPA	STATES	PROVIDERS	LABS
<u>Initial Costs</u>				
<b>Announcement:</b> Prepare responses to comments; prepare/revise/finalize FRN; facilitate internal EPA review/concurrence; publish FRN	0.25 FTE \$25K	N/A	N/A	N/A
<b>National Standards for Studies and Accreditation of PE Study Providers:</b> Prepare draft standards; facilitate internal EPA review and concurrence; facilitate coordination with NELAC; revise/finalize standards; publish	0.25 FTE \$40K	N/A	N/A	N/A
<b>Design PE Study Provider Accreditation Program:</b> Design application and application review process; develop checklists for application review and on-site assessments consistent with standards; design documentation procedures; design/develop information management and tracking system; prepare standard operating procedures; develop revocation/appeals process; design communication procedures	0.25 FTE \$50K	N/A	N/A	N/A
<b>Implement PE Study Accreditation Program:</b> Distribute applications; receive/process/review applications; conduct on-site assessments; prepare reports; implement information management and tracking systems; conduct communications/information distribution	1.5 FTE \$150K	N/A	N/A	N/A
<b>Obtain Accreditation:</b> Prepare and submit application; participate in on-site assessment; respond to requests for additional information	N/A	NELAC	ELAB	N/A
<b>Initial Studies:</b> Design studies; develop study plan; announce study; manufacture materials; verify materials; distribute materials; receive and process results; report	N/A	NELAC	ELAB	N/A
<b>National Data Base:</b> Design data base and reporting formats; develop instructions/reporting formats for PE Study Providers; test/de-bug; implement	EID	N/A	N/A	N/A

OPTION 8 SUMMARY OF ESTIMATED COSTS				
COST ELEMENT	ESTIMATED COST TO STAKEHOLDER GROUPS (\$ AND FTE)			
	EPA	STATES	PROVIDERS	LABS
<u>Routine Costs</u>				
<b>Update National Standards:</b> Identify issues; develop changes and revise standards; facilitate EPA review/concurrence; publish	0.25FTE \$30 K	N/A	N/A	N/A
<b>Maintain PE Study Provider Accreditation Program:</b> Conduct re-accreditation; take revocation actions as needed; conduct routine communications; accredit new PE Study Providers; make changes to procedures/checklists/reports consistent with updated standards; conduct ample verification program	EID	N/A	N/A	N/A
<b>Conduct Studies:</b> Design studies; announce; manufacture and distribute materials, receive and process results; report	N/A	NELAC	All costs recovered thru fees	N/A
<b>Participate in Studies:</b> Select PE Study Provider(s); analyze materials; prepare results reports	N/A	N/A	N/A	ELAB
<b>National Data Base:</b> Conduct data entry/verification; make modifications consistent with updated standards as needed; make improvements/corrections as needed; develop routine reports; monitor status and trends	EID	N/A	N/A	N/A

**Abbreviations**

- N/A Not applicable. No significant costs incurred by this stakeholder group for this activity.
- EID Estimate in development (by ORD or OW).
- ELAB Environmental Laboratory Advisory Board (ELAB) will assist with estimate.

## **Option 8: EPA Oversees One or More Government or Non-profit PE Study Providers**

### **Evaluation**

Overall, this option is analogous to Option 1, with the exception that the study provider is a non-profit rather than a profit organization. This option provides for a relatively high degree of national consistency. The fact that EPA retains oversight responsibilities causes EPA's costs to be somewhat higher than other options, but may make this option more appealing to the states.

### **SCORE**

#### Legal Concerns

EPA may lack direct statutory authority to accredit PE study providers.

For-profit private sector PE study providers would likely object on legal grounds to EPA's decision to disqualify profit-based organizations.

EPA could not compel the states to use the national program. State participation likely would be achieved eventually on a voluntary basis through NELAC. Current participation is voluntary based on State interest in using the EPA studies.

#### National Consistency

Level of consistency would depend on specificity of the national standards and resources available for EPA oversight of PE study providers.

#### Quality of PE Studies

Depends on EPA resources available to fund on-site audits of PE study providers and a PE sample verification program.

#### Cost to EPA

PE study design, manufacturing, distribution, and data management/scoring functions would be supported with user fees.

EPA resources would be needed for standard setting (initial standards development and annual review/revision/updating), selection and oversight of qualified PE study providers, and data base development and maintenance.

\_\_\_\_\_ Impact on States

Implementation schedule allows ample time for states to obtain necessary budget appropriations or make statutory/regulatory changes.

State expenditures should be limited to purchasing PE studies; they need not incur oversight costs for monitoring the performance of PE study providers. This constitutes a savings for some states.

Any states that serve as PE study providers would be subject to EPA oversight/accreditation. This should not be objectionable to the states if they are involved in the standard-setting process.

\_\_\_\_\_ Cost of Program to Laboratory Community

Laboratories would pay market prices for participating in PE studies.

EPA could have leverage to ensure that small laboratories are offered affordable studies of limited scope.

Only a portion of total program costs would be passed on to regulated community; EPA would retain responsibility for significant costs of oversight and standards development/maintenance.

\_\_\_\_\_ Implementation Timetable

Requires approximately 2 years to implement.

\_\_\_\_\_ TOTAL FOR OPTION 8