Implementation Plan

Pb Performance Evaluation Program

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Implementation Plan for the Pb Performance Evaluation Program

Ambient Air Monitoring Group
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency
RTP, NC 27711

Foreword

This document is available as a PDF file on the Internet under the Ambient Monitoring Technical Information Center (AMTIC) Homepage (http://www.epa.gov/ttn/amtic/npepqa.html). The document can be read and printed using Adobe Acrobat Reader software, which is freeware that is available from many Internet sites (including the EPA web site).

Abstract

The purpose of this Pb-PEP Implementation Plan is to provide the necessary technical, logistical, and administrative information to successfully implement the federally implemented program. It is intended to establish a framework for communication among the organizations participating in this program, as well as allowing interested parties to understand the implementation aspects of the PEP. The specific purposes include identifying:

- provide background on the Pb-PEP
- each important phase of the program and explaining how it will be implemented.
- the roles and responsibilities of all affected agencies and organizations
- the specific lines of communication between the EPA organizations, the monitoring organizations, and the ESAT contractors
- the pertinent milestones involved with this program
- the resources required for successful implementation
- the logistical elements, field and laboratory, required for this program
- the data management activities to ensure the resultant data is properly recorded, transferred, and archived
- the necessary quality assurance and quality control procedures required to ensure the quality of the data meets the objectives of the program
- the assessment and reporting components
- the training and certifications that are required to fulfill the technical aspects of the program

Contents

Section ***Page***

Appendices

Figures

Tables

List of Abbreviations

AAMG	Ambient Air Monitoring Group
AQAD	Air Quality Assessment Division
AQS	Air Quality System
CFR	*Code of Federal Regulations*
CV	coefficient of variation
DOPO	delivery office project officer
DQA	data quality assessment
DQOs	data quality objectives
EPA	Environmental Protection Agency
ESAT	Environmental Services Assistance Team
FEM	Federal Equivalent Method
FRM	Federal Reference Method
FS	field scientist
MQOs	measurement quality objectives
NAAQS	National Ambient Air Quality Standards
NERL	National Exposure Research Laboratory
NIST	National Institute of Standards and Technology
NRMRL	National Risk Management Research Laboratory
OAQPS	Office of Air Quality Planning and Standards
ORD	Office of Research and Development
PE	performance evaluation
PEP	Performance Evaluation Program
$PM_{2.5}$	particulate matter $\leq$ 2.5 microns
PQAO	primary quality assurance organization
QA	quality assurance
QAPP	quality assurance project plan
QA/QC	quality assurance/quality control
QMP	quality management plan
RPO	Regional Project Officer
SLAMS	state and local monitoring stations
SOP	standard operating procedure
SPM	special purpose monitor
STAG	State and Tribal Assistance Grants
TOPO	task order project officer
TSA	technical systems audit

1.0 INTRODUCTION

1.1 Pb Monitoring Program

On November 12, 2008 EPA substantially strengthened the national ambient air quality standards (NAAQS) for lead (see 73 FR 66934). EPA revised the level of the primary (health-based) standard from 1.5 micrograms per cubic meter ($\mu g/m^3$) to 0.15 $\mu g/m^3$, measured as total suspended particles (TSP) and revised the secondary (welfare-based) standard to be identical in all respects to the primary standard. In conjunction with strengthening the lead (Pb) NAAQS, EPA identified the need for states to improve existing lead monitoring networks by requiring monitors to be placed in areas with sources that emit one ton per year (tpy) or more of lead and in urban areas with more than 500,000 people. Depending on specific circumstances, States may have the option of using monitoring for either lead in TSP (Pb-TSP) or lead in PM_{10} (Pb-PM_{10}) using approved Federal Reference Methods (FRM's) or Federal Equivalent Methods (FEM's) to demonstrate compliance.

Due to the promulgation of the lower Pb NAAQS, EPA made some changes in the QA requirements in 40 CFR Part 58 Appendix A. The following are the highlights of the changes that occurred in Appendix A:

- **DQO Goals -**EPA utilized the DQO process to determine appropriate precision and bias measurement quality objectives. Measurement quality objectives for precision will be 20% for a 90% confidence limit coefficient of variation and an overall absolute bias upper bound goal of 15%. Goals will be assessed on 3 years of data at the PQAO level of aggregation.

- **Flow Rates-**No changes occurred to flow rate. Flow rate verification will be implemented monthly (PM_{10} Lo-Vol) or quarterly (TSP Hi-Vol) and flow rate performance evaluations will be implemented every six months.

- **Collocated Monitoring-**No changes occurred to the collocation requirements. Collocation will continue to be required at 15% of each method designation within a primary quality assurance organization at a 1-in-12 day sampling frequency. EPA added language encouraging monitoring organizations to site the first collocated sampler in each network at the highest concentration site. This will allow the site to operate over the longest time period and since it may be the site that affects the NAAQS and it is allowable to substitute collocated data for missing data from the primary monitor, this siting would be advantageous for improving data completeness at a very important site. Routine/collocated data pairs will be used when Pb concentrations of both samples are greater than or equal to 0.02 $\mu g/m^3$. Prior to 2008, this cutoff value was 0.15 $\mu g/m^3$.

- **Pb Strip Audits-**The requirement for the analysis of 6 Pb audit strips per quarter (3 strips at 2 concentration ranges) has not changed. However, the audit concentrations ranges have changed. The lower concentration range is 30-100% of the NAAQS and the higher concentration range is 200-300% of the NAAQS.

- **Pb-Performance Evaluation Program (Pb-PEP)-**The implementation of an audit similar to the $PM_{2.5}$ Performance Evaluation program (PEP) is a new requirement and it provides some assessment of overall bias but will be a mix of one or two Pb-PEP audits with additional collocated sampling. The number of audits required is based on the number of routine sites within a primary quality assurance organization PQAO. The program will require the same number of audit samples as required for $PM_{2.5}$ meaning:

    - PQAOs with $\leq$ 5 sites require 5 audits (1 Pb-PEP, 4 collocated)
    - PQAOs with $>$ 5 sites require 8 audits (2 Pb-PEP, 6 collocated)

Implementation of the Pb-PEP for Pb monitoring is new and is the focus of this Implementation Plan.

1.2 The Pb Performance Evaluation Program (PEP)

Since the data for the SLAMS network is used for NAAQS comparisons, the quality of this data is very important. Therefore, a quality system has been developed to control and evaluate the quality of data in order to make NAAQS determinations within an acceptable level of confidence. During the development of the Pb NAAQS, the EPA used the data quality objective process to determine the allowable measurement system imprecision and bias that would not significantly effect a decision makers ability to compare pollutant concentrations to the NAAQS. The precision requirement (20% CV) and bias requirement ($\pm$15%) are based on total measurement uncertainty, which incorporates errors coming from all phases (field sampling handling, analysis etc.) of the measurement process. The collocated samples provide adequate estimates of precision. The Pb-PEP, if properly implemented, can provide the bias estimate.

The Pb-PEP is a quality assurance activity which will be used to evaluate measurement system bias of the Pb monitoring network. A performance evaluation is defined as a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of the an analyst or laboratory. In the case of the Pb-PEP, the goal is to evaluate total measurement system bias, which includes measurement uncertainties from the field and the laboratory activities. The pertinent regulations for this performance evaluation are found in 40 CFR Part 58, Appendix A, section 3.3.4.4. The strategy is to collocate a portable Pb TSP air sampling instrument within 2 to 4 meters of a routine SLAMS air monitoring instrument, operate both monitors in exactly the same manner, and then compare the results. In addition to collocation with a portable audit sampler, 4 or 6 (depending on number of sites within a PQAO) collocated samples as described in 40 CFR Part 58, Appendix A, section 3.3.4.3 will be sent to the audit laboratory. EPA expects that these collocated samples would be submitted on a monthly basis to the audit laboratory.

The implementation of the Pb-PEP is a monitoring organization responsibility. However, similar to the PM2.5 PEP program, EPA has included a federally implemented Pb-PEP and provides monitoring organizations the option to self implement or utilize the federally implemented program. Self implementation will require monitoring organizations to meet a level of independence and adequacy. Appendix A provides the information on adequacy and

independence. Since this information may change over the years, the Appendix will also be posted on AMTIC and will be reviewed annually and updated as necessary.

EPA will use the Environmental Services Assistance Team (ESAT) Contract that is currently in place in each Region to provide the necessary field and laboratory activities. Each EPA Region will implement the field component of this activity while Region 9 will operate the laboratory component. In addition, the EPA NHERL Metrology Laboratory will function as a field standards verification facility.

The Pb-PEP can be segregated into a field and a laboratory component. The following information provides a brief description of these activities. Detailed standard operating procedures (SOPs) will be developed for all field and laboratory activities.

Field Activities:

TSP portable audit samplers will be used in a collocated manner to perform the evaluations. These samplers have been approved by EPA as a Federal Reference Method and are designed to be durable, rugged, and capable of frequent transport. These samplers are constructed in modules with each module weighing no more than 40 pounds each. Specific detailed operating instructions will be found in the Pb-PEP Quality Assurance Project Plan (Pb-PEP QAPP) and the Standard Operating Procedures (SOPs) which are under development and being designed specifically for this program.

The following steps must be observed to ensure the quality of the data:

- adherence to the vendor's operations manual for the proper operation of the sampler; this includes the proper assembly, transport, calibration, and operation
- adherence to the Pb-PEP Field SOPs
- adherence to the standards, principles, and practices outlined in the Pb-PEP QAPP
- completion of the required certification training program
- special attention must also be given to any activity involving filter handling (loading, transport, removal, etc.); this area contains the greatest potential for measurement uncertainty and care must be given to the proper handling of the TSP glass fiber filters and 47 mm Teflon filters (both may be used in this program)

Field Activity 1, Pb-PEP audit

1. One fully trained field scientist will transport a portable Pb-PEP sampling device to an established Pb site which shall be located at any of the SLAMS/SPM sites within each PQAO.

2. The field scientist will assemble the instrument, collocate the sampler, perform a calibration following the SOPs, install a filter and operate the instrument to the same 24-hour sampling mode as the routine instrument (midnight to midnight).
3. If scheduling allows, the field scientist will leave this location to set up an additional 24-hour performance evaluation at another routine sampling location. If the schedule does not allow for another set up, the field scientist may perform additional activities at the site.
4. The field scientist shall return to each site after 24-hour sampling time, download the stored electronic monitoring data, remove and properly store the filter for transport, and disassemble the instrument.
5. The field scientist shall properly package the filter following the QA guidelines for transport to the pre-determined audit laboratory.

Field activities 2, Collocated Audit Sample

Monitoring organizations are required to implement collocated monitoring at 15% of the Pb sites within their network as described in 40 CFR Part 58 Appendix A Section 3.3.4.3. In addition to this requirement, the monitoring organization will sample an additional 4-6 collocated samples and send these samples to either their own independent Pb-PEP laboratory or to the national Pb-PEP laboratory (Region 9) for analysis. Monitoring organization will follow their own SOPs and QAPP to perform this additional collocation. If utilizing federal implementation, the monitoring organization will be required to fill out a field chain of custody form that will be included with each filter.

Laboratory Activities:

The Pb-PEP FRM performance evaluation also requires extensive laboratory activities, including filter handling, sample extraction, analysis, data entry/management and archival. Region 9 will develop the Pb-PEP laboratory. Specific detailed instructions will be found in the Pb-PEP QAPP and the SOPs which are under development and being designed specifically for this program.

In addition to the Good Laboratory Practices (GLP) which must be followed, the following activity must also be observed concerning the laboratory activity

- adherence to the vendor's operations manual for the proper operation of the extraction and analytical equipment.
- adherence to the SOPs for the program.
- adherence to the standards, principles, and practices outlined Pb-PEP QAPP
- special attention must also be given to any activity involving filter handling. This area contains the greatest potential for measurement uncertainty and care must be given to the proper handling of both TSP and 47 mm Teflon filters.

NOTE: Monitoring organizations deciding to self-implement Pb-PEP may choose to use the Region 9 National Pb-PEP for analysis with the appropriate allocation of STAG funds.

1.3 Purpose of this document

The purpose of this Pb-PEP Implementation Plan is to provide the necessary technical, logistical, and administrative information to successfully implement the federally implemented program. The specific purposes include identifying:

- provide background on the Pb-PEP
- each important phase of the program and explaining how it will be implemented.
- the roles and responsibilities of all affected agencies and organizations
- the specific lines of communication between the EPA organizations, the monitoring organizations, and the ESAT contractors
- the pertinent milestones involved with this program
- the resources required for successful implementation
- the logistical elements, field and laboratory, required for this program
- the data management activities to ensure the resultant data is properly recorded, transferred, and archived
- the necessary quality assurance and quality control procedures required to ensure the quality of the data meets the objectives of the program
- the training and certifications that are required to fulfill the technical aspects of the program
- the assessment and reporting components

As stated earlier, monitoring organizations can choose to self-implement the Pb-PEP or allow for federal implementation. Self implementation will require the development of an adequate program and an established level of independence. Both adequate and independence are be described in this document (see Appendix A). However the detail in this document should not be construed as the necessary requirements for a self-implemented program. This document's intent is to focus on the federal program and can be used by monitoring organizations in their implementation decisions.

2.0 ROLES AND RESPONSIBILITIES

The degree of complexity and the number of agencies involved with the Pb monitoring program and the subsequent Pb-PEP requires that the flow of information and associated communications be structured to optimize the collective resources. The only realistic perspective on implementing this program is one that recognizes that deployment and operation of this network is a shared responsibility among all the involved organizations. The purpose of the following descriptions of roles across programs is to facilitate communications, and to outline very basic responsibilities. Figure 2.1 provides a basic diagram of the organization and lines of communication.

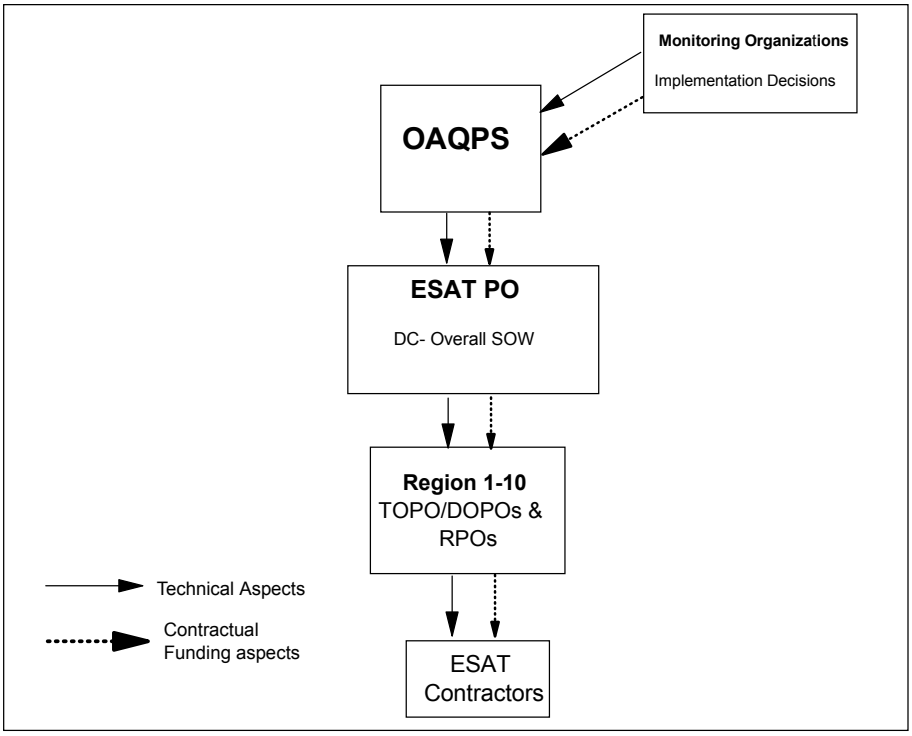

Figure 2.1 Organizational lines of communication

2.1 Monitoring Organizations

EPA could not effectively plan and execute this program without monitoring organization participation. State and local agencies bear a tremendous level of responsibility for developing, implementing, and tracking the entire national Pb monitoring program. It is imperative that the monitoring organizations work with the EPA Regional Offices throughout this process to identify problems as early as possible, and to help find solutions to many of these issues. The monitoring organizations have the following specific responsibilities:

If self-implementing the Pb-PEP:

- implementing the Pb-PEP at the same frequency and at comparable adequacy to the federal program and adhering to the definition of independent assessment (see Appendix A)
- undergoing training and certification activities
- procuring necessary equipment and consumables
- developing the necessary SOPs and QA procedures into their respective QAPPs
- transmitting data to AQS
- selecting the sites for evaluation

If utilizing the Federal Pb-PEP:

- operating their Pb monitoring network according to the established regulations and guidelines; this includes proper siting, operations, and quality assurance procedures
- assisting, through review activities, in the development and revisions of pertinent Pb-PEP guidance documents
- on a yearly basis, determining whether to continue utilizing the federal implementation of the Pb-PEP
- identifying the sites within their monitoring network where Pb-PEP evaluations will be performed each year
- ensuring a site operator is on-site when the Pb-PEP field scientist arrives and performs the evaluation; this includes communicating with the field scientist, operating the routine monitor in the normal operating mode, and generally supporting the Pb-PEP
- ensuring the success of the program by performing various oversight activities such as technical systems audits of field and laboratory activities
- reviewing routine and performance evaluation data and working with the EPA Region on corrective actions

2.2 EPA Office of Air Quality Planning and Standards (OAQPS)

OAQPS has the overall responsibility for ensuring the quality of the nation's ambient air data. OAQPS has developed specific regulations for the development of a quality system as found in 40 CFR Part 58, Appendix A. OAQPS has the following responsibilities to ensure the development of this Pb-PEP Program:

- providing a contractual vehicle for the manufacturing and distribution of the Pb-PEP portable evaluation sampler
- developing and or continuing the Memorandum of Understanding with the ESAT Office
- working with the EPA Regions to determine which monitoring organizations will utilize the federally implemented Pb-PEP
- acquiring the appropriate STAG funds to implement the federally implemented Pb-PEP program.
- transferring the necessary funds to the EPA Regional ESAT contracts management division to support the Pb-PEP and to the Region 9 office for laboratory equipment and consumables

- developing the Pb-PEP Implementation Plan, the ESAT Scope of Work (SOW), field standard operating procedures (SOPs), Pb-PEP.
- developing the field and laboratory personnel requirements
- developing the field and laboratory training activities, participating in training, and supplying national experts to answer specific technical questions
- developing a list of primary quality assurance organizations (PQAOs) who are monitoring Pb and SLAMS and SPM sites.
- developing field and laboratory information management systems
- assessing the Pb-PEP concentration information entered into the AQS data base
- initiating and instituting a communications network and acting as a liaison to groups working on the Pb-PEP
- interacting with the monitoring organizations concerning the set-up, operation, and data results of the performance evaluations
- ensuring the success of the program by performing various oversight activities such as management systems reviews

Most budgetary and technical planning activities are coordinated through OAQPS. The Ambient Air Monitoring Group (AAMG) within the Air Quality Assessment Division (AQAD) is ultimately responsible for this Implementation Plan, most technical components (with support from the EPA Regional Offices and monitoring organizations), and the resource estimates underlying program implementation. Various forms of resource guidance necessary for the State and Tribal Assistance Grants (STAG) distribution is coordinated through OAQPS. In addition, the OAQPS National Air Data Group is responsible for the AQS data management system.

2.3 ESAT Organization

The ESAT contract is administered by the Office of Superfund Remediation and Technology Innovation (OSRTI) Technology Innovation and Field Services Division (TIFSD) Analytical Services Branch (ASB). OAQPS has entered into a memorandum of understanding with this office in order for the ESAT contract to provide the services necessary for Pb-PEP. The ESAT is organized of contracting officers (COs) at the Headquarters office in DC and with Task Order Project Officers (TOPOs), Delivery Order Project Managers (DOPOs) and Regional Project Officers (RPOs) within each Region. The AMTIC website[1] provides the current ESAT contacts list.

Some important aspects of the ESAT contract include:

- only the TOPO/DOPO, RPO and COs are authorized to give instructions or clarification

[1] http://www.epa.gov/ttn/amtic/npepqa.html

(technical direction) to the ESAT contractor on the work to be performed. This technical direction is provided in writing
- the work assignments will be prepared by the TOPO/DOPO and are effective only upon approval by the Contracting Officer

The EPA Contracts Manual describes the roles and responsibilities of contracting officers, specialists and project officers which need not be explained here. The important roles and responsibilities for the PEP are described below

Head Quarters Contracting Officers
- working with OAQPS on the securing, obligating, committing and distributing funds for work performed under the ESAT Contract.
- developing a Memorandum of Understanding with OAQPS
- ensuring work assignment activities fall within the ESAT Scope of Work
- approving work assignments

Regional PO
- providing overall management and overseeing performance of respective regional ESAT personnel
- reviewing region specific invoices with input from TOPO/DOPO
- assisting in the preparation Pb-PEP work assignments
- assisting in the development of the *FRM Performance Evaluation Program Implementation Plan* and the ESAT Scope of Work as it relates to the Pb-PEP
- ensuring there is qualified contractual personnel available to implement, facilitate, and perform the Pb-PEP evaluations
- providing administrative and logistical support for the ESAT contract
- communicating on a regular basis with program participants (OAQPS, Region, etc.)

TOPO/DOPO

The TOPO/DOPO will, in most cases, be a technical person from the Regional air monitoring branch/division who will be responsible for assisting in the technical aspects of the program. Some of the TOPO/DOPO activities may also include the activities listed in Section 2.4, but the responsibilities, as they relate to the ESAT contract, include the following:

- preparing (with RPO) Pb-PEP work assignments
- setting up a file system containing all relevant documentation including notes of conversations with the contractor and other items that will provide an audit trail of their actions under the work assignment as well as all technical information related to the Pb-PEP

- reviewing the contractors workplan and preparing findings on proposed tasks, labor hours skill mix, and materials and quantities
- monitoring compliance with the work assignments
- tracking dollars and hours, providing technical direction (in accordance with the terms of the contract) and reviewing monthly technical and financial reports
- verifying contractor representations of deliverables received and accepted, and/or progress made
- communicating contractor performance and administrative/logistical issues to RPO

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2.4 EPA Regional Office

The EPA Regional Offices are the major communication link with monitoring organizations and OAQPS. This role is absolutely necessary for the development of effective policies and programs. For the Pb-PEP, the Regional offices have the following specific responsibilities:

All Regions--

- assisting in the development of all pertinent Pb-PEP evaluation guidance documents
- reviewing and approving the workplans submitted by the ESAT contractors
- identifying TOPO/DOPOs to oversee the technical aspects of field activities that are performed by the ESAT contractors
- training and certifying ESAT field personnel after initial training
- providing technical oversight of the field activities by performing technical systems audits of these activities
- providing a yearly schedule of site evaluations for the ESAT contractors
- working with monitoring organizations in developing a yearly schedule of site evaluations
- informing monitoring organizations of an upcoming performance evaluation
- evaluating the performance evaluation data and informing monitoring organizations of significant differences
- participating in training activities, including multi-State conferences, EPA satellite broadcasts, and other training vehicles
- Attending conference calls and meetings on performance evaluation activities

Region 9 (including items listed above)--

- identifying work assignment managers to oversee the technical aspects of laboratory activities that are performed by the ESAT contractors
- developing the primary laboratory for this program with respect to logistical, technical, and analytical support, including necessary facilities to store, and archive filters and extracts.
- training and certifying ESAT laboratory personnel after initial training

- providing technical oversight of the laboratory activities by performing technical systems audits of these activities

2.5 ESAT Contractors

The ESAT contractors will perform the specific tasks associated with the Pb-PEP. The ESAT contractors responsibilities include:

- developing a work plan and cost estimates for each work assignment
- staffing appropriately to meet the requirements of the work assignment
- successfully implementing the activities described in the work plan and work assignment
- learning and implementing SOPs
- understanding government regulations as they relate to contracts and inherent government function

2.6 Other Affected Entities

EPA Office of Research and Development (ORD)

The ORD's primary role in the implementation of the Pb-PEP will be as a technical consultant and advisor. This action will be primarily through the National Environmental Research Laboratory (NERL) which provides many of the technical infrastructure elements for the program. ORD also has the overall responsibility for designating all air monitors as Federal Reference or Federal Equivalent Method. The portable TSP audit sampler must be designated by ORD through their Federal Reference and Equivalency program. This overall responsibility includes:

- designating Pb samplers as FRM/FEM and providing technical support
- providing technical support for the national procurement contracts
- providing guidance for field and analytical activities

In addition, the ORD National Risk Management Research Laboratory (NRMRL) Metrology Laboratory will provide annual verification of the flow/pressure/temperature standards used for the Pb-PEP.

3.0 COMMUNICATIONS

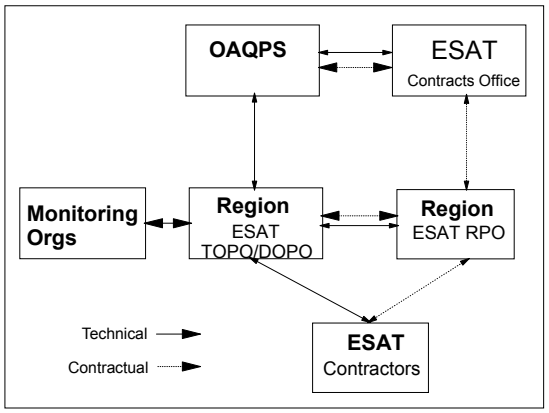


Figure 3.1 Communication pathways

An organized communications framework is needed to facilitate the flow of information among the parties discussed in Section 2.0 as well as other users of the information produced by the Pb network. Figure 3.1 represents the principal communications pathways. In general, ESAT contractors will be responsible for keeping the Regional TOPO/DOPOs and RPOs fully informed about technical progress, issues and contractual obligations. On the technical side, the EPA Regional TOPO/DOPOs will be responsible for communicating with monitoring organizations and informing OAQPS on issues that require technical attention. Contractual issues will be conveyed from the ESAT contractor through RPO's to the ESAT Contracts Office and if necessary, to OAQPS. The communication network will be described as it relates to planning, implementation assessment and reporting stages.

3.1 Planning (6/09 through 12/09)

During the planning stages, technical discussions on the implementation aspects will take place in order to review and concur on the products developed by OAQPS and the EPA Regions. OAQPS will take the lead in the development of drafts of the Implementation Plan, the field SOPs and the Pb-PEP QAPP. OAQPS will also draft a memo each July that will be used by monitoring organizations to decide whether to self-implement the Pb-PEP or allow for federal implementation. The Region 9 laboratory will take the lead on the development of the laboratory methods and will address the laboratory sections of the Pb-PEP QAPP. OAQPS will distribute this information to the ESAT contacts. Pb-PEP personnel will have an opportunity to comment on the drafts until there is general agreement on the various aspects of the program. The documents will then be distributed on AMTIC for wider review and comment by monitoring organizations. In order to facilitate this process OAQPS will organize two workgroups

Laboratory Workgroup - This Workgroup is made up of personnel from OAQPS, Region 9 and Region 7. It was established in 3/09 to develop the laboratory capabilities of Region 9 and Region 7. Although there is a need for one National Pb-PEP laboratory, Region 7 also supports OAQPS in providing check analysis of laboratory audit strips. Both Region 9 and 7 will use a consistent extraction and analysis method are working together to develop one method (ICP-MS).

ESAT Workgroup - This workgroup was established in 7/09 to discuss the technical, contractual and implementation activities of the ESAT contract, and will include OAQPS, the

EPA Regional DOPO/TOPOs and RPO's, and the ESAT Contracts Office (as needed). At the planning stages, it will not include ESAT contractor personnel. The frequency of the call will be determined by the Workgroup and will include topics such as:

- personnel requirements
- funding and equipment acquisition
- work assignment development
- implementation schedules
- logistics

Monitoring organizations deciding to self-implement the Pb-PEP will be invited to attend the Workgroup meetings to ensure they develop an adequate program.

Notes from each Workgroup call will be taken and distributed electronically within five working days of the call. Workgroup participants will have an opportunity to comment on the notes which will be revised as appropriate.

3.1.1 Regional Communication with Monitoring Organizations

Prior to implementation, the EPA Regions and monitoring organizations will select the sites that will be visited in the calendar year. The site selection will be based on the regulations in 40 CFR Part 58 Appendix A and on discussions with the primary quality assurance organization (PQAOs). A tentative evaluation schedule for the year will then be developed that will take into account the logistics, and monitoring frequencies of each monitor. This information will then be distributed to each affected PQAO for review and comment. Communication at this level will be the responsibility of the EPA Regional DOPO/TOPOs

3.2 Implementation (1/2010 - 4)

3.2.1 National Communication

During implementation, the ESAT Workgroup will remain the primary mode of communication for the participants in the program. ESAT contractors may be involved in the call in order to supply technical information and progress reports. Since most of the planning aspects should be completed, these calls will be scheduled at frequencies of once a month, for the first year, and will be used primarily for updates, progress reports and issue resolution. Any issues discussed that result in a change in how the Pb-PEP will be implemented will also be communicated through the ESAT Workgroup and on AMTIC. Once implementation is found to be fairly routine and most issues resolved, conference calls will be reduced to a quarterly frequency.

3.2.2 Regional Communication

The following types of communication will take place at the Regional level

ESAT Contractors

The ESAT contractors will have frequent communication with Regional DOPO/TOPOs on the progress of their activities and any problems/issues associated with them. Resolution of these issues should take place in the Regions unless it is something that could affect the implementation of the program at a national level, where it can be discussed and resolved through the ESAT Workgroup conference call.

ESAT Lab/ Field Communication

Since the Region 9 laboratory will support the field activities for the 10 Regional ESAT contracts, frequent communication will be required in the following areas:

Field communication to lab:

- upon shipment of filters to the laboratory, including date of shipment, number of boxes, a listing of each filter and the shipping tracking number
- electronic and flash drive mailing of field data from data loggers for each sample

Lab communication to field:

- upon receiving filters and data from the field
- issues related to field information

Each Region will designate a field and laboratory communications coordinator from the ESAT contract staff to ensure adequate communications.

Monitoring Organizations

Prior to implementation of the Pb-PEP, the EPA Regions will have worked with the monitoring organizations to develop an implementation schedule for their respective Region. One week prior to an actual visit, the Regional TOPO/DOPO and/or the ESAT field scientist will call the monitoring organization to inform them of the upcoming evaluation and to coordinate any necessary field activities.

3.3 Assessment Communication

During the assessment of the evaluation results, the following communication avenues will be developed.

3.3.1 National

Data from the Pb-PEP, once validated, will uploaded to AQS. If possible, the data will be placed in the AQS system and will remain inaccessible until the value from the routine sampler is rerted to AQS. At that point a comparison of the two values through AQS software will occur. Further discussion on this will take place in Section 7. OAQPS, the EPA Regional TOPO/DOPO and monitoring organizations will assess this information. During ESAT Workgroup conference calls, the data will be discussed as it relates to any observed trends (i.e., overall bias, bias of particular instruments), corrective action needed or additional assessments.

There is also a need to assess the implementation of the Pb-PEP. This will take place during management systems reviews of EPA Regions (see section 8). It is anticipated that OAQPS will be instituting a QA meeting once a year. During this meeting, time will be devoted to assessing the implementation of the Pb-PEP. By 4/2011, an assessment report will be written by OAQPS discussing the positive/negative aspects of the first year of the program including any information coming from the meeting or any Regional, or monitoring organization assessments of the Program.

3.3.2 Regional and Monitoring Organization Assessments

Detailed reviews and discussion of the Pb-PEP data will occur at the EPA Regional/monitoring organization level. If data is outside acceptance criteria, the Regions and monitoring organizations may decide to perform additional PEs at the site(s) where the out-of-criteria values were generated. Information on these corrective actions will be forwarded back to OAQPS in order to track the number of corrective actions and there outcome for future improvements to the Pb-PEP.

Regions will forward technical systems audits (TSAs) performed on the ESAT contractors to OAQPS for review and use during program assessments. Monitoring organizations will also be asked to provide any assessments they have performed on the Pb-PEP to the Regions and OAQPS.

3.4 Reporting Communication

It is critical to the success of the program that any pertinent information that is collected is reported in a timely fashion in order to implement improvements in the quality of routine Pb data as well as to improve the implementation of the Pb-PEP.

3.4.1 National Reporting

Every year OAQPS will develop a QA summary report that will provide a data summary of the QA activities performed during the calendar year and will include information that can be retrieved and assessed through AQS. The PE data will be included in this report. The ESAT Workgroup will have input to the content and structure of the report and will have the opportunity for internal peer review prior to distribution on AMTIC.

Every three years OAQPS will develop a QA report assessing three years worth of data. This report differs in the yearly report in that it will be more interpretive and will integrate all facets of the QA program. The ESAT Workgroup will have input to the content and structure of the report and will have the opportunity for internal peer review prior to distribution on AMTIC.

3.5 AMTIC

Another important avenue of communication on QA activities is AMTIC. AMTIC presently has an area devoted to Pb monitoring[1] and an area devoted to the Pb-PEP[2]. Important information and guidance documents will posted in these areaa. EPA will utilize AMTIC extensively throughout the planning, implementation, assessment, and reporting processes.

3.6 Summary

A good line of communication is important to establish early and it must be followed to ensure that all parties receive the appropriate information in a timely manner. Figure 3.1 presented the general lines of communication. By following this figure and using the Workgroups currently established, it is anticipated that the Pb-PEP should be implemented in an efficient manner. Table 3-1 provides a summary of the technical aspects that each organization will be responsible for communicating

[1] http://www.epa.gov/ttn/amtic/pb-monitoring.html
[2] http://www.epa.gov/ttn/amtic/npepqa.html

Table 3.1 Overview of Principal Communication Lines.

OAQPS	Program requirements, training procedures, guidance documentation, contractual information, program funding, data analysis, coordination, QA reporting.
ORD	Federal Reference and Equivalency information, technical advice. Logistics on field standards verification
EPA Regions	Field and laboratory support, monitoring organization implementation schedules, data assessments, corrective action , TSAs, information on the project officers and task managers, work plan review information, ESAT progress reports.
ESAT Contractors	Information concerning the specific tasks of the performance evaluation, any feedback to the operation and training procedures, information concerning the annual work plans, implementation progress, information on the operation of the FRM portable audit sampler itself.
ESAT RPOs	Any information concerning the training, personnel and specific tasks of the performance evaluations, information concerning the financial, administration or logistical support of the program
Monitoring Organizations	Information concerning the network, the specific sites to be evaluated, any required training, guidance needed, information on the operation of the routine monitor itself, any feedback on the entire program, TSAs

4.0 TIME LINES/MILESTONES

In order to ensure that the PEP is implemented in calendar year 2010, many aspects of the program must be completed in a timely and efficient fashion.

4.1 Planning Time Lines

Figure 4.1 provides the key planning aspects of the program that must be completed within the specified time frames in order to meet a 1/1/2010 implementation date.

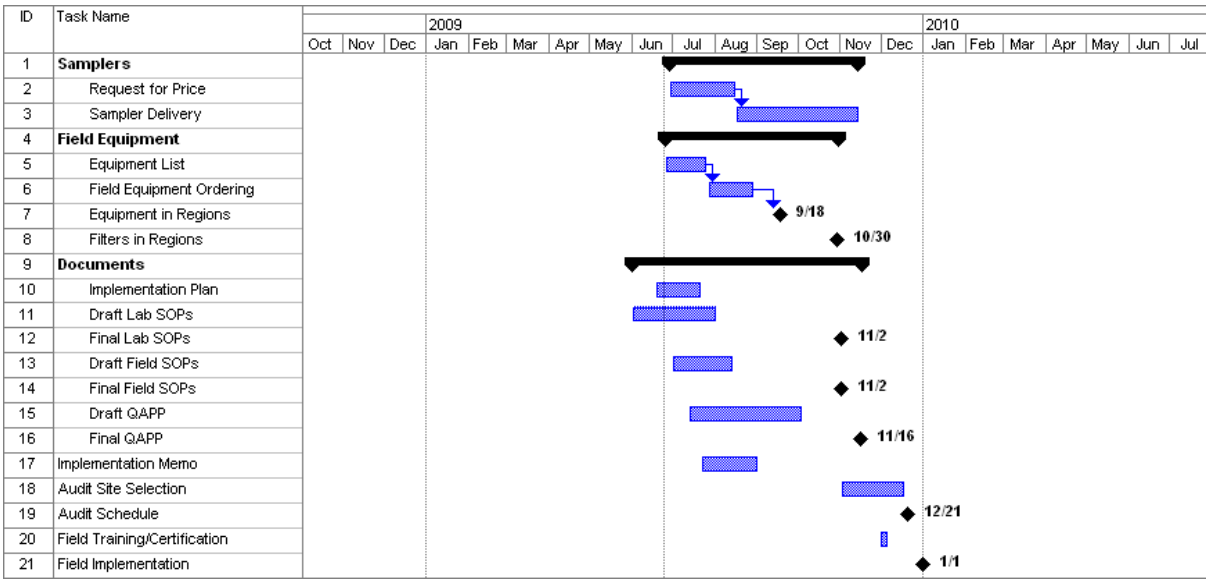


Figure 4.1 Planning Timeline

A brief explanation of the timeline is provided below

Samplers

Request for Price - OAQPS is purchasing two portable TSP samplers per Region. Modifications are being made to be able to transport the instruments safely. We expect to award a vendor by August, 2009

Sampler Delivery- OAQPS expect delivery of all samplers to the EPA Regions by November, 2009

Field Equipment

Equipment List- A complete list of equipment will be completed by July, 2009

Equipment Ordering- All equipment for the Regions will be ordered by August, 2009

Equipment in Regions- by September, 2009

Filters in Regions- TSP Filters will be purchased through a National Filter Contract in

OAQPS and distributed to the Regions by October, 2009

Documents

Implementation Plan-OAQPS is expected to complete a draft of this document by July, 2009 and finalize it by August, 2009

Lab SOPs- Region 9 and 7 will complete draft laboratory SOPs by July, 2009 and finalize these by November 2009

Field SOPs- OAQPS is expected to complete a draft of this document by August, 2009 and finalize these by November 2009

Pb-QAPP- OAQPS is expected to complete a draft of this document by the beginning of October, 2009 and finalize it by November, 2009

Implementation Memo- Is the memo to the monitoring organization asking for decisions to self-implement or utilize federal implementation. OAQPS will develop the memo in July, 2009 and will provide monitoring organization until Aug 31, 2009 to make decisions. A memo similar to this will be sent out each year.

Audit Site Selection- Monitoring organization will provide the Regions information on which sites to audit in 2010. Sites will be selected by mid-December, 2009

Audit Schedule- ESAT field scientists working with EPA Regional TOPO/DOPOs will submit a tentative audit schedule to the monitoring organization in December for approval.

Field Training /Certification- for ESAT and monitoring organizations self implementing will be held in early December, 2009

4.2 Implementation Time Lines

There are some other important dates that must be met during implementation activities. They involve both laboratory and field activities.

4.2.1 Laboratory Time Lines

Unlike $PM_{2.5}$ PEP, the Region 9 laboratory does not need to prepare the TSP filter media prior to sampling so TSP filter media will be sent directly to each EPA Regional Office. Based on some initial estimates of proposed Pb sites in each state, the total number of samples (PEP and collocated) arriving at the Region 9 lab is estimated at around 300 per year. This equates to approximately 25 samples a month. This number of samples is conducive to batching all samples arriving in one month together for one analysis run. Therefore, the laboratory will schedule analysis for the last week each month (if there are more than 2 working days in that week). A tentative schedule for 2010 would be the following:

Jan 25	Feb 22	Mar 29	April 26	May 24	June 28
July 26	Aug 23	Sept 27	Oct 25	Nov 22	Dec 27

A new schedule will be posted on AMTIC each year. The Region 9 laboratory will alert the Regions and any monitoring organizations using the laboratory at least two weeks in advance if there is a change in the batch analysis schedule.

Data Input/Assessment/Upload

It is anticipated that an automated data entry system will be in place so that minimum data entry will be required. Once a batch of samples has completed analysis, the data will be reviewed, verified, and validated. This process will be completed in 10 working days. Upon data validation and acceptance by the EPA TOPO/DOPO, the data will be uploaded to AQS. This should be completed within 5 working days from data validation. The data will only be available to monitoring organizations once they upload the routine data results.

4.2.2 Field Time Lines

Pb-PEP filters will be collected within 48 hours of the sample end date. In most instances the field scientist will collect the filters within 8 hours of the sample end date unless the scientist is visiting multiple sites in the sampling week. The collocated filters can be collected by the monitoring organization during the next scheduled sampling day. PEP samples will be sent the day of removal by next day delivery to the Region 9 laboratory. Data will be immediately downloaded from the portable sampler and stored in two mediums (laptop hard drive and flash drive). One flash drive of the data will be shipped with the sample(s). Within 8 hours of sample removal the sampler data will also be transmitted, via modem, to the appropriate laboratory.

4.2.3 Implementation Summary

Table 4-1 provides a summary of the key activities discussed on the implementation sections above.

Table 4-1 Implementation Summary

Implementation Phase	Activity	Acceptable Timeframe
Laboratory	Sample Analysis	30 days
	Data Input/review/validation	10 working days
	AQS Upload	5 working days of data validation
Field	Filter Collection PEP Collocated Sample	 8-48 hours from sample end date/time Next normal sample collection period
	Sample Shipping PEP Collocated sample	 Day of sample collection (unless Friday) Within 3 days of sample collection

4.3 Assessment Timeliness

In order to assess the PE data, the data from the routine sampler must also be available in AQS. Monitoring organization requirements for data upload to AQS is 90 days after the quarter in which the data is collected. If possible, submittal of routine sampler data as soon as possible is encouraged if data assessment is to occur in a timely manner.

4.3.1 OAQPS Assessments

Once both routine data and PE data for a site are in AQS, OAQPS, Regions and monitoring organizations can use the AQS data evaluation programs to assess this information. The statistics for these assessments can be found in 40 CFR Part 58 Appendix A. In addition, the AMP255 report in AQS provides the appropriate statistical assessment and the Data Assessment Statistical Calculator (DASC) tool will be revised to provide the Pb-PEP statistics. The DASC tool can be found on AMTIC[1]. Initially OAQPS will review this information quarterly and will summarize their comments on ESAT Workgroup conference calls. Every year, after the July certification date EPA will post a version of the AMP255 report on AMTIC as an annual summary.

4.4 Reporting Time Lines

4.4.1 OAQPS Reporting

QA Reports

As mentioned in Section 3, OAQPS plans on the development of a yearly QA Summary Report and the interpretive QA Report every three years. The yearly report will be based on a calendar year and will be completed around August, when data from the previous calendar year should be reported to AQS. The three year QA Report will be generated 9 months after the last valid entry of routine data by the monitoring organizations for the final year.

[1] http://www.epa.gov/ttn/amtic/parslist.html

5.0 RESOURCES

This section will explain the source of funding, the development of resource estimates, and the schedule for resource allocations for the Pb-PEP.

5.1 Source of Funds

Since the Pb-PEP is a monitoring organization responsibility, the source of funds for the Pb-PEP are 105 State and Tribal Assistance Grants (STAG). Every year funds will be allocated to the monitoring organizations to operate the Pb Ambient Air Quality Monitoring Program. A portion of these funds are allocated for performing the Pb-PEP. Each year the primary quality assurance organization (PQAO) will decide to either self-implement or utilize the federal Pb-PEP. Decisions on whether a PQAO will choose to continue federal implementation must take place by August of the previous calendar year to allow the ESAT contract enough time to appropriately staff for following calendar year. Funds will be appropriately reallocated from the STAG funds to EPA in order to implement the audit for that PQAO.

5.2 Resource Estimates

Table 5-1 provides estimates for the FY09 (planning), FY10 (year 1) activities respectively. The FY10 estimate will reflect out year costs unless there is an increase in the number of sites requiring Pb monitoring.

5.2.1 FY 09-Year 0, Planning (blue font)

Since the first year of implementation of the Pb-PEP starts 1/1/2010, FY09 and the months of October through December of FY10 will be used to plan the Pb-PEP, acquire the necessary personnel, capital equipment/consumables, and develop and implement training activities. Figure 4.1 provides a schedule for these activities. Table 5-1 was developed in order to estimate the resources required for FY09, but was based on the personnel and the sites that will be running in the full Pb air monitoring network. Important points about the FY09/10 estimates follow:

Samples –Based on initial estimates of the size of the Pb monitoring network and the distribution of Pb-monitoring sites within PQAOs, it is estimated that about 300 samples (~70 Pb-PEP and ~230 collocated) will be collected each year if all PQAOs utilized the federal Pb-PEP.

Table 5-1 Pb-PEP Cost Estimate for FY2009 and FY2010

							FY09	FY10
Field Capital/Consummable Costs			Needed	Cost /unit			Cost	Cost
Samplers (2/Region + 2 RTP)			22	5000			$110,000	
Calibration Kit (1/Region + 1 RTP)			11	2000			$22,000	
Shipping Containers			50	10			$500	
Filters			120	8.5			$1,020	$1,020
Standard Recert			11	165				$1,815
Misc/Maintenance			10	1000			$10,000	$20,000
						Sub Tot	**$143,520**	**$22,835**
Field Implementation		Number	Hours	$/hour	Flight	Hotel/Per		
Training		12	20	60	375	390		$23,580
Implementation		70	18	60				$75,600
Prep/Reporting/Eval		70	4	60				$16,800
Travel		70				240		$16,800
			Samples	$/shipment				
Sample Shipping			70	8				$560
	Miles/audit	Number of audits	Total Miles	Miles per Gal	Number of Gal	$/gal		
Gas	300	70	21000	15	1400	2.5		$2,625
						Sub Tot.		**$135,965**
Lab Costs								
	Samples	Cost* /Sample						
Analysis	300	110						**$33,000**
Equipment							$10,000	$5,000
SOP/QAPP							$30,000	
Data Base Management			Hours	$/hour				
			160	120			$19,200	$5,000
						Sub Tot	**$59,200**	**$43,000**
					Pb Pep Total		**$202,720**	**$201,800**

Field capital equipment - Capital equipment costs for the field include portable audit sampling devices, verification standards, miscellaneous equipment (travel boxes etc.), consumables (filters, gloves), information management devices, and transportation. Two portable samplers will be purchased for each Region since it is possible that a field scientist may utilize two portable samplers in one day (sites in close proximity) and it is important for each EPA Region to have minimally one spare sampler.

Field Implementation – Field personnel used for the $PM_{2.5}$ PEP will be trained and certified for the Pb-PEP. The sample collection activities between the two programs will be very similar. EPA made the assumption that about 50% of the trips scheduled for Pb-PEP will include a $PM_{2.5}$ PEP and therefore travel costs can be shared between to two programs. Therefore, training and implementation costs are reduced by 25% for the Pb-PEP.

Lab Costs – Region 9 ESAT personnel provide routine analytical services for the Region which includes metals analysis for soils and water. Costs for Pb analysis by ICP-MS are estimated at $110.00/sample. The cost includes sample preparation through data reporting and is comparable to other analytical laboratories. Since the Region was not doing air sample analysis, approximately $20,000 was provided to develop standard operating procedures, to undergo federal equivalent method acceptance testing and application procedures and to assist OAQPS in the development of the laboratory portion of the QAPP.

Laboratory capital equipment – Since the laboratory already conducts this type of analysis, a limited amount of extraction/analytical equipment and consumables are needed. Start-up costs for equipment/consumables have been estimated at $10,000 and $5,000 in the out years.

5.2.2 FY2101- Year 1, Implementation (red font)

Table 5-1 also represents the resource estimate for the first year of implementation. FY2010 will represent implementation of the PEP starting 1/1/2010 for the active sites within the fiscal year. Important points about the FY2010 estimate follow.

Field and laboratory capital costs- The majority of the capital costs have been have been allocated in FY09. Therefore the costs in FY2010 reflect field and laboratory consumable costs, and the cost of having the flow rate standards verified at the EPA National Risk Management Research Laboratory (NRMRL) Metrology Laboratory.

Field and laboratory FTE Costs - These cost make up the majority of costs and should be constant from year to year as long as the program is implemented at the federal level. It should be noticed that for field implementation a number of 70 Pb-PEP samples is used since this represents the 1 or 2 PEP audits that are implemented by the ESAT field scientists. However the analysis costs use both these ~70 PEP samples and the ~230 collocated samples that are sent to the national Pb-PEP laboratory from the monitoring organizations for a total of 300 samples.

Shipping - Next day shipping to the laboratories and ground shipping from the laboratories will be an expense incurred in FY2010. Since shipping will not require cold transportation, it will be a nominal expense.

Total Costs per PQAO - Base on the data in Table 5-1, a preliminary estimate of the costs for the Pb-PEP program for PQAOs with ≤ 5 sites would be $3,300 (1 PEP 4 collocations) and PQAOs with > 5 sites would cost $5,250 (2 PEP 6 collocations)

5.3 Personnel

Personnel will be required for three types of activities: field implementation, filter analysis, and standards certification.

In general, the PEP requires personnel with a degree in the environmental sciences, preferably in atmospheric science. Due to the nature of the PEP and the care in which the sample filters must be prepared and handled, personnel must be able to understand and follow standard operating procedures (SOPs), document and communicate important information, and be able to make decisions in situations that are not covered in SOPs. Clear verbal and written communication skills are required. The following are brief descriptions of the duties for the three activities mentioned above.

Field Scientist - are responsible for transporting a portable TSP federal reference method (FRM) audit sampling device to an established Pb site which shall be located at any of the SLAMS/SPM sites within each EPA Region. The field scientist shall be prepared for transport of the sampling device in various environmental situations (e.g., various weather conditions, the tops of buildings, distant rural settings). For ease of operations and the safety of the operators, the portable audit sampler was designed in sections with each individual section not weighing more than 40 lbs. Field personnel must be able to lift/carry these sections up stairs and/or ladders. Due to the nature of the sampler, ground transportation of the sampler is encouraged. Extensive travel will be required of field personnel and flexible hours (10 hour days etc) may be necessary. The field scientist will perform the following activities.

1. A yearly allotment of filters will be received from EPA. Receipt of the shipment should be checked for gross damage, logged in, and stored in an appropriate manner.
2. The field scientist will contact the monitoring organization to ensure that they are aware of a scheduled visit.
3. The field scientist will prepare filters and equipment for travel to the field site.
4. The field scientist will assemble the instrument, collocate the sampler, perform a verification following SOPs, install a filter and operate the instrument to the same 24 hr. sampling mode as the routine instrument (midnight to midnight).
5. If scheduling allows, the field scientist may leave this location to set up an additional 24-hour performance evaluation at another routine sampling location or perform additional activities at the site if so tasked.
6. The operator shall return to each site after 24-hour sampling period, download the stored electronic monitoring data, and enter additional information as required, remove and properly store the filter for transport, and disassemble the instrument.
7. The operator shall properly package the filter following the chain-of-custody procedures for transport to the Region 9 laboratory.

Filter Analysis Personnel - The personnel at the filter preparation laboratory have the following duties:

1. **Laboratory supplies and consumables**- The laboratory will maintain supplies and consumables necessary for preparation and analysis of TSP and PM10 filters (47 mm Teflon).
2. **Filter receipt** -Laboratories will receive filters either by mail or carried in by the field scientist. The filters will be logged in following chain of custody procedures, checked for integrity, initially entered into the laboratory information management system (LIMS) and appropriately stored until ready for analysis. Field data for each sample will also be checked to ensure completeness and this information will either be entered or downloaded into the LIMS.
3. **Filter extraction and analysis-** Each month, filters not yet analyzed will be batched as appropriate, extracted and analyzed according to SOPs**.**
4. **Filter data entry and preparation for field activities or storage** -Filter post-field information and necessary data from extraction and analysis will be entered on data entry sheets or in the LIMS along with appropriate QA/QC. Checks of QA/QC information will determine corrective action.
5. **Concentration calculation**-The LIMS will be used to calculate final concentrations in $\mu g/m^3$.
6. **Quality Assurance** -Quality assurance and quality control samples will be included in each run of routine samples. This information will be reviewed to verify and validate routine data.
7. **Data transfer to AQS-**Once data validity is assured, the data will be uploaded to the AQS system via AQS data upload protocols.

Standards Certification Personnel- A laboratory will be dedicated to certifying flow rate, temperature and barometric pressure transfer standards. Standards certification personnel will have the following duties:

1. **Primary standard certification** - will ensure that the primary standards used in the certification laboratory will be compared to a NIST primary standard once a year.
2. **Instrument receipt** - transfer standards will be received by each EPA Region. Certification lab personnel will log in the instruments and inspect them for damage.
3. **Standards verification** - will compare the transfer standards against the primary standards per SOPs.
4. **Documentation/communication**- will document all verifications via hardcopy or electronic records and appropriately file this information.
5. **Instrument distribution**- will distribute transfer standards and verification information back to appropriate Regional offices.

5.4 Equipment

5.4.1 Field Equipment

Table 5-2 represents the equipment required for the field. Most of the equipment needed for the Pb-PEP is already available in the Region since the equipment needs are very similar to the $PM_{2.5}$ PEP. OAQPS will purchase the TSP filters (through the national filter procurement contract), the portable audit samplers and transport containers, and the flow/temperature pressure verification devices and will develop the field data sheets and the chain of custody sheets. The remaining equipment will be purchased at the regional level. **The use of trade names or vendors does not constitute an endorsement by the Agency.**

Table 5-2 Field Equipment List

Activity	Required Equipment	Identified Source
Initial Set-up	Knife	Available through PM $_{2.5}$ PEP
	Tool kit (screw driver, pliers, etc.)	
Checks	Transfer standards (1 per region)	BGi Hi-Vol calibrator Performs flow/temp/pressure
	Watch/clock check device	Available
Maintenance	Cleaning solution	Available through PM $_{2.5}$ PEP
	Soft bristle brush	Available through PM $_{2.5}$ PEP
	Cotton swabs	Available through PM $_{2.5}$ PEP
	Cleaning cloth	Available through PM $_{2.5}$ PEP
	Distilled water	Available through PM $_{2.5}$ PEP
	Isopropyl Rubbing Alcohol	Available through PM $_{2.5}$ PEP
Operation	Clipboard/log book	Available through PM $_{2.5}$ PEP
	pencils	Available through PM $_{2.5}$ PEP
	permanent marker	Available through PM $_{2.5}$ PEP
	FRM portable audit sampler (1)	
	Backup FRM portable audit samplers (1)	
	Sampler transport carrying cases (1 set)	
	Ropes	Available through PM $_{2.5}$ PEP
	Folding ladder	Available through PM $_{2.5}$ PEP
	Gloves (powder free)	
	Forceps	
	Data down loader device	Available through PM $_{2.5}$ PEP
	Laptop computer	Available through PM $_{2.5}$ PEP
	Field data sheets	
	Chain of custody sheet (COC)	
	TSP filters	
	Field blank filters	
	Packing envelope for filters	
	Anti Static ziplock bags (13”x9”) for samples	
	Plastic ziplock bags for field and COC sheet	
Data Transfer	Pre-labeled Federal Express Packages	
	Modem	
	Data Logger	Available through PM $_{2.5}$ PEP
	SD Memory Cards	Sandisk (1 GB)
	SD Memory Card Reader	

5.4.2 Lab Equipment

Table 5-3 represents a listing of the equipment and consumable required by the Region 9 laboratory. Costs associated with some of the equipment are estimates. **The use of trade names or vendors does not constitute an endorsement by the Agency.**

Table 5-3 Laboratory Equipment List

Activity	Description	Details
Preparation	Hot Block Digestion System	
	Pipettors	variable volume for dispensing reagents and acids
	Pipettes	calibrated fixed volume and digital variable volume with appropriate plastic
	Nitric Acid (HNO_3), concentrated	ACS Reagent Grade or better, suitable for trace metals analysis.
	Gloves	
	Tweezers	
	Polypropylene Digestion Vessels	Environmental Express P/N SC505 or equivalent
	Ribbed Watch Glass,	Environmental Express P/N SC505 or equivalent
	Polycarbonate Transfer Racks	Environmental Express P/N SC200 or equivalent
	Paper cutter or scissors	
	Plastic or Teflon wash bottles	
	Glass Fiber Filter	EPA National Filter Procurement
	Teflon Filters	EPA National Filter Procurement
Analysis	ICP-MS	Perkin Elmer Elan DRC Plus
	Autosampler	Cetac Autosampler, or equivalent
	Autodilutor	Cetac Autodilutor, or equivalent
	Peristaltic Pump	Gilson Minipuls3 Peristaltic Pump, or equivalent
	Refrigerated Circulator	Polyscience 6105 - Refrigerated Circulator, or equivalent
	Argon gas supply	high-purity grade, 99.99%
	Auto-sampler tubes	
	volumetric flasks,	Class A graduated cylinders, and funnels (glass and/or metal-free plastic)
	volumetric pipettes	Class A
	storage bottles	Narrow-mouth with screw closure, 125-mL to 1-L capacities
	Automatic pipettes	capable of delivering volumes of 10 to 1,000 µL
	disposable pipette tips	Metal-free

5.5 SOPs, QAPPs and Other Documentation

OAQPS is utilizing internal funds to develop the Pb-PEP Implementation Plan, the field SOPs and the majority of the QAPP. It will utilize STAG funds and contractor support for the development of the laboratory SOPs and the laboratory portion of the QAPP.

5.6 Training

One annual training/certification session is anticipated for field activities. Since Region 9 already has developed the capability to perform Pb analysis, a training session for analysis is not needed. STAG funds will be allocated for each field scientist to attend the field training session. Training is discussed in more detail in Section 9.

6.0 LOGISTICS

Logistics is defined as the science dealing with procurement, maintenance and transport of materials, facilities and personnel or the handling of the details of an operation. This section will focus on these activities to ensure proper implementation of the Pb-PEP. The logistics of the Pb-PEP will be an integrated effort by all affected participants. Table 6-1 suggests how the logistics will be outlined.

Table 6-1 Logistical Support

STAKEHOLDER	LOGISTICAL SUPPORT
OAQPS	Provide STAG funding, regulations, guidance, SOPs, training, contractual vehicle support, support for the development of the calibration laboratory data analysis.
Regions	Provide support for the development of the Regional laboratory, provide project officers and task monitors, provide oversight, ensure communications with monitoring organizations and OAQPS
ESAT Contractors	Provide trained personnel with administrative support
ESAT Division	Provide liaison support between OAQPS and the ESAT contractors
Monitoring Organizations	Provide operational support of the monitoring network, develop site criteria, ensure operator is present during performance evaluation

The logistical support issues will be detailed in the Quality Assurance Project Plan, standard operating procedures, and other guidance documentation which is under development and designed specifically for the Pb-PEP. The logistical issues in general terms will address the following concerns:

1 Program Initialization: One-time set-up activity such as equipment purchasing and distribution, development of guidance documentation, and training.

2 Field activity: Pre-trip planning including site selection, visit scheduling, monitoring organization notification, travel arrangements, and implementation.

3 Laboratory activity: Regional support for the laboratory including communications, preparation and implementation activities

6.1 Program Initialization

The following logistics issues will be covered during the planning stages of the Pb-PEP.

6.1.1 Contract/task negotiation and funding

OAQPS will work with the Superfund ESAT Contracts Management Office to negotiate the appropriate scope of work. Time lines for these activities are found in Figure 4.1. OAQPS will be responsible for providing a description of the personnel requirements, and developing a draft and final scope of work that will be reviewed and approved by the ESAT TOPO/DOPOS/RPOs.

6.1.2 Equipment

Equipment Selection, Purchase and Inventory

Lab equipment- The Region 9 laboratory has the appropriate laboratory equipment (see Table 5.5). The Regional DOPO will develop an initial inventory of the equipment, spare parts, and consumables purchased. During implementation, the ESAT lab contractors will keep a running inventory of spare parts, consumables and any additional capital equipment purchases which will be available for TOPO/DOPO review. Inventories of consumable equipment should not get below a 2 months supply.

Field equipment- OAQPS, with review from the Pb-PEP ESAT Workgroup, will select the appropriate field capital equipment and consumables (see Table 5-4) within the timelines provided in Figure 4.1. This equipment will be distributed to the Regions by November, 2009. During implementation, the ESAT field contractors will keep a running inventory of consumables and any additional capital equipment purchases which will be available for TOPO/DOPO review. Inventories of consumable equipment should not get below a 2 months supply.

Field transportation- Ground transportation for field personnel have been funded with STAG resources that will transferred to ESAT Office for acquisition. Vehicles used in the $PM_{2.5}$-PEP will be shared for the Pb-PEP activity. Once vehicles are selected the ESAT contractors will be responsible for maintenance.

Sample filters- OAQPS has a national contract for filters. Filters will be purchased by OAQPS and sent to the 10 EPA Regions.

6.1.3 Operating Procedures

Standard operating procedures for both the field and laboratory activities will be developed by OAQPS and the Region 9 laboratory and reviewed and approved by the ESAT Workgroup.

Drafts that will be adequate to initiate the ESAT work assignment will be completed in July with final SOPs completed as indicated in Section 4.

Field SOPs- The field SOPs would include procedures on:

- Equipment inventory/maintenance
- Preparation
- Communications (Regions/ State and locals)
- Equipment set-up/take-down
- Calibrations
- Sample handling, chain-of-custody
- Sampling
- Data entry/transfer
- Sample shipping
- Documentation/filing
- QA/QC activities

Lab SOPs- The field SOPs would include procedures on:

- Equipment inventory/maintenance
- Preparation
- Communications (Regions/ State and locals)
- Calibrations
- Filter conditioning
- Filter shipping (to field)
- Filter handling, chain-of-custody, archiving
- Pre-sampling and post-sampling weighing
- Data entry/transfer
- Documentation/filing
- QA/QC activities

6.1.4 Training

Field Training - The field training session will be combined with the annual $PM_{2.5}$ PEP training/certification session. A formal training schedule/agenda will be developed by the end of October, 2009. The ESAT field contractors will be trained on the SOPs in the areas mentioned in the previous section above. Trainers will include OAQPS personnel and contractors who have developed the SOPs. It is anticipated that field training will be a 2-day event devoted to hands on training and testing/certification. TOPO/DOPOs will also participate in the training activity as well as any monitoring organizations that may be self-implementing the program.

6.2 Field Logistics

6.2.1 Site Selection-

The SLAMs/SPM sites that are scheduled to be up and running by 1/1/2010 will be the pool of sites from which the initial audit sites will be selected. Although an evaluation will eventually be performed on all sites, the performance evaluations should be initially implemented at sites that have or are expected to have concentrations around the NAAQS. Also, since it is cost effective to perform Pb-PEP and $PM_{2.5}$-PEP audits in the same week (to allow cost sharing between the programs), thought should be given to selecting $PM_{2.5}$ and Pb sites in close proximity to one another.

Monitoring organizations will be asked to select the sites they feel meet the criteria above and provide a list of sites for the evaluations conducted in each calendar year on or before October 1, of the previous year. The Regional WAMS, with the assistance of the ESAT contractors, will attempt to determine the most efficient site visit schedule. This schedule should be based upon:

1. the criteria in CFR
2. meeting the schedule set up for the routine sampler being evaluated.
3. the sites that are closest in proximity to each other (can be visited within the same day or week)

For each site, a Site Data Sheet will be developed that contains information such as:

AQS Monitor Site ID	Monitor ID
Method Designation	Monitor Make and Model
Site Coordinates	Site Type
Reporting Organization	Reporting Organization Contact
Street address	Directions to the site (from Regional Office)
Directions to the site from major thoroughfare	Safety concerns
Additional equipment needed (ropes, ladders etc.)	Closest Hospital (address)
Closest Express Mail Facility	Closest Hardware Store
Recommended Hotel (address)	Important free form notes
Closest site	2nd closest site

This information listed above can be placed on one sheet and included in a site file (filed by AQS Site ID) and in a site notebook for each field scientist. Software such as MapQuest@ (Internet accessible) can help provide information on directions to sites. In addition, maps for each state and city where a monitor is located will be acquired. Sites can be placed on these maps along with the site IDs,

6.2.2 Field Visit Scheduling

Based upon the site selection criteria, an implementation schedule will be developed for each calendar year by mid-December of the previous year that will be disseminated to each monitoring organization. The schedule will be based upon the number of evaluations that can be practicably completed in a week. For example there may be areas where a number of sites can be evaluated on the same day whereas other areas that are so remote that only one site will be visited. Since there may be more than one task that can be implemented at a site, during the development of the site visit schedule, the tasks that will be implemented at each site during that visit will be identified by the TOPO/DOPO and identified on the schedule.

During Pb-PEP implementation, the ESAT personnel and TOPO/DOPO will meet regularly to discuss progress as it relates to the site schedule. The schedule will be updated as required and monitoring organizations will be contacted as the schedule changes.

One week prior to an evaluation visit, the field scientist and/or TOPO/DOPO will contact the monitoring organization to make them aware of the visit and ensure the routine monitor is operating on schedule and to find out if there are any particular site access problems where special equipment will be needed (ropes, ladders etc.). Details, such as where and when to meet the routine operator, will be discussed.

6.2.3 Field Sampling

Filter Receipt --

The EPA Regions will receive a years supply of TSP filters from OAQPS. The field scientist will inspect the filters thoroughly for defects. If a large percentage of filters are failing the inspection, OAQPS should be immediately notified and the defective filters shipped back.

Field Preparation --

Prior to a evaluation excursion for the week, and based upon the number of sites to be visited, the sampling equipment and consumables will be inspected to ensure proper operation and adequate supplies. At least one spare portable monitor should be on hand. Filters will be selected and stored appropriately (per SOPs) for transport to the sites. Filter chain-of custody forms should be started and the filters should be checked to ensure integrity. Site data sheets should be available for each site. For initial visits, some of the information on the site data sheets may be blank and must be completed during the first visit. The field scientists will review the site schedule to be sure that they understand which tasks will be implemented at the sites they are visiting that week.

Field Implementation--

Field scientists will travel to the sites and contact the person (typically the site operator) that will allow them access to the monitoring site. The portable FRM monitors will be transported to within 2-4 meters of the routine monitor, set-up and calibrated per the SOPs. Filters will be installed and the monitor set to run on the required midnight-to-midnight schedule. The field scientist will then either perform additional tasks as required at this site or proceed to another site for sampling. If there are any delays in the sampling schedule, the ESAT field scientist will contact the affected monitoring organization(s) and also contact the Regional TOPO/DOPO.

Upon completion of sampling, the field scientist will return to the site(s), download the data per SOPs, remove the sampling filter, visually inspect the filter and store it appropriately for transport to the laboratory. During data download it is suggested that the field scientist and the routine operator exchange or compare monitor download information. This would help determine that the monitors were operating properly and were indicating the same sampling conditions. Each field scientist will have a portable laptop and/or data logger. Either hardware device may be used to download monitor information but it will eventually need to be stored on the laptop. A flash drive of this information is required to be sent to the national laboratory along with the filters, field data sheets and chain of custody. The field data sheet and chain of custody form can be found in Appendix B.

Safety- Safety in the field is of primary importance. Sites should not be visited or set-up in conditions that are deemed unsafe. Unsafe conditions include weather as well as monitoring platforms where the field scientist feels that he/she cannot transport or set up the monitor without jeopardizing their personnel safety. If these situations arise, the field scientist should document this so mechanisms can be instituted to make the platform safely accessible for a performance evaluation. The field scientist should also know where the closest emergency facilities are located. This information should be included on the site data sheet.

Filter Transportation--

It is important that the filters be properly stored and transported to the national laboratory as soon as possible. It is suggested that filters be shipped via next day express mail the same day that they are removed from the monitors. Copies of the field data sheet, chain-of-custody form and a diskette of the monitor information will be included in the shipment.

OAQPS will utilize a blanket contract with a next day delivery vendor. The locations of the closest shipping centers will be identified for each site. Preprinted shipping labels will be developed for the field scientist. The field scientist will keep a copy of the chain of custody form which would include the number of containers shipped and the air bill number. The day of shipping, the field scientist will inform the national laboratory of the shipment and provide the laboratory with the number of containers shipped and the air bill number.

Return to Station--

Upon completion of a sampling excursion the field scientist will return to the Regional Office. The field scientist will ensure all equipment and consumables are properly stored and determine if resupply or equipment maintenance is required. An electronic copy of the weeks' field information will be transferred to the TOPO/DOPO. Vehicles will be serviced as required. The field scientist will debrief the TOPO/DOPO on the field excursion including whether the site visits remain on schedule.

6.3 Laboratory Logistics

6.3.1 Preparation

From the months of June through December 2009, the Region 9 national laboratory will be preparing for routine implementation of the Pb-PEP. OAQPS will coordinate a conference call with Region 9 laboratory to ensure activities are on track for implementation in 2010.

All equipment and consumables for laboratory implementation will be at the laboratory by November 2009. The laboratory personnel will be responsible for developing and maintaining an equipment, spare parts, and consumable supply lists. During implementation, inventories of consumables should not go below a 2 months supply.

6.3.2 Laboratory Implementation

Laboratory logistics activities during implementation include

- Communications
- filter receipt
- sample tracking

The laboratory implementation activities as they relate to filter extraction and analysis will be covered in the Pb-PEP laboratory SOPs.

Communications—

During Pb-PEP implementation, the TOPO/DOPOs will be in communication with the laboratory personnel as deemed necessary. OAQPS will continue the monthly ESAT Workgroup conference call which will include the appropriate laboratory personnel. In addition to these regular communications, laboratory personnel will inform TOPO/DOPOs if problems arise in the laboratory aspects of the program.

The laboratory personnel will also have communications with the Regions they are supporting.

Filter Receipt –

The laboratory will not only receive Pb-PEP filters from the ESAT Field scientists but will receive 4 to 6 collocated filters directly from the monitoring organizations. Each year OAQPS will develop a listing of PQAOs that have SLAMS/SPM Pb monitoring sites that will require the implementation of Pb-PEP and be shipping the laboratory collocated sample filters. The laboratory will use this list to ensure they are receiving filters within the appropriate timeframe. If not, the laboratory will contact the EPA Region TOPO/DOPO who will follow up with the PQAO.

Sample Tracking–

The laboratory shall track filters from sample receipt to AQS upload using Table 6-2. All filters that are received will be placed on this tracking form. If filters are voided for some reason along the process, a flag should be included on the form. The Tracking Form should help inform field scientists, EPA Regions and monitoring organizations at what stage of implementation a filter is undergoing. Based upon the concepts for the LIMS (see Section 7) the information on this form will be included on other data entry screens and therefore the Filter Tracking Form will simply be a reporting feature. This form may be posted to AMTIC on a monthly or quarterly basis.

Table 6-2 Filter Tracking Form

Filter Tracking Form								
Filter ID	Region	PQAO	PEP Filter (P) Collocated Filter (C)	Sample Date	Laboratory Receipt Date	Sample Analyzed	AQS Upload Date	Flag

Laboratory Maintenance--

A maintenance list will be developed for all sensitive capital equipment. The list will contain the item, its maintenance schedule and date columns that will be filled in when scheduled or unscheduled maintenance is performed. This list will be included in the laboratory SOPs and Pb-PEP QAPP.

7.0 DATA MANAGEMENT

Success of the Pb-PEP rely on data and their interpretation. It is critical that data be available to users and that these data are:

- Reliable
- Of known quality
- Easily accessible to a variety of users
- Aggregated in a manner consistent with it prime use.

In order to accomplish this activity, information must be collected and managed in a manner that protects and ensures its integrity. This encompasses multiple activities including: where data is produced, how it is transferred and archived, the various levels of validation, and ultimately, how decision makers will evaluate the data. In order to perform these multiple activities a laboratory information management system (LIMS) will developed. The Region 9 Pb-PEP LIMS will be run on local area networks with appropriate security and back-up safeguards.

Most of the data collected from the Pb-PEP will be collected through automated systems at laboratory. These systems must be effectively managed by using a set of guidelines and principles by which adherence will ensure data integrity. The EPA has a document entitled *Good Automated Laboratory Practices (GALP)*. The *GALP* defines six data management principles:

1. DATA: The system must provide a method of assuring the integrity of all entered data. Communication, transfer, manipulation, and the storage/recall process all offer potential for data corruption. The demonstration of control necessitates the collection of evidence to prove that the system provides reasonable protection against data corruption.

2. FORMULAE: The formulas and decision algorithms employed by the system must be accurate and appropriate. Users cannot assume that the test or decision criteria are correct; those formulas must be inspected and verified.

3. AUDIT: An audit trail that tracks data entry and modification to the responsible individual is a critical element in the control process. The trail generally utilizes a password system or equivalent to identify the person or persons entering a data point, and generates a protected file logging all unusual events.

4. CHANGE: A consistent and appropriate change control procedure capable of tracking the system operation and application software is a critical element in the control process. All software changes should follow carefully planned procedures, including a pre-install test protocol and appropriate documentation update.

5. STANDARD OPERATING PROCEDURES (SOPS): Control of even the most carefully designed and implemented systems will be thwarted if appropriate procedures are not followed. The principles implies the development of clear directions and Standard Operating Procedures (SOPs); the training of all users; and the availability of appropriate user support documentation.

6. DISASTER: Consistent control of a system requires the development of alternative plans for system failure, disaster recovery, and unauthorized access. The control principle must extend to planning for reasonable unusual events and system stresses.

The principles listed above apply to both the Region 9 LIMS and the central information management systems (AQS).

7.1 Performance Evaluation Data Collection

The Pb-PEP is dependent upon the collection of quality data which will come from several different sources, such as the Pb-PEP field and laboratory activities as well as the field and laboratory data collection activities for the routine sampling activities where a PE was performed.

Each of the individual stakeholders are responsible for collecting quality data from their area of influence and distributing the data to the appropriate participant. Table 7-1 represents the data management structure for the Pb-PEP.

Table 7-1 PEP Data Management Structure

STAKEHOLDER	TYPE OF DATA	DISTRIBUTION
Regions	Sites to participate in the performance evaluation for the year	-To monitoring organizations -To ESAT contractor
Monitoring organization field monitoring staff	Filter ID from the operation of their Primary Pb monitor, AQS site ID, POC, and Method Code. Note: Method Code can be determined if sampler make and model are known.	-To the ESAT field scientist during Pb-PEP
	Chain of custody information for collocated sample.	-To Region 9 laboratory
Field Performance Evaluation Operator	Data from the operation of the FRM portable audit sampler	-To Region 9 laboratory -To Regional TOPO/DOPO -To monitoring organization staff.
State/local agency laboratory staff	Routine sample data	Use same distribution and validation procedures as all other Pb data produced by the monitoring organization, then uploaded to AQS.

STAKEHOLDER	TYPE OF DATA	DISTRIBUTION
Performance Evaluation Laboratory Analyst	Pb Laboratory Data	-To LIMS -To AQS
Performance Evaluation Laboratory Manager	Comprehensive Performance Evaluation Reports	-To EPA Regions -To monitoring organization QA Manager -To OAQPS

7.1.1 Pb Performance Evaluation Portable Sampler Data

The Pb portable sampler, once appropriately programmed, provides all the required data that needs to be collected by the field scientist with the exception of the filter ID. Data download will be accomplished by utilizing either a lap top computer or data download link just after recovery of the performance evaluation sample. Additional information may be documented to supplement the information collected automatically. Once the standard fields that will be automatically generated by the Pb portable sampler are downloaded to the field laptop, the filter ID, and AQS site ID and any freeform notes about the sampling activity will be input.

7.1.2 Pb Primary Sampler Data

The primary sampler will be operated in accordance with its normal operational schedule. The data acquired by the routine field operator will follow its normal path as detailed in the monitoring organizations QAPP and SOPs.

7.1.3 Performance Evaluation Laboratory Data

The performance evaluation laboratory will be operated by ESAT personnel according to the appropriate laboratory SOPs. The data acquired by the laboratory will be collected and validated as detailed in the Pb-PEP SOPs and QAPP. The data will be handled by a management information system that acquires data both manually and automatically.

7.1.4 Routine Laboratory Data

The routine laboratory will be operated in accordance with its normal operational procedures. The data acquired by the laboratory should follow its normal path as detailed in the monitoring organizations QAPP and SOPs.

7.2 Performance Evaluation Data Transfer and Archiving

Data transfer and archiving in the Pb-PEP will take place at multiple levels. Table 7-2 presents information such as where various data are produced, and how/when it will be archived/transferred.

Table 7-2 Data Transfer and Archiving

Data Produced	How to Archive	When to Transfer
Performance Evaluation Field Sampler Data	Download each field data set to lap-top computer or data link. Archive data to second computer at main field office	Transfer data via flash drive with each sample to Region 9 Laboratory. Data will also be transferred via modem.
Performance Evaluation Laboratory	Back-up of database occurs each night as per laboratory computer network storage procedures	Validated data to AQS once a month

Concentration data will be uploaded to the AQS database in a Precision & Accuracy Transaction. This transaction will be one that will allow for reporting of P&A data without having both concentration values available at the same time.

7.3 Information Management Flow

Figure 7.1 provides a flow of the information management system for the PEP. In general, hardcopy/electronic information will be collected at various stages of the field and laboratory procedures. The field information will be stored at both the Regional field office and in Region 9. The required AQS fields, once verified and validated will be uploaded to AQS where it will be compared with the routine data that has been uploaded from the State and local agencies. The Pb-PEP QAPP will provide the details of this procedure.

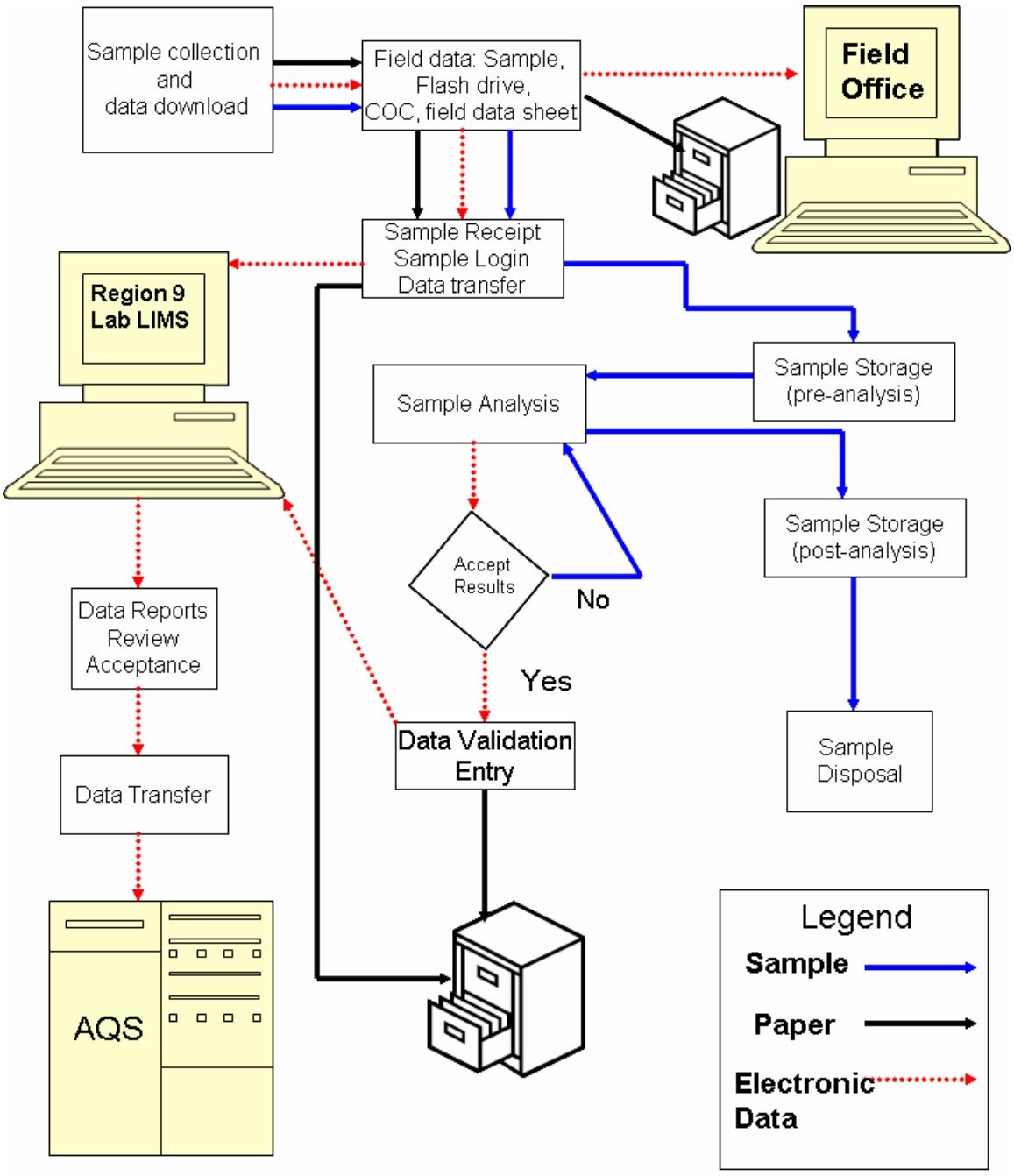


Figure 7.1 Pb-PEP Information/Sample Flow

8.0 QUALITY ASSURANCE/QUALITY CONTROL (QA/QC)

8.1 Overview

An important concern in any organization that is collecting and evaluating environmental data must be the quality of the results. A quality system must be developed and documented to ensure that the Pb monitoring, in general, and specifically the Pb-PEP evaluation results:

- meet OAR's regulatory and scientific data needs;
- satisfy customers expectations;
- comply with applicable standards and specifications;
- comply with statutory (and other) requirements, and
- reflect consideration of cost and economics.

A quality system is a structured management system describing the policies, objectives, principles, organizational authority, responsibility, accountability, and implementation plan of an organization for ensuring quality in its work processes, products, and services. The Pb-PEP is a QA/QC procedure that is part of the quality system of the Ambient Air Quality Monitoring Program. However, the Pb-PEP must be able to evaluate and control the data quality within its own environmental data operations. Therefore, QA/QC procedures must be developed for the PEP. The following are key assumptions or ideas that should be kept in mind:

- **The DQO Process drives the quality system**- The DQO Process for the Pb program established the acceptable risk (decision error) for total bias at $\pm$ 15%. The Pb-PEP data will be used to assess total bias. Therefore, EPA must control the quality of the Pb-PEP data so that this bias estimate can be made within a specified level of confidence.

- **QA/QC activities are required to evaluate and control Pb-PEP measurement system bias and precision-** The measurement system represents all data collection activities, from the field through data reduction and reporting to AQS. At each phase of this process, errors can occur. Development of QA/QC activities are necessary in order to understand where these errors are occurring, determine their magnitude, and to improve data quality.

- **Independent assessments and internal quality control are important**- Development of QA/QC activities requires both components. An independent assessment provides an objective review of the Pb-PEP measurement system. Technical system audits would be considered independent assessments. Internal quality control includes types of samples that allow personnel implementing the measurement system real-time information to evaluate and control measurement error in order to meet the DQOs. Collocated PE

samples and the use of various blanks and duplicates will be used to control various phases of the measurement system.

- **QA data represents routine data precision and bias**- The intent of a good quality system is to collect enough precision and bias information to adequately represent the measurement uncertainty of the routine Pb-PEP data with a specified degree of confidence.

To assure the quality of data from air monitoring measurements, two distinct and important interrelated functions must be performed. One function is the control of the measurement process through broad quality assurance activities, such as establishing policies and procedures, developing data quality objectives, assigning roles and responsibilities, conducting oversight and reviews, and implementing corrective actions. The other function is the control of the measurement process through the implementation of specific quality control procedures, such as audits, calibrations, checks, replicates, routine self-assessments, etc. In general, the greater the control of a given monitoring system, the better will be the resulting quality of the monitoring data.

The development of the QA/QC activities for the Pb-PEP requires a coordinated effort between EPA Headquarters and Regions, and the monitoring organization community. Elements of the QA/QC activities include planning, implementation, assessment, and reporting. The topics within each element will be discussed in their perspective sections

This intent of this Section is to describe how the major phases of the Pb-PEP quality system will be implemented, not to describe the detailed technical aspects or rationale for the quality system. The quality system will be thoroughly described in the Pb-PEP QAPP. The implementation strategy will discuss the following sections:

- QA Roles and Responsibilities
- Implementation
- Assessments
- Reporting

8.2 QA Roles and Responsibilities

The three major entities involved in the Pb implementation include the Federal organizations (OAQPS and EPA Regions), monitoring organizations and ESAT Contractors. Following the theme of planning, implementation, assessment and reporting, Table 8-1 provides a list of the QA roles and responsibilities of these organizations. Table 8-1 illustrates that a number of activities (e.g., DQOs, field/laboratory training) are shared responsibilities that will be discussed and coordinated through the ESAT Workgroup.

Table 8-1 QA Roles and Responsibilities

Pb QA Activities	
Activity/Organization	**Responsibilities (** * indicates a contributing role of review/comment/or assistance)
Planning	
OAQPS	QA Regs, DQOs, Implementation Plan, PEP QAPP, acceptance criteria, guidance documentation, training program, field SOPs, lab SOPs*, management system reviews, AMTIC
EPA Regions	DQOs*, Implementation Plan*, PEP QAPP*, guidance documentation*, training*, field SOPs*, lab SOPs, technical systems audit
Monitoring Orgs	PEP QAPP development*, program planning review*
ESAT Contractors	Review of Work Plan, SOPs, PEP QAPP, QA related guidance
Implementation	
OAQPS	field/laboratory training, ESAT Workgroup, AMTIC
EPA Regions	ESAT WAM, QAPP approval, data reviews, quality control, corrective action , local training
Monitoring Orgs	Routine monitoring including data verification/validation
ESAT Contractors	Training certification, internal QC implementation, data verification/validation
Assessments	
OAQPS	Management systems reviews, technical systems audits, data quality assessments, critical review reports
EPA Regions	technical systems audits, data quality assessments
Monitoring Orgs	technical systems audits, data quality assessments
EPA Metrology Lab	field standards verification
ESAT Contractors	Performance audits, data quality assessments
Reporting	
OAQPS	P&A reports, QA reports, Data quality assessments, MSR reports
EPA Regions	Technical system audit reports,
Monitoring Orgs	Technical system audit reports, data reports
ESAT Contractors	QA reports,

8.3 Planning

The majority of the QA planning efforts will initially occur with the OAQPS QA Team and the ESAT Workgroup. These groups have contributed to the development of this Implementation Plan.

8.3.1 Pb Data Quality Objectives

In FY2008, OAQPS implemented the DQO process in order to identify the bias and precision required to make attainment/nonattainment decisions within a known level of confidence. The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 20% and bias as an upper 95% confidence limit for the absolute bias of 15 % . The DQO process will be used by the OAQPS QA team to develop the implementation requirements for Pb-PEP and the acceptance criteria for

various quality control samples implemented at the various measurement phases of the PEP data collection effort (Tables 8-2 and 8-3)

8.3.2 Methods

In order to ensure consistent implementation of Pb-PEP environmental data operations, EPA will develop draft field and laboratory SOPs by the end of July 2009 that will be available for review and comment. Final versions will be completed by November 2009 before training activities.

8.3.3 PEP QA Project Plan

Planning for the development of the quality system will be implemented through the ESAT Workgroup. The major planning document for this activity is the Pb-PEP QAPP. EPA policy requires that all projects involving the generation, acquisition, and use of environmental data be planned and documented and have an Agency-approved quality assurance project plan or QAPP prior to the start of data collection. The primary purpose of the QAPP is to provide an overview of the project, describe the need for the measurements, and define QA/QC activities to be applied to the project, all within a single document. Effective implementation of the QAPP assists project managers in keeping projects on schedule and within the resource budget. Agency QA policy is described in the Quality Manual and EPA QA/R-1, *EPA Quality System Requirements for Environmental Programs.* In addition the EPA QA Management Staff has developed guidance for the development of QAPPs. These documents can be found on the Quality Staff Website[1].

8.3.4 QA Training

Training will be discussed in Section 9.0. The field and laboratory training will include:

- Calibrations
- Quality control activities
- Corrective actions requirements
- Data verification/validation
- QA reporting

OAQPS will be responsible for implementing the QA training activities.

[1] http://www.epa.gov/quality1/

8.4 QA/QC Implementation

Table 8-1 presents a listing of the implementation responsibilities of the organizations participating in the Pb-PEP. Implementation in the Pb-PEP quality system is defined as those quality assurance activities that attempt to control and/or evaluate either the entire measurement system or a phase of the system.

8.4.1 Verifications/Calibrations of Field Standards

Field standards (flow/pressure/temperature) will need to be verified and or calibrated once a year. Verification is defined as confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. Verification of the accuracy of a standard is established by (1) relating the output to a standard of higher authority and (2) demonstrating that the repeatability of the transfer standard is within the limits. Calibration refers to the comparison of a measurement standard, instrument, or items with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments. The Pb-PEP QAPP will identify any equipment or instrumentation that requires verification/calibration to maintain acceptable performance and will indicate the acceptance criteria and the frequency of these calibrations along with corrective actions. Verification/calibration activities follow a three step process:

1. Certifying the calibration standard and/or transfer standard against an authoritative standard. This activity will be accomplished once a year by the EPA RTP Metrology Laboratory. This laboratory currently verifies the $PM_{2.5}$ PEP standards.
2. Comparing the standard against an OAQPS traveling standard that will be used to verify the samplers one a year. The flow rate percent differences between the verification standards and the traveling standard must be $\leq$4%
3. Comparing the standard against the routine sampling/analytical instruments. This check will occur each day of sampling. Although this check is primarily used to ensure the sampling instrument is operating properly, it can also be used as a check against the standard since the standard can be also checked against the second sampling instrument in the Region if the first is out of the acceptable range. If both sampling instruments are out of acceptable range, one might suspect the standard.

As mentioned in bullet 1, EPA will utilize the EPA Metrology laboratory or standards verifications. This lab will house a set of primary standards that will also be certified once a year against NIST standards. The primary standards will then be used to verify the transfer standards that are used in the field. The transfer standard laboratory will set up a schedule to receive all the field transfer standards in the November/December time frame for verification

8.4.2 Quality Control

Quality Control (QC) is the overall system of technical activities that measures performance against defined standards to verify that they meet the stated requirements established by the customer that are used to fulfill requirements for quality. Figure 8.1 represents the flow of some of the more important QC samples that will be used to evaluate and control data quality at various phases of the Pb-PEP. Field and laboratory personnel will implement these checks.

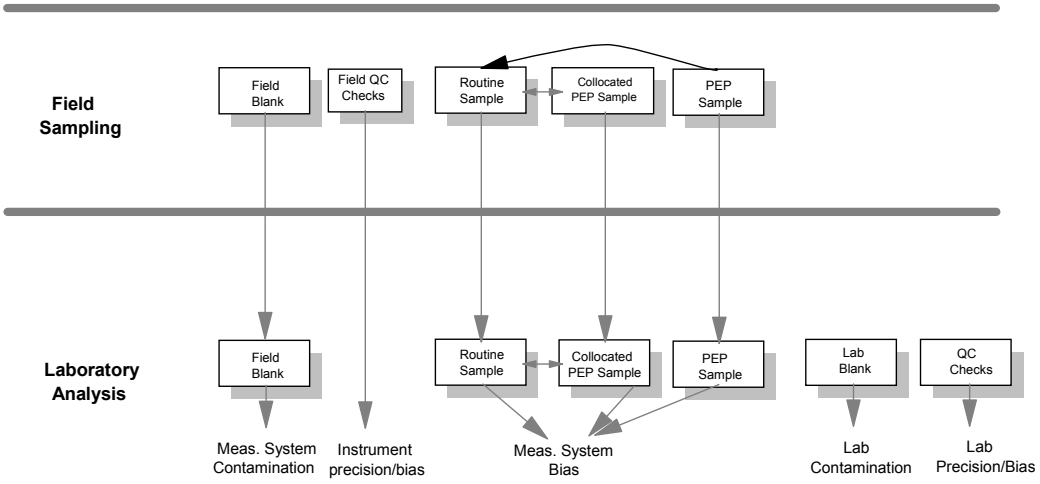


Figure 8.1 QC Sample Flow

Tables 8-2 and 8-3 summarize the criteria and frequency of the QC checks that will be used in the laboratory and the field respectively. The PEP QAPP will describe the procedures for each check, corrective actions and the statistical formulas for assessing the data.

Table 8-2 Laboratory QC Checks (details in R9 Laboratory SOP)

Parameter	Frequency	Criteria
Correlation Coefficient	Each ICAL	$\geq$ 0.995
Instrument Calibration Verification	After ICAL	90 - 110%
Continuing Calibration Verification	Every 10 Samples	90 - 110%
Calibration Blank	After each ICV/CCV	< ½ QL
Second Source Calibration Blank	After ICAL	90 - 110%
Quantitation Limit Standard	After ICAL & after every 40 analytical samples	60 - 140%
Method Blank	Each Batch	< ½ QL
Lab Control Sample (LCS)	Each Batch	85 - 115%
LCS Duplicate, Precision	Each Batch (For PM 10 Filter Only)	$\leq$ 20 RPD
Matrix Duplicate, Precision	Every 20 samples (For TSP Filter Strip Only)	$\leq$ 20 RPD
Matrix Spike, Accuracy	Every 20 samples (For TSP Filter Strip Only)	70 - 130%
Internal Standard	Every analysis	60 - 125% of initial CB
Audit Strips	1/quarter	$\pm$ 10%

Table 8-3 Pb-PEP Field QC

Requirement	Frequency	Acceptance Criteria
Calibration Standards		
Flow Rate Transfer Std.	1/yr	±2% of NIST-traceable
Field Thermometer	1/yr	Std.
		± 0.1° C resolution
Field Barometer	1/yr	± 0.5° C accuracy
		± 1 mm Hg resolution
		± 5 mm Hg accuracy
Sampling Instrument Calibration/Verification		
Flow Rate (FR) Calibration	If multi-point failure	± 2% of transfer standard
FR multi-point verification	1/yr	± 2% of transfer standard
One point FR verification	every set-up	± 4% of transfer standard
External Leak Check	every 5 sampling events	80 mL/min
Temperature Calibration	If multi-point failure	± 2% of standard
Temp multi-point verification	1/yr	± 2°C of standard
One- point temp Verification	Every set-up	± 4°C of standard
Pressure Calibration	If multi-point failure	±10 mm Hg
Pressure Verification	Every set-up	±10 mm Hg
Clock/timer Verification	Every set-up	± 5 min
Audits (Traveling Standard)		
Flow rate audit	1/yr	± 4% of audit standard
Temperature Audit	1/yr	± 2°C
Pressure Audit	1/yr	±10 mm Hg
Blanks		
Field Blanks	1 every 4 audits	
Precision Check		
Collocated samples	2/year	CV ≤ 20%
Check Standards Verification (Traveling Standard)		
FR multi-point verification	1/yr	± 4% of transfer standard
Temp multi-point verification	1/yr	± 2°C of standard
Pressure Verification	1/yr	±10 mm Hg
		± 5 min

8.5 Assessments

An assessment is an evaluation process used to measure the performance or effectiveness of the system and its elements. For the Pb-PEP, assessments will include: technical systems audits and management systems reviews. Table 8-1 indicates the organizations responsible for the various assessments.

The quality system for Pb has been developed at three levels of oversight. Since EPA policy states that data collected using the public resources must have a quality system in place and it also states that quality assurance is an inherently governmental function, OAQPS and the EPA

Regions have developed a quality system that will allow for independent assessments of the quality assurance program at each level to ensure that the DQOs are met.

Technical Systems Audit (TSA) - A systems audit is an on-site review and inspection of a monitoring organizations ambient air monitoring program to assess its compliance with established regulations governing the collection, analysis, validation, and reporting of ambient air quality data. The EPA Regions will perform technical systems audits of the field and laboratory activities once a year. Key personnel to be interviewed during the audit are those individuals with responsibilities for: planning, field operations, laboratory operations, QA/QC, data management, and reporting.

To increase uniformity of the TSA, an audit checklist will be developed and included in the Pb-PEP QAPP. It will review activities similar to the training certification forms but be more detailed.

The auditor will prepare a brief written summary of findings, organized into the following areas: planning, field operations, laboratory operations, quality assurance/quality control, data management, and reporting. Problems with specific areas should be discussed and an attempt made to rank them in order of their potential impact on data quality. For the more serious of these problems, audit findings will be drafted from which corrective actions will be implemented.

Management Systems Reviews (MSR) - This is a qualitative assessment of a data collection operation or organization to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. This would allow OAQPS to assess consistency of operation among the Regions and improve the quality system. The AAMG QA Team proposes implementing 2-3 management systems reviews each year of the EPA Regions on their implementation of the Ambient Air Monitoring Program and will include a review of Pb-PEP activities.

8.6 Reporting

Many of the QC checks discussed above result in measurement data that can be used to compute statistical indicators of data quality. The following types of reports are anticipated

Data quality assessment (DQA) -is the scientific and statistical evaluation to determine if data are of the right type, quality, and quantity to support their intended use. The Pb-PEP QA/QC data can be statistically assessed at various levels of aggregation to determine its quality. The statistics to be used to evaluate bias are included in 40 CFR Part 58 Appendix A. A formal DQA will be performed by OAQPS every three years.

P & A Reports - This reports will be generated annually and evaluate the precision and bias data against the acceptance criteria using the statistics documented in *40 CFR Part 58*. These reports

will be generated through the AMP255 reports on AQS system and will be responsibility of OAQPS. However, any person with AQS access can generate these reports at any time.

Assessment Reports - Technical systems audits and network reviews will be on file at the EPA Regional office and OAQPS. The audit check sheets will be sent to OAQPS for central filing. AQS will include an audit tracking area that will allow the placement of dates when an audit was implemented. Management systems reviews will be on file in AAMG with tracking information on AQS.

9.0 FIELD TRAINING/CERTIFICATION OF PERSONNEL

Prior to implementation on 1/1/2010, all personnel involved in the field aspects of the Pb-PEP will be trained. Personnel include EPA Regional TOPO/DOPOs, ESAT contractors and any monitoring organization that are self-implementing the program. Field training for the Pb-PEP will involve four phases:

1. **Classroom lecture**- will include an overall review of the Pb program and it's relation to the Pb-PEP. Classroom lectures will also be implemented for each training module (see below) but may be accomplished through remote training prior to hands-on activities.
2. **Hands-on activities**- After a class room lecture, personnel will be taken to the training area where the field/lab activities will be demonstrated and then the trainees will perform under instruction.
3. **Certification-Written exam-** a written test to cover the activities of importance in each of the training modules.
4. **Certification-Performance evaluation**- this is a review of the actual field implementation activities under evaluation by the trainer/evaluator.

In FY09, training is scheduled for the December time frame. In subsequent years, annual training will be sometime between October and mid-December.

Field training is expected to last two full days; one day of lecture and hands-on, and one day of training/certification. Trainers and trainees may be required to be available a third day for any individuals requiring additional training.

Field Training Modules
Field training will be segregated into the following discreet modules:

< Site visit scheduling
< Communication
< Equipment inventory and maintenance
< Filter receipt/ storage/tracking
< Calibration/verification
< Monitor set-up/filter installation
< Filter removal/storage/shipping
< Data download/storage/transfer
< QA/QC
< Monitor diassembly/packing
< Documentation /filing/records

9.1 Certification

Certification will help to ensure that field personnel are sufficiently trained to perform the necessary Pb-PEP activities at a level that does not compromise data quality and also inspires confidence in the Pb-PEP by the monitoring organizations.

Both the written exam and the performance review are considered part of the certification requirements. The written exam is gauged to a review of the more critical aspects of the Pb-PEP and to identify where the individual requires additional training. The performance review is focused on ensuring that the individual understands and follows the SOPs. The trainer(s) will evaluate the trainees implementation of the field modules mentioned above.

The intent of the certification activities is not to fail individuals but to determine where additional training is required in order to ensure that the Pb-PEP is implemented comparably across the Nation. If there are enough individuals failing a particular module, it may also indicate that the classroom or hands-on training were not appropriate. In any case, failure by individuals of parts of either written or performance evaluation will indicate that additional training in these areas are required. Trainees will be required to attend additional training on these modules. Trainers will be available for an additional day of field/lab training and will ensure personnel are certified by the end of the training session.

If the certification/retraining activities identify individuals that appear to be incapable of performing the field/lab activities, the ESAT Regional Project Officers will be notified and appropriate action will be taken.

9.2 Additional/Out Year Training

Each year a training/certification/recertification session will be scheduled which will cover the majority of the field scientists needing certification/recertification. However, it is expected that there will be contractor personnel turnover and therefore the need for additional training beyond the annual training course. Since Regional ESAT TOPO/DOPOs will be trained and certified along with ESAT contractors. These certified TOPO/DOPOs will be given all training course material and will be certified to train additional ESAT personnel. In addition, OAQPS will make available to the Regions an opportunity for training additional personnel in RTP as long as schedules can be negotiated.

Appendix A

Pb-PEP Adequacy and Independence Criteria: Monitoring Rule Requirements and Supplemental Guidance July 2009

The underlying document provides the most current adequacy and independence criteria for the Pb-PEP. It is used to help monitoring organization decide to allow for federal implementation of this program or to self-implement.

This attachment is a living document which will be reviewed annually and revised as needed. Subsequent revisions will be posted as separate documents on AMTIC at <http://www.epa.gov/ttn/amtic/pmpep.html>. A revision may not be necessary every year. Each subsequent memo that announce the opportunity for monitoring organizations to assume their performance evaluation programs will reference the most current revision to the Pb-PEP Adequacy Document. Questions and Comments on this Document may be sent to Dennis Crumpler, OAQPS lead for the $PM_{2.5}$ Performance Evaluation Program. crumpler.dennis@epa.gov . Please send a courtesy copy of your communication to your respective EPA Regional Pb-PEP lead or Quality Assurance Manager.

Pb-PEP Program Adequacy and Independence Criteria: Monitoring Rule Requirements and Supplemental Guidance

Glossary (taken from the Current Field and Laboratory Operating Procedures)

AQS	Air Quality System (EPA data base for ambient monitoring data)
COC	Chain of Custody form
COR	For EPA, the Contracting Officer's Representative on a given contract; he or she could be a Work Assignment Manager (WAM), Task Order Delivery Officer (TOPO), or Delivery Order Project Officer (DOPO)
ESAT	Environmental Services Assistance Team
FS	A field scientist is a person certified by the U.S. Environmental Protection Agency (EPA) as completing a required training program as being capable and responsible for conducting FRM PEs. That person would have a 2- or 4- year college degree in a physical or life science or scientific instrumentation or have equivalent training or work experience.
FRM	Federal Reference Method
NIST	National Institute of Standards and Technology
OAQPS	Office of Air Quality Planning and Standards
Pb-PEP	$PM_{2.5}$ Federal Reference Method *Performance Evaluation Program*
PQAO	Primary Quality Assurance Organization
QAPP	Quality Assurance Project Plan
SOP	Standard Operating Procedures

Overview of Monitoring Rule Requirements

- Monitoring plans or the QAPP shall provide for the implementation of a program of independent and adequate audits of all monitors providing data for SLAMS and PSD, including provisions of adequate resources for such audit programs. (40 CFR 58 Appendix A section 2.4). Starting January 1, 2009, this requirement also applies to SPM monitors using FRM, FEM, or ARM methods which also meet the requirements of Appendix E of 40 CFR 58, unless alternative QA procedures are approved by the Regional Administrator. (Appendix A, section 1; 40 CFR 58.20; and 40 CFR 58.11(a)(2)) EPA interprets this requirement to apply only to SLAMS, PSD, and SPM monitors that measure NAAQS pollutants.)
- Primary quality assurance organizations with 5 or fewer Pb monitoring sites are required to have 5 valid independent audits per year; primary quality assurance organizations with greater than 5 sites are required to have 8 valid audits per year. The implementation of an audit similar to the $PM_{2.5}$ Performance Evaluation program (PEP) is a new requirement and it provides some assessment of overall bias but will be a mix of one or two Pb-PEP audits with additional collocated sampling. The number of audits required is based on the number of routine sites within a primary quality assurance organization PQAO. The program will require the same number of audit samples as required for $PM_{2.5}$ meaning:
    - PQAOs with $\leq$ 5 sites require 5 audits (1 Pb-PEP, 4 collocated)
    - PQAOs with > 5 sites require 8 audits (2 Pb-PEP, 6 collocated)
- The regulation requires100 percent completeness (meaning whatever it takes to get 5 or 8 valid samples).

Guidance – General

- The general requirement for a program of independent and adequate audits means that any monitoring organization implementing a Pb-PEP program must provide for independence and adequacy for both field and lab implementation elements of the Pb-PEP program.
- QAPP and SOPs for implementation will be reviewed and approved by the EPA Region.
- monitoring organization Pb-PEPs should have an adequate number of audit samplers, including back-ups.
- If equipment is borrowed from the Regional Pb-PEP program, there must be some formal agreement that the monitoring organization agency will repair or replace damaged equipment in a timely manner.
- Since only 1 or 2 Pb-PEP-like audits are required, these will be scheduled as appropriate throughout the year. However EPA would like to have the collocated samples collected on a quarterly bases so at a minimum, 4 collocated samples would be collected quarterly and if 6 are required, they would be interspersed in 2 of the 4 quarters.
- The implementation of the Pb-PEP program by monitoring organizations requires an enhanced QA system for the Pb-PEP. Comparability between Federally-conducted and monitoring organization Pb-PEPs is essential. Biannual collocations of all Pb-PEP samplers in each Region are one of the critical QC activities in the Pb-PEP. These "parking lot studies" provide
    - First, a comparison of sampler performance;
    - Second, a comparison of the technical performances of the monitoring organization and the Region's personnel, and
    - Third, a comparison of all Regions at the National level.

  In addition to the collocations, annual TSAs of the monitoring organization programs will be necessary, just as TSAs are necessary for EPA's ESAT-run Pb-PEP in each Region.

  The EPA, via contractor support, will compile a nationwide Pb-PEP QA summary report each year and will compile a 3-year report in the fourth year. These reports will include comparisons of the collocations and TSAs Regionally and nationally as well as results of the audits of the FRM network. The frequency of these reports will be re-evaluated annually.

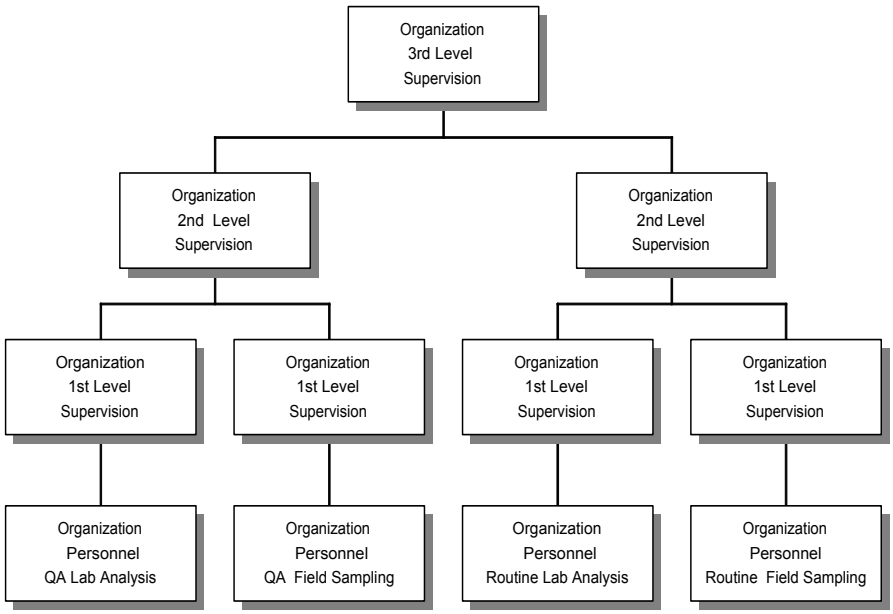
Independence of the monitoring organization Pb-PEP Program

40 CRF part 58 Appendix Section 2.2 states: "The monitoring organization must provide for a quality assurance management function -- that aspect of the overall management system of the organization that determines and implements the quality policy defined in a monitoring organization's QMP…The quality assurance management function must have sufficient technical expertise and management authority to conduct independent oversight and assure the implementation of the organization's quality system relative to the ambient air quality monitoring program and should be organizationally independent of environmental data generation activities." (EPA has a good example of a QMP for OAQPS http://www.epa.gov/oar/oaqps/qa/qmp.pdf. In the preamble to the October 17, 2006, Federal

Register that promulgated the recent revisions of the aforementioned monitoring regulations, EPA explained that "An independent organization could be another unit of the same agency that is sufficiently separated in terms of organizational reporting and which can provide for independent filter weighing and performance evaluation auditing." Independent assessment, as defined in Figure 1, is required to ensure that an appropriate level of independence is maintained during monitoring organization implementation of the Pb-PEP.

Figure 1. Independent assessment

Independent assessment - an assessment performed by a qualified individual, group, or organization that is not part of the organization directly performing and accountable for the work being assessed. This auditing organization must not be involved with the generation of the routine ambient air monitoring data. An organization can conduct the Pb-PEP if it can meet this definition and has a management structure that, at a minimum, will allow for the separation of its routine sampling personnel from its auditing personnel by two levels of management, as illustrated below. In addition, the sample analysis of audit filters must be performed by separate laboratory facility using separate laboratory equipment. Field and laboratory personnel would be required to meet the Pb-PEP Audit field and laboratory training and certification requirements. The monitoring organizations will be required to participate in the centralized field and laboratory standards certification and comparison processes to establish comparability to federally implemented programs.



Adequacy of the monitoring organization Pb-PEP Program

The field and lab SOPs will be the primary source for the adequacy requirements. Basically, monitoring organizations deciding to self-implement the Pb-PEP will have to maintain a comparable program. The elements reported below are considered the important aspects for maintaining comparability. The SOPs will be revised annually. The revision process begins with a discussion of operational issues during the certification and recertification courses. Necessary revisions are drafted and then vetted again through a semiformal review process including public comment period. Consequently, the monitoring organizations that conduct Pb-PEP are encouraged to participate in the training and SOP review process

Pb-PEP Field Operations -- Critical Steps and Activities

The Pb-PP Field SOP will contain following requirements:

1. Initial training and certification of audit personnel through EPA's federally-implemented Pb-PEP Field scientist course prior to an Agency's implementation of the program.

    a. The Pb-PEP is the "Gold Standard" for network bias (and relative accuracy on a local basis); therefore, uniform and consistent implementation remains a primary objective. Operator and sampler performance are held to high standards. Comprehensive record keeping, the quality control of the filter exposure and handling, and careful data validation are critical activities. EPA will provide the initial training in a timely manner for every monitoring organization that needs to get certified to self-implement their program. We will tailor the course to the specific roles that the monitoring organization is assuming—field operations, lab operations, or both. The course may be as much a forum for a given agency to fine tune their Pb-PEP QAPPs as it is for training. Monitoring organization Field Lab Scientist may also attend EPA national training and recertification courses.
2. Annual recertification of audit personnel either by
    a. Attending an annual Pb-PEP certification or recertification course;
    b. Attending a Regionally implemented recertification course conducted by a certified, EPA regional or OAQPS trainer;
    c. Local recertification conducted by an independent organization (contractor) that has been certified by OAQPS and commissioned by the respective EPA Regional Office; see alternative during collocation events—element 13 below.
3. Existence of a back-up sampler, for the circumstance of having a sampler failure near the end of a quarter or year; which would otherwise jeopardize completeness. These may be made available from the federally run Pb-PEP program.
4. Performance leak check, pressure, temperature, time and flow rate check at <u>every audit</u>. Data recorded and available upon request.
5. The frequency for field blanks is one per year which would be performed during actual collocation with the Pb-PEP audit sampler.

6. Generation of one trip blank per year during the same trip as the field blank. The trip blank would be valid only if it is associated with a valid Pb-PEP audit.
7. Pb-PEP sampler should be positioned horizontally within 2-4 meters of the target routine sampler and any other sampler in the vicinity and 1 meter vertically, of primary sampler's (monitor's) inlet.
8. Use of antistatic bags and corrugated (stiff) shipping envelopes to reduce sample bending/mutilation during storage and shipping.
9. The exposed filter shipment and delivery goal is to recover it within 8-48 hours of the end of the sampling event, and shipped the same day via Fedex or other service, delivery to laboratory with next day "morning" delivery, unless the sample is collected on Friday. A more rapid delivery is always acceptable. A 48-hour collection is permissible if the site is inaccessible on holidays and weekends; however, Friday audits or Thursdays before Friday Holidays should be avoided if at all possible.
10. Monitoring organization-operated Pb-PEPs will implement a chain of custody protocol and require completed field data sheets for each Pb-PEP event. EPA will furnish Chain of Custody (COCs) and Field Data Sheets (FDSs) to those agencies that utilize the Federal Pb-PEP lab service. COCs and FDSs and all QA/QC data should be filed and made available upon request. As a general rule, Pb-PEP files should be held for 4 years plus the current calendar year in order to address any regulatory data-driven decision appeals. Electronic files of the forms will be available to fully self implementing programs upon request and are encouraged for the sake of consistency in reporting.
11. Audit samplers must be inspected and cleaned, if necessary, on quarterly basis or more frequently if circumstances dictate—Pb-PEP equipment must be pristine. An example would be an audit conducted during a period when a dust storm occurred
12. The Pb-PEP sampler requires an annual multi-point verification and /or calibration for all parameters (pressure, temperature, flow) using an NIST traceable standard that is independent from the routine operational verification standard.
13. To accommodate monitoring organization Pb-PEP programs which may be limited by travel budgets or policies of their agencies, the EPA has modified several QA oversight activities for monitoring organization that are self-implementing : (a) Periodic Sampling events using collocated Pb-PEP Samplers; (b) Technical Systems Audits of Pb-PEP field scientists and supporting gravimetric laboratories, and (c) on-site recertification for monitoring organization Field Scientists.
    a. ***Collocations:*** In those Regions where monitoring organizations assume the responsibilities associated with the Pb-PEP, collocations will serve as an assessment of the comparability of Federal/State/Tribal/Local programs and the resulting Pb-PEP data.
        i. Each monitoring organization-run Pb-PEP shall participate in one collocation joint activity with the respective Region's ESAT-run Pb-PEP field operations. The schedule will be worked out through the EPA Regional Office.
        ii. Each Regional and monitoring organization program needs to set-up and operate the collocation through all measurement phases as if it were performing a routine audit. After considerable deliberation among the monitoring organization agencies and EPA Regions who have been participating in collocations, it was determined that monitoring organization employees are required to conduct all the necessary procedures in joint collocation studies. (This is the only way one would

capture all potential sources of measurement error that might cause a program to be dissimilar to the federally implemented Pb-PEP.)

iii. It is important that the monitoring organization have a back-up operator in case the primary operator cannot perform all the requisite functions during the collocation, e.g., due to an unforeseen emergency the monitoring organization employees must return to home or office.

b. ***Technical Systems Audits***--monitoring organization- implemented Pb-PEPs will be subject to one annual technical systems audit of the field activities and support laboratories. These audits will typically be conducted by the Regional Pb-PEP Lead and will involve an on-site review of field and or lab activities, a review of data acquisition, management and record keeping and relevant QA/QC procedures.

i. The EPA Regional Pb-PEP Lead may use the collocation events to conduct audits. The review would also qualify as a recertification of the monitoring organization field scientist(s).

ii. The EPA Regional Pb-PEP Lead will specify that paperwork for at least one quarter of Pb-PEP activity, be submitted by the monitoring organization Pb-PEP for a TSA review.

c. ***Recertifications of Field scientists—***The EPA Regional Pb-PEP Lead may, at their discretion, utilize the field activity reviews and TSAs to recertify monitoring organization Pb-PEP field personnel.

i. The TSA and evaluation forms will be reported to OAQPS for compiling in a national oversight record. OAQPS will compile an annual summary and include the summaries in a detailed Triennial Pb-PEP QA Report.

ii. These forms are in the currently approved QAPP, which is available on AMTIC at http://www.epa.gov/ttn/amtic/pmpep.html, or they can be requested from the National Pb-PEP Lead at OAQPS.

Pb-PEP Laboratory (Lab) -- Critical Steps and Activities

Monitoring organizations that are self implementing Pb-PEP must use laboratory services that are independent of the laboratory performing routine data analysis. Monitoring organizations who self-implement field activities can still utilize the Region 9 Pb-PEP analytical services and are encouraged to do so. If not the independent laboratory will be required to adhere to the following:

1. The Pb-PEP Lab's QAPP and SOPs should be available, reviewed, and approved by the respective Regional Pb-PEP Lead or QA manager prior to implementation; then subsequently, made available upon request. Their elements, specifications and QA/QA criteria should be equivalent to those of the federally implemented Pb-PEP.
2. Initial training through Federal Pb-PEP sanctioned course prior to implementation.
   a. Operational differences can exist between lab procedures of thee monitoring organizations independent laboratory and the federally-run Pb-PEP. However the operational difference should not affect data quality. EPA will require the

monitoring organizations independent laboratory labs to retain the same levels of QA/QC.

3. The Pb-PEP Lab must be independent of the monitoring organization's laboratory performing routine FRM routine analysis.
4. The Pb-PEP Lab and analyst will be audited annually by the EPA Region or OAQPS; recertification of lab technicians is part of the process.
5. All Pb-PEP Labs must meet QC requirements as described in Pb-PEP lab SOPs
6. Reagents and laboratory standards should be of the same quality as the federally implemented Pb-PEP laboratory.
7. COCs and Field Data Sheets should be recorded and stored and made available upon request, according to the schedule laid out in the Field and Lab SOPs. Digital versions are available on the AMTIC website.
8. The Pb-PEP lab will archive extracts for current year plus last calendar year in cold storage.
9. The Pb-PEP Lab will follow AQS format for reporting QA data to appropriate fields in AQS.
10. The Pb-PEP Lab will load data into AQS within 15 days of analysis
11. The Pb-PEP Lab will participate in any Pb-PEP sanctioned performance evaluations that may occur to test laboratory comparability (round robins, proficiency tests etc.).
12. The Pb-PEP Lab (or in the case of an monitoring organization Pb-PEP program, it might be the client PQAO) submits annual report of results to EPA in format specified by EPA.

Appendix B

Pb-PEP Field Data Sheet and Chain of Custody Form

The following two forms will be used by:

1. Personnel providing federal implementation of the Pb-PEP program,
2. monitoring organizations using the federal program and shipping the collocated filters to the Pb-PEP National Laboratory in Region 9, and
3. any monitoring organization that is self implementing and utilizing the Pb-PEP National Laboratory in Region 9.

For the field data sheet, monitoring organizations shipping the collocated samples and self-implementing monitoring organizations using the Region 9 laboratory are required to complete, at a minimum, the following information in the "Sampling Event" section:

- AQS Site ID
- Setup Date
- Site Name
- Primary Monitor Sampler Serial Number
- PEP Sampler (or collocated sampler) serial number
- Field Scientist (person either conducting sampling or retrieving filters)

and the following information in the "PB-PEP Exposure Data" section:

- Filter ID
- Elapsed time
- Total Volume
- Start Date/Time
- Stop Date Time
- Filter Integrity
- Sampler Flags
- Field Flags

These fields have been highlighted on the form.

All information on the Chain of Custody Form should be completed. There should be a one-to-one match of forms (two forms) to sample filters shipped.

Pb-PEP Field Data Sheet

Highlighted areas are minimum completion requirements for monitoring organizations submitting filters to the Region 9 National Laboratory

Sampling Event Information			
AQS Site ID		Pb-PEP Audit or Collocation Setup Date	
Site Name		Primary SLT Sampler Serial No.	
Field Scientist		Pb-PEP TSP (or collocated sampler) Serial No.	

Parameter Check Device	Make/ Model	Serial No.
Multi-Standard[1]		
Temperature Standard		
Barometric Pressure Standard		
Flow Rate Standard		
Time Checks OK?	☐ Yes ☐ No (describe)	
Monitoring Site Criteria OK?	☐ Yes ☐ No (describe)	

[1] *Use this line for multi-standard instruments (e.g., BGI TriCal and DeltaCal) when used for all three checks.*

Pb-PEP Sampler Verification Checks [2]				Date:
Leak Check	**Criteria**	**Beginning P**	**Ending P**	**Verification OK?**
2-Minute Interval	Change < 5 cmH_2O	cmH_2O	cmH_2O	☐Yes ☐ No
Bar. Pressure	**Criteria**	**Ref Standard**	**Sampler**	**Verification OK?**
Ambient	± 10 mmHg	mmHg	mmHg	☐Yes ☐ No
Temperature	**Criteria**	**Ref Standard**	**Sampler**	**Verification OK?**
Ambient Sensor	± 2°C	°C	°C	☐Yes ☐No
Flow Rate Verification				
Audit Standard FR (Cal.) Check	**Criteria**	**Ref Standard**	**Sampler**	**Verification OK?**
	< 4% difference	CFM	CFM	☐Yes ☐No
Design Flow Rate "Q" Check	**Criteria (±4%)**	**Ref Standard**	**Design**	**Verification OK?**
	38.4 to 41.6 CFM	CFM	40 CFM	☐Yes ☐ No

[2] *Indicate only the final result of the check after all troubleshooting has been done. Document troubleshooting in the "Notes" section below and/or in the field notebook. If troubleshooting is unsuccessful, the sampler must be recalibrated or repaired before conducting a sampling event. Fill out a new Field Data Sheet for the replacement sampler.*

Pb-PEP Exposure Data			
Filter ID		Filter Retrieval Date/Time:	
Elapsed Time (ET)		**Filter Integrity OK?**	☐ Yes ☐ No (describe)
Total Volume (m^3)			
Flow Rate (CFM)	Q:	Avg:	CV: ??
Start Date/Time		**Data Download OK?**	☐ Yes ☐ No (describe)
Stop Date/Time			
Temperature (°C)	Max:	Min:	Avg:
Bar. Pressure (mm Hg)	Max:	Min:	Avg:
Field Blank ID		Sampler Flags[3]:	
Trip Blank ID		Field Flags:	
Collocated Filter ID(s)[4]			

[3] *Make sure to add (EST) flag in "Sampler Flags" if runtime is outside of 1380- 1500 minute range.*

[4] *For parking lot studies, all the IDs can be listed on one form*

PEP Chain-of-Custody Form for Pb-PEP

This COC form will be used for the transportation/tracking of both the Pb-PEP samples collected by ESAT contractors and the collocated filters from monitoring organizations utilizing federal implementation AND by monitoring organizations that are self- implementing the program but using the Region 9 laboratory for analytical services.

PART I – FIELD SITE

Sampling Event Information		
Filter ID	__ __ __ __ __ __ __ __	
Primary Quality Assurance Org. (PQAO)	__ __ __ __	
Arrival Date at Site		Sampler Operator:
Site Name & Description		
Primary SLT Sampler	Make/Model:	Serial No.:
AQS Site ID		
Other Operators or Observers		

Sampling Event Filter Data		
Sampling Date:	Retrieval Date:	Time:
Sample Type		
☐ RO - Routine ☐ FB - Field Blank (RO Filter ID:__ __ __ __ __ __ __ __) ☐ Other (describe)		
☐ CO - Collocated ☐ TB - Trip Blank (RO Filter ID __ __ __ __ __ __ __ __)		
Event Filter Integrity (after sampling): ☐ OK ☐ Reject (describe) Integrity Flag:		

PART II – FIELD FILTER SHIPPING TO LAB

Shipment Date		Affiliation:	
Shipped by		Shipping Destination:	
Airbill No.		Shipped via: ☐ Federal Express ☐ Other	

On completion of Part I-II, the field scientist keeps one copy and sends the top (original) copy to the laboratory with the filter.

PART III – LABORATORY

Date Received		Received by:	Integrity Flag:
Shipment Integrity OK?	☐ Yes ☐ No		

The analytical laboratory will DATE-STAMP and attach the COC form to the receiving log-book, in which same info is recorded.

Notes: