Quality Assurance Project Plan for the Federal Lead (Pb) Performance Evaluation Program

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Research Triangle Park, NC

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Quality Assurance Project Plan for the Federal Lead (Pb) Performance Evaluation Program

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Foreword

U.S. Environmental Protection Agency (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 (QAPP) before the start of data collection. The primary purpose of the QAPP is to provide a project overview, describe the need for the measurements, and define quality assurance/quality control (QA/QC) activities to be applied to the project, all within a single document.

This document represents the QAPP for the environmental data operations involved in EPA's Lead (Pb) Monitoring Network Performance Evaluation Program. This QAPP was generated using the following EPA monitoring and QA regulations and guidance:

- 40 Code of Federal Regulations (CFR) Part 50 Appendix G
- 40 CFR Part 58 Appendices A and C
- *EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans*
- *EPA QA/G-5, Guidance for Quality Assurance Project Plans*.

All pertinent elements of the QAPP regulations and guidance are addressed in this QAPP.

This document has been reviewed by EPA Regional Work Assignment Managers responsible for implementing the performance evaluation program (PEP) in their respective regions and is considered acceptable (see the following approval page).

Mention of corporation names, trade names, or commercial products does not constitute endorsement or recommendation for use.

Acknowledgments

This QAPP is the product of the combined efforts of the EPA's Office of Air Quality Planning and Standards (OAQPS); and EPA Regional Offices. The review of the material in this document was accomplished through the activities of the Pb QA Workgroup. The following individuals are acknowledged for their contributions.

EPA Regions

Region

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Acronyms and Abbreviations

AAMG	Ambient Air Monitoring Group
ACS	American Chemical Society
ADQ	audit of data quality
AFC	Agency File Code
AMTIC	Ambient Monitoring Technology Information Center
ANOVA	analysis of variance
ANSI	American National Standards Institute
APTI	Air Pollution Training Institute
AQAD	Air Quality Assessment Division
AQS	Air Quality System
ASTM	American Society for Testing and Materials
AWMA	Air and Waste Management Association
CAA	Clean Air Act
CAS	Chemical Abstracts Service
CB	calibration blank
CCV	Continuing Calibration Verification
CFR	Code of Federal Regulations
CMD	Contracts Management Division
CO	Contracting Officer
COC	chain of custody
CV	coefficient of variation
DOCOR	Delivery Order Contracting Officer Representative
DOPO	Delivery Order Project Manager
DQA	data quality assessment
DQO	data quality objective
EDD	electronic data deliverable
EDO	environmental data operation
ESAT	Environmental Services Assistance Team
EPA	Environmental Protection Agency
FB	field blank
FCS	failed collocated sample
FDS	field data sheet
FEM	Federal equivalent method
FRM	Federal reference method
FS	field scientist
GLP	good laboratory practice
ICP-MS	inductively coupled plasma mass spectrometry
ICV	initial calibration verification
ID	identification
LA	laboratory analyst

Acronyms and Abbreviations (continued)

LCS	laboratory control standard
LIMS	laboratory information management system
MB	method blank
MD	matrix duplicate
MDL	minimum detection limit
MQO	measurement quality objective
MS	matrix spike
MSR	management system review
NAAQS	National Ambient Air Quality Standards
NCore	National core monitoring network
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
OAR	Office of Air and Radiation
ORD	Office of Research and Development
OSRTI	Office of Superfund Remediation and Technology Innovation
P&A	precision and accuracy
PAMS	Photochemical Assessment Monitoring Station
Pb	lead
PE	performance evaluation
PEP	performance evaluation program
$PM_{2.5}$	particulate matter $\leq$ 2.5 microns aerodynamic diameter
PM_{10}	particulate matter $\leq$ 10 microns aerodynamic diameter
$PM_{10-2.5}$	coarse particulate matter (aerodynamic diameter >2.5 and <10 microns)
POC	parameter occurrence code
PQAO	primary quality assurance organization
PTFE	polytetrafluoroethylene
Q_a	sampler flow rate at ambient (actual) conditions of temperature and pressure.
Q_s	sampler flow rate adjusted to standard conditions (1atm and 25^o C)
QA/QC	quality assurance/quality control
QA	quality assurance
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QL	quantitation limit
QLS	Quantitation Limit Standard
RPD	relative percent difference
RPO	Regional Project Officer
RTP	Research Triangle Park
SCV	Source Calibration Verification
SIP	State Implementation Plan
SLAMS	state and local monitoring stations

Acronyms and Abbreviations (continued)

SLT	state/local/tribal
SOP	standard operating procedure
SOW	scope of work
SPMS	special purpose monitoring stations
STAG	State and Tribal Assistance Grant
T_a	temperature, ambient or actual
TB	trip blank
TOCOR	Task Order Contracting Officer Representative
TOPO	Task Order Project Officer
TSA	technical system audit
TSP	total suspended particulate
V_a	air volume, at ambient or actual conditions
WACOR	Work Assignment Contracting Officer Representative
WAM	Work Assignment Manager
XRF	x-ray fluorescence

1.0 QA Project Plan Identification and Approval

Title: Quality Assurance Project Plan- Federal Lead (Pb) Performance Evaluation Program

QAPP Category - 1

The attached Quality Assurance Project Plan (QAPP) for the Federal Pb Performance Evaluation Program (PEP) is hereby recommended for approval and commits the participants of the program to follow the elements described within.

Signature: _____ **Date:** 8/27/2014
OAQPS QA Manager Office of Air Quality Planning and Standards

Signature: _____ **Date:** 8/27/14
OAQPS Pb-Performance Evaluation Program QA Lead

Signature: _____ **Date:** May 28, 2014
Region 1

Signature: _____ **Date:** 5/14/2014
Region 2

Signature: _____ **Date:** 5/22/2014
Region 3

Signature: _____ **Date:** 6/19/14
Region 4

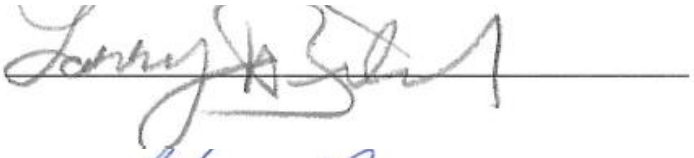
Signature: _____ **Date:** 6-17-14
Region 5

Signature: _____ **Date:** 5/14/14
Region 6

Signature: _____ **Date:** 5/14/14
Region 7

Signature: _____ **Date:** 6/26/14
Region 8

Signature:
Region 9



Date: 6/24/14

Signature:
Region 10

Date: 5/23/14

2.0 Table of Contents

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3.0 Distribution

A copy of this QAPP will be distributed to the Regional Work Assignment Managers (WAMs), Task Order Project Officers (TOPOs), or Delivery Order Project Managers (DOPOs). Since there is personnel turnover, the list of WAM/TOPOs/DOPOs that will receive a copy of this document, as well as the document itself, will be posted on the Pb-PEP site on EPA's Ambient Monitoring Technical Information Center (AMTIC)[1]. The AMTIC site will be updated annually. The WAM/TOPOs/DOPOs will be responsible for distributing the QAPP to each Environmental Services Assistance Team (ESAT) contractor participating in the environmental data operations of the PEP. The Regional WAMs/TOPOs/DOPOs should also provide a copy of this QAPP to their Regional Quality Assurance Managers (QAMs). Any monitoring organization self-implementing the Pb-PEP will have access to this document on AMTIC.

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

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4.0 Project/Task Organization

This element will provide the EPA and other involved parties with a clear understanding of the role that each party plays in the Pb-PEP and will provide the lines of authority and reporting for the project.

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 role descriptions is to facilitate communications and to outline basic responsibilities.

4.1 The PEP Workgroup

The PEP Workgroup consists of the EPA Regional Work Assignment Contracting Officer Representatives (WACORs), Task Order Contracting Officer Representatives (TOCORs), Delivery Order Contracting Officer Representatives (DOCORs), for the ESAT contract, and state/local/tribal (SLT) agencies that have opted to run at least the field operations component of the PEP in their jurisdictions. The PEP ESAT field and laboratory personnel are invited to participate in the conference calls. The PEP Workgroup, which is chaired by the Office of Air Quality Planning and Standards (OAQPS) National PEP Project Leader, meets at least twice per year and more often if needed. The PEP Workgroup serves in an advisory role and assists in the review and revision of PEP guidance documents, such as the PEP field and laboratory standard operating procedures (SOPs) and the PEP QAPP. Revisions to these documents, which may have national implications or issues that are national in scope, are reviewed by the National Ambient Monitoring QA Strategy Workgroup.

4.2 EPA Office of Air Quality Planning and Standards

OAQPS has the overall responsibility for ensuring the quality of the nation's ambient air monitoring 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:

- Provide a contractual vehicle for the manufacturing and distribution of the Pb-PEP portable evaluation sampler.
- Develop and or continue the memorandum of understanding with the ESAT Office.
- Work with the EPA Regions to determine which monitoring organizations will utilize the federally implemented Pb-PEP and to determine how many Pb-PEP audits are required per PQAO.

- Receive and allocate the appropriate State and Tribal Assistance Grant (STAG) funds to implement the federal Pb-PEP program.
- Transfer the necessary funds to the EPA Regional ESAT Contracts Management Division (CMD) to support the Pb-PEP and to the Region 9 office for laboratory equipment and consumables.
- Distribute filters to the regional field offices or Pb-PEP laboratories.
- Develop and update the Pb-PEP Implementation Plan, the Pb-PEP QAPP, the ESAT Scope of Work (SOW), and field SOPs.
- Develop the field and laboratory personnel requirements.
- Develop the field and laboratory training activities, participate in training, and provide technical, support, and guidance to regional Pb-PEP contacts.
- Develop a list of primary quality assurance organizations (PQAOs) which are monitoring Pb at state and local air monitoring stations (SLAMS) and special purpose monitoring (SPM) sites.
- Develop field and laboratory information management systems.
- Upload audit data to the air quality system (AQS) database.
- Assess the Pb-PEP concentration information and completeness data entered into AQS.
- Initiate and implement a communications network and act as a liaison to groups working on the Pb-PEP.
- Interact with the monitoring organizations concerning the setup, operation, and data results of the performance evaluations.
- Ensure the success of the program by performing various oversight activities such as management system reviews and/or technical systems audits (TSAs).

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 QAPP, 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 STAG distribution are coordinated through OAQPS. In addition, the OAQPS National Air Data Group is responsible for the AQS data management system.

4.3 ESAT Organization

The ESAT contract is administered by the Office of Superfund Remediation and Technology Innovation (OSRTI) Technology Innovation and Field Services Division Analytical Services Branch. OAQPS has entered into a memorandum of understanding with this office in order for the ESAT contract to provide the services necessary for the Pb-PEP. The ESAT contractor is managed by contracting officers (COs) at the Headquarters office in Washington, D.C. and with WACORs/TOCORs/DOCORs, and Regional Project Officers (RPOs) within each Region. RPOs are necessary because each Region awards an ESAT contract to assist in the implementation and

execution of the program. The AMTIC Web site[2] provides the current ESAT contacts list. Since the list may change, contact names will not be included in this document, but will be posted on AMTIC and updated on an annual basis.

Some important aspects of the ESAT contract include:

- Only the WACOR/TOCOR/DOCOR, RPO, and COs are authorized to give instructions or clarification (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 TOCOR/DOCOR and are effective only upon approval by the CO.

The EPA Contracts Manual describes the roles and responsibilities of COs, specialists, and project officers; these need not be explained here. The important roles and responsibilities for the Pb-PEP are described below.

Contracting Officers

- Work with OAQPS to secure, obligate, commit, and distribute funds for work performed under the ESAT contract (or other contract vehicle as appropriate).
- Ensure work assignment activities fall within ESAT's SOW.
- Approve work assignments, task orders, and delivery orders.

Contracting Specialists

- Work with OAQPS or Regional ESAT WACOR/TOCOR/DOCORs to modify contracts or track the use of funds for work performed under the ESAT contract (or other contract vehicle as appropriate).

Headquarters Project Officers

- Serve as regional liaison between the RPO and the CO.
- Provide contract-wide administration.
- Develop a memorandum of understanding with OSRTI.

Regional Project Officers

- Provide overall management and oversee performance of respective regional ESAT personnel.
- Review region-specific invoices with input from WACORs, TOCORs, and DOCORs.
- Prepare (with WACOR/TOCOR/DOCOR) Pb-PEP work assignments, task orders, and delivery orders.
- Assist in developing ESAT work assignments, task orders, and delivery orders.

[2] http://www.epa.gov/ttn/amtic/pbpep.html

- Ensure that there are qualified contractual personnel available to implement the Pb-PEP.
- Provide administrative and logistical support for the ESAT contract.
- Regularly communicate with program participants (OAQPS, Region, etc.).

Work Assignment, Task Order, and Delivery Order Contracting Officer Representatives

In most cases, the WACOR/TOCOR/DOCOR, as a technical resource from the regional air monitoring branch/division, will be responsible for assisting in the technical implementation of the program. Some of the WACOR/TOCOR/DOCOR's activities, as they relate to the ESAT contract, are the following:

- Communicate with the National PEP Project Leader about the current status of funding for the federally implemented Pb-PEP.
- Prepare (with RPO) Pb-PEP work assignments, task orders, and delivery orders.
- Set 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 the contractor's actions under the contract, as well as all technical information related to the Pb-PEP.
- Review the contractor's work plan and prepare findings on proposed tasks, labor hours, skill mix, and materials and quantities.
- Monitor compliance with the work assignments.
- Track dollars and hours, provide technical direction (in accordance with the terms of the contract), and review monthly technical and financial reports.
- Verify contractor representations of deliverables received and accepted, and/or progress made.
- Communicate contractor performance, budgetary, and administrative/logistical issues to the RPO and to the National PEP Project Leader.
- Review validation data and accept or reject Pb-PEP audits.

4.4 EPA Regional Offices

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:

- Assist in the development of all pertinent Pb-PEP evaluation guidance documents.
- Review and approve the work plans submitted by the ESAT contractors.
- Identify WACORs/TOCORs/DOCORs to oversee the technical aspects of field activities that are performed by the ESAT contractors.
- Train and certify ESAT field personnel and/or self-implementing agencies after initial training.

- Provide technical oversight of the field activities by performing annual TSAs of these activities.
- Work with monitoring organizations in developing a yearly schedule of site audits and provide this schedule to the ESAT contractors.
- Inform monitoring organizations of an upcoming performance evaluation.
- Evaluate the performance evaluation data and inform monitoring organizations of significant differences.
- Participate in training activities, including national and regional conferences, EPA satellite broadcasts, and other training vehicles.
- Attend conference calls and meetings on performance evaluation activities.

Region 9 (including items listed for all regions):

- Identify WAMs to oversee the technical aspects of laboratory activities related to high volume total suspended particulate (TSP) and low volume PM_{10} Pb analyses that are performed by the ESAT contractors.
- Develop and operate the primary laboratory for the Pb analyses with respect to logistical, technical, and analytical support, including necessary facilities to store and archive filters and extracts.
- Maintain and certify proficiency of ESAT laboratory personnel after initial training.
- Provide technical oversight of the laboratory activities by performing TSAs of these activities.

Region 4 (including items listed for all regions):

- Identify WAMs to oversee the technical aspects of laboratory activities related to low volume Pb-PM_{10} PEP filter preparation that are performed by the ESAT contractors.
- As a secondary role, identify WAMs to oversee the technical aspects of laboratory activities related to low volume Pb-PM_{10} PEP filter preparation that are performed by the state, local, and tribal agencies.
- Develop the primary laboratory for the low volume Pb-PM_{10} filter loading with respect to logistical, technical, and analytical support, including necessary facilities to store, distribute, and receive filters. The laboratory will also provide for the cleaning of cassettes.
- Train and certify ESAT laboratory personnel after initial training.
- Provide technical oversight of the laboratory activities by performing TSAs of these activities.

4.5 ESAT Contractors

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

- Develop a work plan and cost estimates for each work assignment, task order, or delivery order.
- Provide qualified staff to meet the contract requirements.
- Successfully implement the activities described in the work plan and work assignment, task order, or delivery order.
- Receive training and certification(s) to perform field and laboratory Pb-PEP activities, as appropriate.
- Understand government regulations as they relate to contracts and inherent government functions.

4.6 State, Local, and Tribal Agencies

EPA could not effectively plan and execute this program without SLT organization participation. The SLT agencies bear the heaviest responsibility for developing and implementing the national Pb Monitoring Program, as well as for optimizing the data quality. Conversely, the Pb-PEP provides an invaluable quality assurance/quality control (QA/QC) function on the overall performance of the network and often identifies potentially serious sampler performance problems, site problems, or laboratory issues. It is imperative that SLT organizations work with the EPA regional offices to make every Pb-PEP audit event successful. They should identify problems that will impede the mission of the Pb-PEP as early as possible and help find solutions. The SLT organizations have the following specific responsibilities:

General monitoring site accommodations:

- Ensure that there is sufficient space for collocating an audit monitor and low volume Pb-PM_{10} monitor or high volume Pb-TSP monitor, while still meeting siting requirements listed in 40 CFR Part 58, Appendix E and the Pb-PEP SOP.
- Ensure that each site is safely accessible for a Pb-PEP audit.
- Ensure that each site meets the applicable state or federal Occupational Safety and Health Administration safety requirements (includes providing secured ladders and appropriate safety rails and/or cages).
- Ensure that adequate power is available for the Pb-PEP samplers.
- If the above siting criteria cannot be met, the EPA Regional PEP leader must be consulted before continuing with the Pb-PEP audit.
- SLT monitoring programs are required to supply to the PEP analytical support laboratory either four or six samples annually from their collocated monitor at the collocated Pb monitoring sites.

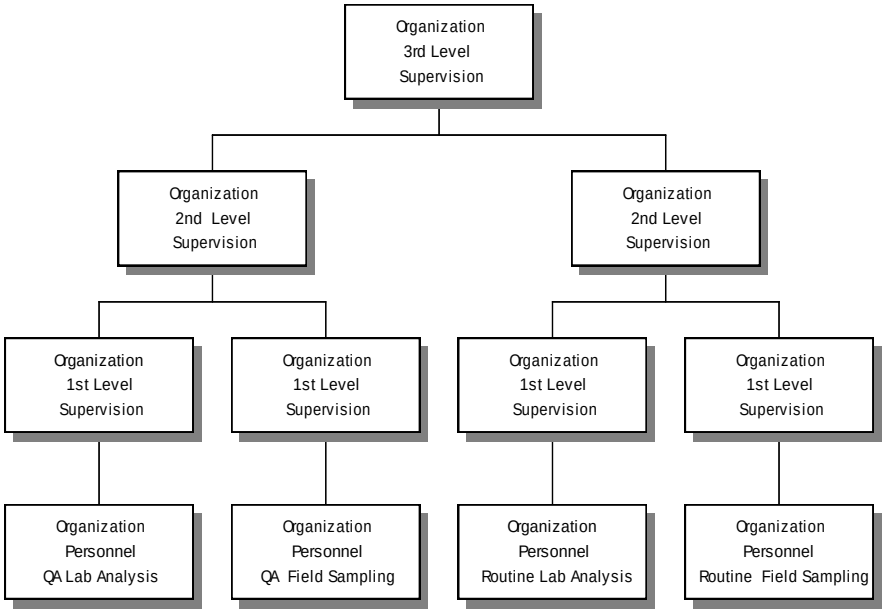
If an SLT chooses to implement the Pb-PEP:

- Implement a comparable or equivalent Pb-PEP at the frequency prescribed by the federal regulations in 40 CFR Part 58, Appendix A.

- Adhere to the definition of independent assessment (see Figure 4-1).
- Participate in consistent Pb-PEP specific training and certification activities.
- Procure necessary equipment and consumables.

Independent assessment—An assessment that is performed by a qualified individual, group, or organization that is not part of the organization that is directly performing and accountable for the work being assessed. This auditing organization must not be involved with generating the routine ambient air monitoring data. An independent organization could be another unit of the same agency, which is sufficiently separated in terms of organizational reporting and can provide for independent filter weighing and performance evaluation (PE) auditing.

An organization can conduct the PEP if it can meet the above 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. In addition, the audit filters must be analyzed by separate laboratory facility using separate laboratory equipment. Field and laboratory personnel would be required to meet the PEP field and laboratory training and certification requirements. The SLT organizations are also asked to consider participating in the centralized field and laboratory standards certification process.



Organizations that are planning to implement the PEP must submit a plan that demonstrates independence to the EPA regional office that is responsible for overseeing QA-related activities for the Ambient Air Quality Monitoring Network.

Figure 4-1. Definition of an Independent Assessment

- Develop the necessary SOPs and QA procedures into their respective QAPPs.
- Participate in annual collocation precision studies of the SLT and federally deployed Pb-PEP samplers.
- If necessary, transmit data to the AQS according to the schedule outlined in the monitoring QA regulations and procedures provided by EPA. (If an SLT chooses the federal Pb-PEP, or chooses to use the PEP analytical support laboratory, the data are transmitted automatically.)
- Select the sites for evaluation.
- If using a third-party laboratory, require that laboratory to participate in an annual round-robin PE if available. This is not required if the SLT uses EPA's Pb-PEP laboratory for its filter analyses.
- Prepare a laboratory annual report in an EPA-specified format and submits it to EPA. This is not required if the SLT uses EPA's Pb-PEP laboratory for its filter analyses.
- Submit to an annual TSA of their Pb-PEP activities by the EPA Regional PEP Leader or QAM.

If using the federal PEP:

- Operates the routine Pb federal reference method (FRM)/FEM monitoring network according to the established regulations and guidelines, including proper siting, operations, and QA procedures.
- Creates an accurate list of SLAMS, SPMS or tribal sites with addresses, AQS identifications (IDs), makes and models of routine sampling equipment, and sampling schedules.
- Assists, through PEP Workgroup activities, in the development of pertinent PEP guidance documents.
- On a yearly basis, determines whether to continue using the federal implementation of the PEP.
- Identifies the sites within the routine Pb FRM/FEM monitoring network for PEs and the associated sampling schedules.
- Ensures that an Agency representative is aware of when the PEP Field Scientist (FS) arrives and performs the evaluation. The evaluation includes communicating with the operator, operating the routine monitor in the normal operating mode (including posting site results to the AQS), and generally supporting the PEP.
- Conducts follow-up of the audit to ensure a valid routine concentration (for a routine PEP pair) is collected for comparison. If a valid pair has not been collected, a "make-up audit" is strongly encouraged).
- Ensures the program's success by performing various internal oversight activities of the SLT monitoring networks, such as TSAs of field and laboratory activities.
- Participates in training activities, including multi-state conferences, EPA satellite broadcasts, and other training vehicles.
- Reviews routine and PE data and works with the EPA Region on corrective actions.

4.7 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, advisor, and arbiter of technical issues. This action will be primarily through the National Environmental Research Laboratory, which provides many of the applied research elements for the program. ORD also has the overall responsibility for designating all air monitors as an FRM or FEM. The FRM/FEM portable PM_{10} low volume audit samplers must be designated by ORD through its Federal Reference and Equivalency Program (40 CFR Part 53). **The high volume TSP samplers are not given FRM/FEM designation. The method is described in 40 CFR Part 50, B as a specification that high volume TSP samplers must follow.** The overall responsibilities of ORD include the following:

- Designate PM_{10} low volume Pb samplers as FRM/FEM and provide technical support.
- Provide technical support for the national monitor procurement contracts.
- Arbitrate Pb-PEP technical issues.
- Provide 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.

EPA Contracts Management Division Responsibilities

The CMD, within the Office of Acquisition Management, is responsible for issuing contracts and various national procurements. These contracts are developed in concert with OAQPS AQAD technical staff. The CMD is responsible for all communications with vendors and extramural contract organizations. The CMD's responsibilities include the following:

- Developing national contracts for the sampler purchases and filter purchases and working with ORD and Office of Air and Radiation (OAR) contracts and technical staff to provide these products.
- Providing support to COs and contract support staff for national procurements for federal implementation of the Pb-PEP, major equipment repairs, and equipment upgrades.

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5.0 Problem Definition/Background

The background information provided in this element will place the problem in historical perspective, giving readers of the QAPP a sense of the project's purpose and position relative to the Ambient Air Monitoring Program.

5.1 Problem Statement and Background

In 1970, the Clean Air Act (CAA) was signed into law. Under the CAA, the ambient concentrations of six criteria pollutants (particulate matter, sulfur dioxide, carbon monoxide, nitrogen dioxide, ozone, and lead) are regulated. The CAA requires monitoring organizations to monitor these criteria pollutants through the Ambient Air Quality Surveillance Program as defined in 40 CFR Part 58.

On November 12, 2008, EPA substantially strengthened the national ambient air quality standards (NAAQS) for Pb (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 TSP, and revised the secondary (welfare-based) standard to be identical in all respects to the primary standard. In conjunction with strengthening the Pb NAAQS, EPA identified the need for states to improve existing Pb monitoring networks by requiring monitors to be placed in areas with sources that emit one half ton per year or more of Pb and in urban areas with more than 500,000 people. Depending on specific circumstances, states may have the option of using monitoring for either Pb in TSP (Pb-TSP) or Pb in PM_{10} (Pb-PM_{10}) using approved FRMs or FEMs 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 40 CFR Part 58 Appendix A:

- **Data Quality Objective (DQO) Goals-** Measurement uncertainty 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} low volume) or quarterly (TSP high volume) and flow rate performance evaluations will be implemented every 6 months.
- **Collocated Monitoring-**No changes occurred to the collocation requirements. Collocation will continue to be required at 15% of each method designation within a PQAO 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. 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 six Pb audit strips per quarter (three strips at two concentration ranges) has not changed. However, the audit concentration ranges have changed. The lower concentration range is 30 to 100% of the NAAQS and the higher concentration range is 200 to 300% of the NAAQS. This activity does not affect the Pb-PEP; however, the service lab for the PEP will participate in inter-laboratory comparative PEs.
- **Pb-Performance Evaluation Program (Pb-PEP)**-The implementation of an audit similar to the $PM_{2.5}$ PEP is a new requirement and it provides some assessment of overall bias. An additional focus on the laboratory analysis and the local primary sampler operating proficiency is included in the new Pb-PEP. The program as a whole will be a mix of one or two conventional PEP-like independent audits with additional collocated sampling conducted by the state or local agency using an independent analytical laboratory.

This QAPP focuses on one QA activity, the Pb-PEP, which is associated with Pb monitoring. The background and rationale for the implementation of the Pb FRM/FEM monitoring network can be found on the Office of Air and Radiation web site[3].

With the end use of the air quality samples as a prime consideration, various networks can be designed to meet one of the following six basic monitoring objectives:

- Determine the highest concentrations to occur in the area covered by the network
- Determine representative concentrations in areas of high population density
- Determine the impact on ambient pollution levels of significant source or source categories
- Determine general background concentration levels
- Determine the extent of regional pollutant transport among populated areas and in support of secondary standards
- Determine the welfare-related impacts in more rural and remote areas.

The monitoring network consists of four major categories of monitoring stations that measure the criteria pollutants. These stations are described below.

The SLAMS and Tribal Monitoring Network[4] consists of ~4,000 monitoring stations whose size and distribution are largely determined by the needs of tribal, state and local air pollution control agencies to meet their respective Tribal Implementation Plan and State Implementation Plan (SIP) requirements.

[3] http://www.epa.gov/air/lead/
[4] http://www.epa.gov/ttn/amtic/slams.html

The NCore Network[5] is a multi-pollutant network that integrates several advanced measurement systems for particulate matter, gaseous pollutants, and meteorology. The NCore network is a relatively new network of approximately 80 sites that has been operating since January 2011.

The Special Purpose Monitoring Stations (SPMS) network provides for special studies needed by the monitoring organizations to support their SIPs and other air program activities. The SPMs are not permanently established and, thus, can be easily adjusted to accommodate changing needs and priorities. The SPMs are used to supplement the fixed monitoring network as circumstances require and resources permit. If the data from SPMs are used for SIP purposes, they must meet all QA and methodology requirements for SLAMS monitoring.

The Photochemical Assessment Monitoring Station[6] (PAMS) network is required to measure ozone precursors in each ozone non-attainment area that is designated as serious, severe, or extreme. The required networks have from two to five sites, depending on the population of the area. The current PAMS network has approximately 80 sites.

This QAPP only focuses on the QA activities of the SLAMS, Tribal, NCore, and SPM networks and the objectives of these networks, which include any Pb sampler used for comparison to the NAAQS.

Throughout this document, the term "decision maker" will be used. This term represents the individuals who are the ultimate users of ambient air monitoring data and, therefore, may be responsible for activities such as setting and making comparisons to the NAAQS and evaluating trends. Because there is more than one objective for these data and more than one decision maker, the quality of the data will be based on the highest priority objective, which was identified as the determination of attainment of the NAAQS.

Since the data for the monitoring networks can be used for NAAQS comparisons, the quality of these data is very important. Therefore, a 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 DQO process to determine the allowable measurement system imprecision and bias that would not significantly affect a decision maker's ability to compare pollutant concentrations to the NAAQS. The precision requirement (20% coefficient of variation [CV]) and bias requirement ($\pm$15%) are based on total measurement uncertainty, which incorporates errors coming from all phases (e.g., field sampling, handling, analysis) of the measurement process. The collocated samples provide adequate estimates of precision and bias. The Pb-PEP, if properly implemented, can provide the bias estimate.

[5] http://www.epa.gov/ttn/amtic/ncore/index.html
[6] http://www.epa.gov/ttn/amtic/pamsmain.html

Pb-PEP Description

A PE 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 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 PE are found in 40 CFR Part 58, Appendix A, section 3.3.4.4. The number of audits required is based on the number of routine sites within a PQAO. The program will require the same number of audit samples as required for $PM_{2.5}$, however the responsibility for collecting the PEP samples may be shared between EPA and the SLT monitoring agencies:

- PQAOs with $\leq$ 5 sites require five audits (one EPA or independent audit, four SLT site-collocated audits)
- PQAOs with > 5 sites require eight audits (two EPA or independent audits, six SLT site-collocated audits)

The Pb PEP QAPP focuses on one QA activity, the Pb-PEP, which is associated with Pb monitoring. The background and rationale for the implementation of the Pb FRM/FEM monitoring network can be found on the Office of Air and Radiation Web site[7].

The strategy is to collocate a portable Pb air sampling instrument with a routine SLAMS or SPMS air monitoring instrument, operate both monitors in the same manner, and then compare the results. In addition to this collocation with an independent portable audit sampler, four or six filter samples (depending on number of total sites within a PQAO) as described above and in 40 CFR Part 58, Appendix A, Section 3.3.4.3 will be collected by SLTs from sites at which they operated their own collocated samplers for precision. EPA expects that these collocated samples would be collected and submitted as soon as possible to the EPA's PEP analytical support laboratory.

The implementation of the Pb-PEP is a monitoring organization responsibility. However, similar to the $PM_{2.5}$ PEP program, EPA has developed and implemented a federal Pb-PEP to acquire the independent PEP samples. Monitoring organizations have the option to self-implement the independent collection of PEP samples or they may utilize the federally implemented program. Self-implementation will require monitoring organizations to meet a level of independence and adequacy. 40 CFR Part 58 Appendix A and a guidance document by OAQPS at http://www.epa.gov/ttn/amtic/files/ambient/pm25/qa/pepadequacy.pdf provides the information on adequacy and independence. Since this information may change over the years, the guidance document will also be posted on AMTIC and will be reviewed annually and updated as necessary.

[7] http://www.epa.gov/air/lead/

EPA will use the ESAT contract that is currently in place in each Region to provide the necessary field and laboratory activities for the federally implemented program. Each EPA Regional Office will implement the field component of this activity. The EPA Region 9 Laboratory located in Richmond, CA, will be responsible for the lab analysis of high volume filters. An independent laboratory capable of performing X-ray fluorescence (XRF) analysis of the low volume PM_{10} Pb filters will be selected by OAQPS. In addition, the EPA NRMRL Metrology Laboratory will function as a field standards verification facility. The EPA Region 4 laboratory will provide back-up capabilities for the high volume filter analysis if the Region 9 laboratory requires assistance. OAQPS's technical support contractor will provide data management support including development and maintenance of web-enabled data entry forms, web reporting utilities, and posting final results to AQS. Note that some Agencies can assume the full responsibility of conducting the independent audits in their jurisdiction if they can meet the independence and adequacy requirements.

6.0 Project/Task Description

The purpose of this element is to provide the participants with a background understanding of the project and the types of activities to be conducted, including the measurements that will be taken and the associated QA/QC goals, procedures, and timetables for collecting the measurements.

6.1 Description of Work to be Performed

In general, the measurement goal of the Pb-PEP is to estimate the bias of routine Pb FRM/FEM national network, aggregated at various levels. These levels of aggregation are: local, tribal and state; PQAO; regional; and national levels. This is accomplished by: collocating a Pb-PEP sampler with a routine state, local or tribal Pb sampler; collecting a 24-hour sample; and comparing the two concentrations in units of micrograms per cubic meter ($\mu g/m^3$) measured at local conditions. The applicable regulations for this activity can be found in 40 CFR Part 58, Appendix A, Section 3.3.4.4.

The following sections describe the measurements required for the routine field and laboratory activities for the network. Independent field measurements will be performed by EPA's Regional ESAT contractors or by independent SLT PEP auditors. The SLT agencies will also provide four or six sample filters from at least one collocated site in each PQAO's network. High volume TSP samples will be analyzed with inductively coupled plasma mass spectrometry (ICP-MS) and low volume PM_{10} filters will be analyzed using XRF spectroscopy.

The following information provides a brief description of these activities. Detailed SOPs have been developed for all field and laboratory activities and have been distributed to all field, laboratory, and regional contacts identified on the distribution list described in Element 3.0, *Distribution*. These SOPs can be found on the AirQA Web site (https://www.sdas.battelle.org/AirQA/) under Pb PEP, Documentation, and on the AMTIC Web site (http://www.epa.gov/ttnamti1/). Figure 6-1 provides a basic description of the Pb-PEP.

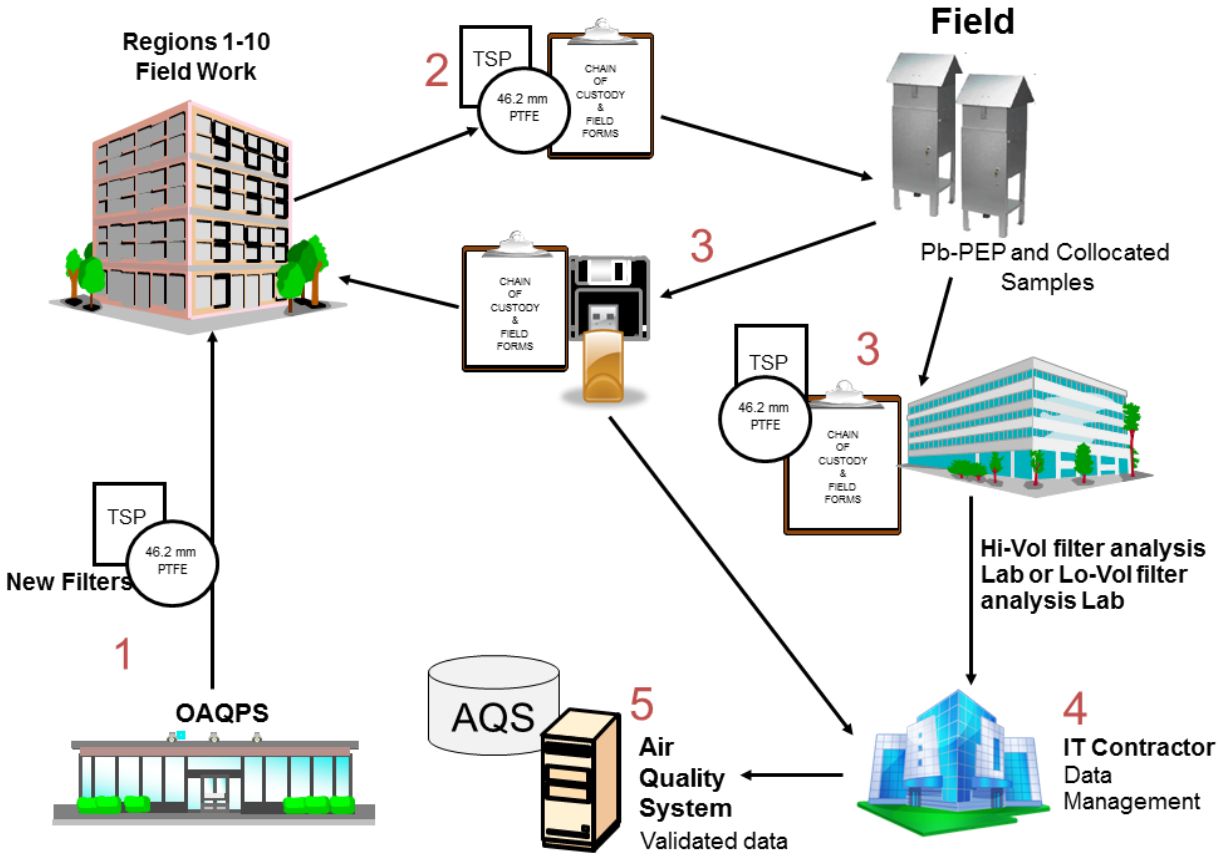


Figure 6-1. The Lead (Pb) PEP Overview

- EPA procures 8 inch × 10 inch high volume glass fiber filters and 47 mm polytetrafluoroethylene (PTFE) filters for the Pb high volume TSP and low volume PM_{10} samplers, respectively, operating in the national network for the calendar year.
- EPA subjects the production lot of these filters to acceptance testing that is required by the applicable FRM (see 40 CFR Part 50 Appendices B, G and L). SLTs generally receive glass fiber and 47 mm filters by ordering from OAQPS for their monitoring programs. Consequently, the SLTs may use their own supply of filters for their collocated PEP samples if the filters originate with the production lots purchased and tested by OAQPS under the national contract.
- EPA will distribute high volume filters directly to EPA Regions where they will be inventoried, inspected, and prepared for the field. Low volume filters for the Federal independent audits will be loaded into cassettes and shipped upon request to the requestor by EPA's designated handler, which is currently the EPA Region 4 Filter Weighing Lab.
- The auditor will initiate the electronic chain of custody (COC)/field data sheet (FDS) form on the AirQA Web site and print a hard copy to carry to the field. The SLT-collocated PEP sample COCs will be initiated by the operator or auditor designated by the SLT in the same manner.

- The auditor or SLT collocated sampler operator will take the filters and COC/FDS form to the field and operate the collocated Pb audit sampler (TSP or low volume PM_{10}).
- The auditor will collect and send high volume filters and signed copies of the COC/FDS forms to the Region 9 Pb-PEP Laboratory. Low volume filters will be collected and sent to EPA's designated XRF laboratory along with signed copies of the COC/FDS forms. A copy of the field data, instrument download data, and associated sampling records for all audits will be kept at the auditor's field office.
- The auditor or SLT collocated sampler operator will electronically enter the data from the COC/FDS form and upload the raw sampler data files on OAQPS's Pb-PEP data management Web site, AirQA, which is hosted and maintained by the technical support contractor.
- The Region 9 Pb-PEP Laboratory will receive, inspect, and analyze the high volume filters. EPA's designated XRF laboratory will receive, inspect, and analyze the low volume filters. Each support lab will validate their analytical results and submit analytical results along with electronic copies of the signed COC/FDS forms to OAQPS's technical support contractor via the AirQA Web site. The low volume cassettes will be shipped back to the EPA Region 4 Filter Weighing Lab to be washed and prepared for re-distribution.
- OAQPS's technical support contractor will process the electronic data submitted by the field and lab, associate the related data elements in the Pb-PEP database, perform automated data validation checks against the Pb-PEP acceptance criteria, and submit data for EPA's final review and approval.
- Each Region's Pb-PEP Lead (or designated QA Officers) will review the automated Pb-PEP validation results, indicate approval or rejection, and initiate investigation of any questionable data.
- OAQPS's technical support contractor will prepare and upload the approved data to EPA's AQS.
- The OAQPS program lead will assess the data calculating the bias statistic to determine bias within the Pb monitoring network.

6.2 Field Activities

There are two types of field operations of the Pb-PEP: independent Pb-PEP collocated audits and additional SLT collocated sampling runs. The independent Pb-PEP audits are conducted by the ESAT contractor or approved organization that performs a completely independent sampling event once if the PQAO contains five monitoring sites or less or twice if the PQAO contains more than five monitoring sites. Additional SLT collocated audits are conducted by the SLT at an existing collocated site at a rate of four or six samples according to the criteria above. These samples are separate from the normal collocated runs prescribed by the monitoring collocation requirements. In other words, these samples cannot be counted as a normal collocated run and Pb-PEP audit sample. This process is repeated for both high volume sampling and low volume sampling. Both high volume and low volume sampling methods must be audited. Individual methods within the high volume and low volume groups should be grouped together as one for

the aggregate count to determine the number of audits necessary. All sampling must be conducted in conformance to the prescribed FRM. General instructions are found in this Pb-PEP QAPP and specific instructions are detailed in the Pb-PEP high volume and low volume field SOPs.

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

- Samples must be collected and handled in a manner that adheres to the specifications in this QAPP and the SOPs for field activities.
- The samplers must be operated in adherence to the manufacturers' operating manuals, which discuss the sampler's proper transport, assembly, calibration, verifications, operation, and maintenance. All deviations must be identified in the PEP or SLT's SOP for that sampler and the applicable QAPP. Changes to the procedures of the independent audits will be vetted among and approved by the PEP work group.
- Siting criteria and operating schedules must adhere to specific site requirements defined in 40 CFR Part 58 Appendices D and E for the identified sites. An exception may be where a sampler is not properly sited according to 40 CFR Part 58, but the monitoring organization has an approved waiver from the EPA Regional ambient air monitoring program.
- Personnel who perform the Federal and SLT independent PEP audits must complete the required initial training and then participate in recertification training at least every 2 years. This training may be provided by qualified PEP trainers in the 10 EPA regional offices or OAQPS.
- For SLT collocated audits, agencies that have personnel other than independent auditors to set up these sampling events and collect the filter samples should ensure that the operators have been fully trained on the applicable requirements of the Pb monitoring network "Implementation Plan". The SLT auditors should be independent from the routine operators and preferably part of the QA staff.

The performance requirements of the Pb-PEP air sampler are specified in 40 CFR Part 50, Appendix B for TSP high-volume samplers and Appendix Q for PM10 low volume samplers. Appendix Q refers to the technical specifications for the low-volume samplers as stated in Appendix L; the only difference in the two methods is the absence of the $PM_{2.5}$ separator. Required recovery times and shipping schedule are provided in Section 6.4.4. Table 6-1 summarizes some of the more critical performance requirements.

Table 6-1. Design/Performance Specifications

Equipment	Acceptance Criteria	Reference
Pb-TSP Filter Design Specifications (Certified by Vendor)		
Size	20.3 ± 0.2 × 25.4 ± 0.2 cm	40 CFR Part 50, Appendix B, Section 7.1.1
Exposed Area	406.5 cm^2	40 CFR Part 50, Appendix B, Section 7.1.2
Medium	Glass Fiber	40 CFR Part 50, Appendix B, Section 7.1.3
Collection efficiency	99%	40 CFR Part 50, Appendix B, Section 7.1.4
Maximum pressure drop	*42–54 mm Hg at 1.5 std m^3/min*	40 CFR Part 50, Appendix B, Section 7.1.5
pH	*6–10*	40 CFR Part 50, Appendix B, Section 7.1.6
Integrity	2.4 mg maximum weight loss	40 CFR Part 50, Appendix B, Section 7.1.7
Tear Strength	500g min for 20mm strip in weakest dimension	40 CFR Part 50, Appendix B, Section 7.1.9
Pb-TSP Sampler Performance Specifications		
Min/Max sampler flow rate at actual conditions	1.1 to 1.7m^3/min	40 CFR Part 50, Appendix B, Section 7.2.2 and 7.2.3
Flow regulation	1.000 ±5% m^3/hr	40 CFR Part 50, Appendix L, Section 7.4
Flow rate sensor	Readable to nearest 0.02 m^3/min	40 CFR Part 50, Appendix B, Section 7.4.2
Ambient temperature sensor	-30°C–45°C 0.1°C res. ±1.0°C accuracy	Volume II–MS. 2.12 40 CFR Part 50, Appendix B, Section 7.5
Barometric pressure	500–800 mm Hg ± 5 mm res	40 CFR Part 50, Appendix B, Section 7.6.1 and 7.6.2
Clock/timer	± 5 minutes/24-h sample	No Reference
Pb-PM_{10} Filter Design Specifications (Certified by Vendor)		
Size	46.2-mm diameter ± 0.25 mm	40 CFR Part 50, Appendix L, Section 6.1
Medium	Polytetrafluoroethylene	40 CFR Part 50, Appendix L, Section 6.2
Support ring	Polymethylpentene or equivalent inert material 0.38–± 0.04 mm thick 46.2 ± 0.25 mm outer diameter 3.68 (± 0.00 mm, -0.51 mm) width	40 CFR Part 50, Appendix L, Section 6.3
Pore size	2 µm	40 CFR Part 50, Appendix L, Section 6.4
Filter thickness	30–50 µm	40 CFR Part 50, Appendix L, Section 6.5
Maximum pressure drop	30 cm H_2O at 16.67 LPM	40 CFR Part 50, Appendix L, Section 6.6
Maximum moisture pickup	10-µg increase in 24 hr	40 CFR Part 50, Appendix L, Section 6.7
Collection efficiency	99.7%	40 CFR Part 50, Appendix L, Section 6.8

Equipment	Acceptance Criteria	Reference
Filter weight stability	<20 µg	40 CFR Part 50, Appendix L, Sections 6.9.1 and 6.9.2
Alkalinity	<25.0 microequivalents/g	40 CFR Part 50, Appendix L, Section 6.10
Pb-PM$_{10}$ Sampler Performance Specifications		
Sample flow rate	1.000 m^3/hr	40 CFR Part 50, Appendix L, Section 7.4
Flow regulation	1.000 ± 5% m^3/hr	40 CFR Part 50, Appendix L, Section 7.4
Flow rate precision	2% CV	40 CFR Part 50, Appendix L, Section 7.4
Flow rate accuracy	± 2%	40 CFR Part 50, Appendix L, Section 7.4
External leakage	<80 mL/min	40 CFR Part 50, Appendix L, Section 7.4
Internal leakage	<80 mL/min	40 CFR Part 50, Appendix L, Section 7.4
Ambient temperature sensor	−30°C to 45°C 0.1°C resolution and ± 2°C accuracy	Volume II–MS. 2.12 40 CFR Part 50, Appendix L, Section 7.4
Filter temperature sensor	−30°C–45°C 0.1°C resolution and ± 1.0°C accuracy	Volume II–MS. 2.12 40 CFR Part 50, Appendix L, Section 7.4
Barometric pressure	600 mm Hg to 800 mm Hg 5-mm resolution and ± 10-mm accuracy	Volume II–MS. 2.12 40 CFR Part 50, Appendix L, Section 7.4
Clock/timer	Date/time 1 min resolution and ± 1 min/mo accuracy	Volume II–MS. 2.12 40 CFR Part 50, Appendix L, Section 7.4

The independent air samplers used by ESAT contractors will be purchased and distributed by EPA OAQPS. The samplers procured must be designated as FRM or meet FRM specifications in 40 CFR Part 50,
B (high volume) and Appendix L (low volume). SLT agencies that conduct independent audits must also use independent FRM samplers for their sampling events. The FRM-compliant sampling instruments should be intrinsically capable of accurately sampling for TSP- or PM_{10}-borne Pb. Nevertheless, the Pb-PEP auditors are responsible for verifying the performance parameters of the audit Pb samplers after assuming custody of the samplers. Quarterly internal audits of the samplers and annual verifications of calibrators are performed thereafter. Element 15.0, *Instrument/Equipment Testing, Inspection, and Maintenance Requirements*, lists all the primary operational equipment requirements for the Pb-PEP data collection operations. All additional support equipment will be listed in the Pb-PEP high volume and low volume field SOPs.

6.2.1 Independent PEP Sampling Events

The independent PEP sampling events are covered in detail in the Pb-PEP field SOPs for audits conducted by Federal ESAT contractors and SLT auditors. A summary of events is included in

this QAPP in Section 6.4.3.

6.2.2 SLT Collocated Site PEP sampling events

These events are performed at sites with collocated samplers that are owned and operated by SLT agencies. The samplers are routinely used to collect samples for precision measurements of the SLT's network to which the site belongs. SLT agencies will follow their own SOPs for sample collection while adhering to the provisions regarding sample shipping, data upload to the AIRQA database and audit validation prescribed in the Pb-PEP SOP and Pb-PEP QAPP.

6.2.3 Critical "Field Data" Measurements

The most critical measurement is the total amount of air drawn through the filter during a sampling event. The mass of Pb that has been deposited on the filter is divided by this value to determine the 24-hour average concentration of Pb during the sampling event. The PM_{10} is also dependent on the flow rate of the sampler, which determines how precisely the particulate matter separator at the inlet eliminates particles larger than PM_{10} from the filtrate. Table 6-2 lists the measurements that are made by the air sampler (or possibly other instruments) and are stored in the instrument for downloading during sample recovery.

Table 6-2. Field Measurement Requirements

Information to be Provided	Availability				Format	
	Anytime[a]	End of Period[b]	Visual Display[c]	Data Output[d]	Digital Reading[e]	Units
Pb-TSP Samplers						
Flow rate, average for the sample period	✱	✓	✱	✓	XX.X	m^3/min
Sample volume, total	✱	✓	✓	✓	XX.X	m^3
Temperature, ambient, minimum, maximum, average for the sample period	✱	✓	✓	✓†	XX.X	°C
Barometric pressure, ambient, minimum, maximum, average for the sample period	✱	✓	✓	✓†	XXX	mm Hg
Date and time	✓	—	✓	—	YY/MM/DD HH:mm	Yr/mo/day hr min
Sample start and stop time settings	✓	✓	✓	✓	YY/MM/DD HH:mm	Yr/mo/day hr min
Sample period start time	—	✓	✓	✓	YYYY/MM/DD HH:mm	Yr/mo/day hr min
Elapsed sample time	✱	✓	✓	✓	HH:mm	Hr min
Elapsed sample time out of specification[f]	—	✓	✓	✓	On/off	
User-entered information, such as sampler and site identification	✓	✓	✓	✓	As entered	
Pb-PM_{10} Samplers						
Flow rate, 30-second maximum interval	✓	—	✓	✱	XX.X	L/min
Flow rate, average for the sample period	✱	✓	✱	✓	XX.X	L/min
Flow rate, coefficient of variation for the sample period	✱	✓	✱	✓	XX.X	%CV
Flow rate, 5-minute average out of specification[f]	✓	✓	✓	✓	On/off	
Sample volume, total	✱	✓	✓	✓	XX.X	m^3
Temperature, ambient, 30-second interval	✓	—	✓	—	XX.X	°C
Temperature, ambient, minimum, maximum, average for the sample period	✱	✓	✓	✓	XX.X	°C
Barometric pressure, ambient, 30-second interval	✓	—	✓	—	XXX	mm Hg
Barometric pressure, ambient, minimum, maximum, average for the sample period	✱	✓	✓	✓	XXX	mm Hg
Filter temperature, 30-second interval	✓	—	✓	—	XX.X	°C
Filter temperature, differential, 30-minute interval, out of specification[f]	✱	✓	✓	✓ ●	On/off	
Filter temperature, maximum differential from ambient, date, time of occurrence	✱	✱	✱	✱	X.X, YY/MM/DD HH:mm	°C, Yr/mo/day hr min
Date and time	✓	—	✓	—	YY/MM/DD HH:mm	Yr/mo/day hr min
Sample start and stop time settings	✓	✓	✓	✓	YY/MM/DD HH:mm	Yr/mo/day hr min
Sample period start time	—	✓	✓	✓ ●	YYYY/MM/DD HH:mm	Yr/mo/day hr min
Elapsed sample time	✱	✓	✓	✓ ●	HH:mm	Hr min
Elapsed sample time out of specification[f]	—	✓	✓	✓ ●	On/off	
Power interruptions >1 min, start time of first 10 power interruptions	✱	✓	✱	✓	1HH:mm, 2HH:mm, etc.	Hr min
User-entered information, such as sampler and site identification	✓	✓	✓	✓ ●	As entered	

✓ Provision of this information is required.

† Legacy high volume samplers, if they use volumetric flow control, do not provide ambient temperature and barometric pressure. These values are necessary, however, to convert the flow rate recorded at standard conditions to flow rate at local conditions. The FRM allows a 24-hour average value supplied by the nearest National Weather Service reporting facility to be used if the ambient temperature and barometric pressure are not measured directly at the site. These measurements may also be made at the site with National Institute of Standards and Technology (NIST) Traceable instruments that have been certified to perform within acceptable accuracy within a year of the sampling event.

— Not applicable.

✱ Legacy high volume samplers do not provide very much real-time data. Provision of this information is optional. If information related to the entire sample period is optionally provided before the end of the sample period, the value provided should be the value calculated for the portion of the sample period completed up to the time the information is provided.

[a] Information must be available to the independent PEP auditor at any time the sampler is operating, whether it is sampling or not.

[b] Information relates to the entire sample period and must be provided following the end of the sample period until the auditor manually resets the sampler or the sampler automatically resets itself upon the start of a new sample period.

[c] Information shall be available to the auditor visually.

[d] Information will be available as digital data at the sampler's data output port following the end of the sample period until the auditor manually resets the sampler or the sampler automatically resets itself upon the start of a new sample period.

[e] Digital readings, both visual and data output, shall have no less than the number of significant digits and resolution specified.

[f] Flag warnings may be displayed to the auditor by a single-flag indicator or each flag may be displayed individually. Only a set (on) flag warning must be indicated; an unset (off) flag may be indicated by the absence of a flag warning. Sampler users should refer to Section 10.12 of Appendix L about the validity of samples for which the sampler provided an associated flag warning.

In addition to the measurements collected in Table 6-2, supporting field data will also be collected. These additional parameters are identified in the Pb-PEP high volume and low volume field SOPs and help to identify the samples, ensure proper COC, holding times, and data quality. The information may also be important for validating data that appear to be unusual or unexpected. This information is recorded on the COC/FDS Form.

6.3 Laboratory Activities

The Pb-PEP requires two separate analyses depending on the size range of the Pb particulate, the samplers which collect it, and the filter media on which it is collected.

ICP-MS Analysis for Glass Fiber Filters (High Volume TSP Sampling)
The primary activities and steps are:

- Preparation of extraction fluids and check standards for the ICP-MS
- Calibration and verification of ICP-MS
- Receipt of filter samples from the Federal and SLT independent auditors, and from the collocated sampler operators or auditors
- Recording COC data into the laboratory information management system (LIMS)
- Filter handling,
- Sample extraction
- Analysis of extracts with ICP-MS instrument
- Resulting data entry and validation
- Sample filter and extract retention and archival, and
- Transmittal of the results and validation data to the AIRQA Web site.

EPA Region 9 operates the Pb-PEP laboratory for the high volume Pb-TSP samples. Specific detailed instructions will be available in the laboratory SOPs. They are attached as **Appendix 3**.

XRF Analysis for PTFE 47 mm Filters (Low-Volume PM_{10} Sampling)
The primary activities and steps are:

- Receipt of filter samples from the Federal and SLT independent auditors, and from the collocated sampler operators
- Recording COC data into the LIMS
- Filter handling
- Analyze check standards with the XRF instrument
- Load Filters into XRF sample holders
- Subject Filters and blanks to XRF analysis
- Resulting data entry/management,
- Sample filter and extract retention and archival

- Transmittal of the results and validation data to the AIRQA Web site.
- Returning filter cassettes to the designated originator of the filters, presumably EPA Region 4 PEP support laboratory in Athens, GA.

EPA OAQPS will secure the Pb-PEP analytical XRF laboratory services for the low volume Pb-PM_{10} samples. Since this will be a commercial vendor, specific detailed instructions will be found in the laboratory SOPs. They are attached as **Appendix 4**.

The participating analytical support laboratories will implement an internal QA/QC program that incorporates the pertinent elements of good laboratory practices (GLPs). The GLP will include the following:

- Establishing specific QA goals and implementing procedures for the particular analyses performed in support of the PEP.
- Adherence to the vendor's operations manual for the proper operation of the extraction and/or analytical equipment (ICP-MS and XRF spectroscopy).
- Adherence to the SOPs for the program.
- Adherence to the standards, principles, and practices outlined in the Pb-PEP QAPP.
- Special attention must also be given to any activity involving filter handling. This area contains the greatest potential for introducing measurement uncertainty, and care must be given to the proper handling of both TSP and PM_{10} filters.

Table 6-3 provides the performance specifications of the laboratory environment and equipment.

Table 6-3. Laboratory Performance Specifications

Equipment	Acceptance Criteria
Pb-TSP Analyses	
Inductively Coupled Plasma Mass Spectrometer	MDL </= 0.0075 µg/m^3
Reagent Water	laboratory deionized water as described in EPA Region 9 Laboratory SOP 825.
Nitric Acid (HNO_3)	concentrated, trace metals grade or better (e.g. Baker Instra-Analyzed)
Argon gas supply	high-purity grade, 99.99%
Pb-PM_{10} Analyses	
X-Ray Fluorescence Spectrometer	MDL </= 0.0075 µg/m^3

6.3.1 Critical Laboratory Measurements

For generating a concentration, the critical lab measurement of high-volume TSP samples is the Pb concentration in μg/filter strip. This value is used to calculate the Pb concentration on the full TSP filter that, when divided by the air volume in cubic meters (m^3) pulled through the filter, provides a final concentration ($\mu g/m^3$). With respect to the XRF analysis, the resulting value is expressed as $\mu g/cm^2$. This value is multiplied by a specified exposed area for the 46.2 mm (4.62 cm) PTFE PM_{10} filter. Then it can be divided by the 24-hour volume of air sampled through it for the average concentration. In addition to these critical measurements, supporting laboratory data will also be collected to help identify the samples, ensure proper COC, holding times, and data quality. These additional parameters are described in more detail in Section13.0 *Analytical Methods Requirements* and in the laboratory SOPs.

6.4 Schedule of Activities

The Pb-PEP consists of laboratory and field activities that must be coordinated and completed in a timely and efficient manner for the program to be successful. This includes activities such as acquiring equipment and supplies, developing sampling and analytical schedules, initiating the COC/FDS forms, conducting the setup and sampling event at the site, extracting and analyzing filters, performing QC checks and data validation, and uploading to the AQS database. The sections below describe some of the time-critical components of conducting Pb-PEP audits. Additional detail is provided in the Pb-PEP SOPs.

6.4.1 Pb-PEP Audit Frequency

The sampling design has been codified in 40 CFR Part 58, Appendix A, Section 3.3.4.4, as:

"Each year, one performance evaluation audit, as described in section 3.2.7 of this appendix, must be performed at one Pb site in each primary quality assurance organization that has less than or equal to five sites and two audits at primary quality assurance organizations with greater than five sites. In addition, each year, four collocated samples from primary quality assurance organizations with less than or equal to 5 sites and six collocated samples at primary quality assurance organizations with greater than 5 sites must be sent to an independent laboratory, the same laboratory as the performance evaluation audit, for analysis."

In addition to the required criteria above, the Pb-PEP will audit all SLAMs and SPM Pb monitoring sites per PQAO over a 6-year period.

Pb sampling in the NAAQS and NCore network may be conducted using either the high volume or low volume sampling method. In determining how many Pb-PEP audits are required for a PQAO, all Pb monitoring sites, regardless of sampling method, must be added together to determine the correct audit frequency. The one exception will be that low volume PM_{10} sites in

the NCore network are treated as one PQAO. In this situation, each primary ***NCore*** PM_{10} Pb sampler will be audited once per year.

6.4.1.1 Pb-PEP at NCore

The NCore network is treated as its own PQAO when planning low volume PM_{10} Pb-PEP audits. Every primary, low volume PM_{10} Pb sampler at an NCore site will receive one Pb-PEP audit annually. The reason this frequency of audits was instituted was because that the NCore network contains only 20 sites with PM_{10} Pb samplers. 15% of these would provide an insufficient number of audits to calculate bias with any degree of confidence. If a PQAO has agreed to self-implement their Pb-PEP, they will be responsible to conduct an audit of each primary NCore PM_{10} Pb sampler in their jurisdiction.

There are approximately five NCore sites that have collocated PM_{10} Pb samplers. EPA is requesting that each of these collocated sites provide four SLT collocated sampler samples to the PEP analytical support laboratory during the course of a calendar year.

To sum up for the Pb-PEP, TSP samplers at NCore sites are to be treated like any other Pb samplers in the individual monitoring organization PQAOs. In other words such samplers go into the 6-year cycle, for one or two independent PEP audits, depending on the total number of Pb monitoring sites (which might include any non-NCore, low volume PM-10 Pb sites) in the PQAO.

6.4.2 Pb-PEP Sampling Schedule

On or before December 1, EPA Regions will work with monitoring organizations to select and develop a list of sites for the evaluations to be conducted for the next calendar year. The Regional WAM/TOPO/DOPOs, with the assistance of the ESAT contractors, will attempt to determine the most efficient site visit schedule. This schedule should be based upon the following:

- CFR requirements for audit frequency
- Network audit completeness (all sites audited in 6 years; all NCore PM_{10} Pb low volume samplers each year)
- Meeting the same monitoring schedule as the monitoring agency's routine samplers to be evaluated
- Site proximity (the sites that are closest in proximity to each other may be visited within the same day or week)
- Coordination with other audit programs ($PM_{2.5}$ and $PM_{10-2.5}$ PEP, and NPAP) if possible.

PEP audits should be conducted on normal sampling days so that the evaluation does not create additional work for the monitoring organizations. However, if the monitoring organization is amenable to perform a PE on a day other than a routine sampling day and is willing to post the

result to AQS, the Pb-PEP visit can be scheduled for that day.

SLT Collocated Sampling Events

SLTs have been instructed through the Pb monitoring QA Implementation Guidance to provide the collocated site samples from sampling events that are on different days than the precision sampling events. They are supposed to be seasonably distributed; however, if a make-up is needed the seasonality can be disregarded.

6.4.3 General Sequence of Pb-PEP Activities

6.4.3.1 "Independent" FRM Pb-PEP audit

Below is a list of activities, in general chronological order, that are performed by Pb-PEP field personnel (auditors) and the laboratory to conduct an **"Independent"** FRM Pb-PEP audit:

EPA, ESAT staff and independent SLT auditors who participate in the Pb-PEP are certified through hands-on exercises and a written examination in the operation, conduct, and management of the Pb-PEP activities. This activity is coordinated by the EPA OAQPS PEP program lead if the training event is conducted at the national level or by the EPA Regional PEP lead if conducted at the regional level.

1. The EPA WAM/TOPO/DOPO selects the Pb sites to be audited for the current calendar year by the Pb-PEP.
2. The WAM/TOPO/DOPO, auditor, and monitoring organization coordinate scheduling site visits if needed.
3. The auditor and site operators coordinate the details of the audit. EPA distributes boxes of glass fiber filters for the high volume TSP sampling to each EPA regional office and each SLT independent auditing group. EPA or its designated handler ships the PM_{10} filters to the auditor.
4. Each high volume filter recipient pulls a randomly chosen filter from the box and ships to the ICP-MS laboratory for lot blank analysis. PM_{10} filter blanks are supplied to the XRF laboratory by OAQPS or the designated handler.
5. The auditor transports the audit sampler to the site and evaluates the site for safety prior to setup.
6. The auditor assembles the sampler and sets the date/time, then performs leak checks, barometric pressure verifications, temperature (ambient and filter) verifications, and flow rate verifications.
7. The auditor performs the field blank exercise, if needed, and installs the sampling filter.
8. The auditor programs the sampler to run during a 24-hour sampling event (midnight to midnight).

9. The sampler pulls ambient air through a filter over a 24-hour time period on the scheduled date/time.
10. The auditor recovers the filter and downloads recorded sampling event summary data
11. The auditor disassembles the sampler.
12. The auditor packages the recovered filter and ships it along with the COC/ FDS forms to the analytical laboratory.
13. The auditor will enter the data from the COC/ FDS form(s) and upload the raw sampler data files to the OAQPS Pb-PEP data management Web site.
14. The Pb-PEP laboratory receives filters, logs them in as appropriate, and performs extraction and/or analysis.
15. The Pb-PEP laboratory reviews and validates the laboratory data.
16. EPA's technical support contractor will process the electronic field and laboratory data, associate related elements in the database, perform manual and automated data validation checks, and make the data available for review and approval.
17. The Regional Pb-PEP Leads (or designated QA Officers) approve data that are to be loaded into the AQS.
18. The OAQPS National Pb-PEP Lead ensures the Pb-PEP data are being validated on a timely basis and are acceptable and complete for AQS upload.
19. EPA's technical support contractor loads data into the AQS.
20. The OAQPS National Pb-PEP Lead uses the data to calculate the annual bias estimate.

6.4.3.2 SLT-owned Collocated site PEP samples

1. The SLT collocated sites from which samples are collected will be selected by the SLT. If the resulting data suggest there may be an operational issue, the use of that site in subsequent years will be determined in consultation with the associated EPA regional office.
2. The EPA regional office Pb-PEP contact and monitoring organization coordinate scheduling site visits if needed.
3. The SLT's site operators (and auditor(s), if utilized) coordinate the details of the sampling event used to collect the samples for the PEP.
4. If the SLT requests a separate supply of filters for PEP use, EPA OAQPS will ship the glass fiber filters or PM_{10} filters to the contact supplied by the SLT. A random sample of the glass fiber filters is taken from the box and supplied to the ICP-MS laboratory for a lot/lab blank. Each year EPA will be supplying a supply of 10 unused 47 mm PTFE filters to the XRF lab for background analysis. If the SLT uses a separate box of filters supplied by EPA and it is used for more than one year, the SLT should send one filter from the box in every year it is used beyond the first year.

5. If the SLT uses their own stock of filters, the person preparing the audit cassettes should send at least one randomly selected filter from the originating box of filters, whether glass fiber or 47 mm PTFE, to the appropriate ICP-MS lab or XRF laboratory.
6. The SLT operator or independent operator should note any parameter of the monitoring site that does not comply with the applicable regulations for Pb sampling. This information should be entered on the COC/FDS in the comment section. If a waiver has been issued for the site to be exempted for one or more requirements, the waiver should be noted also in the comments.
7. The SLT operator (or auditor) completes as much information as possible on the web-enabled COC/FDS at the AIRQA Web site.
8. The SLT's collocated sampler is typically permanently installed at the monitoring site; therefore transport and setup will not be necessary. The SLT operator (or auditor) performs leak checks, barometric pressure verifications, temperature (ambient and filter) verifications, and flow rate verifications.
9. The SLT operator (or auditor) should perform at least one field blank exercise per year per site from which PEP samples are derived.
10. The SLT operator (or auditor) installs the sampling filter.
11. The SLT operator (or auditor) programs the sampler to run during a 24-hour sampling event (midnight to midnight) that coincides with a routine sampling event of the site's primary sampler, but that is on a different day than a normal precision measuring event.
12. The sampler pulls ambient air through a filter over a 24-hour time period on the scheduled date/time.
13. The SLT operator (or auditor) recovers the filter and downloads recorded sampling event summary data. Post-sampling verification checks may be requested dependent on the make and model of the audit sampler, or if pre-sampling verification checks were outside of expected operating parameters
14. The SLT operator (or auditor) packages the recovered filter and ships it with the COC/ FDS forms to the analytical laboratory. EPA will supply prepaid shipping labels if the SLT requests it.
15. The SLT operator (or auditor) will complete the data entry on the web-enabled COC/ FDS form(s) and upload the raw sampler data files to the OAQPS Pb-PEP data management Web site.
16. The Pb-PEP laboratory receives filters, logs them in as appropriate, and performs either the extraction and ICP-MS analysis or the XRF analysis.
17. The Pb-PEP laboratory reviews and validates the analytical data and transfers it to the web-enabled QA Web site.
18. EPA's technical support contractor ensures the electronic field and laboratory data successfully merge, and the automated data validation checks occur. They make the data available for review and approval.
19. The Regional Pb-PEP Leads (or designated QA Officers and Independent SLT-PEP auditors) approve data that are to be loaded into the AQS.

20. The OAQPS National Pb-PEP Lead ensures the Pb-PEP data are being validated on a timely basis and are acceptable and complete for AQS upload.
21. EPA's technical support contractor loads data into the AQS.

6.4.4 Implementation Time Lines

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

6.4.4.1 Field Activities

For best practice, the independent PEP and SLT-PEP auditor should retrieve the filters within 24 hours of the end of the sample exposure period. For independent PEP audits additional time should be minimized. A passive blank could be collected to determine potential passive contamination during long periods when the sampler is not running. Another way to avoid this potential contamination is to arrange to retrieve the filter at or near the same time that the SLT agency retrieves the routine primary filter for that site's sampling event. Additional studies may be conducted to determine the potential impact of passive contamination over several days between the conclusion of the sampling event and retrieval. The SLT collocated site operator should retrieve the PEP sample at the same time the primary routine Pb filter sample is retrieved.

Ideally, the independent PEP and SLT-PEP auditor or SLT collocated site operator should ship PEP samples on the day of retrieval to the appropriate laboratory. However, the retrieval schedules for multi-site audit trips or long distances from offices may necessitate a need for more flexibility. The independent PEP auditor or SLT collocated site operator should ship the exposed filters within 48 hours of the end of the sampling period. Downloaded data from the portable sampler and COC/FDS data will be uploaded to the AIRQA Web site for Pb-PEP upon arrival back to the field office. Table 6-4 provides a summary of the key activities discussed above.

6.4.4.2 Laboratory Activities

Because Pb is very stable once deposited on a filter, the expedited analysis of individual samples is not critical. It is more practical and economically desirable to accumulate a number of filters for batch processing. The batch holding time for all filters is set at a maximum of 30 calendar days from receipt by the laboratory until analysis is performed. Validation and transmittal of the laboratory results to the QA Web site should be complete within 15 days.

Table 6-4. Implementation Summary

Activity	Holding Time	From	To
AUDITOR arrives on site and loads filter in the sampler	NA	AUDITOR Office	Mounting in sampler
Filter exposure	24 hours	Midnight (~12:00 a.m.) of prescribed sampling day	Midnight (~12:00 a.m.) following the sampling day
Filter collection[a]	≤ 24 hours	End of sampling period	Recovery

Sampler data collection	NA	Recovery	Site exit
Shipped to laboratory (best practice)	≤ 48 hours	End of sampling period	Shipment
Transmittal of sampler run data, FDS, and COC	24 hours	Upon arrival at field office	QA Web site
Laboratory analysis	≤ 30 days	Sample Delivery Date at lab	Analysis
Data Validation and Web Transmittal	15 days	Completion of analysis	Upload to AIRQA Web site

6.4.5 Assessment Time Lines

6.4.5.1 Data Availability

The Pb-PEP laboratories should complete data validation and transmit/upload it to the QA Web site within 15 days of the conclusion of the analysis of that batch. This data is immediately available to the PEP auditors, the SLT operators of the collocated site samplers, and Regional PEP leads. The Regional PEP leads are to review and approve or disapprove the recorded and posted results by the end of each month. This is so that additional audits may be scheduled in the event that a result has been invalidated due to circumstances associated with the conduct of the audit. Note that an ambient concentration below the validation threshold does not by itself constitute a reason for repeating an audit.

Each Pb-PEP audit result is posted to AQS as a conjugate to the monitoring site's value as derived from the primary, routine sampler. In order for the Pb-PEP data to post in AQS, the site's measured value must be already posted in AQS. SLT agencies are required to post SLAMS data to AQS within 90 days after the end of the quarter as shown in Table 6-5. The PEP technical support contractor will attempt to post available PEP data on or about the 15th of every month. PEP data that do not post will be placed back in the queue until the next posting date, at which time another attempt will be made to post it. Consequently, for SLT site data that are submitted after the quarterly due date, the PEP data will post at the next opportunity. If an SLT site's data have been posted and they do not see PEP data within 45 days after the last posted sampling event, they should contact the Regional PEP contact to investigate the status of the PEP data.

Table 6-5. Data Reporting Schedule for AQS

Reporting Period	Due Date
January 1–March 31	June 30
April 1–June 30	September 30
July 1–September 30	December 31
October 1–December 31	March 31

6.4.5.2 Data Assessments

The Regional ESAT contractors are tasked to provide initial reviews and assessments of the Pb-PEP field data. The Region 9 ESAT contractor and the Pb XRF analytical lab are tasked to provide full validation and assessments of the Pb-PEP laboratory data. The Regional EPA contacts are tasked to provide a final assessment of the Pb-PEP audit before it can be uploaded to AQS. Following the monitoring organization's submittals of quarterly Pb FRM/FEM data, OAQPS (via the support contractor) will load the Pb-PEP data into the AQS. The Pb-PEP Laboratory Managers and the OAQPS technical support contractor(s) will review the Pb-PEP data. They will report to the ESAT Workgroup and QA Workgroup any significant Pb-PEP operations issues that are reflected by the data. Once both routine data and PE data for a site are in the AQS database, OAQPS, EPA regions, and monitoring organizations can use the AQS data evaluation programs, based on data quality assessment techniques, to assess this information. National bias is determined based on statistical equations given in 40 CFR Part 58, Appendix A, Section 4.

6.4.6 OAQPS Reporting Time Lines

6.4.6.1 QA Reports

OAQPS will issue an Annual QA Summary Report through the use of the AQS AMP 255 Report. Additional data will be available to the Regional PEP lead and participating SLT agencies through the QA Web site. It will include:

- Basic statistics of the data including completeness;
- Pb-PEP audit results vs. routine SLAMS results;
- Results of collocation studies for precision of Pb-PEP samplers;
- QC charts for the laboratory;
- Pb-PEP sampler performance vs. acceptance criteria; and
- Results of blank analyses.

From the statistical analyses and results, Pb-PEP TSA findings, and a summary of the annual standard certifications, all collected over the course of each calendar year, a more comprehensive report will be generated. The Annual QA Report should be completed 6 months from the end of December of the calendar year which it represents. Every third annual report will be superseded by and incorporated into an interpretive 3-year QA Report drafted in the year following the third year in the evaluation period. In other words, this report is a composite of the third year's data and information and two previous annual reports, but with a more narrative interpretation and evaluation of longer term trends with respect to Pb-PEP sampler and operational performance. The first three-year report for the Pb-PEP will be drafted in 2014 and cover years 2011-2013.

6.4.6.2 Assessment Reports

OAQPS will perform a QA assessment of the Pb-PEP ESAT contractors and SLT organizations that have assumed some or all of the independent Pb-PEP activities as specified in Table 6-6. Initial assessment findings will be documented and reported back to the audited organization within 15 working days after the assessments. Final assessment reports, including responses to findings and follow-up activities, will be submitted to the National Pb-PEP Project Leader at OAQPS by the end of the first quarter of the following year to have the results summarized in the Annual QA Summary and 3-year QA Reports.

6.5 Project Assessment Techniques

An assessment is an evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, "assessment" is an all-inclusive term used to denote any of the following: audit, PE, management systems review (MSR), peer review, inspection, or surveillance. Definitions for each of these activities can be found in the glossary (Appendix A). Section 20.0, *Assessments and Response Actions*, presents the details of the assessments. Table 6-6 provides information on the organizations implementing the assessment and the frequency of these assessments.

Table 6-6. Assessment Schedule

Assessment Type	Assessment Agency	Frequency
TSA of auditor and field operations	EPA Regional office	One per year
Surveillance of auditor's operations	OAQPS at annual recertification of auditors or by the EPA Regional office as needed	One per year unless there is a need for additional Regional surveillance
Performance test of supporting Analytical Laboratories	NAREL and OAQPS	One per year
TSA of the laboratory operations	OAQPS or NAREL	One every 3 years
Data quality assessment	OAQPS	Every year

6.6 Project Records

The field and laboratory programs will establish and maintain procedures for the timely preparation, review, approval, issuance, use, control, revision, and maintenance of documents and records. Table 6-7 represents the categories and types of records and documents that are applicable to document control for Pb-PEP information. Information on key documents in each category is explained in more detail in Element 9.0, *Documentation and Records*.

Table 6-7. Critical Documents and Records

Categories	Record/Document Types
Management and organization	Reporting agency information Organizational structure Personnel qualifications and training Training certification Quality management plan Document control plan EPA directives Grant allocations Support contract
Site information	Network description Site characterization file Site maps Site pictures
Environmental data operations	Quality Assurance Project Plans Standard operating procedures Field and laboratory notebooks Sample handling/custody records Inspection/maintenance records
Raw data	Any original data (routine and quality control data) including data entry forms
Data reporting	Air Quality Index Report Annual state and local monitoring stations' air quality information Data/summary reports Journal articles/papers/presentations
Data management	Data algorithms Data management plans/flowcharts Data management systems
Quality assurance (QA)	Good laboratory practices Network reviews Control charts Data quality assessments QA reports System audits Response/corrective action reports Site audits

7.0 Data Quality Objectives and Criteria for Measurement

The purpose of this element is to document the DQOs of the project and to establish performance criteria for the environmental data operation (EDO) that will be used in generating the data.

7.1 Data Quality Objectives

DQOs are qualitative and quantitative statements derived from the DQO process that clarify the monitoring objectives, define the appropriate type of data, and specify the tolerable levels of decision errors for the monitoring program. By applying the DQO process to the development of a quality system for Pb, EPA guards against committing resources to data collection efforts that do not support a defensible decision.

During the process of revising the Pb NAAQS, the monitoring requirements for Pb were reviewed and included monitoring options such as:

- Change in *averaging time* of the indicator from the fixed quarterly average to either a rolling quarterly or monthly average; and a
- Option in *monitoring device* from the current FRM, the high volume TSP sampler, to use the low volume PM_{10} sampler in some circumstances.

Using the DQO process, EPA explored how changes in design value averaging times, sampling frequency, data completeness, precision, and bias affect one's ability to compare Pb estimates to a NAAQS value. A report on the DQO process can be found on the EPA AMTIC Web site[8]. Based on this evaluation, EPA identified a measurement quality objective (MQO) for precision of 20% for a 90% confidence limit CV and an overall absolute bias upper bound goal of 15%.

The Pb-PEP provides the measurements upon which the bias component of the national network DQO is evaluated. In many environmental measurements, bias can be measured and evaluated by simply introducing standard reference material into a measurement phase and evaluating the results. Because there is no accurate way of introducing a known concentration of Pb particles into a Pb sampler, the Pb-PEP was developed to serve, as closely as possible, as a reference standard by which a relative network bias can be determined.

This value will be generated by the combined data from the independently acquired PEP filter samples and samples from SLT collocated samplers that are submitted to and analyzed by the PEP laboratory. The dataset will also include similarly acquired data from the low volume PM_{10} samplers at NCore and other sites. Goals will be assessed on 3 years of data at the PQAO level of aggregation. While not mandated by the regulations, the bias for the different types of samplers and origin of the filters will also be determined from the dataset.

[8] http://www.epa.gov/ttn/naaqs/standards/pb/data/20080929DQO.pdf

7.1.1 Proposed Measurement Quality Objectives for Precision and Bias Data Quality Indicators

Once a DQO is established, the quality of the data must be evaluated and controlled to ensure that it is maintained within the established acceptance criteria. MQOs are designed to evaluate and control various phases (e.g., sampling, preparation, analysis) of the measurement process to ensure that total measurement uncertainty is within the range recommended by the DQOs. The MQOs can be defined in terms of the following data quality indicators:

Accuracy - A term that is frequently used to represent closeness to "truth" and includes a combination of precision and bias error components. The term "accuracy" has been used throughout the CFR and in some of the elements of this document. It is quite difficult if not impossible to make accurate real-time measurements of airborne Pb-containing particulate matter, therefore the accuracy of filter based measurements must be apportioned into measurement of precision and bias.

Precision - A measure of mutual agreement among individual measurements of the same property usually under prescribed similar conditions. This is the random component of error.

Bias - The systematic or persistent distortion of a measurement process, which causes error in one direction. Bias is determined by estimating the positive and negative deviations from the true or reference value as a percentage of the true or reference value.

Representativeness—A measure of the degree in which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

Detectability—The determination of the low-range critical value of a characteristic that a method-specific procedure can reliably discern.

Completeness—A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions. Data completeness requirements are included in the reference methods (40 CFR Part 50).

Comparability—A measure of confidence with which one dataset can be compared to another. Since the PEP data are generated in the same manner, with the small exception that PEP MQOs may be slightly tighter, comparability is not an issue at any level of aggregation. The PEP's collocation events for precision will also provide an indication of the comparability of the data produced from independent PEP audits and the results of analyzing the filters from SLT-owned collocated samplers.

7.2 Pb-PEP Measurement Quality Objectives

The Pb-PEP is, in essence, a small monitoring program. However, because it has the added importance of being the program used to estimate bias at the PQAO level, it must have a greater level of data quality than the national ambient air monitoring program. Tables 7-1, 7-2 and 7-3 list the MQOs for the field and laboratory activities of the Pb-PEP. Acceptance criteria have been developed for each of these MQO attributes. In theory, if these MQOs are met, measurement uncertainty should be controlled to the levels that will provide high confidence that the values can be compared to the DQO.

Some MQOs for Pb-PEP are more stringent than routine Pb measurement quality objectives of the national network. More detailed descriptions of these MQOs and how they will be used to control and assess measurement uncertainty will be described in other elements of this QAPP and in the SOPs.

The new Pb NAAQS requires that concentrations be reported at local or actual conditions. New samplers include temperature and pressure sensors in the sampling unit to record the flow rate at local conditions. Older model samplers without this capability may be used; however they require a conversion using a 24-hour average ambient temperature and pressure measurement. These data may be collected from other calibrated samplers that are at the monitoring site, or they may deploy separate NIST traceable instruments to take these measurements over the 24-hour run period.

Table 7-1. Pb Performance Evaluation Program Field Measurement Quality Objectives

Criteria	Frequency	Acceptable Range	Information (CFR, Method 2.2 or 2.8)	Flag
Sample Recovery	all filters	8–48 hours	Part 50 App B	
Sampling Period	all filters	1440 minutes ± 60 minutes midnight to midnight	Part 50 App B sec 8.15	
Sampling Instrument				
Average Flow Rate	every 24 hours of op	1.1-1.7 m^3/min (40-60 CFM)	Part 50 App B sec 8.8	
Filter			Part 50 App B sec 7.1	
Visual Defect Check (unexposed)	all filters	see reference	Part 50 App B sec 8.2	
Collection Efficiency	all filters	99 %	Part 50 App B sec 7.1.4	
Pressure Drop Range	all filters	42-54 mm Hg	Part 50 App B sec 7.1.5	
pH	all filters	6–10	Part 50, App B sec 7.1.6	
Pb Content	all filters pre-sampling batch check	< 75 µg/filter	Part 50, App G sec 6.1.1 Method 2.8 sec 6.2.1	
Verification/Calibration				
One-point Flow Rate Verification	During Set-up prior to every sample day	±7% from transfer standard; but within the range 1.1-1.7 m^3/min local conditions	Part 58 App A Method 2.2 sec 2.6	
One-point Temp Verification	During set-up prior to every sample day	± 2ºC of transfer standard		
Pressure Verification	During set-up prior to Every sample day	± 10 mm Hg of transfer standard		
Verification/Calibration				
System Leak Check	During pre-calibration check	Auditory inspection with faceplate blocked	Method 2.2 sec 2.0	
Flow Check (volumetric flow control)	After receipt, after motor maintenance or failure of 1-point check and 1/yr	5 points over range of 1.1 to 1.7 m^3/min within ± 5% limits of linearity	Method 2.2 sec 2.6	
Clock/timer Verification	Every visit	± 5 min	recommendation	
Precision				
PEP Collocated Samples	1/quarter/Region or Implementing SLT Agency; at least one will be at an SLT's collocated sampler site	PD ≤ 10% of samples > 0.02 µ/m^3 (cutoff value)	Pb-PEP Requirement	
flow resistance plate[a] verification	2/yr	Best fit curves from testing with 5 discs PD ≤5% at all points	Method 2.2 sec 2.6	
Audits				
Semi Annual Internal Flow Rate Audit	2/yr	±10% of audit standard if the unit is mass flow controlled, or if volume flow controlled, the design value specified by the manufacturer	Part 58, App A, sec 3.3.3	
Blanks				
Field Filter Blank (FB)	1/sample batch	< MDL	recommendation	
Trip Blank (TB)	≈ 10% of all filters	< MDL	per Field SOP	
Monitor Maintenance				
Inlet cleaning	1/3 mo	cleaned	recommendation	
Motor/housing gaskets	~400 hours	Inspected replaced	Method 2.2 sec 7	
Recommended Maintenance	per manufacturers' SOP	per manufacturers' SOP	NA	
Data Completeness	annual	100%		
Reporting Units	all filters	µg/m^3 at local temperature and pressure.	Part 50 App R	
Lower Detectable Limit	1/yr	0.02 µg/m^3	Part 50 App G sec 2.3	
Verification/Calibration Standards and Recertifications - All standards should have multi-point certifications against NIST Traceable standards				
Flow Rate Transfer Std.	1/yr	Resolution 0.02 m^3/min ± 2% reproducibility	Part 50, App B sec 7.8	
Field Thermometer	1/yr	2º C resolution	Part 50, App B sec 7.5	
Field Barometer	1/yr	± 5 mm Hg resolution	Part 50, App B sec 7.6	
Verification/Calibration				

[a]The PEP samplers' responses to pressure drop will be tested semi-annually by placing a series of plates with decreasing number of same size holes on the sampler. The curve generated by plotting the downstream flow rate against the number of holes can be compared to the previous curves to determine how the sampler is responding to pressure drop over time. This test can also be used to compare flow rates and performance of samplers across the PEP fleet. An action level of a 5% drop in flow has been temporarily established until the program has enough data to determine what the long-term performance behavior of the high volume samplers will exhibit.

Table 7-2. ICP-MS Laboratory Measurement Quality Objectives

Parameter	Code	Frequency	Criteria	Corrective Action Upon Criteria Failure	Flag
Initial Calibration	ICAL	Each day or every sample batch	≥ 0.995 Correlation Coefficient	No analysis until acceptable results	NF
Instrument Calibration Verification	ICV	After ICAL	90–110%	No analysis until acceptable results	NF
Continuing Calibration Verification	CCV	Every 10 Samples	90–110%	No analysis until acceptable results	NF
Calibration Blank	CB	After each ICV/CCV	< ½ QL	Stop analysis, recalibration and analysis of samples bracketed by unacceptable result	NF
Second Source Calibration Verification	SCV	Each batch	90–110%	No analysis until acceptable results	NF
Quantitation Limit Standard	QLS	After ICAL & after every 40 analytical samples	60–140%	Determine the cause and re-analyze.	
Method Blank	MB	Each Batch	< ½ QL	If sample results are non-detects or > 5 times MB accept results If sample results detectable and < 5 times MB rerun extract or prepare new strips	NF J
Lab Control Standard	LCS	Each Batch	85–115%	Re-analyze once to verify. If the recovery is still unacceptable (1) For PM_{10} filter, all associated results are reported and qualified (2) For TSP filter strip, the MB, LCS, and all associated samples must be re-prepared and re-analyzed if there is enough sample to work with.	J J
LCS Duplicate, Precision	LCS-D	Each Batch (PM 10Only)	≤ 20 RPD	Re-analyze once to verify. If exceeded again flag	J
Matrix Duplicate, Precision	MD	Every 20 samples (TSP Only)	≤ 20 RPD	Re-analyze sample and duplicate once. If exceeded again flag	J
Matrix Spike, Accuracy	MS	Every 20 samples (TSP Only)	70–130%	If the MS does not meet these criteria, examine other QC results to determine if a matrix problem exists. If laboratory performance is in control, the poor MS accuracy is likely to be matrix-related	J
Internal Standard	IS	Every analysis	60–125% of initial CB	If the intensities of the internal standards for the ICV, CCV, or CB are out-of-control, recalibrate and re-analyze the samples affected If the intensities of the internal standards for the ICV, CCV, and CB are within control limits but sample internal standards are out-of-control, rerun the sample or rerun at an appropriate dilution.	
Audit Strips		1/quarter	90–110%	Re-analyze extract. If failure extract/run another set.	
Reagents (HNO_3 and HCL)		NA	ACS reagent grade		
Pb nitrate Pb $(NO_3)_2$		NA	ACS reagent grade (99.0% purity)		

Table 7-3. XRF Laboratory Measurement Quality Objectives

Parameter	Code	Frequency	Criteria	Corrective Action Upon Criteria Failure	Flag
Filter Visual Defect Check (unexposed)	FDC	all filters	Correct type, size, no pinholes, defects or contamination	Discard filter and replace with filter meeting specifications.	
Pb blank filter Acceptance Testing	N/A	~ 20 test filters per lot	90% of filters < 4.8 ng Pb/cm2	Reject lot, request new filters from vendor.	
Pre Sampling Filter Holding Time	HTE	all filters	< 30 days before sampling	Required only if filters will be used for PM_{10} mass as well as Pb. If only used for Pb then 30 day pre-sampling holding time not required. Reweigh filters that exceed pre holding time criteria.	
Analysis Audits	FAA	6 filters/quarter, 3 at each concentration range	10% (percent difference)	Troubleshoot XRF unit and re-run samples.	
Lab Filter Blank	LFB	1/ sample run	<.003 µg/m3	Investigate areas for contamination including XRF unit, work area, petri slides, and background Pb in filter. Investigate filter handling procedures.	
Thin Film Standards (standard reference materials)	TFS	Beginning and end of each analytical run	XRF conc. + 3x the 1 sigma uncertainty overlaps the NIST certified conc.+ 1x its reported uncertainty	Troubleshoot and/or service the XRF unit. Recalibrate and rerun samples. Recertify thin film standards if necessary.	
Run time quality control standards, checking peak areas, background areas, centroid and FWHM	RTS	Beginning and end of each analytical run	Target value + 3 SD	Troubleshoot and/or service the XRF unit. Recalibrate and rerun samples.	
XRF analyzer calibration (at least two thin film standards per element)	XAC	1/year or when significant repairs or changes occur or QC limits exceeded	XRF conc. + 3x the 1 sigma uncertainty overlaps the NIST certified conc. + 1x its reported uncertainty.	Troubleshoot and recalibrate the XRF unit. Rerun samples.	
XRF detector digital signal processor calibration	XSP	1 per week	Within manufacturer specifications	Troubleshoot and recalibrate the XRF unit. Rerun samples.	

8.0 Special Training Requirements/Certification

The purpose of this element is to ensure that any specialized or unusual training requirements to conduct the Pb-PEP are implemented. Within this element, the procedures are described in sufficient detail to ensure that specific training skills can be verified, documented, and updated as necessary.

OAQPS has developed a two-fold Pb-PEP training program. The first aspect of the training program is to ensure all monitoring personnel have a baseline level of knowledge about the Ambient Air Monitoring Network, the principles and operation of the Pb-PEP, and the QA procedures. This phase of training is ongoing and includes the following:

- National-level conferences and training workshops
- An air training facility for hands-on experience
- National- and Regional-level conference calls
- Individual sessions upon request
- All documentation of SOPs and current materials used in Pb-PEP training are posted on the AMTIC website at http://www.epa.gov/ttnamti1/pbpep.html and on the AIRQA Web site at https://www.sdas.battelle.org/AirQA/

Focused training for the Pb-PEP includes the following, and is required at least once every two years for staff who conduct Pb-PEP audits.

- Specific, extensive hands-on field and laboratory training sessions, which are sponsored and developed by OAQPS, and involve the ESAT contractors, regional personnel, and monitoring organization personnel.
- A certification program to "certify" the ESAT field and laboratory personnel. This certification will involve a written test, as well as a performance test. Failure of either of these tests will result in retraining until the personnel achieve successful certification.

8.1 OAQPS Training Facilities

EPA, through its regional laboratories and OAQPS, has multiple training facilities, which provide the capacity to:

- Develop internal expertise in Pb monitoring and analysis
- Have monitoring equipment readily accessible to EPA staff for questions and concerns
- Perform field and laboratory training for personnel at EPA, regional, monitoring organizations, and ESAT
- Perform special studies (study monitor performance, evaluate measurement uncertainty)
- Perform research studies for future monitoring activities.

8.2 Training Program

The field and laboratory Pb-PEP training program will involve the following four phases:

Classroom lecture. This will include an overall review of the Pb program and the consequential importance of the Pb-PEP. Classroom lectures will also be implemented for each training module. Revisions to the training modules and SOPs are made based on suggestions from Pb-PEP field scientists and a subsequent annual evaluation and consensus of the EPA Pb-PEP WAM/TOPO/DOPOs and the QA Workgroup.

Hands-on activities. After a classroom lecture, personnel will be taken to the training area where the field/laboratory activities will be demonstrated, and then the trainees will perform the same activity under instruction.

Certification–written exam. A written test will be administered to trainees to cover the information and activities of importance in each of the training modules.

Certification–performance exam. This is a review of the actual field implementation activities by the trainer/evaluator. Appendix B contains PE forms for this review.

Trainers will include OAQPS personnel from the AAMG QA Team, as well as regional Pb-PEP QA staff and contractors who are certified by OAQPS to conduct Pb-PEP field and laboratory audits.

8.3 Field Training

All personnel, which include EPA Regional WAM/TOPO/DOPOs and ESAT contractors, will be trained before performing Pb-PEP field data collection activities. Representatives of monitoring organizations are welcome to attend this training to satisfy the training requirement for their implementation of the Pb-PEP.

Field training/recertification will be conducted at a facility designated by OAQPS. One full certification course (if needed) and one recertification course will be conducted at least every two years. Additional training may be arranged at the discretion of OAQPS.

Field training for full certification may last up to two full days. Trainers are usually required to be available after the training for any individual trainees requiring more instruction.

Field training will include the following topics:

- Introduction to the Pb-PEP
- Planning and preparation
- Filter receipt, storage, and handling
- Sampler transport, placement, and assembly
- System checks

- Programming the run
- Filter exposure and concluding the sampling event
- COC
- Use of FDS
- Use of the online FDS entry forms and the OAQPS data management Web site
- Data verification via the AIRQA Web site
- QA/QC and information retention
- Troubleshooting in the field: When to perform multipoint verifications and calibrations (not typically performed in the field).

8.4 Laboratory Training

Region 9 performs Pb analysis on a routine basis for the Region 9 facilities. Consequently the Region 9 laboratory is required to have an established training program for ESAT contractors and will not need a separate specific Pb-PEP training related to filter extraction and analysis. However, personnel at the XRF contract laboratory are required to have their own training program. At both laboratories, personnel specifically used for the Pb-PEP filter analysis will be provided additional training related to the following topics that may be more ambient air related:

- Communications
- Filter handling
- COC and use of FDS
- Data entry and data transfer.

These topics could be covered through web-based training, attending the field certification training, or by EPA personnel.

8.5 Certification

Certification is required by EPA and will help ensure that field and laboratory 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. This certification is required at least once every two years for EPA regional leads, SLT staff, and ESAT contractors who are involved in the Pb-PEP.

Both the written exam and the performance review are considered part of the certification requirements. The written exam is gauged to review the more critical aspects of the Pb-PEP and to identify where the individual requires additional training. The written test will be generated by OAQPS. A score of 90% is required for passing the written exam. The PE is focused on ensuring that the individual understands and follows the SOPs. The trainer(s) will evaluate the trainees' implementation of the topics identified in the field and laboratory sections above. Appendix B provides the qualitative check forms that will be used during the evaluation of field and laboratory performance.

The intent of the certification activities is not to fail individuals, but to determine where additional training is required to ensure that the Pb-PEP is implemented consistently across the nation. By testing and evaluating each module, the trainer(s) will be able to identify the areas where individuals will require additional training. If many individuals fail a particular component, this may indicate that the classroom or hands-on training is not adequate. In any case, failure by individuals of parts of either the written or hands-on PE will indicate that more training is required. Trainees will be required to attend additional training on these components. Trainers will be available for an additional day of field/laboratory training and will ensure that personnel are certified by the end of the training session.

If the certification or recertification activities identify individuals who appear to be incapable of properly performing the field/laboratory activities, the ESAT WAM/TOPO/DOPOs and RPOs will be notified to initiate remedial action.

8.6 Additional Pb-PEP Field and Laboratory Training

Annual certifications and recertifications will be arranged and conducted by OAQPS. Personnel turnover is expected among Pb-PEP contractors and monitoring organizations. Occasionally, the Pb-PEP contracts will be awarded to new contractors. This situation will dictate that a second full training course needs to be conducted in the same year. The WAM/TOPO/DOPOs will contact OAQPS as soon as possible when training is required. The following two options are available for training in these circumstances:

- Because WAM/TOPO/DOPOs will be trained and certified along with ESAT contractors, the WAM/TOPO/DOPOs are certified to train additional ESAT personnel.
- Individual training arranged at the discretion of OAQPS at its Research Triangle Park (RTP) air training facility.

OAQPS will work with the regional Pb-PEP leaders and the WAM/TOPO/DOPOs to determine the need for training and what method is logistically the most efficient for all involved.

8.7 Additional Ambient Air Monitoring Training

Appropriate training will be available to personnel supporting the Ambient Air Monitoring Program, commensurate with their duties. Such training may consist of classroom lectures, workshops, teleconferences, and on-the-job training. Over the years, many courses have been developed for personnel involved in ambient air monitoring and QA aspects. Formal QA/QC training is offered through the following organizations:

- EPA, OAQPS, AQAD (http://www.epa.gov/air/oaqps/organization/aqad/io.html)
- Air & Waste Management Association (AWMA) (http://www.awma.org)
- EPA Air Pollution Training Institute (APTI) (http://www.epa.gov/apti)

- EPA Office of Environmental Information (http://www.epa.gov/quality/trcourse.html)
- EPA regional offices

9.0 Documentation and Records

The purpose of this element is to define the records critical to the project, the information to be included in reports, the data reporting format, and the document control procedures to be used.

A document, from a records management perspective, is a volume that contains information and describes, defines, specifies, reports, certifies, or provides data or results pertaining to environmental programs. As defined in the Federal Records Act of 1950 and the Paperwork Reduction Act of 1995 (now 44 U.S.C. 3101-3107), records are: "...books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the U.S. Government under Federal Law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them..."

The following information describes the document and records procedures for the Pb-PEP. In EPA's QAPP regulation and guidance, EPA uses the term "reporting package," which will be defined as all of the information required to support the concentration data reported to EPA. This information includes all data required to be collected, as well as data deemed important by the Pb-PEP.

9.1 Information Included in the Reporting Package

9.1.1 Data Reporting Package Format and Document Control

The Pb-PEP has structured its records management system according to EPA's File Plan Guide (see http://www.epa.gov/records/tools/toolkits/filecode). A file plan lists office records and describes how they are organized and maintained. A good file plan is one of the essential components of a recordkeeping system and is key to a successful records management program, and can help complete the following:

- Document activities effectively
- Identify records consistently
- Retrieve records quickly
- Determine disposition of records no longer needed
- Meet statutory and regulatory requirements.

The Pb-PEP records management system uses the Agency File Codes (AFCs) to facilitate easy retrieval of information during EPA TSAs and reviews. The Pb-PEP records management also follows EPA records schedules, which constitute EPA's official policy on how long to keep

Agency records (retention) and what to do with them afterwards (disposition). More information on EPA records schedules can be found at the EPA Web site[9].

Table 9-1 includes the documents and records that will be filed according to the statute of limitations discussed in Section 9.3, *Data Reporting Package Archiving and Retrieval*. To archive the information as a cohesive unit, all the Pb-PEP information will be filed under the major code "Pb-PEP," followed by the AFC function code and schedule numbers listed in Table 9-1. For example, Pb-PEP project plans would be filed under the heading "Pb-PEP/301-093-006.1," and COC forms would be filed under "Pb-PEP/301-093-006.3." Each field and laboratory SOP provides instruction on the proper filing of data collected during the particular procedure.

Table 9-1. Pb-PEP Reporting Package Information

Agency File Code		Category	Record/Document Types
Function	**No.**		
301-093	**006**	**Program Management Files**	
	006.1	Management and organization	Organizational structure for the U.S. Environmental Protection Agency (EPA) and how the Regions and Environmental Services Assistance Team (ESAT) contractors fit into running the Pb-PEP Performance Evaluation Program (Pb-PEP) Organizational structure for the support contractors Pb-PEP project plans and subsequent revisions Quality Management Plan
	006.2	Monitoring site information	Site characterization file (site data sheets) Site maps Site pictures Monitoring Organization site contact information
	006.3	Field operations and data acquisition (by EPA Regional staff or contractors on behalf of EPA)	Quality Assurance Project Plans (QAPPs) Standard operating procedures (SOPs) Field logbooks and communications Sample handling/Chain-of-Custody (COC) Forms Documentation of instrument inspection and maintenance Field testing of Pb-PEP equipment
	006.4	Communications (contractor technical project activity)	Telephone record and e-mail between ESAT contractor and monitoring organizations Telephone record and e-mail between ESAT contractor and the Contract Officer's Representative (COR)

[9] http://www.epa.gov/records/policy/schedule

Table 9-1. Pb-PEP Reporting Package Information (Continued)

Agency File Code		Category	Record/Document Types
Function	**No.**		
301-093	006.5	Communications (EPA project activity)	Telephone record and e-mail between EPA Regional or headquarters staff and monitoring organizations and vice versa Telephone record and e-mail between EPA Regional and other EPA personnel (headquarters to Regions and vice versa)
	006.6	Equipment and instruments used by contractors in the Pb-PEP (records about charged time to the support of the program would reference AFC 405-202)	Procurement logs Inventories of capital equipment, operating supplies, and consumables Repair and maintenance (e.g., vendor service records, calibration records) Retirement or scrapping
405	**202**	**Contract Management Records**	
	202.1	Contract administration	Work assignments, task orders, delivery orders, and work plans Contractor monthly reports Technical directives from the COR to the contractor Invoices for consumables Requisite qualifications of field scientists (FSs) and laboratory analysts (LA) for Pb-PEP-related, contractor-implemented activities Training records and certificates of ESAT contractors conducted and issued by the EPA Regional ESAT COR
404-142-01	**179**	**Special Purpose Programs**	
	179.1	Data administration and integration	Data management plans/flowcharts Raw data: any original data (routine and quality control [QC] data), including data entry forms Data algorithms Documentation of Pb-PEP database (PED) $PM_{2.5}$ PED data Field Data Sheets and COC Forms
404-142-01	**173**	**Data Files Consisting of Summarized Information**	
	173.1	Data summaries, special reports, and progress reports	Data/summary/monthly field activity reports Journal articles/papers/presentations Data validation summaries

Table 9-1. Pb-PEP Reporting Package Information (Continued)

Agency File Code		Category	Record/Document Types
Function	**No.**		
108-025-01-01	**237**	**State and Local Agency Air Monitoring Files**	
	237.1	QA/QC Reports	3-year Pb-PEP QA reports Pb-PEP data quality assessments QA reports Response/corrective action reports Site audits
405	**036**	**Routine Procurement**	
	036.1	Acquisition of capital equipment and supplies by EPA (either headquarters or Regional office)	Needs assessments and reports Program copies of purchase requests Requests for bids or proposals Proposals, bids, or quotations Bills of lading Warranties and certificates of performance Evaluations of proposals, bids, quotations, or trial installations
403-256	**122**	**Supervisors' Personnel Files and Duplicate Official Personnel Folder Documentation**	
	122.1	Personnel qualifications, training, and certifications	COR training certifications Certification as a Pb-PEP FS and/or LA Certification as a Pb-PEP FS trainer and/or LA trainer

9.1.2 Notebooks

The following types of notebooks will be required of field and laboratory personnel.

Field/Laboratory Notebooks. The Pb-PEP will require each FS and Laboratory Analyst (LA) to keep a notebook. Each notebook will be uniquely numbered and associated with the individual and the Pb-PEP. Although data entry forms are associated with all routine environmental data operations, the notebooks can be used to record additional information about these operations. In the laboratory, notebooks may also be associated with the temperature and humidity recording instruments, the refrigerator, calibration equipment/standards, and the analytical balances used for this program.

Field/Laboratory Binders. Three-ring binders may be used by each FS and will contain the appropriate data forms for routine operations, as well as inspection and maintenance forms and SOPs. Laboratories may keep records in their own LIMS.

Sample Shipping/Receipt Notebook. The sample shipping notebook will be kept by the FS and include information pertaining to sample shipments to the laboratories. The notebook will be

uniquely numbered and associated with the Pb-PEP program. It will include standard forms and areas for free-form notes. The laboratories may keep these records as a part of their own LIMS.

Field/Laboratory Communications Notebook. One communications notebook will be issued to each FS and LA to record communications. Element 21.0, *Reports to Management* provides more information about this activity.

9.1.3 Electronic Data Collection

All raw data required for calculating Pb concentrations, including QA/QC data, are collected electronically or on the data forms that are included in the field and laboratory SOPs. Field measurements listed in Element 6.0, Table 6-2 will be collected. Both the primary field and laboratory data will be collected electronically and primary data will be used to electronically calculate a final concentration. More details about this process can be found in Element 18.0, *Data Acquisition Requirements*, and Element 19.0, *Data Management*.

Various hard copies are created from electronic systems, such as database reports and spreadsheets used by the FS and others. Hard copies that are determined to be permanent record (e.g., data that lead to significant findings or conclusions) should be filed as a data reporting package to ensure that all Pb-PEP data are properly archived.

It is anticipated that other instruments will provide an automated means for collecting the information that would otherwise be recorded on data entry forms. Information on these systems is detailed in Element 18.0, *Data Acquisition Requirements*, and Element 19.0, *Data Management*. To reduce the potential for data entry errors, automated systems will be used where appropriate and will record the same information that is found on data entry forms. To provide a backup, a hard copy of automated data collection information will be stored as specified by EPA records schedules in project files.

9.1.4 Hand-Entered Data

Some data forms will be entered by hand. These forms can be found at the end of each field and laboratory SOP. All hard copy information will be completed in indelible ink. Corrections will be made by inserting one line through the incorrect entry, initialing and dating this correction, and placing the correct entry alongside the incorrect entry, if this can be accomplished legibly, or by providing the information on a new line.

9.1.5 E-mail and Attachments

EPA and ESAT contractors should use their own in-house e-mail and archiving protocols. All Pb-PEP e-mails should be saved or backed up routinely on a network server. Any e-mails or attachments that provide documentation noteworthy to the program such as data validation investigations, site observations, or official inquiries should be printed and stored in the Field/Laboratory Communications Notebook.

9.2 Reports to Management

In addition to the reporting package, various reports will be required by the Pb-PEP.

9.2.1 Laboratory Monthly Report

The laboratories will provide the oversight designee (TOPO/WACOR/DOCOR) with a written progress report at the end of each month. ESAT staffed laboratories will maintain a complete record of laboratory monthly progress reports or equivalent as required by the contract. Contract laboratories will adhere to the reporting stipulations in the current contract. The WACOR/TOCOR/DOCOR may request more information to be included in the monthly reports if he/she deems that it is necessary.

9.2.2 Field Monthly Report

The FS will provide the WAM/TOPO/DOPO with a written progress report at the end of each month (the deadline is the 15th calendar day of the following month unless otherwise specified by the WAM/TOPO/DOPO). See the Pb-PEP Field SOPs for the details of this report. This monthly report will be filed according to the schedule outlined in Table 9-1. If the FS also conducts $PM_{2.5}$ PEP audits, the Pb-PEP and $PM_{2.5}$ PEP reports may be merged together to avoid duplicating work.

The Monthly Progress Report (Form COM-2 from Pb-PEP Hi-Vol Field SOP and Pb-PEP Lo-Vol SOP) will convey the following information:

- Reporting date—The beginning and end date that the report covers
- Reporter—The person who is writing the reports
- Progress—Progress on field activities
  - Evaluations scheduled within the reporting date
  - Evaluations conducted within the reporting date
- Issues
  - Old issues—Issues reported in earlier reports that have not been resolved
  - New issues—Issues that arise within the reporting date
- Actions—The action necessary to resolve issues, including the person(s) responsible for resolving them and the anticipated dates when they will be resolved.

The WAMs/TOPOs/DOPOs may request more information to be included in the monthly reports if they deem that it is necessary.

9.3 Data Reporting Package Archiving and Retrieval

The information listed in Table 9-1 will be retained by the ESAT contractor for 4 years, and it is based on a calendar year (i.e., all data from calendar year 2009 will be archived until December 31, 2013). Upon reaching the 4-year archival date, the ESAT contractor will inform OAQPS and the regional Pb-PEP lead that the material has met the archive limit and will ask for a decision whether further archiving or disposal should be conducted.

10.0 Sampling Design

The purpose of this element is to describe all of the relevant components of the Pb-PEP sampling design, the key parameters to be estimated, the number and types of samples to be expected, and how the samples are to be collected.

10.1 Scheduled Project Activities, Including Measurement Activities

Element 6.0, *Project/Task Description,* Section 6.4 details the critical time lines and activities for the Pb-PEP.

10.2 Rationale for the Design

This QAPP reflects the EDOs for a QA activity, not a routine monitoring activity. The sampling design has been codified in 40 CFR Part 58, Appendix A, Section 3.3.4.4, as described below.

Each year, one performance evaluation audit, as described in section 3.2.7 of this appendix must be performed at one Pb site in each primary quality assurance organization that has less than or equal to 5 sites and two audits at primary quality assurance organizations with greater than 5 sites. In addition, each year, four collocated samples from PQAOs with less than or equal to 5 sites and six collocated samples at primary quality assurance organizations with greater than 5 sites must be sent to an independent laboratory, the same laboratory as the performance evaluation audit, for analysis.

On or before December 1, the regional WAM/TOPO/DOPOs will select the sites that meet the above criteria and compile a list of sites to be audited during the next calendar year. The Regional WAM/TOPO/DOPOs, with the assistance of the ESAT contractors, will determine the most efficient site visit schedule. This schedule will be based on

- CFR requirements for audit frequency
- Meeting the same monitoring schedule as the routine sampler being evaluated (this prevents the site from having to run and post an additional sample for the PE audit to AQS)
- Site proximity (the sites that are closest in proximity to each other can be visited within the same day or week).

10.3 Design Assumptions

The intent of the sampling design is to determine that the total measurement bias is within the DQOs described in Element 7.0, *Data Quality Objectives and Criteria for Measurement*. The sampling design will allow the Pb-PEP data to be statistically evaluated at various levels of aggregation to determine whether the DQOs have been attained. Data quality assessments will be aggregated at the following four levels:

Monitor Type. Monitor/method designation.

PQAO. All monitors within a PQAO.

Region. All contained within an EPA region

National. All monitors and possibly aggregated by method designation.

OAQPS believes it is important to stratify monitors by method designation to assist in the determination of instrument-specific bias (i.e., a particular make and model).

The statistical calculations for the assessments are found in 40 CFR Part 58, Appendix A. Once both the routine and PE data are in the AQS database, these calculations will be performed on the data and will allow for the generation of reports at the levels specified above.

The DQO for the Pb-PEP is based on how the NAAQS for Pb is determined. Attainment of the NAAQS for Pb is based on a rolling 3 month average from data collected from individual monitors; therefore, it is important to assess the PE data against the DQO at the same frequency and level of aggregation. The Pb-PEP data have limited use at the unique monitor level of aggregation. At the PQAO and national levels of aggregation, a sufficient amount of Pb-PEP data will be available to evaluate bias. The uncertainty of the Pb-PEP data will be controlled and evaluated by using various QA/QC samples described in Element 7.0, *Data Quality Objectives and Criteria for Measurement*, and Element 14.0, *Quality Control Requirements*. For example, the aggregation of the collocated samplers over the 3-year period will determine the precision of the program. Use of various blanks, verification checks, and inter-laboratory comparison studies can help to determine bias.

10.3.1 Representativeness

Representativeness is a measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition. The Pb-PEP design attempts to represent parameter variations at a sampling point by locating a high volume Pb-PEP sampler within 2 to 4 meters of the primary routine sampler and by operating the Pb-PEP sampler on the same sampling schedule as the routine sampler. In the same way, the low volume Pb-PEP sampler will be placed within 1 to 4 meters of the primary routine sampler and by operating the Pb-PEP sampler on the same sampling schedule as the routine sampler. The assumption is that the air within these areas is homogenous; therefore, both monitors will sample the same Pb load.

10.4 Procedure for Locating and Selecting Environmental Samples

The physical location of the routine monitor is the responsibility of the monitoring organizations and does not affect the intent of the PE. Site location information is entered by the monitoring organization into the AQS database. The critical piece of information is the AQS site ID (state, county, unit, parameter occurrence code), which must be entered into AQS for primary data to be loaded into the database. The ESAT FS will have access to this information.

For each site, the ESAT contractor will complete a Site Data Sheet (Form SD-01) that contains the following information:

- AQS site ID
- Monitor parameter occurrence code (POC)
- Method designation
- Monitor make and model
- Site coordinates
- Network type (SLAMS/Ncore)
- Reporting organization
- Reporting organization contact
- Street address
- Directions to the site (from the Regional office)
- Directions to the site from a major thoroughfare
- Safety concerns
- Additional equipment needed (ropes, ladders)
- Closest hospital (address)
- Closest express mail facility
- Closest hardware store
- Recommended hotel (address/phone)
- Important free-form notes
- Closest Pb site
- Closest $PM_{2.5}$ site

The information listed above will be kept in a site file (filed by AQS site ID) and included in a site notebook for each FS. 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.

Sites will not be visited and samplers will not be set up in conditions that are deemed unsafe. Unsafe conditions may include bad weather or monitoring platforms where the FS feels that he/she cannot transport or set up the monitor without jeopardizing his/her personnel safety. The FS will document the occurrence of any unsafe conditions so that mechanisms can be instituted to address the issue. This information will be conveyed to the WAM/TOPO/DOPO.

10.5 Classification of Measurements as Critical/Noncritical

Sections 6.2.2 and 6.3.1 classify the critical field and laboratory measurements for the Pb-PEP. Although the field and laboratory SOPs contain many additional measurements, they are considered noncritical.

10.6 Validation of Any Non-Standard Measurements

Because the Pb-PEP is deploying only FRM and FEM samplers and will be operating these samplers according to the established SOPs, there will not be any non-standard measurements. Also, because the Pb-PEP will be sending its filters to a certified laboratory using an FEM method for analysis, there will not be any non-standard measurements from the analysis of the filters.

11.0 Sampling Methods Requirements

The Pb-PEP provides for measurement of the mass concentration of Pb in ambient air over a 24-hour period. Two sets of SOPs for field sampling (*Field Standard Operating Procedures for the Federal Lead (Pb) Performance Evaluation Program:Hi-Vol Pb-TSP Audits and Field Standard Operating Procedures for the Federal Lead (Pb) Performance Evaluation Program:Lo-Vol Pb-PM_{10} Audits)* have been developed for the Pb-PEP and are to be used in all sampling activities under this QAPP. The following section will provide summaries of some of the more detailed information in the field SOPs. These summaries do not replace the SOPs.

11.1 Sample Collection and Preparation

The use of one portable FRM monitor is required for collecting Pb samples for the Pb-PEP. Because the goal is to provide comparable results across the nation, using one make and model of portable monitor to evaluate all of the routine monitors is advantageous. Using a single sampler model reduces the chances that bias and imprecision among different portable instrument models will confound the routine monitor comparisons.

11.1.1 Preparation

Before conducting an evaluation excursion for the week, the sampling equipment and consumables will be inspected to ensure proper operation and adequate supplies are available based upon the number of sites to be visited. Filters will be requested and stored per SOPs for transport to the sites. The filter COC/FDS will be initiated using the AIRQA Web site. Site data sheets, which contain information on characteristics for each site, will be available. For initial visits, some of the information on the site data sheets may be blank and must be completed during the first visit. The Pb-PEP FS will review the site schedule to be sure that they understand which tasks will be implemented at the sites they are visiting in a particular audit trip.

11.1.2 Field Sample Collection

The FS will travel to the monitoring sites to conduct the audits. Access to the monitoring site may be granted to the FS via meeting on site or another pre-arrangement. It is recommended, but not required, that the site operator be present during the audit. The portable high volume FRM monitors will be transported to within 2 to 4 meters of the routine monitor, assembled, and systems verified per the Pb-PEP field SOPs. The portable low volume FRM monitors will be transported to within 1 to 4 meters of the routine monitor, assembled, and systems verified per the Pb-PEP field SOPs. The filters will be installed and the monitor will be set to run on a midnight-to-midnight local standard time schedule. The FS 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 FS will contact the affected monitoring organizations and will also notify the Regional WAM/TOPO/DOPO.

Upon completion of sampling, the FS will return to the site(s), remove the sampling filter, visually inspect the filter, store it appropriately for transport to the laboratory, and download the data per the field SOPs. Each FS will have a laptop and digital data storage media to download and store sampler data. The FS should also contact the site operator to determine if the site sampler completed its run. If the run was not completed, the site should be re-audited at some point during the year.

11.1.3 Filter Transportation

It is important that the filters be properly stored and transported to the laboratory as soon as possible. Ideally, filters will be shipped the same day that they are removed from the monitors via next-day delivery. Filters and COC/FDSs will be included in the shipment. The FS will keep a copy of the FDS/COC Form (to file under Pb-PEP/301-093-006.3) and will record the number of filters shipped and the air bill number in the field notebook. On the day of shipping, the FS will contact the laboratory via email or phone to make its personnel aware of the shipment and to provide the laboratory with the number of filters shipped and the air bill number.

11.1.4 Return to Station

Upon completing a sampling excursion, the FS will return to the regional office and **enter the FDS/COC data into the electronic form on the Web site**. A second copy of the audit's field data will be stored at the field office and provided to the EPA Regional WAM/TOPO/DOPO. The WAM/TOPO/DOPO will use the COC/FDS form to QC the FS's data entry on the Web site. The WAM/TOPO/DOPO will mark the audit run as "Approved" if it passes the automated critical QC checks. The FS will also ensure that all equipment and consumables are properly stored and determine if ordering supplies or performing equipment maintenance are required. Vehicles will be serviced as required. The FS will debrief the WAM/TOPO/DOPO on the field excursion and will include information about whether the site visits remain on schedule.

11.1.5 Field Maintenance

A maintenance list will be developed by the Pb-PEP field personnel for all sensitive capital equipment. The list will contain columns for item, maintenance schedule, and date that will be filled in when maintenance (scheduled or unscheduled) is performed. See Element 15.0, *Instrument/Equipment Testing, Inspection, and Maintenance Requirements,* for this information.

11.2 Support Facilities for Sampling Methods

The analytical support facilities for the federally implemented Pb-PEP will be provided by the Region 9 laboratory in Richmond, CA for the high volume filters and by a contract laboratory selected by OAQPS for the low volume filters. These laboratories have been shown to meet the MQOs described in Tables 7-2 and 7-3, respectively.

11.3 Sampling/Measurement System Corrective Action Process

11.3.1 Corrections to the SOPs

The ESAT contractors are responsible for implementing this QAPP and the field SOPs and are responsible for the quality of the data. All methods will be reviewed and implemented by the ESAT contractors. If changes or corrections are required to the methods or QAPP, the ESAT contractor will notify the Regional WAM/TOPO/DOPO in writing. The Regional WAM/TOPO/DOPO will then convey the issue to the Pb ESAT Workgroup, which will review the change and attempt to classify it according to the effect that the change would have on the data. The classes follow:

- Class 1—The change improves the data and the new procedure replaces the current procedure. If the change is found to be acceptable by the ESAT Workgroup, a new SOP section will be issued that can be inserted into the compendium. The document control information in the heading will contain a new revision number and date. A Quality Bulletin will be completed to describe the change, and it will be distributed to all Regional WAMs/TOPOs/DOPOs and ESAT personnel.
- Class 2—The change provides for an alternate method that does not affect the quality of the data but may provide for efficiencies in some circumstances or be more cost effective. If the change is found to be acceptable by the Pb-PEP community, the original SOP will not be altered, but an addendum to the procedure will be initiated by EPA OAQPS that describes the modification and provides an alternate method.
- Class 3—The change is grammatical in nature and does not reflect a change in the procedure. The changes will be highlighted and modified during a Class 1 change (where appropriate) or will be corrected during the development of a full revision to the document.

Upon agreement by the ESAT Workgroup to institute a change, hard copies of Class 1 and 2 changes will be distributed using the Quality Bulletin illustrated in Figure 11-1.

Quality Bulletin

Subject:	Number _____ Date _____ Page _____of_____ Supersedes No. _____ Dated _____

Replace and Discard Original

Add Material to Document

Notes:

_____
Pb QA Coordinator

Retain this bulletin until further notice	☐
Discard this bulletin after noting contents	☐
This bulletin will be invalid after (Date) _____	☐
This bulletin will be incorporated into quality	☐
Procedure No. _____ by (Date) _____	☐

Figure 11-1. Illustration of ESAT Workgroup Quality Bulletin.

11.3.2 Data Operations

Corrective action measures in the Pb-PEP will be taken to ensure that the DQOs are attained. There is the potential for many types of sampling and measurement system corrective actions. Table 11-1 lists some of the expected problems and corrective actions needed for a well-run Pb-PEP. Some corrective actions can be addressed in the field while others are better addressed in a clean laboratory. This table does not attempt to dictate the appropriate location for repairs or troubleshooting but rather gives examples of potential issues and solutions.

Table 11-1. Field Corrective Action

Item	Problem	Action	Notification
Pre-Sampling Event Activities			
Filter inspection	Pinhole(s) or tear(s)	1) Additional filters will be brought to the site; use one of them. Void filters with pinholes or tears	1) Document on the FDS
Leak test	Leak outside acceptable tolerance (Table 7-1)	1) Completely remove the flow rate measurement adapter, reconnect it, and perform the leak test again 2) Inspect all seals and O-rings, replace them as necessary, and perform the leak test again 3) Check sampler with different leak test device 4) Use back-up sampler	1) Document in a log book 2) Document in a log book; notify the Regional WAM/ TOPO/DOPO; flag the data since the last successful leak test 3) Document in a log book; notify the Regional WAM/TOPO/DOPO
Ambient pressure verification	Out of specification (Table 7-1)	1) Make sure pressure sensors are exposed to the ambient air and are not in direct sunlight 2) Call the local airport or other source of ambient pressure data and compare that pressure to pressure data from the monitor's sensor. Pressure correction may be required 3) Connect a new pressure sensor	1) Document on the FDS 2) Document on the FDS 3) Document on the FDS; notify Regional WAM/TOPO/DOPO

Table 11-1. Field Corrective Action (Continued)

Item	Problem	Action	Notification
Ambient temperature verification.	Out of specification (Table 7-1)	1) Make sure that thermocouples are immersed in the same liquid at same point without touching the sides or bottom of the container	1) Document on the FDS
		2) Use ice bath or warm water bath to check a different temperature. If the temperature is acceptable, perform the ambient temperature verification again	2) Document on the FDS
		3) Connect a new thermocouple	3) Document on the FDS; notify the Regional WAM/ TOPO/DOPO
		4) Check the ambient temperature with another National Institute of Standards and Technology-traceable thermometer	4) Document on the FDS; notify the Regional WAM/TOPO/DOPO
Sample flow rate verification	Out of specification (Table 7-1)	1) Completely remove the flow rate measurement adapter, reconnect it, and perform the flow rate check again	1) Document on the FDS
		2) Perform the leak test	2) Document on the FDS
		3) Recalibrate the flow rate	3) Document on the FDS; notify the Regional WAM/TOPO/DOPO
		4) Verify it again; flow rate must be within ±5% of limits of linearity	4) Document on the FDS
Sample flow rate	Consistently low flows are documented during the sample run.	1) Check programming of the sampler flow rate	1) Document in the log book
		2) Check the flow with a flow rate verification filter and determine if the actual flow is low	2) Document in the log book
Post-Sampling Event Activities			
Elapsed sample time	Out of specification (Table 7-1)	Check programming; verify power outages	Notify the Regional WAM/ TOPO/DOPO
Elapsed sample time	Sample did not run	1) Check programming	1) Document on the FDS; notify the Regional WAM/TOPO/DOPO
		2) Try programming the sample run to start while the operator is at the site	2) Document in the log book; notify the Regional WAM/TOPO/DOPO

Table 11-1. Field Corrective Action (Continued)

Item	Problem	Action	Notification
Power	Power interruptions	Check line voltage	Notify the Regional WAM/ TOPO/DOPO
Power	Liquid crystal display (LCD) panel is on, but the sampler is not working	Check the circuit breaker	Document in the log book
Filter inspection	Torn filter or otherwise suspect particulate matter on the filter	1) Inspect area downstream of where filter rests in the sampler and determine if particulate matter has been bypassing filter	1) Document on the FDS
Data downloading	Data will not transfer to laptop computer	Document key information on the sample data sheet; make sure the problem is resolved before data are written over in the sampler microprocessor	Notify the Regional WAM/ TOPO/DOPO

11.4 Sampling Equipment, Preservation, and Holding Time Requirements

This section details the requirements needed to prevent sample contamination, the volume of air to be sampled, temperature preservation requirements, and the permissible holding times to ensure against degradation of sample integrity. In addition, Element 15.0, *Instrument/Equipment Testing, Inspection, and Maintenance Requirements*, provides information on sampler maintenance to reduce the potential of contamination or the collection of samples that do not represent the population of interest.

11.4.1 Sample Contamination Prevention

The Pb-PEP has rigid requirements for preventing sample contamination. Powder-free, antistatic gloves are worn while handling filters in the laboratory and the field. Filters should remain in protective boxes or a container where a few can be taken in the field but remain protected. Upon removal of filters from the sampler, they are folded in half lengthwise, placed in a glassine envelope and then into a shipping envelope for filter shipping to the laboratory.

11.4.2 Sample Volume

High volume Pb-PEP audit samplers operate at a rate of 1.1 m^3/min to 1.7 m^3/min to collect approximately 1750 m^3 of ambient air over a 24 hour period. Low volume Pb-PEP audit samplers operate at 16.67 liters per minute to collect approximately 24 m^3 of ambient air over a 24-hour period. Sampling time is expected to be 24 hours (midnight to midnight). The sample period must not be less than 23 hours or greater than 25 hours. If this occurs, the sample will be flagged, the Regional WAM/TOPO/DOPO will be notified, and the audit will not be approved.

11.4.3 Temperature Preservation Requirements

The glass fiber and Teflon® Pb-PEP filters have no temperature preservation requirements. The best practice would be to avoid placing the filters in extreme heat or cold.

11.4.4 Permissible Holding Times

The glass fiber and Teflon® filters used for the Pb-PEP have no specified holding time requirements for the laboratory. The general rule is for the filters to be analyzed within the month they are received so they may be validated and posted to the AIRQA Web site at the end of the month. In the field, there is no holding time to use the filters, but the 46.2 mm Teflon® filters should be used within 30 days. After recovery, all filters should be shipped to the laboratory as soon as possible to allow the laboratory enough time to analyze the filters by the end of the month for validation and posting.

12.0 Sample Handling and Custody

Due to the potential use of the Pb-PEP data for comparison to the NAAQS and the requirement for care in handling the sample collection filters, sample COC procedures will be followed. The laboratory SOPs and the field SOPs provide detailed instruction on filter-handling and COC procedures, which will not be included in this section.

Due to the amount of PM that is expected on these filters, improper filter handling can be a major source of error. Care must be taken when handling both exposed and unexposed filters. Filters should be handled in a manner to prevent them from being damaged or contaminated. Similarly, rough handling of exposed filters should be avoided because this may dislodge collected PM on the filters.

COC forms are used to ensure that

- Filters are processed, transferred, stored, and analyzed by authorized personnel.
- Sample integrity is maintained during all laboratory phases of sample handling and analyses.
- An accurate written record is maintained of sample handling and treatment from the time of receipt from EPA, through laboratory procedures, to disposal.

Proper sample custody minimizes accidents by assigning responsibility at each stage of sample handling and ensures that problems will be detected and documented if they occur. A sample is in custody if it is in actual physical possession of authorized personnel or if it is in a secured area that is restricted to authorized personnel. As illustrated in Figure 6-1, which appears in Element 6.0, *Project/Task Description*, the FDS/ COC form is printed from the AIRQA Web site and follows the filter into the field. The FDS/COC is completed at the end of the audit and is sent to the laboratory with the filter. Prior to shipping, the FDS/COC information is entered into the AIRQA Web site and the Pb-PEP laboratory's sample tracking system, where electronic records will be kept. In addition, the ESAT auditor will retain a copy of the COC in the field office as a record.

13.0 Analytical Methods Requirements

The analytical methods described below provide for the analysis of either TSP glass fiber filters or 46.2 mm Teflon® filters in the Pb-PEP. High volume TSP samplers will be used to audit TSP monitoring sites and these samplers will use the glass fiber filters. Low volume PM_{10} samplers will be used at low volume PM_{10} monitoring sites and these samplers will use the 46.2 mm Teflon® filters. The Region 9 laboratory will receive and analyze the glass fiber filters using ICP/MS, and an OAQPS contract laboratory will receive and analyze the 46.2 mm Teflon® filters using XRF.

The Region 9 laboratory provides routine analysis of environmental samples for a number of media (air/water/soil) for Region 9. It maintains a compendium of methods for the specific analytical technique but also support activities such as glassware cleaning, waste management, sample archive etc. The primary analytical methods for the high volume Pb-PEP are the extraction technique *Standard Operating Procedure 409 Digestion for Lead on Filters* and the analysis technique *Standard Operating Procedure 509 Determination of Lead on Filters by ICP/MS*. The following sections summarize methods 409 and 509. The 409 and 509 methods listed above have passed EPA equivalency testing defined in 40 CFR Part 53 Section 33 and been deemed FEMs in accordance with the FRM for high volume sampling listed in 40 CFR Part 50 Appendix G and the FRM for low volume sampling listed in 40 CFR Part 50 Appendix Q.

The OAQPS contract laboratory will be selected through the EPA contract laboratory mechanism. The contract laboratory selected will be required to use an approved FEM for the XRF analysis of the 46.2 mm Teflon® filters. The contract laboratory will provide a QAPP and an SOP to EPA, and the national Pb-PEP lead will review the documentation. In addition, the laboratory will be given audit filters to analyze to verify the laboratory's precision and minimum detection limit (MDL) to ensure that they can provide acceptable precision and quantification. The laboratory must be able to demonstrate precision on the test filters to 10% and an MDL of at least 0.02 $\mu g/m^3$. If the method, audit, and documentation are acceptable, EPA will enlist the laboratory's services.

13.1 Inductively Coupled Plasma Mass Spectrometry Analysis

13.1.1 Extraction of TSP Filters for ICP-MS Analysis (SOP 409)

The Region 9 SOP 409 provides sample preparation procedures for the determination of lead on PM_{10} filters or TSP filters by ICP-MS. This SOP is based on *40 CFR Part 50, Appendix G—Reference Method for the Determination of Lead in Suspended Particulate Matter Collected from Ambient Air*. This SOP extends the scope of the procedure to the digestion of PM_{10} filters and makes further modifications to utilize disposable labware to minimize contamination. Deviations from the reference method are described in Appendix A of 409 and the analyte and Chemical Abstracts Service (CAS) number are listed in Appendix B of 409.

In this method, nitric acid is dispensed into a digestion tube containing a PM_{10} filter or a $^3/_4$ inch × 8 inch TSP filter strip. Lead in the filter paper is digested by covering the tube with a watch glass and refluxing the sample via a hot block in the dilute acid mixture for 60 minutes. After digestion, the tube is allowed to cool. The digestate is then brought up to a final volume of 50 mL with reagent water, is capped, and shaken thoroughly. The digestate is set aside (with the filter in the digestion tube) for at least 30 minutes to allow the nitric acid trapped in the filter to diffuse into the digestate. The digestate is shaken thoroughly and allowed to settle for at least an hour. The sample is then ready for analysis by ICP-MS using SOP 509 *Determination of Lead on Filters*.

13.1.2 Analysis of TSP Filters Using ICP-MS Analysis (SOP 509)

SOP 509 provides procedures for the determination of lead in PM_{10} filter or TSP filter strip by ICP-MS. This SOP is based on procedures in EPA Method 200.8, *Determination of Trace Elements in Waters and Wastes by ICP–MS*, Rev. 5.4, May 1994. Deviations from the reference method are described in Appendix A of Method 509 and the analyte, CAS number, and quantitation limit (QL) are listed in Appendix B of Method 509.

This SOP describes the determination of lead on filter samples by ICP-MS after digestion with nitric acid or nitric acid/hydrochloric acid solution. Sample solutions are introduced by pneumatic nebulization into a plasma, in which desolvation, atomization, and ionization occurs. Ions are extracted from the plasma through a differentially pumped vacuum interface and separated on the basis of their mass-to-charge ratio by a quadrupole mass spectrometer. The ions transmitted through the quadrupole are detected by an electron multiplier. Ion intensities at each mass are recorded and compared to those obtained from external calibration standards to generate concentration values for the samples. Results are corrected for instrument drift and matrix effects using certified internal quality control standards. Additional corrections are applied as necessary to correct for isobaric and polyatomic elemental interferences.

13.1.3 Analytical Equipment and Method

A complete listing of the analytical equipment is found in laboratory SOP 509.

13.2 X-Ray Fluorescence Analysis

XRF analysis is based on energy dispersive X-ray fluorescence of elemental components in a thin film sample. The emissions of X-ray photons from the sample are integrated over time and yield quantitative measurements of elements ranging from aluminum (Al) through uranium (U) and semi-quantitative measurements of sodium (Na) and magnesium (Mg). A spectrum of X-ray counts versus photon energy is acquired and displayed during analysis, with individual peak energies corresponding to each element and peak areas corresponding to elemental concentrations.

As an example, the PANalytical Epsilon 5 XRF analyzer utilizes a side window dual anode X-ray tube with both scandium (Sc) and tungsten (W) anodes. X-rays are focused on one of 11

secondary targets, which in turn emit polarized X-rays used to excite a sample. X-rays from a secondary target or the tube are absorbed by the sample, exciting electrons to high level orbitals. As the electrons return to their ground state, photons are emitted which are characteristic of the quantum level jumps made by the electron; the energy of the emitted photons are, therefore, characteristic of the elements contained in the sample. The fluoresced photons are detected in a solid state germanium X-ray detector. Each photon that enters the detector generates an electrical charge whose magnitude is proportional to the photon's energy. The electrical signals from the detector are sorted into energy channels, counted, and displayed. A sample spectrum consists of characteristic peaks superimposed on a background caused by the scatter of X-rays from the tube into the detector.

13.3 Internal QC and Corrective Action for Measurement System

13.3.1 Corrections to the SOPs

The Region 9 methods are reviewed and approved by Region 9 EPA personnel including the Region 9 Laboratory Team Lead, the Region 9 Laboratory QAM, and the Region 9 Laboratory Director. The ESAT contractors are responsible for implementing this QAPP and the laboratory SOPs, and they are responsible for the quality of the data. All methods will be reviewed and implemented by the ESAT contractors. If changes or corrections are required to the laboratory SOPs or QAPP, the ESAT contractor will notify the Regional WAM/TOPO/DOPO and the Laboratory Team Lead in writing. The WAM/TOPO/DOPO will then convey the issue(s) to the Pb ESAT Workgroup, which will review the changes and attempt to classify them according to the effect the changes would have on the data.

The contract laboratory methods are reviewed and approved by the contract laboratory as needed. New revisions to the SOP will be forwarded to the National Pb-PEP lead at OAQPS. The contract laboratory will monitor and assess the changes in the SOP to ensure proper implementation.

13.3.2 Data Operations

A QC notebook or database (with electronic backups) will be maintained and will contain QC data and entry forms, calibration and maintenance information, and routine internal QC checks. Control charts will be maintained for a number of important QC components. These charts may allow for the discovery of excess drift that could signal an instrument malfunction. Corrective action measures in the Pb-PEP will be taken to ensure data of adequate quality. The laboratory's SOPs and Section 14 will provide additional information on these activities. Table 13-1 lists several filter preparation and analysis QC checks.

Table 13-1. Filter Preparation and Analysis Checks

Activity	Method and Frequency	Requirements	Action If the Requirements Are Not Met
Post-sampling inspection, documentation, and verification	Examine the filter and Field Data Sheets (FDSs) and COC for correct and complete entries.	No damage to filter; FDS/COC complete; sampler operated properly	Notify the Pb-PEP Laboratory Manager; flag filters in LIMS
Filter handling	Observe handling procedures	Use powder-free and antistatic gloves and smooth forceps (Teflon®).	Flag any mishandled filter in the LIMS
Filter integrity check	Visually inspect each filter	No pinholes, separation, chaff, loose material, discoloration, or filter non-uniformity	Flag any defective filter in the LIMS
Filter identification	Ensure filter number of filter and FDS/COC are the same.	Make sure the numbers are written legibly and compare	Flag any mislabeled sample in the LIMS and check with field personnel.
Internal QC	See Section 14 and analytical SOPs	Pass requirements	May require repeat analysis on extracts or second extraction and analysis

13.4 Filter Sample Contamination Prevention

The analytical support component of the Pb-PEP has requirements for preventing sample contamination. Powder-free and antistatic gloves are worn while handling 46.2 mm Teflon® filters, and TSP filters are only handled on unexposed edges. The 46.2 mm Teflon® filters are only handled with smooth non-serrated Teflon® forceps on the outer reinforcing support ring. Laboratory "Best Practices" should be employed while handling filters of any kind.

In the field component of the Pb-PEP, glass fiber filters are handled only on the edges, and the filters should be loaded in the transport cassette/carrier in a clean area in the office. The transport cassette should have a snap cover that should be in place during handling until the sample is loaded onto the high volume sampler. Each glass fiber filter should be packed for shipping in individual envelopes, and shipped in a protective envelope. The 46.2 mm Teflon® filters are shipped with a plastic lid covering the filter. The Teflon® filters should stay covered and in their cassettes to avoid contamination from the field. 46.2 mm Teflon® filters are covered with the plastic cap and kept in individual antistatic bags for shipping. Organizations outside the ESAT operated Pb-PEP may choose to remove the 46.2 mm Teflon® filters from the cassettes if facilities exist where this can be done without risk of contamination.

14.0 Quality Control Requirements

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 QA activities, such as establishing policies and procedures, developing DQOs, 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 QC procedures, such as audits, calibrations, checks, replicates, and routine self-assessments. In general, the greater the control that can be achieved of a given system, the better the resulting quality of the monitoring data.

QC is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that the stated requirements established by the customer are met. In the case of the Ambient Air Quality Monitoring Network, QC activities are used to ensure that measurement uncertainty, as discussed in Element 7.0, Quality Objectives and Criteria for Measurement Data, is maintained within acceptance criteria for the attainment of the DQO.

14.1 QC Procedures

Day-to-day QC is implemented through various check samples or instruments that are used for comparison. The MQO tables (Tables 7-1 to 7-3) in Element 7.0, *Quality Objectives and Criteria for Measurement Data,* contains a complete listing of these QC samples, as well as other requirements for the Pb-PEP. The procedures for implementing the QC samples are included in the field and laboratory SOPs, respectively. The following information provides some additional descriptions of these QC activities, how they will be used in the evaluation process, and what corrective actions will be taken when they do not meet acceptance criteria.

14.1.1 Calibrations

Calibration is the comparison of a measurement standard or instrument with another standard or instrument to report, or eliminate by adjustment, any variation (deviation) in the accuracy of the item being compared. The purpose of calibration is to minimize bias.

For the Pb-PEP, calibration activities follow a two-step process:

- **Step 1.** Certifying the calibration standard and/or transfer standard against an authoritative standard.
- **Step 2.** Comparing the calibration standard and/or transfer standard against the routine sampling/analytical instruments.

Calibration requirements for the critical field and laboratory equipment are found in Tables 7-1 through 7-3; the details of the calibration methods are included in the calibration section (Section 16.0, *Instrument Calibration and Frequency*) and in the field and laboratory SOPs.

14.1.1.1 Field Calibration Evaluation

Field equipment calibrations will be evaluated using independent NIST traceable standards.

Accuracy of field verification/calibration checks—Single check (quarterly) basis (d_i). The percentage difference, d_i, for a single calibration check, i, is calculated using 40 CFR Part 58, Appendix A, Equation 1, where X_i represents the standard value (known) and Y_i represents the indicated (measured) value.

$$d_i = \frac{Y_i - X_i}{X_i} \times 100$$

In general, sampling or analysis will not be conducted unless verifications meet acceptance criteria. In the event of a failure, troubleshooting and corrective action will take place and the verification/calibration will be performed again. If the instrument cannot be calibrated, a spare will be used. If a field situation arises where a spare sampler cannot be used, the sample may be taken, but it will be flagged appropriately.

14.1.1.2 Initial and Continuing Laboratory Calibration Verification

An initial calibration is performed daily or for each batch of analysis using a blank and a minimum of three calibration standards. A linear calibration forced through zero is used for calculation. Refer to Section 7, Table 7.2 for acceptance criteria.

If an initial calibration fails because of one standard, a fresh solution of that standard may be reanalyzed and substituted for the standard that failed. If the failure is repeated (or the problem is not isolated to one calibration point), the system must be repaired so that the criteria are satisfied before any samples are analyzed.

The calibration is verified by the analysis of an initial calibration verification (ICV), calibration blank (CB), and source calibration verification (SCV). If the criteria for those standards are not met, take corrective action as needed before continuing with analysis, including reanalysis or re-preparation and reanalysis of the initial calibration if necessary.

To check instrument performance and verify the accuracy and stability of the calibration, analyze an ICV and a continuing calibration verification (CCV) standard. The ICV is analyzed immediately following initial calibration and the CCV at a frequency of one per 10 analytical samples and at the end of the analytical run. The recovery of the analyte in the ICV and CCV are calculated as follows:

$$\%R = \frac{M}{T} \times 100$$

where
%R = percent recovery of the standard
M = measured concentration of the analyte, µg/L
T = true concentration of the analyte in the ICV/CCV, µg/L

14.1.1.3 Second Source Calibration Verification

Analyze a second source calibration verification (SCV) daily to verify the calibration standards and acceptable instrument performance. If the measured concentration is not within ± 10% of the true value, the method performance is unacceptable. The source of the problem must be identified and corrected before proceeding with analyses.

The recovery of the analyte in the SCV is calculated as:

$$\%R = \frac{M}{T} \times 100$$

where
%R = percent recovery of the standard
M = measured concentration of the analyte, µg/L
T = true concentration of the analyte in the SCV, µg/L

14.1.2 Blanks

Blank samples are used to determine contamination arising principally from the following four sources: the environment from which the sample was collected/analyzed, the reagents used in the analysis, the apparatus used, and the operator/analyst who performed the data operation. The following five types of blanks will be implemented in the Pb-PEP:

Field Blank - These provide an estimate of total measurement system contamination. By comparing information from laboratory blanks against the field blanks, the contamination from field activities can be assessed. Details about using field blanks can be found in the Field SOP. The acceptance goal for field blanks is for the blanks concentration to be less than the laboratory method detection limit.

Trip Blank - These are used to measure possible contamination to filters during transportation to and from sampling locations. They provide a frame of reference in case field blanks exhibit mass gain higher than the acceptance levels. Trip blanks shall represent approximately 10% of all Pb-PEP filters. Trip blanks should be used in conjunction with field blanks but not at the same frequency. Details about using the trip blanks can be found in field SOPs. The acceptance goal for trip blanks is for the blanks concentration to be less than the laboratory method detection limit.

Laboratory Blank -These provide an estimate of contamination occurring at the analytical facility. Details about using the laboratory blanks can be found in lab SOP 509.

Calibration Blank - The stability of the baseline must be monitored by analyzing a CB immediately after every ICV/CCV standard. If the value of the CB result is less than one half the QL, the result is acceptable. If the value of the CB result equals or exceeds one-half the QL, the analysis may not continue. The cause of the high CB result must be determined and the problem corrected. The instrument must be re-calibrated and all samples not bracketed by acceptable CB results must be re-analyzed.

Method Blank - Analyze at least one MB with each batch of 20 or fewer field samples in an SDG. MB values $\geq$ ½ the QL indicate potential laboratory or reagent contamination. Use the following guidelines to determine when samples must be re-prepared, re-analyzed, and flagged as estimated:

- If the MB analyte value is $\geq$ ½ the QL and the sample result is less than five times the MB analyte amount, rerun the MB once to verify and if still unacceptable: (1) For PM_{10} filter, all associated results are to be reported and qualified as estimated "J", (2) For TSP filter strip, the MB and all associated samples must be re-prepared and re-analyzed if there is enough sample to work with. The associated sample results can also be reported but will be qualified as estimated "J".
- If the MB analyte value is $\geq$ ½ the QL and the sample result is non-detected or is greater than five times the MB analyte concentration, report sample results without qualification.

14.1.3 Precision Checks

Precision is the measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. To meet the DQOs for precision, the Pb-PEP must ensure the entire measurement process is within statistical control. The following two types of precision measurements will be made in the Pb Program:

- Collocated monitoring (see Section 14.1.3.1.)
- Filter duplicates (see Section 14.1.3.2.).

14.1.3.1 Collocated Monitoring

To evaluate the total measurement precision of the Pb-PEP fleet of samplers, collocated monitoring study will be implemented. Twice a year, the FS will complete a collocation study. One collocation study is defined as setting up and operating an extra Pb-PEP sampler at a routine monitoring site; repeating the process in a 6 month period until all Pb-PEP samplers have been compared. The data from the two Pb-PEP samplers and the SLT sampler will be compared. If the Pb-PEP samplers differ by more than 10% using Equation 10 below, the FS will troubleshoot the sampler that has the highest percent difference from the SLT sampler. The SLT will be used

as a "referee" if there is a difference between the Pb-PEP samplers. This process will be completed twice per year. This study will assess bias among the Pb-PEP sampler fleet.

Evaluation of collocated data. Collocated measurement pairs are selected for use in the precision calculations only when both measurements are above 0.02 μg/m^3. The following algorithms will be used to evaluate collocated data.

Percent difference for a single check (d_i). The percentage difference, d_i, for each check is calculated by using 40 CFR Part 58 Appendix A, Equation 10, where X_i represents the concentration produced from the primary sampler and Y_i represents the concentration reported for the duplicate sampler.

$$d_i = \frac{Y_i - X_i}{(Y_i + X_i)/2} \times 100$$

CV for a Single Check (CV_i). The coefficient of variation, CV_i, for each check is calculated by dividing the absolute value of the percentage difference, d_i, by the square root of two.

$$CV_i = \frac{|d_i|}{\sqrt{2}}$$

Precision of a single sampler—semi-annual basis ($CV_{j,q}$). For Pb sampler *j*, the individual coefficients of variation ($CV_{j,q}$) during the semi-annual period are pooled using 40 CFR Part 58 Appendix A, Equation 11, where $n_{j,q}$ is the number of pairs of measurements from collocated samplers during the semi-annual period.

Equation 11

$$CV = \sqrt{\frac{n \cdot \sum_{i=1}^{n} d_i^2 - \left(\sum_{i=1}^{n} d_i\right)^2}{2n(n-1)}} \cdot \sqrt{\frac{n-1}{X^2_{0.1,n-1}}}$$

The 90% confidence limits for the single sampler's CV are calculated using 40 CFR Part 58, Appendix A, Equation 13 (upper confidence limit) and Equation 14 (lower confidence limit).

Equation 13

$$\text{Upper 90\% Confidence Interval} = D + t_{0.95,df} \cdot \frac{s}{\sqrt{n_j}}$$

Equation 14

$$\text{Lower 90\% Confidence Interval} = D - t_{0.95,df} \cdot \frac{s}{\sqrt{n_j}}$$

Precision of a single sampler—annual basis. For particulate sampler *j*, the individual coefficients of variation, CV_i, produced during the calendar year are pooled using 40 CFR Part 58 Appendix A, Equation 11, where n_j is the number of checks made during the calendar year. The 90% confidence limits for the single sampler's CV are calculated using Equations 13 and 14.

Corrective action: Collocated Study. Samplers in a collocation study that measure a CV >10% require corrective action. The FS will troubleshoot the sampler that has the highest percent difference from the SLT sampler. If the CV remains between 10 and 20%, the regional contact will be alerted to the problem. Paired CVs and percent differences will be control charted to determine trends. Problems and solutions will be reported as soon as possible to the EPA Regional WACOR/TOCOR/DOCOR and appropriately filed under response and corrective action reports (Pb-PEP/108-025-01-01-237.1, see Element 9.0, *Documentation and Records*).

14.1.3.2 Duplicate Laboratory Measurement

Matrix Duplicate (For TSP Filter Strip Only)

One matrix duplicate (MD) must be analyzed for every 20 or fewer field samples. Treat the MD as a routine sample.

Calculate the relative percent difference (RPD) using the following equation:

$$RPD = \frac{|Cmd - C|}{(Cmd + C)/2} \times 100$$

where
RPD = relative percent difference
C_{md} = measured concentration in the MD, corrected for sample preparation and any dilutions
C = measured concentration in the routine sample, corrected for sample preparation and any dilutions

Apply precision criteria in Section 7, Table 7.2 for samples with analyte levels $\geq$ QL. If control limits are exceeded, re-analyze the sample and duplicate once. If the control limits are exceeded again, flag the associated sample result as estimated (J).

Laboratory Control Standard Duplicate (For PM_{10} Filter Only)

Analyze one laboratory control standard (LCS) duplicate with each batch of 20 or fewer samples in an SDG. Recovery of analytes in the LCS is calculated as:

$$\%R = \frac{M}{T} \times 100xD$$

where
%R = percent recovery of the standard
M = measured concentration of the analyte, µg/L
T = true concentration of the analyte in the LCS, µg/L

If the recovery of the LCS does not meet the recovery criteria in Section 7, Table 7.2, re-analyze once to verify. If the recovery is still unacceptable, the analyte is judged to be out- of-control and the source of the problem must be identified and resolved. All samples associated with the out-of-control LCS are to be reported and qualified as estimated "J".

14.1.4 Accuracy or Bias Checks

Accuracy is defined as the degree of agreement between an observed value and an accepted reference value and includes a combination of random error (precision) and systematic error (bias). The following three accuracy checks are implemented in the Pb-PEP Program:

- Field QC
  - Flow, Barometric Pressure, Temperature
- Laboratory QC
  - Quantitation Limit Standard, Lab Control Standard, Matrix Spike, Sample QC

1.4.1.4.1 Field Bias/Accuracy Quality Checks

Flow Rate

The Pb-PEP FS will implement a flow rate verification with each setup. Details of the implementation aspects of the audit are included in Field SOP Pb-PEPF-5. The verification is implemented by measuring the analyzer's normal operating flow rate using a certified flow rate transfer standard. The audit (actual) flow rate and the corresponding flow rate indicated or assumed by the sampler are reported. The procedures used to calculate measurement uncertainty are described below.

Accuracy of a single sampler—single check (quarterly) basis (d_i). The percentage difference, d_i, for a single flow rate audit, i, is calculated using 40 CFR Part 58, Appendix A, Equation 1, where X_i represents the audit standard flow rate (known), and Y_i represents the indicated flow rate.

$$d_i = \frac{Y_i - X_i}{X_i} \times 100$$

Bias of a single sampler—annual basis (D_j). For an individual particulate sampler j, the average (D_j) of the individual percentage differences (d_i) during the calendar year is calculated using 40 CFR Part 58, Appendix A, Equation 4, where n_j is the number of individual percentage differences produced for sampler j during the calendar year.

$$Dj = \frac{1}{n_j} \times \sum_{i=1}^{n_j} d_i$$

The single sampler acceptance criterion is found in Table 7-1. If the verification violates the acceptance criterion, the FS will check the sampling instrument for internal and external leaks,

ensure that temperature and pressure are within acceptable ranges, and run the verification procedure a second time. If the verification result is still unacceptable, a multipoint verification should be performed by the FS. If the multi-point verification indicates that the sampler is operating outside of the acceptance criteria found in Table 7-1, a flow rate calibration is required. Then the single-point flow rate verification will be repeated. If the sampler fails to meet the acceptance requirement after calibration, or a flow rate calibration in the field is not possible, a back-up sampler will be used (assuming it meets the acceptance criteria) while the affected instrument is being evaluated/repaired.

Barometric Pressure

The TSP sampler has a built-in atmospheric pressure sensor. The sensor's output is processed to allow control of the sampling flow rate to the design value under actual ambient conditions of temperature and pressure.

To perform a routine verification, the barometric pressure sensor reading is verified at ambient pressure through comparison with the reading from an external standard of known accuracy. If a pressure difference of more than 10 mmHg is observed, a multipoint verification/calibration of the pressure-sensing and display system is required before the sampler may be used to perform an evaluation.

Temperature

The TSP sampler has a built-in atmospheric temperature sensor. The ambient temperature sensor is verified at a single point using an external temperature standard of known, NIST-traceable accuracy. If a temperature difference of more than 2^{o}C is observed, a multipoint verification/calibration of the temperature sensor is required before the sampler may be used to perform an evaluation.

14.1.4.2 Laboratory Bias/Accuracy Checks

Quantitation Limit Standard

To verify the ability to detect target analytes near the QL, a QL standard (QLS) must be analyzed at the beginning of the analytical run and after each 40 analytical samples. The recovery of analyte in the QLS is calculated as:

$$\%R = \frac{M}{T} x\ 100$$

where
%R = percent recovery of the standard
M = measured concentration of the analyte, µg/L
T = true concentration of the analyte in the QLS, µg/L

If the QLS recovery does not meet the criteria in Section 7, Table 7.2, determine the cause, take corrective action, and re-analyze the QLS.

Laboratory Control Standard

Analyze one LCS with each batch of 20 or fewer samples in an SDG. Recovery of analytes in the LCS is calculated as:

$$\%R = \frac{M}{T} x\ 100$$

where
%R = percent recovery of the standard
M = measured concentration of the analyte, µg/L
T = true concentration of the analyte in the LCS, µg/L

If the recovery of the LCS does not meet the recovery criteria in Section 7, Table 7.2, re-analyze once to verify. If the recovery is still unacceptable, the analyte is judged to be out- of-control and the source of the problem must be identified and resolved. (1) For PM_{10} filter, all associated results are to be reported and qualified as estimated "J", (2) For TSP filter strip, the MB, LCS, and all associated samples must be re-prepared and re-analyzed if there is enough sample to work with. The associated sample results can also be reported but will be qualified as estimated "J".

Matrix Spike (For TSP Filter Strip Only)

The matrix spike (MS) is designed to provide information about the effect of sample matrix on the measurement system. One MS sample must be prepared for every 20 field samples in an SDG. Spike a filter strip with lead prior to any sample preparation. The spiking level must be the same as that used for the LCS.

Samples identified as field blanks cannot be used for MS sample analysis. MS recovery is calculated as:

$$\%R = \frac{Cms - C}{s} \times 100$$

where
%R = percent recovery
C_{ms} = measured concentration of analyte in the MS, corrected for sample preparation and any dilutions
C = measured concentration of analyte in the routine sample corrected for sample preparation and any dilutions
s = expected spiked analyte concentration in the MS, corrected for sample preparation and any

dilutions

If the value of *C* is less than four times the value of *s*, apply accuracy and precision criteria in 40 CFR Part 58 Section 4.4. If the value of *C* is greater than four times the value of *s*, *%R* is not calculated. If the MS does not meet these criteria, examine other QC results to determine if a matrix problem exists. If laboratory performance is in control, the poor MS accuracy is likely to be matrix-related. Flag any out-of-control results as estimated "J".

Sample QC

Internal Standard Response - Monitor the signal intensity for the internal standard masses throughout the analytical run. This information is useful in detecting instrument drift, sensitivity shift; dissolved solids content, and inherent internal standard (i.e., a natural constituent in a sample). The absolute intensity of the internal standard must not deviate more than 60 to 125% from its original intensity in the calibration blank. If deviations greater than these are observed, examine the internal standard intensities with the following actions:

- If the intensities of the internal standards for the ICV, CCV, or CB are out of control, recalibrate and re-analyze the samples affected by the out-of-control internal standards.
- If the intensities of the internal standards for the ICV, CCV, and CB are within control limits but sample internal standards are out-of-control, rerun the sample or rerun at an appropriate dilution.
- Report results from the original, undiluted, or least diluted sample where the internal standards are within the acceptance limits.

14.2 Sample Batching—QC Sample Distribution

To ensure that the Pb-PEP includes all types of QC samples within an analysis session, the Pb-PEP will use the concept of sample batches. A batch of samples will consist of the samples indicated in Table 14-1. QC samples will be interspersed within the batch to provide data quality information throughout the analytical session. The definition for each QC sample and how they are developed can be found in the field SOP for the field and trip blanks (FB, TB) and in the Laboratory SOP-509 for the laboratory QC checks.

Table 14-1 QC Sample Distribution

Seq.	Description[1]	Seq.	Description	Seq.	Description
1	CB	15	S2	29	S14
2	Cal Std 1	16	S3	30	CCV
3	Cal Std 2	17	S4	31	CB
4	Cal Std 3	18	CCV	32	S15
5	Cal Std 4	19	CB	33	TB
6	ICV	20	S5	34	S17
7	CB	21	S6	35	S18
8	SCV	22	FB	36	S19
9	QLS	23	S8	37	S20
10	MB	24	S9	38	CCV
11	LCS	25	S10	39	CB
12	S1	26	S11	40	QLS *
13	S1-MD	27	S12	41	
14	S1-MS or LCS-D	28	S13	42	

[1]- See Table 7-2 for QC Codes.

NOTE: *Analyze another QLS if more than 40 analytical samples are to be analyzed.

15.0 Instrument/Equipment Testing, Inspection, and Maintenance Requirements

The purpose of this element in the Pb-PEP QAPP is to discuss the procedures used to verify that all instruments and equipment are maintained in sound operating condition and are capable of operating at acceptable performance levels. All instrument inspection and maintenance activities are documented and filed under Pb-PEP/301-093-006.3. See Element 9.0, *Documentation and Records*, for document filing and record details.

15.1 Testing

All TSP samplers used in the Pb-PEP will be designated FRM monitors that have been certified as such by EPA; therefore, the samplers are assumed to be of sufficient quality for the data collection operation. Testing of such equipment is accomplished by EPA through the procedures described in 40 CFR Part 53. Annually, prior to deployment, the FSs within each region will assemble and run all the samplers at the regional site (full collocation). The FSs will perform temperature, time, date, pressure, and flow rate single-point verification checks every day of PE audit sampling. If any of these checks are out of specification (see Tables 7-1 and 7-2), the FS or WAM/TOPO/DOPO will initiate troubleshooting procedures, which may include multipoint verification checks and calibration. If the problem cannot be located and the sampler continues to fail the verification checks, the sampler cannot be used for the PE. The FS should use an alternate sampler and return the sampler to the laboratory for maintenance. If the sampling instrument meets the acceptance criteria, it will be assumed to be operating properly. If a new sampler is acquired for use in the Pb-PEP, it should be subject to a collocation with a sampler shown to be performing satisfactorily in a prior collocation. The results should comply with acceptance criteria for a routine collocation study. If new upgraded FRM sampler hardware is introduced, the same type of testing will be conducted. These tests will be properly documented and filed under Pb-PEP/301-093-006.3.

The Pb-PEP laboratories will use ICP-MS for analyzing the glass fiber filters, and XRF for analyzing the 46.2 mm Teflon® filters for Pb in PM_{10}. The ICP-MS method contains two general stages of operation; sample extraction and sample analysis. At the sample extraction stage, testing will include the analysis of reagents to ensure they are not contaminated. These tests occur in every sample batch. Also, the hot block equipment will be tested during each extraction with the use of a NIST traceable thermometer to ensure proper extraction temperatures. Prior to sample analysis, the laboratory will run a number of calibration checks to ensure proper operation of the analyzer. In addition the QC samples described in Table 7-2 can help to determine proper operation of the ICP-MS analyzer. The XRF method generally involves a sample analysis without extraction. Prior to sample analysis, the laboratory will run a number of calibration checks to ensure proper operation of the analyzer. In the same manner, the QC checks described in Table 7-3 can help to determine the proper operation of the XRF analyzer.

15.2 Inspection

Inspection of various equipment and components can be subdivided into the laboratory and field activities.

15.2.1 Inspection in the Laboratory

There are several items that need routine inspection in the laboratory. Table 15-1 details the items to inspect and summarizes how to appropriately document the inspection.

Table 15-1. Inspections in the Laboratory

Analysis Method	Item	Inspection Frequency	Inspection Parameter	Action If Item Fails Inspection	Documentation Requirement
ICP-MS	Pipettes, glassware	Weekly	Certification status, physical condition	Recertify or replace glassware	Document in log book or bench sheet
	Standards and reagents	Monthly	Certification status	Recertify or discontinue use	Document in log book or bench sheet
	Hot block	Before and during digestion	Achieves proper temperature	Discontinue use and service hot block	Document in log book or bench sheet
	ICP-MS Auto-sampler	Before each run	Physical operation, cleanliness	Clean and/or service unit	Document in log book or bench sheet
XRF	XRF Analyzer	Before each run	Physical operation cleanliness	Clean and/or service unit	Document in log book or bench sheet
	Thin film standards	Weekly	Dents, scratches, discoloration	Verify film, replace if necessary	Document in log book or bench sheet

15.2.2 Inspection of Field Items

There are several FRM sampler parts to inspect in the field operation's maintenance area and in the field before and after a Pb sample has been taken. Checks specific to high volume or low volume sampler are denoted by footnotes. Table 15-2 details these inspections.

Table 15-2. Inspection of Field Items

Item	Inspection Frequency	Inspection Parameter	Action If Item Fails Inspection	Documentation Requirement
Sampler unit	Prior to each sampling run	Contamination, particulate matter	Clean with laboratory wipe and water	Document in the log book
Gasket inspection [a]	Before and after assembly	Not broken, seats correctly, no damage	Replace with new gasket	Document in the log book
Sample downtube [b]	Before each sampling event	Visible particulate	Clean with a dry cloth	Document in the log book
O-rings[b]	Before each sampling event	Not broken, seats correctly, no damage	Replace o-rings	Document in log book
Calibration and working standards	Before each sampling event	Cleanliness, damage	Clean the standard and verify calibration/ ship to vendor for repair	Document in log book and complete REC-01, REC-02 forms (Pb-PEP SOP Section 2)
Filter shipments	After each shipment receipt, before leaving on audit	Correct number and COCs are present	Contact laboratory to reconcile discrepancy	Document in log book or COM-1 (Pb-PEP SOP Section 2)
Filters	Prior to each sampling event	No contamination, pinholes, discoloration	Void filters and return to laboratory	Document in log book

[a] Applies to high volume sampler only

[b] Applies to low volume sampler only

15.3 Maintenance

There are many items that need maintenance attention in the Pb-PEP. This section describes those items according to whether they are laboratory or field activities.

15.3.1 Laboratory Maintenance Items

The successful execution of a maintenance program for the Pb-PEP laboratories is essential to the success of the Pb-PEP. Table 15-3 and 15-4 provide information on laboratory preventive maintenance. Maintenance is completed through the laboratory supervisor or the analyzer vendor.

Table 15-3. Maintenance for ICP-MS Pb-PEP Laboratories

Item	Frequency	Comments
Auto-sampler Rinse Station Reservoir	As needed	Fill with 2% $HN0_3$.
Pump Tubing	Daily	Check for fatigue and wear. Replace as needed.
Cones	Daily Weekly	Inspect for sample residues. Wipe clean or replace with clean cone as needed. Remove and inspect condition of cones. Replace if needed.
Torch Tip	Daily	Check for sample residues. Replace with clean glassware if needed.
Argon Dewar	Daily	Check for sufficient amount and pressure. Order as needed.
Autodiluter	Daily	Rinse thoroughly with reagent water after each use.
Auto-sampler and Peristaltic Pump	Weekly	Wipe spills or residues.
Nebulizer Spray	Weekly	Check, unclog or replace if needed.
Glassware	Weekly	Inspect and clean if needed.
Glassware & Cone alignment	Weekly	Perform X-Y alignment, if needed.
Air filters	Monthly	Clean or replace as needed.
Chiller Coolant	Monthly	Check level and top off as needed.
Vacuum Oil	Monthly	Check level and color, replace with fresh one if needed.

Table 15-4. Maintenance for XRF Pb-PEP Laboratories

Item	Frequency	Comments
Liquid nitrogen dewar	Weekly	Check level and top off as needed, calibrate nitrogen level
X-ray tube cooling water vessel	Weekly	Check level and top off as needed per vendor direction
Vacuum pump oil	Weekly	Check level and top off as needed per vendor direction

A LIMS should be used to manage raw data from the analyzers. These LIMS systems should be backed up weekly to a central server to guard against data loss. A monthly backup of the network file shares used to store and operate the AIRQA database will be performed by EPA contractor(s) according to policies established by EPA Office of Administration and Resource Management.

15.3.2 Field Maintenance Items

There are many items associated with appropriate preventive maintenance of a successful field program. The Pb-PEP field SOPs (high volume and low volume methods) provide procedures for cleaning important components of field equipment. These SOPs can be found on the AIRQA Web site under Pb-PEP, Documentation. Table 15-5 details the appropriate maintenance checks

of the Pb-PEP samplers and their frequency. Footnotes identify elements specific to the high volume or low volume samplers.

Table 15-5. Preventive Maintenance of Field Items

Frequency	Maintenance item
Every visit	1. Inspect sampler and verification/calibration equipment for damage 2. Inspect filter holder frame and rubber gasket for damage [a] 3. Inspect o-rings [b] 4. Inspect downtube [b]
Quarterly (every 3 months)	1. Clean sampler inlet surfaces 2. Clean interior of sampler unit 3. Check condition of sample transport containers 4. Inspect vacuum tubing, tube fittings, and other connections to pump and electrical components; service if necessary 5. Clean downtube [b]

[a] Applies to high volume sampler only
[b] Applies to low volume sampler only

16.0 Instrument Calibration and Frequency

This element of the Pb-PEP QAPP concerns the calibration procedures that will be used for instruments involved in the environmental measurements. Tables 7-1 through 7-3 indicate the instruments that require verification and calibration, the required frequencies of these activities, and the acceptance criteria for these activities. All calibration activities/procedures are described in more detail in the Field and Laboratory SOPs.

Calibrations that involve instrument adjustments should only be accomplished when it is obvious that calibration is required; therefore, the Pb-PEP uses a three-phase approach to calibration, which involves the following:

- One-point verification—These verifications ensure that the calibration is within acceptance limits by performing frequent one-point verifications that do not include instrument adjustments.
- Multipoint verification—Similar to one-point verifications, these occur at established frequencies, as well as when there is a failure of a one-point verification. These multipoint verifications do not include instrument adjustments.
- Calibration—This occurs when there is a failure of a verification. Instrument adjustment occurs at this point and is followed by a one-point verification.

16.1 Instrumentation Requiring Calibration

16.1.1 Laboratory Equipment

ICP-MS

The Region 9 ICP-MS analyzer will require calibration. The lab will perform an initial calibration daily or for every analytical batch, whichever is more frequent and a continuing calibration verification. These calibrations are described in Section 14. Refer to Table 7-2 for frequency, acceptance criteria, and corrective action requirements.

XRF

XRF analyzers typically will require two calibrations; a detector calibration and an analyzer calibration. The detector contains a digital signal processor that is calibrated by repeatedly measuring the beam stop inside the unit. The detector calibration will be completed on a weekly basis. The analyzer is calibrated by analyzing thin film standards. Using at least two standards for each element, the unit calculates a linear regression line. A full analyzer calibration is completed if the daily quality control standard falls outside acceptable limits or when significant repair or maintenance is conducted on the unit. Refer to Table 7-3 for frequency, acceptance criteria, and corrective action requirements.

16.1.2 Field Equipment

TSP Portable Sampler

Upon receipt of a new portable sampler, multipoint verifications will be performed. Multipoint verifications and calibrations typically occur at the field office or laboratory. Refer to Table 7-1 for frequency, acceptance criteria, and corrective action requirements.

The following verifications are routinely performed in the field:

- Verification of the sampler's temperature probes against the working temperature standard
- Verification of the sampler's barometric pressure against the working pressure standard
- Verification of the sampler's volumetric flow rate against the working flow standard
- Verification of the sampler's internal clock against a known time standard.

Temperature Probes

The portable sampler contains an ambient temperature probe. At every sampling event, the FS will perform a one-point field verification of the sensor using a digital NIST-traceable temperature probe (e.g., BGI HiVolCal Model HC-2). A different NIST-traceable calibration device will be used in the field office as a primary standard to perform multipoint temperature verifications once a year or after there has been a one-point verification failure. If the multipoint verification fails to meet the acceptance criteria, a temperature calibration will be performed. Following a calibration where an adjustment is necessary, the working standard will be used to verify the calibration.

Barometric Pressure

A NIST-traceable calibration device (e.g., BGI HiVolCal Model HC-2) will be used in the field for one-point verifications of the portable sampler's pressure sensor during each sampling event. A different NIST-traceable calibration device will be used in the field office as a primary standard to perform multipoint pressure verifications once a year or after there has been a one-point verification failure. If the multipoint verification fails to meet the acceptance criteria, a barometric pressure calibration will be performed. Following a calibration where an adjustment is necessary, the working standard will be used to verify the calibration.

Time Standard

The FS will check the time standard's time and date using the atomic clock, which can be found on the Internet at http://www.time.gov or through a known time standard (e.g., cell phone). Times can be checked each day before heading to the field, particularly where there is no cell phone service at the sampler location(s). **Samplers should be set up based on the local standard time**.

Flow Rate

Before every sampling event, **after leak checks, temperature, and pressure verifications are performed**, a one-point flow rate verification will be performed using a NIST-traceable calibration device (e.g., BGI HiVolCal Model HC-2). It is essential that the flow check be performed after the other verifications because the total flow volume is calculated using the ambient temperature and pressure. A different NIST-traceable calibration device will be used in the field office as a primary standard to perform multipoint pressure verifications once a year or after there has been a one-point verification failure. If the multipoint verification fails to meet the acceptance criteria, a flow rate calibration will be performed. Following a calibration where an adjustment is necessary, the working standard will be used to verify the calibration.

16.2 Calibration Method That Will Be Used for Each Instrument

The calibration methods are described in detail in the field and laboratory SOPs.

16.3 Calibration Standard Materials and Apparatus

Table 16-1 presents a summary of the specific standard materials and apparatus used in calibrating measurement systems for parameters necessary to generate the quality Pb data required. All of the standards meet the acceptance requirements for Tables 7-1 through 7-3 and will be NIST-traceable.

Table 16-1. Calibration Standards and/or Apparatus for Pb Calibration

Parameter	Standard (S) Apparatus (A)	Description	Accuracy or Resolution	Manufacturer's Name	Model Number
Field Equipment					
Temperature	A	Multi-parameter calibrator	Accuracy ±0.2°C Resolution 0.1°C	BGI HiVolCal	HC-2
Pressure	A	Multi-parameter calibrator	Accuracy ±0.1% Resolution 0.01 psig	BGI HiVolCal	HC-2
Flow Rate	A	Multi-parameter calibrator	Accuracy 0.75% of reading Resolution 0.1mL/min	BGI HiVolCal	HC-2
Lab Standards					
Pipettes & Volumetric flasks	A		Class A[a]		
Reagents HNO_3	S		trace metals grade or better[b]	Baker Instra-Analyzed	
Stock Standards	S		NIST Traceable[c]	Spex or Inorganic Ventures	
Argon gas supply,	S		high-purity grade,99.99%		
Film standards	S		50 µg/cm^2 thickness standards certified to ±5%	Micromatter	

[a] Class A Pipettes meet all the requirements of American Society for Testing and Materials (ASTM) E 969-95. Compliance with the Class A Pipette requirements and other laboratory certifying groups is indicated by the letter "A" near the top of each pipette. All pipettes are calibrated in accordance with ASTM E 542 and meet the accuracy requirements of ASTM E 969; borosilicate glass meets ASTM E 438 for Type I, Class A requirements.

[b] Only materials that conform to the American Chemical Society (ACS) specifications such as reagent grade or better will be used.

[c]ICP & ICP-MS standards are assayed by validated ICP and wet chemical procedures to obtain the certified value. Every standard is traceable to a specified NIST SRM. The NIST-traceable density is available on the certificate.

16.4 Calibration Frequency

See Tables 7-1 through 7-3 for a summary of calibration frequencies.

All calibration events, as well as sampler and calibration equipment maintenance, will be documented in field/lab data records and notebooks as indicated in the field and laboratory SOPs. The records will normally be controlled by the ESAT FSs or LAs and located in the laboratory or field offices when in use. Eventually, all calibration records will be appropriately filed under Pb-PEP/301-093-006.6 (see Element 9.0, *Documentation and Records*).

16.5 Standards Recertifications

16.5.1 Field Standards

All primary/calibration and working standards will be certified every year as NIST-traceable using the EPA Metrology laboratory in RTP, NC. OAQPS will work with the regional offices to find an appropriate time frame to conduct re-certifications on the field instruments.

16.5.2 Lab Standards

All glassware will be calibrated in accordance with ASTM E 542 and meet the accuracy requirements of ASTM E 969; borosilicate glass meets ASTM E 438 for Type I, Class A requirements. ICP and ICP-MS standards are assayed by validated ICP and wet chemical procedures to obtain the certified value. Every standard is traceable to a specified NIST SRM. XRF thin film standards will be replaced when the stated manufacturer's tolerances are outside of control limits.

17.0 Inspection/Acceptance for Supplies and Consumables

17.1 Purpose

The purpose of this element is to establish and document a system for inspecting and accepting all supplies and consumables that may directly or indirectly affect the quality of the Pb-PEP data. The Pb-PEP relies on various supplies and consumables that are critical to its operation. By having documented inspection and acceptance criteria, consistency of the supplies can be assured. This element details the supplies/consumables, their acceptance criteria, and the required documentation for tracking this process.

If the Pb-PEP program is being operated in conjunction with the $PM_{2.5}$ PEP, the acceptance and testing of equipment, supplies and consumables may be inspected and documented with the $PM_{2.5}$ PEP supplies using the requirements located in Section 17 of the $PM_{2.5}$ QAPP. In the same way, equipment common to both programs should be shared. This practice will reduce the duplication of effort that could result by implementing the programs separately.

A number of forms will be discussed in the following sections. These forms are found in the Field and Laboratory SOPs, but examples of them are placed at the end of this section. They are:

- Field/Laboratory Inventory Form (INV-01) (Figure 17-1)
- Field/Laboratory Procurement Log Form (PRO-01) (Figure 17-2)
- Field/Laboratory Equipment/Consumable Receiving Report Form (REC-01) (Figure 17-3).

17.2 Critical Supplies and Consumables

This section attempts to describe the needed supplies for the Pb-PEP and includes items for the laboratory and the field. Generally, critical field and laboratory equipment has been selected by the Pb-PEP organizers based on the required performance specifications of resolution, accuracy, and ease of use.

17.2.1 Laboratory Supplies

Table 17-1 is a list of the laboratory equipment required for the ICP-MS analysis of glass fiber filters conducted by the Region 9 laboratory. Equipment that is not deemed critical (affecting data quality) has been left to the Laboratory Manager to select. To maintain consistency in the PE program, all consumables/equipment with a model number (as shown in Table 17-1) will be purchased using the same model number when supplies run low. The LA is required to keep an inventory of all equipment using Field/ Laboratory Inventory Form (INV-01), which is shown in Figure 17-1. A general list of equipment and consumables for the XRF analysis of the 46.2mm Teflon® filters is provided; however, the details may change according to vendor.

Table 17-1. Laboratory Equipment

ICP-MS		
Activity	**Description**	**Details**
Preparation	Logbook	Bound with numbered pages
	Hot Block Digestion System	Environmental Express or equivalent
	Pipettors	Variable volume for dispensing reagents and acids
	Pipettes	Calibrated fixed volume and digital variable volume with appropriate plastic tips
	Nitric Acid (HNO_3), concentrated	ACS Reagent Grade or better, suitable for trace metals analysis.
	Gloves	Powder-free gloves
	Tweezers	Teflon non-serrated
	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	Any house wares vendor
	Plastic or Teflon wash bottles	Capable of dispensing reagent for cleaning
	Glass Fiber Filter	EPA National Filter Procurement
	Teflon Filters	EPA National Filter Procurement
	Stock Standards	Spex or Inorganic Ventures
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
XRF		
Activity	**Description**	**Details**
Preparation	Logbook	Bound with numbered pages, may include bench sheets
	Methanol	ACS Reagent Grade or better
	Squeeze bottle	Capable of dispensing reagent for cleaning
	Stainless Steel Tweezers	Millipore flat tipped tweezers P/N 62-000067 or equivalent
	Kimwipes	Large and small P/N 34255 and P/N 34155 or equivalent
	Mylar sheets	2” x 2” precut squares
	Vacuum oil	Analyzer specific
Analysis	X-ray Fluorescence	PANalytical Epsilon 5 EDXRF or equivalent
	Liquid Nitrogen	Detector cooling

As consumables run low or when new equipment purchases are necessary, the LA will be responsible for assisting in the procurement of these items following the policy and requirements described in the ESAT scope of work. The LA should continue purchasing consumable equipment with the same model numbers as the equipment initially procured unless the Pb-PEP Laboratory Manager suggests a different item due to improved quality, reduction in contamination, improved ease of use, or lower cost (without sacrificing quality). Such changes should be coordinated with the WACOR/TOCOR/DOCOR. The Pb-PEP Laboratory Manager will also present any such proposed equipment changes to the National Pb-PEP Project Lead for approval. The following procedures will be performed by the LA:

- Develop procurement requests as per EPA requirements.
- Upon order, add items to the Field/Laboratory Procurement Log Form (PRO-01).
- Once a month, provide a copy of the PRO-01 to the Pb-PEP Laboratory Manager and the laboratory services ESAT WACOR/TOCOR/DOCOR.
- File PRO-01 under Agency file code "Pb-PEP/301-093-006.6."

17.2.2 Field Equipment and Supplies

The field equipment and supplies are listed in Table 17-2. Quantities for some items in Table 17-2 are not shown because they will vary with the size of the field operation (number of samplers and auditors). The FS is required to keep and inventory all equipment, which include any warranty information.

Table 17-2. Field Equipment and Supplies

Activity	Required Equipment	Identified Source
Initial Set-up	Knife	Available through $PM_{2.5}$ PEP
	Tool kit (screw driver, pliers, etc.)	Available through $PM_{2.5}$ PEP
Checks	Transfer standards (1 per region)	BGI Hi-Vol calibrator performs flow/temp/pressure
	Watch/clock check device	Available through $PM_{2.5}$ PEP
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	FRM portable high volume audit sampler	Tisch TE-5170 or equivalent
	Backup FRM portable high volume audit sampler	Tisch TE-5170 or equivalent
	FRM portable low volume audit sampler	BGI PQ-200A or equivalent through $PM_{2.5}$ PEP
	Backup FRM portable low volume audit sampler	BGI PQ-200A or equivalent through $PM_{2.5}$ PEP
	Permanent marker	Sharpie
	Sampler transport cassette(1 set)	Available from sampler vendor
	Ropes	Available through $PM_{2.5}$ PEP
	Folding ladder	Available through $PM_{2.5}$ PEP
	Gloves (powder free)	Fisher Scientific FB GLV LTX PF or equivalent
	Laptop computer	Available through $PM_{2.5}$ PEP
	Field data sheet (FDS)/ Chain of custody (COC)	Begun electronically from AIRQA Web site
	TSP filters	EPA National Filter Procurement
	Field blank filters	EPA National Filter Procurement
Shipping	Glassine envelope for 8” x 10” high volume filters	www.clearbags.com 10 3/8 x 4 1/2 Glassine Open Side [G25] or equivalent
	Manila envelope for 8” x 10” high volume filters	www.officemax.com #12 Kraft Business Envelope P/N 21642199 or equivalent
	Shipping Box for filters	www.uline.com 12 x 6 x 4" Long Corrugated Box P/N S-4127 or equivalent
	Plastic ziplock bags for field and COC sheet	General house wares vendor
	Pre-labeled shipping airbill	EPA contract shipping vendor
Data Transfer	SD Memory Cards	Sandisk (1 GB minimum)
	SD Memory Card Reader	
	Web access to the AIRQA Web site	

Initial quantities will be worked out with the WACOR/TOCOR/DOCOR in each region. As consumables run low or when new equipment purchases are necessary, the FS will be responsible for assisting in the procurement of these items following the policy and requirements described in the ESAT scope of work. The FS should continue purchasing consumable equipment with the same model numbers as the equipment that was initially procured unless the

Regional WACOR/TOCOR/DOCOR suggests a different item due improved quality, reduction in contamination, increased ease of use, or lower cost (without sacrificing quality). The WACOR/TOCOR/DOCOR will report any equipment changes that could affect the results of sampling events to the National Pb-PEP Project Leader. The following procedures will be required:

- The FS will develop procurement requests as per EPA requirements.
- Upon order, add items to the Field/Laboratory Procurement Log Form (PRO-01).
- Monthly or upon request, provide a copy of the PRO-01 to the Regional WACOR/TOCOR/DOCOR.
- File PRO-01 under Agency file code "Pb-PEP/301-093-006.6."

17.3 Acceptance Criteria

The major pieces of capital equipment are namely the following:

Laboratory	**Field**
Perkin Elmer Elan DRC Plus ICP-MS	Portable sampler
Hot Block digester	Calibration equipment (see Section 16.0, *Instrument Calibration and Frequency*)
Cetac Autosampler, or equivalent	Laptop computer
CetaAutodilutor, or equivalent	
Gilson Minipuls 3 Peristaltic Pump, or equivalent	
Polyscience 6105 - Refrigerated Circulator, or equivalent	
PANalytical Epsilon 5 EDXRF or equivalent	

The equipment and consumables have been selected based upon their advertised specifications on accuracy and resolution, and the portable sampler has been built to FRM performance specifications and has been accepted as such. Upon receipt of equipment, the equipment will be inspected and tested using calibration standards (see Element 16.0, *Instrument Calibration and Frequency*) to ensure they operate within the performance parameters. All equipment is under warranty, and the equipment listed above will undergo yearly calibration and certification as discussed in Element 16.0, *Instrument Calibration and Frequency.*

Both field and laboratory personnel will use procurement logs (PRO-01) (Figure 17-2) to record the purchase of new equipment and consumables. These logs also indicate whether the items were accepted or rejected. In addition, the laboratory and field personnel are required to keep a Field/Laboratory Inventory Form (INV-01) (as shown in Figure 17-1), which lists each equipment item and their warranty dates.

17.4 Tracking and Quality Verification of Supplies and Consumables

Tracking and quality verification of supplies and consumables have two main components. The first is the need of the end user of the supply or consumable to have an item of the required quality. The second need is for the purchasing department to accurately track goods received so that payment or credit of invoices can be approved. To address these two issues, the following procedures outline the proper tracking and documentation process to follow by receiving personnel:

1. Perform a rudimentary inspection of the packages as they are received from the courier or shipping company and note any obvious problems with a receiving shipment, such as crushed box or wet cardboard
2. Sign and date the appropriate purchase order for the incoming items from the files and send to the purchaser.
3. Fill out a Field/Laboratory Equipment/Consumable Receiving Report Form (REC-01) (Figure 17-3), comparing the items and quantity against the purchase order and inspecting the condition of each item
4. If the items received match the purchase order and the condition of the equipment or consumables is acceptable, signify this on the form and file under Agency file code "Pb-PEP/301-093-006.6"
5. If the quantity, items, or condition are not acceptable, complete REC-01 with remarks and send a copy of the form to the Regional WACOR/TOCOR/DOCOR
6. Call the vendor to report the problem with the package/contents
7. Add receipt information to the Field/Laboratory Procurement Log Form (PRO-01) and to the Field/Laboratory Inventory Form (INV-01).

In addition, any conversations that field or laboratory personnel have with vendors will be recorded on a phone communication form, which will also be filed.

Capital equipment will be verified for quality prior to implementation into the program to ensure that they meet the minimum specifications for their intended use. This equipment will be tested to ensure that it meets the specifications published by the manufacturer and the criteria described in Section 7 of this QAPP. Ancillary equipment including consumables may also require testing such as shipping media (glassine envelopes, petri-slides) and data logging devices. Assessments of MQOs may assist in identifying these items. Filter media, both Teflon© low volume filters and glass fiber high volume filters are subjected to EPA specific acceptance testing prior to distribution to SLTs.

Figure 17-1 Field/Laboratory Inventory Form (INV-01)

Field/Laboratory Inventory Form (INV-01)					
Item	**Vendor**	**Model Number**	**Quantity**	**Purchase Date**	**Warranty**

Figure 17-2 Field/Laboratory Procurement Log Form (PRO-01)

Field/Laboratory Procurement Log Form (PRO-01)									
Item	**Model Number**	**Quantity**	**PO#**	**Vendor**	**Date**		**Cost**	**Initials**	**Accept/ Reject**
					Ordered	**Received**			

Figure 17-3. Field/Laboratory Equipment/Consumable Receiving Report Form (REC-01)

Received From:				
Shipped From::				
Shipped Via:				
Shipping Charge	Prepaid	Collect	Freight Bill Number	
Purchase Order Number				
Quantity	Description of Item			Condition
Remarks: Accept Shipment _____ Problem_____				
Notes:				

18.0 Data Acquisition Requirements

This element addresses data not obtained by direct measurement from the Pb-PEP. The majority of data used in the Pb-PEP will be direct measurements acquired by the FSs and LAs working for the Pb-PEP.

18.1 Acquisition of Non-Direct Measurement Data

The Pb-PEP relies on data that are generated through field and laboratory operations; however, some data are obtained from sources outside the Pb-PEP. This element lists these data and addresses quality issues related to the Pb-PEP.

18.1.1 Chemical and Physical Properties Data

Physical and chemical properties data and conversion constants are often required in the processing of raw data into reporting units. This type of information, which has not already been specified in the monitoring regulations, will be obtained from nationally and internationally recognized sources. Other data sources may be used with approval from the National Pb-PEP Project Leader. The following sources may be used in the Pb-PEP without prior approval:

- NIST
- International Organization for Standardization, International Union of Pure and Applied Chemistry, American National Standards Institute (ANSI), and other widely recognized national and international standards organizations
- EPA
- *QA Handbook for Air Pollution Measurement Systems: "Volume II: Ambient Air Quality Monitoring Program" EPA-454/B-13-003, May 2013 - Full Document* and subsequent revisions

18.1.2 Sampler Operation and Manufacturers' Literature

Manufacturers' literature, which includes operations manuals and users' manuals, are another important source of information needed for sampler operation because they frequently provide numerical information and equations pertaining to specific equipment. Pb-PEP personnel are cautioned that such information is sometimes in error and appropriate cross-checks will be made to verify the reasonableness of information in manuals. Whenever possible and especially during acceptance testing, the FSs will compare physical and chemical constants in the operator's manuals to those given in the sources listed above. If discrepancies are found, the FS may raise these issues during Pb-PEP workgroup conference calls and during recertification training sessions.

The following types of errors are commonly found in such manuals:

- Insufficient precision
- Outdated values for physical constants
- Typographical errors
- Incorrectly specified units
- Inconsistent values within a manual
- Use of different reference conditions than those called for in EPA regulations.

18.1.3 Site Information

To determine the site and the monitor that the PE will be compared against, the FS must rely on the site information provided to him/her by the EPA region or the SLT monitoring agency. This information should be included in the site file and stored in the field office. This information will include the following parameters:

- AQS site ID
- Monitor type
- Method designation (routine instrument)
- Parameter Occurrence Codes (POC)
- PQAO.

These values must be available in the AQS database and must be double-checked for accuracy before proceeding to a site. Audit data are very difficult or impossible to load into AQS if any of these parameters are recorded incorrectly during the audit.

18.1.4 External Monitoring Databases

It is the policy of the Pb-PEP that no data obtained from the Internet, computer bulletin boards, or databases from outside organizations shall be used in creating reportable data or published reports without approval from the National Pb-PEP Project Leader. Requests may be raised during the Pb-PEP workgroup conference calls or on an individual basis. This policy is intended to ensure the use of high-quality data in Pb-PEP publications.

Data from the EPA AQS database may be used in published reports with appropriate caution. Care must be taken in reviewing/using any data that contain flags or data qualifiers. If data are flagged, such data shall not be used unless it is clear that the data still meet critical QA/QC requirements. It is impossible to assure that a database, such as AQS, is completely free from errors, including outliers and biases, so caution and skepticism are called for in comparing routine data from other reporting agencies as reported in the AQS. Users will review available QA/QC information to assure that the external data are comparable with Pb-PEP measurements and that the original data generator had an acceptable QA program in place.

19.0 Data Management

19.1 Background and Overview

This element describes the data management operations, including data recording, transformation, transmittal, reduction, validation, analysis, management, storage, and retrieval, pertaining to Pb measurements for the Pb-PEP. This includes an overview of the mathematical operations and analyses performed on raw ("as-collected") Pb data.

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 is responsible for collecting quality data from their area of influence and distributing the data to the appropriate participant. Table 19-1 represents the data management structure for the Pb-PEP.

Table 19-1. PEP Data Management Structure

STAKEHOLDER	TYPE OF DATA	DISTRIBUTION
Regional Pb-PEP Coordinator or Self-Implementer Lead	Sites to participate in the performance evaluation for the year AQS Site ID of the Primary Pb monitor, POC, and Method Code of selected sites. Note: Method Code can be determined if sampler make and model are known	To monitoring organizations -To ESAT contractor -To the ESAT field scientist conducting Pb-PEP
Field Performance Evaluation Operator	Data from the operation of the FRM portable audit sampler including chain of custody information for collocated sample.	-To Regional TOPO/DOPO -To monitoring organization staff. -To Region 9 laboratory
Monitoring organization 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.
Performance Evaluation Laboratory Analyst	Pb Laboratory Data	-To LIMS -To AIRQA Web site
Performance Evaluation Laboratory Manager	Comprehensive Performance Evaluation Reports	-To AQS via contractor

19.2 Information Management Flow

Figure 19-1 provides a flow of the information management system for the Pb-PEP. In general, hardcopy/electronic information will be collected at various stages of the field and laboratory activities. 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 monitoring organizations.

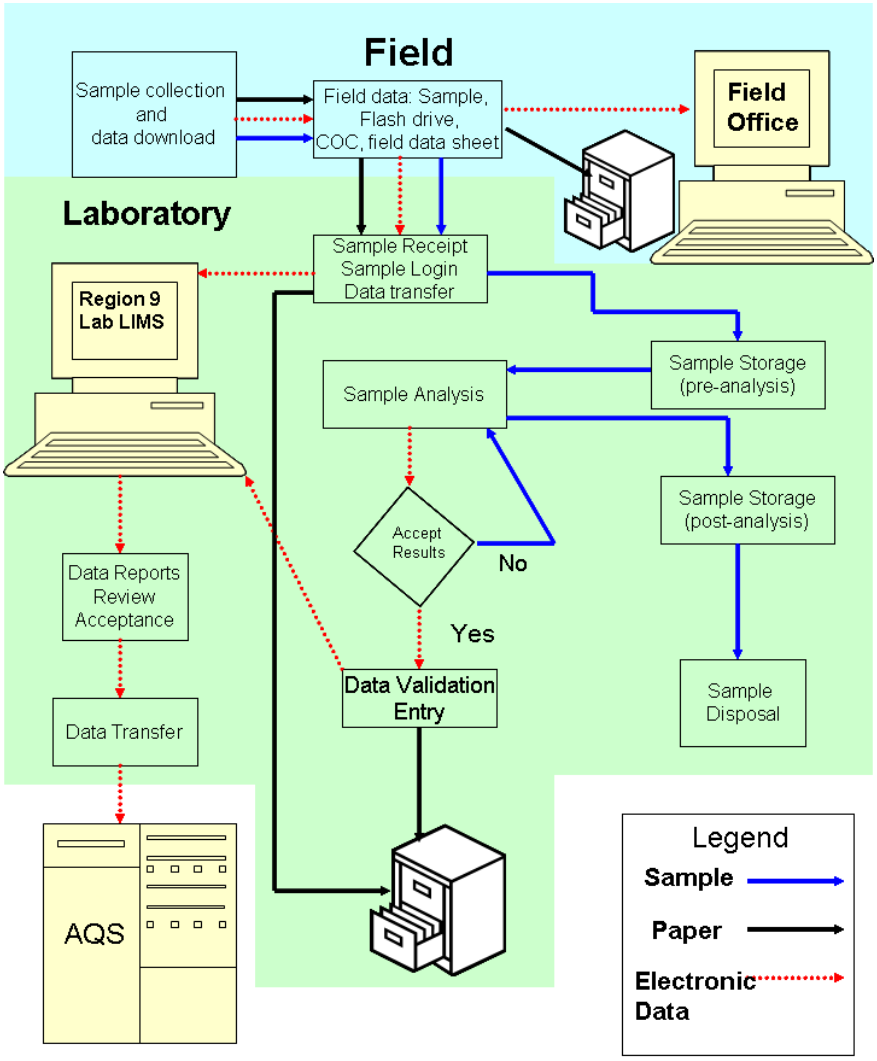


Figure 19-1. Pb-PEP Information/Sample Flow

19.2.1 Field Data

Information from the field will come from two sources: data from the Pb-PEP audit sampler and data from the monitoring organization's primary or collocated sampler.

Pb Performance Evaluation Portable Audit Sampler Data

Before leaving for the audit, the FS will print a FDS/COC from the AIRQA Web site. Each type of filter (routine, field blank, trip blank) requires different information, and the correct type must be selected from the AIRQA Web site. Appropriate filter information should be filled in on the form before the audit. The Pb portable audit 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 and site identifying information. Data download will be accomplished by utilizing a laptop computer immediately 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. The FS will use this information to complete the printed FDS/COC form. Upon arrival back to the field office, the FS will input the information on the hard copy FDS/COC to the online form in the AIRQA Web site. The original hard copy FDS/COC form will be sent along with the filters. The field verifications and site related data, although pertinent, does not need to be captured by the laboratory.

Pb Monitoring Organization 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. The PEP data will be concatenated with the primary sampler data in AQS where the data comparison will be made.

Pb Monitoring Organization Collocated Data

The monitoring organization will also perform four to six additional collocated samples at the collocated site(s) representing the PQAO. The monitoring organization will be required to submit the collocated sample with the COC and field data sheets to the Region 9 laboratory. Since EPA does not dictate the type of sampler the monitoring organization will use (other than the need for the sampler to have FRM/FEM status) the sampler may not be able to electronically record the same type of information as the PEP audit sampler. Therefore, the lab will be required to input information from either the monitoring organization's field data sheet or COC form.

19.2.2 Laboratory Data

Similarly to field data, laboratory data come from the Region 9 ICP-MS laboratory, the contracted XRF laboratory, and the monitoring organization laboratory.

Region 9 ICP-MS Laboratory

The performance evaluation laboratory analyzing the glass fiber filters 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. The data will be handled by a LIMS that acquires data both manually and automatically. The data will be electronically delivered to the AIRQA Web site upon validation. The laboratory deliverables to the AIRQA Web site are: chain of custody, analysis summary/report, and electronic data deliverable (EDD) in Excel format.

XRF Contract Laboratory

The contract laboratory selected to analyze the 46.2 mm Teflon® filters will operate according to the laboratory's current SOP. The data acquired by the laboratory will be collected and validated as detailed in the SOP. The data should be handled by a LIMS that acquires data both manually and automatically. The data will be electronically delivered to the AIRQA Web site upon validation. The laboratory deliverables to the AIRQA Web site are: chain of custody, analysis summary/report, and EDD in Excel format.

Monitoring Organization Laboratory Data

The monitoring organization 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.

19.3 Data Recording

Each method that generates information in the Pb-PEP will have a data form available for hand recording this information. These forms are found at the end of the particular Field or Laboratory SOP that describes the data collection activity, as summarized in Table 19-2.

Table 19-2. List of Pb-PEP Data Processing Operations for Critical Values

Reference	Title	Description (Data Related)
Pb-PEP Field SOP	*Filter Exposure and Concluding the Sampling Event*	Describes how to program the sampler to start and end sampling for a 24-hour period, as well as the acquisition of data from the portable sampler
Pb-PEP Field SOP and Pb-PEP Laboratory SOP	*COC Form and Field Data Sheet*	Describes the field procedure for completing the field portions of the COC Form and Field Data Sheet
AQS Manuals and Guides Web site	*User Guide – Air QA Reports*	Describes how to use the different reports within the AIRQA Web site.
AQS Manuals and Guides Web site[a]	*AQS Data Coding Manual (AQ2)*	Describes the coding of air quality data transactions; describes the various transactions used to create, update, or delete data in the AQS
AQS Manuals and Guides Web site[a]	*AQS User's Guide*	Describes the installation of AQS software, accounts, data input (batch and online), maintenance, and data retrievals (standard reports)

N/A = Not applicable
[a] AQS reference documents can be found at http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm

19.4 Performance Evaluation Data Transfer and Archiving

Table 19-3 presents information such as where various data are produced, and how/when it will be archived/transferred.

Table 19-3 Data Transfer and Archiving

Data Produced	How to Archive	When to Transfer
Performance Evaluation Field Sampler Data	Download each FDS/COC form to laptop computer or data link. Archive data to second computer or flash media at main field office.	Transfer data to the AIRQA Web site after each audit
Performance Evaluation Laboratory	Back-up of database occurs each night as per laboratory computer network storage procedures	Validated data paired to field data in AIRQA once a month and upload to AQS the following month

Concentration data will be uploaded to the AQS database using the most current AQS transaction protocol.

19.5 Data Validation

Data validation is a combination of checking that data processing operations have been correctly performed and of monitoring the quality of the field and laboratory operations. Data validation can identify problems in either of these areas. Once problems are identified, the data can be

corrected or invalidated, and corrective actions can be taken for field or laboratory operations. Numerical data stored in the PB-PEP LIMS are never internally overwritten by condition flags. Flags denoting error conditions or QA status are saved as separate fields in the database, so that it is possible to recover the original data.

The following validation functions are incorporated into the PB-PEP LIMS to ensure the quality of data entry and data processing operations:

- **100% data review.** The FDS/COC forms are subjected to a 100% data review for accuracy and completeness by the FS after each audit. The COC information on the FDS/COC form and laboratory results/deliverables are subjected to a 100% data review by the LA monthly at a minimum. All completed audit records on the AIRQA Web site must be reviewed and, if acceptable, marked "APPROVED" once a month by regional Pb-PEP lead.
- **Range checks.** Simple range checks are performed by the PB-PEP LIMS for almost all monitored parameters. For example, valid times must be between 00:00 and 23:59. Reasonableness checks may also be performed by the LA. For example, in most Regions the summer temperatures should be between 10 and 50°C. Because these range limits for data input are not regulatory requirements, the Pb-PEP Laboratory Manager may adjust them from time to time to better meet quality goals.
- **Completeness checks.** When the data are processed, certain completeness criteria must be met. For example, each sample event must have a start time, an end time, an average flow rate, and operator and technician names. At a minimum, FDSs, COC forms, and pre- and post-weighing data entry forms must be completely filled out.
- **Internal consistency and other reasonableness checks.** Several other internal consistency checks are built into the PB-PEP LIMS. For example, the end time of a filter must be greater than the start time. Computed filter volume (integrated flow) must be approximately equal to the exposure time multiplied by the nominal flow. Additional consistency and other checks will be implemented as the result of problems encountered during data screening.
- **Data retention.** Raw data sheets are retained in the laboratory files for a minimum of four calendar years and are readily available for audits and data verification activities. After 4 years, the FS or LA may request instructions from OAQPS on the disposition of hard copy records and computer back-up media. Sample filters will be archived for 4 calendar years at ambient temperature. At the end of the fourth calendar year, the LA may request instructions from OAQPS on the disposition of archived sample filters. The time frame for retention and disposition of Agency records is determined by EPA records schedules (see Element 9.0, *Documentation and Records*); however records may need to be retained for longer periods (e.g., for legal discovery). Therefore, approval from OAQPS is required before the destruction of records.
- **Statistical data checks.** Errors found during statistical screening will be traced back to original data entry files and to the raw data sheets, if necessary. These checks shall be conducted on a monthly schedule and before any data are submitted to the AQS.
- **Sample batch data validation.** This is discussed in Element 23.0, *Validation and Verification Methods*. Sample batch data validation associates flags, which are generated by

QC values outside of acceptance criteria, with a sample batch. Batches containing too many flags will be rerun and/or invalidated.

Table 19-4 summarizes the validation checks applicable to the Pb-PEP data.

Table 19-4. Validation Check Summaries

Type of Data Check	Electronic Transmission and Storage	Manual Checks	Automated Checks
Data parity and transmission protocol checks	✓		
Data review		✓	✓
Date and time consistency		✓	✓
Completeness of required fields		✓	✓
Range checking			✓
Statistical outlier checking			✓
Manual inspection of charts and reports		✓	
Sample batch data validation			✓

Two key operational criteria for Pb sampling are bias and precision. As defined in 40 CFR Part 58, Appendix A, these are based on differences between collocated sampler results and FRM PEs. The national Pb-PEP lead will evaluate these data as early in the process as possible, so that potential operational problems can be addressed. An objective of the Pb-PEP will be to optimize the performance of its Pb monitoring equipment. Initially, the results of collocated operations were control charted (see Element 14.0, *Quality Control Requirements*) to establish limits to flag potential problems. As the data results accumulate over time, EPA may reassess data quality with higher confidence and adjust the control limits accordingly.

19.6 Data Transformation

Calculations for transforming raw data from measured units to final concentrations are relatively straightforward and many are performed in the sampler data processing unit before being recorded. The following relations in Table 19-5 pertain to Pb monitoring.

Table 19-5. Raw Data Calculations

Parameter	Units	Type of Conversion	Equation
Filter volume (V_a)*	m^3	Calculated from average flow rate (Q_{ave}) in L/min and total elapsed time (t) in min multiplied by the unit conversion (m^3/L)	$V_a = Q_{ave} \times t \times 10^{-3}$
Mass on TSP filter strip or 46.2 mm filter	μg	Calculated from measured concentration reported by instrument, in µg/L (M), the volume of sample solution after sample preparation, in mL (V_f), the initial sample mL (V_i =either filter or strip) and the dilution factor, performed after sample preparation (D)	$C = M \times \frac{V_f}{V_i} \times D$
TSP full filter mass	μg	Calculated from the filter strip mass (μg) multiplied by the number of strips (9) in a TSP filter.	$Pb_{TSP} = C \times 9$
TSP Pb concentration (C_{Pb})	$\mu g/m^3$	Calculated from the laboratory mass (Pb_{TSP}) data and sampler total volume (V_a)	$C_{Pb} = \frac{Pb_{TSP}}{V_a}$
PM_{10} Pb Concentration (C_{Pb})	$\mu g/m^3$	Calculated from the laboratory mass (Pb_{10}) data and sampler total volume (V_a)	$C_{Pb} = \frac{Pb_{10}}{V_a}$

* Federal Reference Method instruments will provide this value.

19.7 Data Transmittal

Data transmittal occurs when data are transferred from one person or location to another or when data are copied from one form to another. Some examples of data transmittal are copying raw data from a notebook onto a data entry form for keying into a computer file and electronic transfer of data over a telephone or computer network. Table 19-6 summarizes data transfer operations.

Table 19-6. Data Transfer Operations

Description of Data Transfer	Originator	Recipient	QA Measures Applied
Field data to AIRQA Web site	Field Scientist	AIRQA Web site	Parity checking; transmission protocols, check against field data sheet information
Filter receiving, Chain-of-Custody Forms, and Field Data Sheets	Field Scientist	Laboratory Analyst	Filter numbers are automatically verified; reports indicate missing filters and/or incorrect data entries; FS checks data entry with 100% review
Laboratory results to AIRQA Web site	Laboratory Analyst	AIRQA Web site	Laboratory data is paired with field data and a validation routine for all pertinent QC checks is completed
Audit data to AQS	Laboratory Analyst	AQS (EPA)	Data transfer is checked by the technical support contractor for AQS

The Pb-PEP will report all Pb ambient air quality data and information specified by the AQS Data Coding Manual[10] in the required format for AQS. Such air quality data and information will be fully screened and validated and will be submitted directly to the AQS via electronic transmission, in the format of AQS, and in accordance with the monthly schedule to the AQS QA area since final Pb-PEP audit results are posted to the production AQS as data pairs. The data pair consists of the Pb-PEP audit measured value and the site's measured (primary monitor) value. SLAMS and NCore sites are required to post their site data to the AQS on the schedule shown in Table 19-7. Because posting the Pb-PEP data requires first obtaining the site's measured value from AQS, Pb-PEP data will not be posted to AQS production until after the due dates in Table 19-7. In cases where the site data have been uploaded to AQS and validated on or before the due date, the Pb-PEP audit data will also be uploaded.

Table 19-7. Data Reporting Schedule

Reporting Period	Due Date
January 1–March 31	June 30
April 1–June 30	September 30
July 1–September 30	December 31
October 1–December 31	March 31

[10] http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm

19.8 Data Reduction and Data Integrity

Data-reduction processes involve aggregating and summarizing results so that they can be understood and interpreted in different ways. The Pb monitoring regulations require certain summary data to be computed and reported regularly to EPA. Examples of data summaries include the following:

- Average Pb concentration
- Accuracy, bias, and precision statistics based on accumulated FRM/FEM data
- Data completeness reports based on numbers of valid samples collected during a specified period.

The integrity of Pb-PEP data reduction can be verified by independent review of the data and algorithms used. Verification of data integrity requires that Pb-PEP data be stored in a manner that permits any data modification to be detected. Detection of data changes is facilitated by the record keeping requirements of the Pb-PEP Laboratory SOPs, which require archiving of hard-copy records for important data (such as analytical batch reports, sample COC forms, and FDSs). These archived records enable EPA to trace raw data used in PEs to original documents, which have been dated and signed by program personnel.

In addition, Pb-PEP Laboratory SOPs require that regular copies of the PB-PEP LIMS data are archived into read-only media (e.g., CD-ROM or back-up tape) and regularly stored at an off-site location. These archival database copies may also be used to evaluate data integrity and to check that data used in a particular PE match the data on hard-copy records.

19.9 Data Analysis

The Pb-PEP is currently implementing the data summary and analysis requirements contained in 40 CFR Part 58, Appendix A. It is anticipated that as the Pb Monitoring Program develops, additional data analysis procedures may evolve. The following specific summary statistics will be tracked and reported for the Pb-PEP:

- Single sampler bias or accuracy (based on flow rate performance audits and the collocation study results)
- Single sampler precision (based on collocated data)
- Network-wide bias and precision (based on collocated data, flow rate performance audits)
- Data completeness.

Equations used for these reports are provided in the Table 19-8.

Table 19-8. Report Equations

Criterion	Equation	Reference
Accuracy of single sampler flow - single check (d_i) X_i is reference flow; Y_i is measured flow	$d_i = \frac{Y_i - X_i}{X_i} \times 100$	40 CFR 58, Appendix A, Section 4.1.1
Bias of a single sampler - annual basis (D_j)- average of individual percent differences between sampler and reference value; n_j is the number of measurements over the period	$D_j = \frac{1}{n_i} \times \sum_{i=1}^{n_j} d_i$	40 CFR 58, Appendix A, Section 4.1.3
Percent difference for a single check (d_i) - X_i and Y_i are concentrations from the primary and duplicate samplers, respectively.	$d_i = \frac{Y_i - X_i}{(Y_i + X_i)/2} \times 100$	40 CFR 58, Appendix A, Section 4.2.1
Coefficient of variation (CV_i) for a single check	$CV_i = \frac{\lvert d_i \rvert}{\sqrt{2}}$	Not referenced in CFR
Pooled coefficient of variation, quarterly basis ($CV_{j,q}$) - CV_i will only be used when the two measurements are both greater than 6 µg/m3	$CV_{j,q} = \sqrt{\sum_{i=1}^{n_j} \frac{CV_i^2}{n_{j,q}}}$	40 CFR 58, Appendix A, Section 4.3.2.1
Completeness	$Completeness = \frac{N_{valid}}{N_{theoretical}} * 100$	Not referenced in CFR

19.10 Data Flagging -Sample Qualifiers

A sample qualifier or a result qualifier consists of alphanumeric characters which indicate both the fact and the reason why the data value:

- did not produce a numeric result,
- produced a valid numeric result, but it is qualified in some respect relating to the type or validity of the result, or
- produced an invalid numeric result that is not to be reported outside the laboratory.

Qualifiers will be used in the field and the laboratory to signify data that may be suspect due to contamination, special events, or failure of QC limits. Appendix C contains a complete list of the data qualifiers for the field and laboratory activities. Qualifiers will be placed on field and laboratory data forms with additional explanations in free-form notes areas. Flags may be generated when sample batch information is entered into the Pb-LIMS and the validation process is run. During the sample validation process, which is discussed in Element 23.0, *Validation and Verification Methods*, the flags will be used to decide on validating or invalidating individual samples or batches of data.

19.11 Data Tracking

The Pb-PEP LIMS contains the input functions and reports necessary to track and account for the whereabouts of filters and the status of data processing operations for specific data. Information about filter location is updated on distributed data entry terminals at the points of significant operations. The following input data are used to track filter location and status:

- Laboratory package receipt (package is opened and filter IDs are logged in)
- Laboratory filter storage/archive (post-analysis)
- Laboratory data reporting (to AQS QA)

Tracking reports may be generated by any personnel with access to the PB-PEP LIMS. The following tracking reports are available:

- List of all filters that have been received but have not been analyzed
- List of all filters analyzed
- List of all filters in the filter archive
- Ad hoc reports (as required by program)

The Pb-PEP Laboratory Manager or designee is responsible for tracking filter status at least once a month and following up on anomalies such as excessive holding time in the laboratory before reweighing.

19.12 Data Storage and Retrieval

Table 19-9 shows archival policies for the Pb data.

Table 19-9. Data Archive Policies

Data Type	Medium	Location	Retention Time	Final Disposition
Chain-of-Custody Forms Field Data Sheets	Hard copy	Laboratory	4 years	Discarded, with permission from OAQPS
Laboratory notebooks	Hard copy	Laboratory	4 years	N/A
Field notebooks	Hard copy	Air Quality Division	4 years	Discarded, with permission from OAQPS
PB-PEP LIMS (excluding audit trail records)	Electronic (online)	Air Quality Division	Indefinite	Back-up media retained indefinitely
PB-PEP LIMS audit trail records	Electronic (back-up tapes)	Air Quality Division	4 years	Discarded, with permission from OAQPS

Filters	Filters	Laboratory	4 years at ambient temperature	Discarded, with permission from OAQPS

The Pb data reside on a Microsoft® Windows-compatible computer in the Pb-PEP weighing laboratory. The security of data in the Pb-PEP LIMS is ensured by using the following controls:

- Network security passwords for access to the project and database files
- Regular password changes (as specified by EPA network security)
- Independent password protection on all dial-in lines
- Logging of all incoming communication sessions, including the originating telephone number, the user's ID, and connect times
- Storage of media, including back-up tapes in locked, restricted access areas.

19.13 Information Management Security

The Pb-PEP LIMS is maintained on the EPA OAQPS QA support contractor's server, and access is restricted to authorized personnel. Data can only be released with the express permission of the National Pb-PEP Project Leader. PE results should not be released for events that have not been posted by the PQAO to AQS. Only validated, approved data are loaded into AQS, where the information becomes public domain. In addition, hard copies of all weighing logs and routine back-up copies of the Pb-PEP LIMS are archived. Comparison of the archived Pb-PEP LIMS copies with current Pb-PEP LIMS permits the detection of unauthorized or altered entries in the current Pb-PEP LIMS.

20.0 Assessments and Response Actions

For the purposes of this QAPP, an assessment is defined as an evaluation process used to measure the performance or effectiveness of the quality system and various measurement phases of the data operation.

The results of assessments indicate whether the QC efforts are adequate or need to be improved. Documentation of all QA and QC efforts implemented during the data collection, analysis, and reporting phases are important to data users and decision makers who can then consider the impact of these control efforts on the data quality (see Element 21.0, *Reports to Management*). Both qualitative and quantitative assessments of the effectiveness of these control efforts will identify those areas most likely to impact the data quality. Periodic assessments of Pb-PEP data quality are required to be reported to EPA. However, the selection and extent of the QA and QC activities used by the Pb-PEP depend on a number of local factors, such as the field and laboratory conditions, the objectives for monitoring, the level of the data quality needed, the expertise of assigned personnel, the cost of control procedures, and pollutant concentration levels.

To ensure the adequate performance of the quality system, the Pb-PEP will perform the following assessments:

- TSAs
- Audits of data quality (ADQs)
- Data quality assessments (DQAs)
- Peer review.

20.1 Assessment Activities and Project Planning

20.1.1 Technical Systems Assessment

A TSA is an evaluation of a data collection operation or organization to establish whether the policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. TSAs are performed both for EPA Regions and monitoring organizations that implement Pb-PEP activities. The Pb-PEP regional TSAs allow OAQPS to assess consistency of operation among the Regions and to improve the quality system. TSAs will be performed for field and laboratory activities.

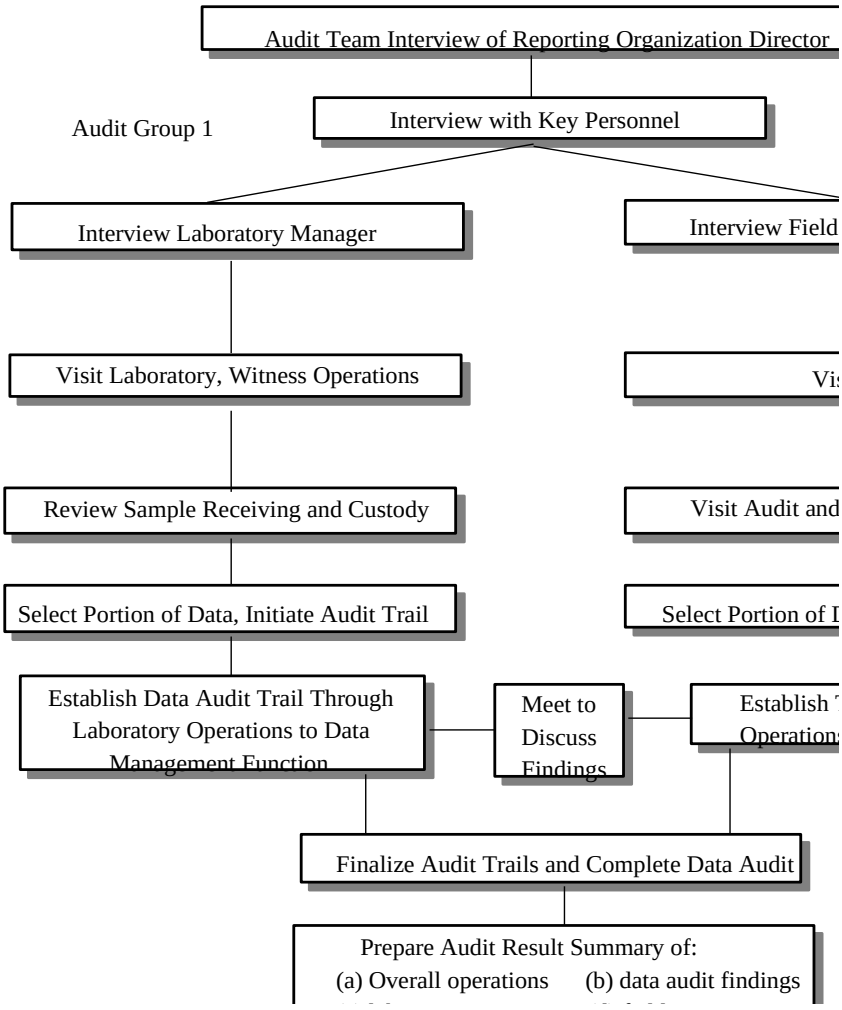
TSAs of the Pb-PEP laboratories and data management operations will be conducted by EPA (OAQPS, ORIA or a Region independent of Region 9) every two years and TSAs of the field operations will be conducted by the Regional WAM/TOPO/ DOPOs annually. This will include any monitoring organization-run Pb-PEP. It is possible that OAQPS would team with the Region during the TSAs of monitoring organization-run Pb-PEPs. TSAs may be conducted as a part of recertifying FSs, where appropriate.

The TSA can be accomplished by a team or by an individual assessor. Key personnel to be interviewed during the assessment are those who have responsibilities for planning, conducting field operations, laboratory operations, QA/QC, data management, and reporting. The TSA will review the following three activities:

- **Field.** Filter receipt, instrument setup, sampling, QA/QC, shipping and record keeping
- **Laboratory.** Sample receipt, sample preparation, analysis, archiving, QA/QC and record keeping.
- **Data management.** Information collection, flagging, data review, security, and upload.

The assessment activities are illustrated in Figure 20-1. To increase uniformity of the TSA, an assessment form will be used which can be found on the AIRQA website and the AMTIC Web site.

Figure 20-1. Audit Activities


Audit Team Interview of Reporting Organization Director
Audit Group 1
Interview with Key Personnel
Interview Laboratory Manager
Interview Field
Visit Laboratory, Witness Operations
Vis
Review Sample Receiving and Custody
Visit Audit and
Select Portion of Data, Initiate Audit Trail
Select Portion of I
Establish Data Audit Trail Through Laboratory Operations to Data Management Function
Meet to Discuss Findings
Establish
Operation
Finalize Audit Trails and Complete Data Audit
Prepare Audit Result Summary of:
(a) Overall operations
(b) data audit findings

TSAs will usually focus on either the field or lab component but rarely both (with the exception of Region 9). The TSA team will prepare a comprehensive written summary of findings organized into the following areas: planning, field operations, laboratory operations, QA/QC, data management, and reporting. Problems with specific areas will be discussed, and an attempt will be made to rank them in order of their potential impact on data quality. For the more serious of these problems, the TSA team will summarize assessment findings on the Assessment Finding Form (Figure 20-2).

Figure 20-2. Assessment Finding Form

Assessment Finding

Assessment Title: _____ Assessment #: _____
Finding #: _____

_____

Finding:

_____

Discussion:

QA Lead Signature: _____ Date: _____

Assessed Agencies
Signature: _____ Date: _____

By design, an Assessment Finding Form will be completed for each major deficiency that requires formal corrective action. This form will include information such as the finding impact, estimated time period of deficiency, site(s) affected, and reason for action. The Assessment Finding Form will notify the laboratory or field office of serious problems that may compromise the quality of the data and therefore require specific corrective actions. These forms are initiated by the TSA team and discussed at the debriefing. If the assessed group is in agreement with the finding, the form is signed by the ESAT organization during the debriefing. If a disagreement occurs, the TSA team will record the opinions of the group assessed and set a time at some later date to address the finding at issue. Assessment finding forms are filed under the AFC heading "Pb-PEP/108-025-01-01-237.1" (see Element 9.0, *Documentation and Records*).

20.1.1.1 Post-Assessment Activities

The major post-assessment activity is the preparation of the assessment report. The report will include the following:

- Assessment title, number, and any other identifying information
- Assessment team leaders, assessment team participants, and assessed participants
- Background information about the project, purpose of the assessment, dates of the assessment, particular measurement phase or parameters that were assessed, and a brief description of the assessment process
- Summary and conclusions of the assessment and corrective action required
- Attachments or appendices that include all assessment evaluations and assessment finding forms.

To prepare the report, the TSA team will meet and compare observations with collected documents and results of interviews and discussions with key personnel. Expected QAPP implementation is compared with observed accomplishments and deficiencies, and the assessment findings are reviewed in detail. Within 30 calendar days of the completion of the assessment, a draft assessment report will be prepared and submitted. The TSA report will be submitted to the appropriate ESAT personnel and appropriately filed under the AFC heading "Pb-PEP/108-025-01-01-237.1."

If the ESAT organization has written comments or questions about the TSA report, the TSA team will review and incorporate them as appropriate and prepare and resubmit a report in final form within 30 days of receiving the written comments. The report will include an agreed-upon schedule for corrective action implementation.

20.1.2.2 Follow-up and Corrective Action Requirements

The Regional office and ESAT may work together to solve required corrective actions. As part of corrective action and follow-up, an Assessment Finding Response Form (Figure 20-3) will be generated by the assessed organization for each Assessment Finding Form submitted by the TSA team. In addition, ESAT will include corrective action in its monthly progress reports. The Assessment Finding Response Form will be signed by the assessed organization and will be sent to the ESAT WAM/TOPO/DOPO, who reviews and accepts the corrective action. The Assessment Finding Response Form will be completed by the assessed organization within 30 days of acceptance of the assessment report. Assessment Finding Response Forms are filed under the AFC heading "Pb-PEP/108-025-01-01-237.1."

Figure 20-3. Assessment Finding Response Form

Assessment Finding Response Form

Assessed Division:_____

Assessment Title: _____ **Assessment #:** _____
Finding #:_____

_____

Finding:

Cause of the problem:

Actions taken or planned for correction:

Responsibilities and timetable for the above actions:

Prepared by: _____ **Date:** _____

Signed by: _____ **Date:** _____

QA Division

Reviewed by: _____ **Date:** _____

Remarks:

Is this assessment finding closed? _____ **When?** _____

File with official assessment records. Send copy to assessed organization.

20.1.2 Audit of Data Quality

An ADQ reveals how the data are handled, what judgments were made, and whether uncorrected mistakes were made. ADQs can often identify the means to correct systematic data reduction errors. An ADQ will be performed annually by OAQPS as part of the TSA. Thus, sufficient time and effort will be devoted to this activity so that the auditor or TSA team has a clear understanding and complete documentation of data flow. Pertinent ADQ questions will appear on the TSA check sheets to ensure that the data collected at each stage maintains its integrity. The ADQ will serve as an effective framework for organizing the extensive amount of information gathered during the audit of laboratory, field monitoring, and support functions within the agency. The ADQ will have the same reporting/corrective action requirements as the TSA**.**

20.1.3 Data Quality Assessments

A DQA is a statistical analysis of environmental data used to determine whether the quality of data is adequate to support a decision based on the DQOs. Data are appropriate if the level of uncertainty is acceptable for the decision based on the data. The DQA process is described in detail in *Guidance for the Data Quality Assessment Process* (EPA QA/G-9) and is summarized below.

- **Review the DQOs and sampling design of the program.** Review the DQOs and define statistical hypothesis, tolerance limits, and/or confidence intervals
- **Conduct preliminary data review.** Review precision and accuracy (P&A) and other available QA reports. Calculate summary statistics, plots, and graphs. Look for patterns, relationships, and anomalies
- **Select the statistical test.** Select the best test for analysis based on the preliminary review and identify underlying assumptions about the data for that test
- **Verify test assumptions.** Decide whether the underlying assumptions made by the selected test hold true for the data and the consequences
- **Perform the statistical test.** Perform test and document inferences and evaluate the performance for future use.

A DQA will be included in the *Pb-PEP Annual QA Report.* Details of these reports are discussed in Element 21.0, *Reports to Management*.

Measurement uncertainty will be estimated. Terminology associated with measurement uncertainty is found within 40 CFR Part 58 Appendix A and includes the following:

- **Precision.** A measurement of mutual agreement among individual measurements of the same property usually under prescribed similar conditions, expressed generally in terms of the standard deviation.

- **Accuracy.** The degree of agreement between an observed value and an accepted reference value; accuracy includes a combination of random error (precision) and systematic error (bias) components, which are due to sampling and analytical operations
- **Bias.** The systematic or persistent distortion of a measurement process, which causes errors in one direction; individual results of these tests for each method or analyzer shall be reported to EPA.

Estimates of the data quality will be calculated on the basis of single monitors, PQAOs, regions, laboratory and will be aggregated to all monitors.

20.1.4 Peer Review

Peer review is a documented critical review of work products. These reviews are conducted by qualified individuals who are independent of those performing the work but are collectively equivalent in technical expertise. OAQPS uses the peer-review process to assess its products and guidance. Any guidance documents or reports developed during the implementation of this program will be reviewed by EPA's QA Strategy Workgroup (facilitated by AAMG), which will serve as a peer reviewer. OAQPS will document comments and responses received as part of the peer-review process.

20.2 Documentation of Assessments

Table 20-1 summarizes each of the assessments discussed above.

Table 20-1. Assessment Summary

Assessment Activity	Frequency	Personnel Responsible	Report Completion	Resolution
TSAs	1/yr	OAQPS and Regional Work Assignment Manager/Task Order Project Officer/ Delivery Order Project Officer (WAM/TOPO/DOPO	30 days after the activity	Environmental Services Assistance Team (ESAT) or State, local, and Tribal (monitoring organization)
ADQs	1/yr	OAQPS (National Pb-PEP Project Leader)	30 days after the activity	WAM/TOPO/DOPOs
DQAs	1/yr	OAQPS and U.S. Environmental Protection Agency (EPA) Regions	120 days after the end of calendar year	EPA Regions and monitoring organization

21.0 Reports to Management

This element describes the quality-related reports and communications to management necessary to support the Pb-PEP.

Effective communication among all personnel is an integral part of a quality system. Regular, planned quality reporting provides a means for tracking the following:

- Adherence to scheduled delivery of equipment, data, and reports
- Documentation of deviations from approved QA and SOPs and the impact of these deviations on data quality
- Analysis of the potential uncertainties in decisions based on the data.

21.1 Communication

An organized communications framework facilitates the flow of information among the participating organizations and other users of the information produced by the Pb network. Figure 21-1 represents the principal communication pathways.

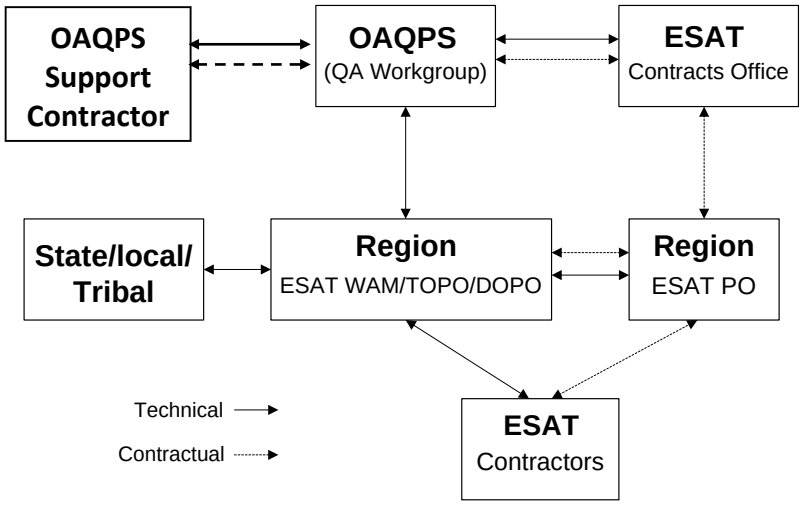


Figure 21-1. Lines of communication.

In general, ESAT contractors will be responsible for informing the Pb-PEP Laboratory Manager, the ESAT WAM/TOPO/DOPO, and the POs about technical progress, issues, and contractual obligations. On the technical side, the ESAT WAM/TOPO/DOPO(s) will be responsible for communicating with monitoring organizations and for informing OAQPS about issues that require technical attention. Contractual issues will be conveyed from the ESAT contractor

through POs to the ESAT Contracts Office and, if necessary, to OAQPS. Table 21-1 lists key EPA ESAT contacts.

The ESAT contractors will frequently communicate with the Pb-PEP Laboratory Manager and the ESAT WAM/TOPO/DOPO on the progress of their activities and any problems/issues associated with them. Resolution of these issues should take place in the Regions unless the issue could affect the implementation of the Pb-PEP at a national level. In those cases, it can be discussed and resolved through the ESAT Workgroup conference call.

Communications among various participants in the Pb-PEP will be critical to the success of the program. The field and laboratory SOPs contain procedures for required communication and for documenting this information.

Table 21-1. Communications Summary

Person	Communicates to	Communication Function
Performance Evaluation Program (Pb-PEP) Laboratory Manager	Office of Air Quality Planning and Standards (OAQPS)	Funding and resource needs National contract performance issues
	Regional Project Officer	Contract performance issues
	Laboratory Analyst (LA)	Review of deliverables Review of data Corrective action Schedule changes
Environmental Services Assistance Team (ESAT) Work Assignment Manager/Task Order Project Officer/Delivery Order Project Officer (WAM/TOPO/DOPO)	Field Scientist (FS)	Audit site selection and scheduling
	OAQPS	Funding and resource needs
	Regional PO	Contract performance issues
LA (ESAT or OAQPS Contractor)	Pb-PEP Laboratory Manager and Laboratory ESAT WAM/TOPO/DOPO	Laboratory progress Problems and issues Scheduling
	FS	Field equipment shipment Filter shipment receipt from field Field procedure issues
	OAQPS or approved contractor(s)	Database management and Air Quality System (AQS) uploads
FS	LA	Filter shipment from field Electronic mailing of field data Filter/equipment requests Schedule changes Field data verification
OAQPS or approved contractor	Pb-PEP Laboratory Manager	Requests for Pb-PEP data Data transfer to the AQS database Data quality issues

Person	Communicates to	Communication Function
National Pb-PEP Project Leader	ESAT WAM/TOPO/DOPO	Funding and resource needs Contract performance issues

21.1.1 Field Communication

Field communications can take place by phone or by e-mail. Important phone messages or conversations should be recorded using the Phone Communication Form (COM-1) in the field communications notebook; however, it is understood that the FS may not be in a position where this is feasible or the conversation is not noteworthy. Using the COM-1 form is most appropriate in situations where important information is exchanged, problems are communicated, issues are resolved or other activities that may support information reported in the monthly report. It is highly encouraged notes will include the following:

- Date
- Time
- Personnel involved
- Issue(s)
- Decision(s)
- Follow-up action(s)
- Follow-up action responsibility
- Follow-up action completed by (date).

If follow-up action is required by the FS, these actions will be included in the monthly progress reports (see Section 9.0, Documentation and Records, Section 9.2.2, Field Monthly Report). At a minimum, the FS will keep the original hardcopy in the field communications notebook. The FS may also choose to keep an electronic record of this information on a PC.

Field communication between the FS and the Regional WAM/TOPO/DOPO may be required. Cellular phones have been provided to each FS for calls related to Pb-PEP activities. The Regional WAM/TOPO/DOPOs should also identify alternates to receive field communications when he or she is not in the office.

21.1.1.1 Equipment Shipment Receipt

Upon request, the laboratory will ship filter media and cassettes to the field offices. On the day of receipt, the FS will contact the LA and will provide the following information to verify receipt:

- Date of shipment
- Number of boxes in shipment
- Tracking number.

21.1.1.2 Pb-PEP Conference Calls

The FS may be asked to participate in Pb-PEP conference calls to discuss progress or resolution of issues. The ESAT WAM/TOPO/DOPO will inform the FS of information that needs to be prepared for the call at least 3 days before the call if possible. During the call, the FS may use the Phone Communication Form (COM-1) to record issues and action items that pertain to his or her activities. These items will be included in the next monthly progress report.

21.1.1.3 Communicating with Monitoring Organizations and Site Operators

Dates for the Pb-PEP audits should be coordinated with the site's normal operating schedule. This coordination must be completed in advance so that the FS and the site operator have ample advanced notice and time to prepare for the audit. The procedure for such communications includes the following:

- The Regional WAM/TOPO/DOPO (or FS, as delegated by the Regional WAM/TOPO/DOPO) will contact each site operator before the audit. Contact must be made by phone if it is within 30 days of the audit, but e-mail is sufficient otherwise.
- About 1 week before the actual evaluation, the FS will call the site operator to confirm that the audit remains on schedule and to confirm meeting arrangements.

21.1.2 Laboratory Communications

Laboratory personnel will use the Phone Communications Form (COM-1) in the same manner as the FS, as described in Section 21.1.1.

21.1.2.1 Equipment Shipment

Once a month or as needed, the laboratory will ship filter media and cassettes to the Regional offices via EPA's contract carrier. On the day of shipment, the LA will communicate with the field contact and will provide the following information by e-mail:

- Date of shipment
- Number of boxes in shipment
- Tracking number.

21.2 Reports

The following section will discuss the various types of reports that will be generated in the Pb-PEP. Table 21-3 provides a summary of this information.

21.2.1 Progress Reports

Field Progress Reports

The FS will provide a written progress report to his or her Regional WAM/TOPO/DOPO at the end of each month (Pb-PEPF-2). The deadline is the 15th calendar day of the following month, unless otherwise specified by the Regional WAM/TOPO/DOPO. The Progress Report Form (COM-2) will be used to convey the following information:

- **Reporting date.** Beginning and end date that is covered in the report
- **Reporter.** Person writing the reports
- **Progress.** Progress on field activities, including evaluations scheduled within reporting date and evaluations conducted within reporting date
- **Issues.** Old issues reported in earlier reports that have not been resolved and new issues arising within the reporting date
- **Actions.** Action necessary to resolve issues, the person(s) responsible for resolving them, and the anticipated dates when they will be resolved.

Laboratory Progress Report

The LA will provide a written progress report to the Pb-PEP Laboratory Manager and the ESAT WAM/TOPO/DOPO at the end of each month (Pb-PEPF-2). The deadline is the 15th calendar day of the following month, unless otherwise specified by the Regional WAM/TOPO/DOPO. Progress Report Form (COM-2) will be used to convey the following information:

- **Reporting date.** Beginning and end dates covered in the report
- **Reporter.** Person writing the reports
- **Progress.** Progress on field activities
  - Receipt - Total number of filters received within a reporting date
  - Analysis- Filters analyzed within a reporting date
  - Data Submission - Valid data submitted to AQS
  - Shipments- Shipments made to each Region within a reporting date
- **Issues.**
  - Old issues. Issues reported in earlier reports that have not been resolved
  - New issues. Issues arising within a reporting date
- **Actions.** Action necessary to resolve issues, including the person(s) responsible for resolving them and the anticipated dates when they will be resolved.

The LA will maintain a complete record of the weekly progress reports in a three-ring binder.

21.2.2 QA Reports

Various QA reports will be developed to document the quality of data for the Pb-PEP. For more information about reporting time lines, please see Element 6.0, *Project/Task Description*, Section 6.4.6. The types of reports include the following:

DQA. This assessment is a 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. Element 24.0, *Reconciliation with Data Quality Objectives*, discusses the statistics to be used to evaluate the data in relation to the DQOs. DQAs will primarily be the responsibility of the EPA Regions (Regional assessments) and OAQPS (national assessments). A DQA will be performed annually.

P&A Reports. These reports will be generated quarterly and annually and will evaluate the precision, accuracy, and bias data against the acceptance criteria using the statistics documented in 40 CFR Part 58. These reports will be generated through AQS and will be the responsibility of OAQPS.

Assessment Reports. TSAs will be on file at the EPA Regional offices and OAQPS.

National QA Reports. A QA report provides an evaluation of QA/QC data for a given time period to determine whether the DQOs were met. QA reports will be more evaluative in nature than the P&A reports in that they will combine the various assessments and the QA data to report on the overall quality system. OAQPS will generate Annual QA Summary Reports and 3-year QA Reports on the Pb-PEP and its resultant data quality.

The Annual QA Summary Reports will include the following:

- Program overview and update
- Quality objectives for measurement data
- Implementation aspects
  - Training and certifications
  - Laboratory QA requirements (QC checks, TSAs, and data validation)
  - Field QA requirements (QC checks, standards certifications, and TSAs)
- DQAs
  - Laboratory and field controls
  - Precision (based on collocated data)
  - Accuracy and bias (based on collocated data, flow rate performance audits)
  - Completeness (Pb-PEP results versus FRM/FEM results)
- Summary

The 3-year QA Report is a composite of the annual reports, but with a more narrative interpretation and evaluation of longer term trends with respect to Pb-PEP sampler and operational performance.

21.2.3 Response/Corrective Action Reports

During TSAs, the response/corrective action reporting procedure will be followed whenever there is a finding in which OAQPS and/or the Region determines may affect data quality. The reporting procedure is designed as a closed-loop system. The Response/Corrective Action Report Form identifies the originator (who reported and identified the problem), states the problem, and may suggest a solution. The form also indicates the name of the person(s) assigned to correct the problem. The assignment of personnel to address the problem and the schedule for completion will be filled in by the appropriate supervisor. The reporting procedure closes the loop by requiring that the recipient state on the form how the problem was resolved and the effectiveness of the solution. Copies of the completed Response/Corrective Action Report Form will be distributed twice: first when the problem has been identified and the action has been scheduled; and second when the correction has been completed. The originator, the Regional WAM/TOPO/DOPO, and the National Pb-PEP Project Leader will be included in both distributions.

21.2.4 Control Charts with Summary

Control charts for field and laboratory instruments will be updated after every new calibration or standardization as defined in the relevant Field and Laboratory SOPs. FSs and LAs are responsible for reviewing each control chart immediately after it is updated and for taking corrective actions whenever an out-of-control condition is observed. Control charts are to be reviewed at least quarterly by the Pb-PEP Laboratory Manager (laboratory instruments) and the ESAT WAM/TOPO/DOPO. Control charts are also subject to inspection during TSAs, and laboratory personnel are responsible for maintaining a readily accessible file of control charts for each instrument. Due to the relatively small number of audits completed, the frequencies may need to be decreased for statistical significance. Minimally, the QC checks should in Table 21-2 should be control charted:

Table 21-2. Control Charting Recommendations

Activity	Quality Control Parameter	Frequency[a]
Field Operations	Average sampler flow rate for a sampling run	Quarterly
	Sampler flow rate verification	Quarterly
	Sampler temperature verification	Quarterly
	Sampler barometric pressure verification	Quarterly
	Collocation study results	After each collocation
	Field and trip blank data	Quarterly
Laboratory Analysis – ICP-MS	Initial calibration blank	Monthly
	Initial calibration verification	Monthly
	Lower level calibration verification	Monthly
	Continuing calibration blank	Monthly
	Continuing calibration verification	Monthly
Laboratory Analysis - XRF	Thin film calibration	Annually if necessary
	Digital signal processor calibration (DSP)	Monthly
	Quality control filters	Monthly

a - Due to the relatively small number of audits completed, the frequencies may need to be decreased for statistical significance.

21.2.5 Data Reporting

The data reporting requirements of 40 CFR Part 58.35 apply to those stations designated as SLAMS or NCore. Required accuracy and precision data are to be reported, at a minimum, on the same schedule as quarterly routine monitoring data submittals; however, it is anticipated that data will be reported to AQS no later than ~45 days of receiving the filter from the field. The required reporting periods and due dates for SLAMS and NCore sites are listed in Table 19-7.

Pb-PEP audit results are posted to AQS as paired data. The data pair comprises the Pb-PEP audit measurement and the site sampler's routine measurement. The site measurement value is taken from the site's posted AQS data for the date of the audit at the primary sampler. Because both

measured values are needed to report Pb-PEP audits to the AQS, the Pb-PEP audit results will not be available until the routine data is submitted.

In cases where the Pb-PEP audit results are available, but the routine measurements are not available before the deadlines in Table 19-7, the Pb-PEP audit results will not be posted until the next quarter's posting. For example, for a routine sample collected on March 31 and posted by the state on or before June 30, the associated Pb-PEP audit results should be posted to AQS by approximately July 31. If the same routine sample's result were not available in the AQS until September 1, the Pb-PEP audit results would not be posted until approximately January 31.

Air quality data submitted for each reporting period will be edited, validated, and entered into the AQS using the procedures described in the *AQS User Guide* and the *AQS Data Coding Manual*[11].

Table 21-3. Report Summary

Report Type	Frequency	Reporting Organization	Distribution
Field progress	Monthly	Environmental Services Assistance Team (ESAT) contractor	Regional Work Assignment Manager/Task Order Project Officer/Delivery Order Project Officer (WAM/TOPO/DOPO)
Laboratory progress	Monthly	ESAT contractor	Performance Evaluation Program (Pb-PEP) Laboratory Manager, ESAT WAM/TOPO/DOPO
Data Quality Assessment (DQA)	1/yr	Office of Air Quality Planning and Standards (OAQPS) and U.S. Environmental Protection Agency (EPA) Regions	ESAT contractor, Regional WAM/TOPO/DOPO, Ambient Monitoring Technology Information Center (AMTIC)
Pb-PEP audit results	Quarterly	OAQPS and authorized contractor	Air Quality System
Pb-PEP precision and accuracy (P&A) (collocation study results)	2/yr	National Pb-PEP Project Leader	Field Scientist, Regional WAM/TOPO/DOPO, AMTIC
TSA of monitoring organization or ESAT Pb-PEP	1/yr	EPA Region	ESAT contractor, assessed agency, National Pb-PEP Project Leader
QA Report	1/3 years	OAQPS and authorized contractor	Internal/external organizations through AMTIC
OAQPS systems audit	1/yr	OAQPS	ESAT contractor, Regional WAM/TOPO/DOPO
Response/corrective action	1/finding	ESAT contractor	ESAT contractor, Regional WAM/TOPO/DOPO, National Pb-PEP Project Leader

[11] http://www.epa.gov/ttn/airs/airsaqs/manuals/

22.0 Data Review, Validation, and Verification Requirements

This element describes how the Pb-PEP will verify and validate the data collection operations associated with the program. "Verification" can be defined as confirmation by examination and provision of objective evidence that *specified requirements* have been fulfilled. "Validation" can be defined as confirmation by examination and provision of objective evidence that the particular requirements for a specific *intended use* are fulfilled. The major objective for the Pb-PEP is to provide data of adequate quality to use in the comparison to routine data. This section will describe the verification and validation activities that occur during a number of the important data collection phases. Earlier elements of this QAPP and the Pb-PEP Field and Laboratory SOPs describe how the activities in these data collection phases will be implemented to meet the DQOs of the program. Review and approval of this QAPP provide initial agreement that the processes described in the QAPP, if implemented, will provide data of adequate quality. To verify and validate the phases of the data collection operation, the Pb-PEP will use various qualitative assessments (e.g., technical systems assessments, network reviews) to verify that the QAPP is being followed and will rely on the various QC samples, inserted at various phases of the data collection operation, to validate that the data will meet the DQOs described in Element 7.0, *Data Quality Objectives and Criteria for Measurement*.

22.1 Sampling Design

Element 10.0, *Sampling Design*, describes the sampling design for the network established by the Pb-PEP. It covers the number of PEs required for each PQAO, as well as the frequency of data collection. These requirements have been described in the CFR; however, it is the responsibility of Pb-PEP to ensure that the intent of the regulations are properly administered and performed.

22.1.1 Sampling Design Verification

Monitoring organizations will work with the EPA Regions to select and develop a list of sites for the evaluations conducted in each calendar year on or before December 1 of the previous year. The Regional WAM/TOPO/DOPOs, with the assistance of the ESAT contractors, will attempt to determine the most efficient site visit schedule. This schedule should be based upon the following:

- CFR requirements for audit frequency as discussed in Element 10.0, *Sampling Design*
- Meeting the same monitoring schedule as the routine sampler being evaluated (to prevent the need for the site to run and post an additional sample for the evaluation)
- Site proximity (the sites that are closest in proximity to each other can be visited within the same day or week).

The Pb-PEP implementation plan can then be reviewed and compared to the AQS data of active SLAMS/Tribal and NCore sites aggregated by PQAO. This can ensure that the Pb-PEP design is

being followed. The implementation plan will also be reviewed during OAQPS and Regional TSAs.

22.2 Sample Collection Procedures

22.2.1 Sample Collection Verification

Sample collection procedures are described in Element 11.0, *Sampling Methods Requirements*, and in detail in the Pb-PEP Field SOPs to ensure proper sampling and to maintain sample integrity. The following processes will be used to verify the sampling collection activities:

- **TSAs.** Will be required by OAQPS and by the EPA Regions annually, as described in Element 20.0, *Assessments and Response Actions*
- **Surveillance.** Will be conducted as required by the EPA Regions and will be used for frequent monitoring of specific data collection phases if deemed necessary.

Both types of assessments will be used to verify that the sample collection activities are being performed as described in this QAPP and in the field and laboratory SOPs. Deviations from the sample collection activity will be noted in Assessment Finding Forms and will be corrected using the procedures described in Element 20.0, *Assessments and Response Actions*.

22.2.2 Sample Collection Validation

The sample collection activity is just one phase of the measurement process. Using QC samples throughout the measurement process can help validate the activities occurring at each phase. The review of QC data (e.g., collocated sampling data, field/laboratory/trip blanks, and sampling/ laboratory equipment verification checks) that are described in Element 14.0, *Quality Control Requirements*, and Element 16.0, *Instrument Calibration and Frequency*, can be used to validate the data collection activities. Any data that indicate unacceptable levels of bias or precision or a tendency (trend on a control chart) will be flagged and investigated. This investigation could lead to a discovery of inappropriate sampling activities.

22.3 Sample Handling

Element 11.0, *Sampling Methods Requirements*, and Element 12.0, *Sample Handling and Custody*, detail the requirements for sampling handling; however, greater detail for both field and laboratory sample handling procedures occur in the Field and Laboratory SOPs, including the types of sample containers and the preservation methods used to ensure that they are appropriate to the nature of the sample and the type of data generated from the sample. There are unique handling concerns with both types of filters and the nature of the collected particles; therefore, sample handling is one of the phases where inappropriate techniques can have a significant effect on sample integrity and data quality.

22.3.1 Verification of Sample Handling

As mentioned in the above section, TSAs and surveillance will be performed to ensure that the specifications mentioned in the QAPP and SOPs are being followed. The assessments would include checks on the identity of the sample (e.g., proper labeling and COC records), packaging in the field, and proper storage conditions (e.g., COC and storage records) to ensure that the sample continues to be representative of its native environment as it moves through the data collection operation.

22.3.2 Validation of Sample Handling

Similar to the validation of sampling activities, the review of data from the collocated sampling and field, trip, and laboratory blanks (described in Element 14.0, *Quality Control Requirements*, and Element 16.0, *Instrument Calibration and Frequency*) and the use of control charts can be used to validate the sample handling activities. Acceptable precision and bias in these samples would lead one to believe that the sample handling activities are adequate. Any data that indicates unacceptable levels of bias or precision or a tendency (trend on a control chart) will be flagged and investigated. This investigation could lead to a discovery of inappropriate sampling handling activities that would require corrective action.

22.4 Analytical Procedures

Element 13.0, *Analytical Methods Requirements*, details the requirements for the analytical methods, while referent to the specific extraction and analysis SOPs. The methods include acceptance criteria (Element 13.0, *Analytical Methods Requirements,* and Element 14.0, *Quality Control Requirements*) for important components of the procedures, along with suitable codes for characterizing and flagging a sample's deviation from the procedure.

22.4.1 Verification of Analytical Procedures

As mentioned in the above sections, both TSAs and surveillance will be performed to ensure that the analytical method specifications mentioned in the QAPP and SOPs are being followed. The assessments will include checks on the identity of the sample. Deviations from the analytical procedures will be noted in Assessment Finding Forms and will be corrected using the procedures described in Element 20.0, *Assessments and Response Actions*.

22.4.2 Validation of Analytical Procedures

Similar to the validation of sampling activities, the following can be used to validate the analytical procedures: reviewing data from laboratory blanks, calibration checks, laboratory duplicates, and other laboratory QC activities described in Element 14.0 (*Quality Control Requirements*), Element 16.0 (*Instrument Calibration and Frequency*), and in the Pb-PEP Laboratory SOPs. Acceptable precision and bias in these samples would lead one to believe that the analytical procedures are adequate. Any data that indicate unacceptable levels of bias or precision or a tendency (trend on a control chart) will be flagged and investigated as described in

Element 14.0, *Quality Control Requirements*. This investigation could lead to a discovery of inappropriate analytical procedures, requiring corrective action.

22.5 Quality Control

Element 14.0, *Quality Control Requirements*, and Element 16.0, *Instrument Calibration and Frequency* of this QAPP specify the QC checks that are to be performed during sample collection, handling, and analysis. These include analyses of check standards, blanks, and duplicates, which indicate the quality of data being produced by specified components of the measurement process. For each specified QC check, the procedure, acceptance criteria, and corrective action are specified in field and laboratory SOPs.

22.5.1 Verification of Quality Control Procedures

As mentioned in the above sections, TSAs and surveillance will be performed to ensure that the QC method specifications mentioned in the QAPP are being followed.

22.5.2 Validation of Quality Control Procedures

Validation activities of many of the other data collection phases mentioned in this subsection use the QC data to validate the proper and adequate implementation of that phase. Therefore, validation of QC procedures will require a review of the documentation of the corrective actions that were taken when QC samples failed to meet the acceptance criteria and a review of the potential effect of the corrective actions on the validity of the routine data. Element 14.0, *Quality Control Requirements*, describes the techniques used to document QC review/corrective action activities.

22.6 Calibration

Element 16.0, *Instrument Calibration and Frequency*, as well as the field (Element 11.0, *Sampling Methods Requirements*) and the analytical (Element 13.0, *Analytical Methods Requirements*) sections of this QAPP detail the calibration activities and requirements for the critical pieces of equipment for the Pb-PEP. The Pb-PEP Field SOPs and the Pb-PEP Laboratory SOPs provide detailed calibration techniques.

22.6.1 Verification of Calibration Procedures

As mentioned in the above sections, TSAs and surveillance will be performed to ensure the calibration specifications and corrective actions mentioned in the QAPP are being followed. Deviations from the calibration procedures will be noted in Assessment Finding Forms and will be corrected using the procedures described in Element 20.0, *Assessments and Response Actions*.

22.6.2 Validation of Calibration Procedures

Similar to the validation of sampling activities, the review of the calibration data described in Element 14.0, *Quality Control Requirements*, and Element 16.0, *Instrument Calibration and Frequency* can be used to validate calibration procedures. Calibration data within the acceptance requirements would lead one to believe that the sample collection measurement devices are operating properly. Any data that indicate unacceptable levels of bias or precision or a tendency (trend on a control chart) will be flagged and investigated as described in Element 14.0, *Quality Control Requirements*, and Element 16.0, *Instrument Calibration and Frequency*. This investigation could lead to a discovery of inappropriate calibration procedures or equipment problems requiring corrective action as detailed in the element. Validation would include the review of the documentation to ensure that corrective action was taken as prescribed in the QAPP.

22.7 Data Reduction and Processing

22.7.1 Verification of Data Reduction and Processing Procedures

As mentioned in the above sections, TSAs and surveillance will be performed to ensure that the data reduction and processing activities mentioned in the QAPP are being followed.

22.7.2 Validation of Data Reduction and Processing Procedures

Data validation is initially completed by the Pb-PEP database on the AIRQA Web site. AIRQA pairs the field data component with the laboratory analysis result to create the final concentration for the sample. The AIRQA database also performs calculations for the required QC activities across the lifetime of the sample. AIRQA completes and produces an automated "verified dataset" that must then be validated by the regional and/or national Pb-PEP leads. This validation is recorded in AIRQA creating a record of the validation. As part of the ADQ discussed in Element 20.0, *Assessments and Response Actions*, the data used for these automated checks will be reviewed to ensure that:

- All audit records conducted are present
- No blanks are in the dataset/records are complete
- QC parameters have been met
- Sampling periods are correct
- Site data is correct
- Sample analysis was performed
- Appropriate qualifiers/flags are properly assigned
- Audits are completed and documented by the regional Pb-PEP leads

23.0 Validation and Verification Methods

Many of the processes for verifying and validating the measurement phases of the Pb-PEP data collection operation have been discussed in Element 22.0, *Data Review, Validation, and Verification Requirements*. If these processes, as written in the QAPP, are followed, the Pb-PEP should obtain the necessary data quality to permit comparison of Pb-PEP with the routine primary samplers. However, exceptional field events may occur and field and laboratory activities may negatively affect the integrity of samples. In addition, it is expected that some of the QC checks will fail to meet the acceptance criteria. Information on problems that affect the integrity of data is identified in the form of flags (Appendix C). It is important to determine how these failures affect the routine data. The review of this routine data and their associated QC data will be verified and validated on a sample basis, on groups of samples, and on a sample batch basis. Element 14.0, *Quality Control Requirements*, discusses the concept and use of sample batching.

23.1 Process for Validating and Verifying Data

23.1.1 Verification of Samples/Audits

The FS initiates the COC for the Pb-PEP audits on the AIRQA Web site. After the audit, the FS enters the field data into the AIRQA Web site. After each interaction with the AIRQA Web site, the FS will review and verify that the information entered on the site is accurate and complete. At the end of each month, a thorough review of the data will be conducted for completeness and data entry accuracy by the laboratory analyst. Data used in the calculation of Pb concentrations or used for evaluating critical validation criteria that are recorded on data sheets by hand will be 100% verified. After verification, these data will be reported electronically to the AIRQA Web site for validation by the Regional Pb-PEP contacts.

23.1.2 Validation of Samples/Audits

Validation of measurement data will occur at two stages during the audit process; after the laboratory analysis, and after the final pairing of the laboratory data with the field data in AIRQA. At different points in the process, the laboratory analyst or FS or may observe instances where the data quality may be affected, and they will document these events or observations in the bench sheets, LIMS or AIRQA Web site. In the case of the laboratory, the laboratory manager will review the data against the laboratory Pb-PEP validation QC criteria listed in Section 7, Tables 7-2 and 7-3 and notations made on the bench sheets and/or LIMS and make a decision regarding validation. In the same manner, the Regional Pb-PEP leads will review the final audit data against the field Pb-PEP validation QC criteria and notations made by the FS using the AIRQA Web site. The AIRQA Web site creates a report that shows the validation criteria, the recorded data for those criteria, and an assessment on if the criteria passed the check. These checks are classified into “critical criteria” and “operational evaluation criteria”. The

"critical criteria" and "operational evaluation criteria" are listed in Table 23-1 AIRQA Critical Criteria Validation Template and Table 23-2 AIRQA Operational Evaluation Criteria Template.

As described above, validation will occur at the end of the analytical process and after the analytical data has been uploaded to the AIRQA Web site and the automated validation routine has been conducted. The laboratory manager, Regional Pb-PEP leads and National Pb-PEP lead will have validation authority for Pb-PEP data. However, to avoid a waste of time and money, the laboratory analyst and FS may request immediate invalidation of a sample in the event of a significant failure or event. Some examples of a significant failure or event may be: malfunction of laboratory analyzer resulting in a total shutdown, malfunction of field sampler, or compromised filters (dropped, damaged, contaminated). Another important situation is a case where an audit is conducted and the SLT sampler does not complete the sample run. In this case, the FS will notify the Regional Pb-PEP lead and reschedule the audit.

23.1.3 Validation Acceptance and Reporting

The Pb-PEP Laboratory Manager will be responsible for determining that data have been validated before submittal to the AIRQA Web site. A summary report documenting all data that was validated and invalidated will be submitted to the Pb-PEP Laboratory Manager and National Pb-PEP lead each month. The Regional Pb-PEP lead will be responsible for validating the final audit concentration generated by the AIRQA Web site. All samples marked as "Approved" will then be entered into AQS by the OAQPS support contractor. The Regional Pb-PEP leads will follow the process described in Element 22 to approve and validate the audits. Audits that fail critical criteria flags or do not meet the weight of evidence consideration will not be marked as "Approved".

Audits that are not marked as "Approved" cannot be posted to the AQS because there is currently no provision in the AQS precision data record format for adding null value codes or data qualifiers.

Table 23-1. AIRQA Critical Criteria Validation Template

Criteria	Frequency	Acceptable Range	Reference
Void Sample/Visual Defect Check	all filters	Sample integrity protected during handling and transport (no contamination, mishandling, etc.)	Part 50 App B sec 8.2
Sampling Period	all filters	1440 minutes ± 60 minutes midnight to midnight	Part 50 App B sec 8.15
Average Flow Rate	every 24 hours of op	1.1-1.70 m3/min (varies with instrument) in actual condition	Part 50 App B sec 8.8
One-point Flow Rate Verification (High Volume TSP Sampling)	During Set-up prior to every sample day	±7% from transfer standard	Part 58 App A Method 2.2 sec 2.6
One-point Flow Rate Verification (Low Volume Sampling)	During Set-up prior to every sample day	±4% from transfer standard ±4% from design set point (16.67LPM)[a]	40 CFR Part 50, App L, Sec 9.2.5 and 7.4.3.1 and 40 CFR Part 58, Appendix A Sec 3.2.3 & 3.3.2
Flow rate percent coefficient of variance (low volume sampling only)	Following each sampling run	CV $\leq$ 2%	40 CFR Part 50, App L Sec 7.4.3.2

[a] One-point flow rate verification is more stringent than the cited reference

Table 23-2. AIRQA Operational Evaluation Criteria Template

Criteria	Frequency	Acceptable Range	Reference
System Leak Check	During precalibration check	Visual and Auditory inspection with faceplate blocked	1) Recommendation
Monitor Siting	1/year	Meets siting criteria or waiver documented	1) 40 CFR Part 58 App E, sections 2-5
Flow Rate Transfer Std.	1/yr	Resolution 0.02 m^3/min ± 2% reproducibility	1) 40 CFR Part 50, App B sec 7.8 2) Method 2.2 section 2.5
Field Thermometer	1/yr	2° C resolution	1) 40 CFR Part 50, App B sec 7.5
Field Barometer	1/yr	± 5 mm Hg resolution	1) 40 CFR Part 50, App B sec 7.6
Clock/timer Verification	1/3 mo.	± 2 min/24-hour	1) Method 2.2. section 2.3
Flow Rate Verification	Prior to each run	≤ ± 4% of target flow rate	1) Part 50 App L Sec 7.4.3.1
Barometric Pressure Verification	Prior to each run	± 10 mm Hg	1) 40 CFR Part 50, App L, Sec 9.3 2) Method 2.12 Table 6-1
Temperature Verification	Prior to each sampling run	± 2°C	1) 40 CFR Part 50, App L, Sec 9.3 2) Method 2.12 Table 6-1
Filter Check	After each sampling run	No contamination, pinholes, discoloration	1) Method 2.12 section 8
Time Check	Prior to each sampling run	± 2 min/24 hours	1) Method 2.2. section 2.3

24.0 Reconciliation with Data Quality Objectives

The DQOs for the Pb-PEP are described in Element 7.0, *Data Quality Objectives and Criteria for Measurement*. This element of the QAPP outlines the procedures that Pb-PEP will follow to determine whether the monitors and laboratory analyses are producing data that are sufficiently consistent to evaluate the bias of the National Pb network. For the data from the Pb-PEP to be used for estimating the bias associated with the National Pb network, the data must be internally consistent, meaning that the data should be precise and unbiased. The following outline is conceptual, and it will be updated with formal statistical procedures once they have been completely developed. For example, the amount of imprecision and bias that is tolerable in the Pb-PEP, while maintaining confidence in the estimates of bias for the National Pb FRM/FEM network, remains to be determined. An assessment of the quality of the data will be made at the PQAO level. The Regional offices and the OAQPS have responsibilities in the DQA.

24.1 Preliminary Review of Available Data

Element 7.0, *Data Quality Objectives and Criteria for Measurement*, of this QAPP contains the details for the development of the DQOs. Element 10.0, *Sampling Design*, of this QAPP contains the details for the sampling design, including the rationale for the design, the design assumptions, and the sampling locations and frequency. If changes in the DQOs or sampling design occur, the potential effect should be considered throughout the entire DQA.

A preliminary data review should be performed to uncover potential limitations to using the data, to reveal outliers, and generally to explore the basic structure of the data. The first step is to review the QA reports. The second step is to calculate basic summary statistics, generate graphical presentations of the data, and review these summary statistics and graphs. This review will be completed by the National Pb-PEP Lead.

24.2 Evaluation of Data Collected While All Pb-PEP Samplers Collocated—Regional Level

Twice per year (semi-annually), all of the Pb-PEP samplers used by a single FS, Region or a number of Regions must be collocated and run at the same location over the same time period. These are often referred to as "parking lot collocations."

The primary objective for collocating all of the samplers of the same method (high volume/low volume) is to determine whether one of the samplers is biased relative to the average of all the samplers and to estimate the repeatability of the instruments. An analysis of variance (ANOVA) will be used to evaluate the first objective. Additionally, an output of the ANOVA is an estimate of the repeatability. The conclusions from the ANOVA will allow EPA to determine whether there is a Pb-PEP sampler that produces results sufficiently different from the average. If this is the case, the instrument should not be used in the Pb-PEP. The estimate of the repeatability can

be used to evaluate the certainty with which the bias of the routine program within the Region can be estimated. Since there may be only two TSP Pb-PEP samplers in each Region, EPA may ask Regions to work together to consolidate samplers at a common area equidistant from Regional Headquarters but in an area with measurable Pb concentrations in order to run a more robust evaluation.

24.3 Evaluation of Data Collected While All Pb-PEP Samplers Collocated—National Level

A major goal of the national review of the data from the collocation of all the Pb-PEP samplers is to determine if the repeatability of the samplers varies greatly by region. OAQPS will check for equal variances across all regions by using standard statistical tests, such as the Bartlett test (an all-purpose statistical test that can be used for equal and unequal sample sizes), the Hartley test (a statistical test that requires equal sample sizes but is designed to find differences between the largest and smallest variances), and Levene's test (an alternative to Bartlett's test for testing for differences among the dispersions of several groups. Levene's test has greater power than Bartlett's for non-normal distributions of data)[12,13]. The conclusions from these tests will allow OAQPS to determine whether corrective action must be taken to reduce the variability for any of the Regions or laboratories. Corrective action will include a formal review of the training and operations to see if the cause for the disparity can be uncovered and corrected. With these data, OAQPS will also be able to evaluate with what certainty the bias of the routine program can be estimated.

[12] Neter, J., W. Wasserman, and M.H. Kutner. 1985. Applied Linear Statistical Models (2nd edition). Homewood, IL: Richard D. Irwin, Inc.

[13] U.S. EPA (Environmental Protection Agency). 2000. Guidance for Data Quality Assessment: Practical Methods for Data Analysis; EPA QA/G-9,QA00 UPDATE. United States Environmental Protection Agency, Office of Environmental Information, Washington, DC, EPA/600/R-96/084. July.

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