United States Environmental Protection Agency	Office of Air Quality Planning and Standards Research Triangle Park, NC 27711	EPA March 2009
Air		

Quality Assurance Document

Quality Assurance Project Plan for the Federal $PM_{2.5}$ Performance Evaluation Program

Foreword

U.S. Environmental Protection Agency (EPA) policy per EPA Order 5360.1 A2 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, plan, and define quality assurance/quality control (QA/QC) activities to be applied to the project, all within a single document.

The following document represents the QAPP for the environmental data operations involved in EPA's $PM_{2.5}$ Monitoring Network Performance Evaluation Program. This QAPP was generated by using the following EPA monitoring and QA regulations and guidance:

- 40 CFR Part 50, Appendix L
- 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*
- *EPA QA/G-9, QA00 update, Guidance for Data Quality Assessment: Practical Methods for Data Analysis*.

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

This document and related PEP SOPs are accessible in PDF format on the Internet on the Ambient Monitoring Technology Information Center's (AMTIC's) Bulletin Board (available at http://www.epa.gov/ttn/amtic/amticpm.html) under the QA area of the $PM_{2.5}$ Monitoring Information. The document can be read and printed using Adobe Acrobat Reader software, which is freeware that is available on many Internet sites, including the U.S. Environmental Protection Agency's (EPA) Web site. The Internet version is write-protected. Hardcopy versions are available by writing or calling:

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This is a living document, which means it may be revised as program objectives and implementation procedures evolve. Comments about technical content and the presentation of this document may be sent to Dennis Crumpler.

The document mentions trade names or brand names. Any mentions of corporation names, trade names, or commercial products do not constitute endorsement or recommendation for use.

Acknowledgments

This QAPP is the product of the combined efforts of EPA's Office of Air Quality Planning and Standards (OAQPS); the Office of Radiation and Indoor Air (ORIA) support laboratories in Las Vegas, NV; EPA's ORIA National Exposure Research Laboratory (NERL) in Montgomery, AL; EPA Regional offices; and State, local, and Tribal (SLT) organizations. Dennis Crumpler of OAQPS led and directed the 2007/2008 update, RTI International conducted the work under EPA contracts 68-D-02-065 and EP-D-08-047, and the $PM_{2.5}$ QA Workgroup reviewed the material in this document. The following individuals are acknowledged for their contributions.

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EPA Regions

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2	Mark Winter
3	Andrew Hass, Cathleen Kennedy, Colleen Walling
4	Greg Noah
5	Basim Dihu and Scott Hamilton
6	John Lay
7	Thien Bui and James Regehr
8	Michael Copeland
9	Mathew Plate
10	Christopher Hall

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Acknowledgments for the February 1999 Version

The following individuals are acknowledged for their contribution to the first edition of the PEP QAPP (February 1999 version), which served as the basis for this update.

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4 Jerry Burger and Herb Barden
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7 Leland Grooms, Mike Davis, and Shane Munsch
8 Ron Heavner, Gordon MacRae, and Joe Delwiche
9 Manny Aquitania and Bob Pallarino
10 Barry Towns, Bill Puckett, and Karen Marasigan.

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Acronyms and Abbreviations

AIRS	Aerometric Information Retrieval System
ANSI	American National Standards Institute
APTI	Air Pollution Training Institute
AQS	Air Quality System
ASTM	American Society for Testing and Materials
AWMA	Air and Waste Management Association
BP	barometric pressure
CAA	Clean Air Act
CFR	*Code of Federal Regulations*
CMD	Contracts Management Division
CMZ	community monitoring zone
CO	Contracting Officer
COC	chain of custody
COR	Contracting Officer's Representative
DAS	data acquisition system
DCO	Document Control Officer
DOPO	Delivery Order Project Officer
DQA	data quality assessment
DQOs	data quality objectives
EDO	environmental data operation
EMAD	Emissions, Monitoring, and Analysis Division
ESAT	Environmental Services Assistance Team
EPA	Environmental Protection Agency
FAR	Federal Acquisition Regulations
FEM	Federal equivalent method
FIPS	Federal Information Processing Standards
FR	flow rate
FRM	Federal reference method
FS	Field Scientist
GIS	geographical information systems
GLP	good laboratory practice
LA	Laboratory Analyst
LAN	local area network
MPA	monitoring planning area
MQOs	measurement quality objectives
MSA	metropolitan statistical area
MSR	management system review
NAAQS	National Ambient Air Quality Standards
NAMS	national air monitoring station
NATTS	National Air Toxics Trend Stations

NCore	National Core multi-pollutant monitoring stations
NIST	National Institute of Standards and Technology
OAQPS	Office of Air Quality Planning and Standards
OARM	Office of Administration and Resources Management
ORD	Office of Research and Development
ORIA	Office of Radiation and Indoor Air
PC	personal computer
POC	pollutant occurrence code
PD	percent difference
PE	performance evaluation
PEP	Performance Evaluation Program
$PM_{2.5}$	particulate matter less than 2.5 microns
PTFE	polytetrafluoroethylene
Q_a	sampler flow rate at ambient (actual) conditions of temperature and pressure.
QA	quality assurance
QAAR	Quality Assurance Annual Report
QAD	Quality Assurance Division Director
QAM	Quality Assurance Manager
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QC	quality control
QMP	Quality Management Plan
RH	relative humidity
R&P	Rupprecht & Patashnick
SIPS	State Implementation Plans
SLAMS	State and Local Ambient Monitoring Stations
SOP	standard operating procedure
SOW	statement of work
SPMS	special purpose monitoring stations
SYSOP	system operator
T_a	temperature, ambient or actual
TOPO	Task Order Project Officer
TSA	technical systems audit
TSP	total suspended particulate
V_a	air volume, at ambient or actual conditions
VOC	volatile organic compound
WAM	Work Assignment Manager

1.0 QA Project Plan Approval

Title: $PM_{2.5}$ Performance Evaluation Program Quality Assurance Project Plan

The attached Quality Assurance Project Plan (QAPP) for the $PM_{2.5}$ Performance Evaluation Program (PEP) is hereby recommended for approval and commits the participants of the program to follow the elements described within.

OAQPS	**Signature:** Dennis W. Crumpler **Name:** Dennis Crumpler, National PEP Lead, for Joe Elkins, QA Manager	**Date:**	3/31/2009
Region 1	**Signature:** **Name:**	**Date:**	4/2/09
Region 2	**Signature:** **Name:**	**Date:**	4/7/09
Region 3	**Signature:** Christopher B Pilla 4/9/09 **Name:**	**Date:**	
Region 4	**Signature:** **Name:**	**Date:**	4/8/09
Region 5	**Signature:** Monica C Paguia / Loretta Lehrman **Name:** Monica C Paguia QA Coordinator / Loretta Lehrman QA Manager	**Date:**	4/7/09
Region 6	**Signature:** **Name:** John Lay R6 TOPO	**Date:**	4/1/09
Region 7	**Signature:** Diane Harris **Name:**	**Date:**	04/15/2009
Region 8	**Signature:** **Name:**	**Date:**	
Region 9	**Signature:** **Name:**	**Date:**	
Region 10	**Signature:** **Name:** CHRIS HALL, AIR QA LEAD	**Date:**	3/31/09

For convenience signature lines have been copied and pasted into this composite page. PDF versions of all complete individual signature pages are on file with the OAQPS PEP Project Lead.

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3.0 Distribution

A copy of this QAPP will be distributed to the individuals who are listed in Table 3-1. The Regional Work Assignment Managers (WAMs), Task Order Project Officers (TOPOs), or Delivery Order Project Managers (DOPOs) will be responsible for distributing the QAPP to each Environmental Services Assistance Team (ESAT) contractor that participates in the environmental data operations of the PEP. The Regional WAMs/TOPOs/DOPOs should also to provide a copy of this QAPP to their Regional Quality Assurance Managers (QAMs).

Table 3-1. Distribution List

Name	Address	Phone Number	E-mail
ESAT			
Headquarters ESAT Program Manager Colleen Walling	U.S. Environmental Protection Agency (EPA) Headquarters Ariel Rios Building 1200 Pennsylvania Ave., NW Mail Code: 5203P Washington, DC 20460	(703) 603-8814	walling.colleen@epa.gov
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Lynette Gallion	(Mail Code: 3805R)	(202) 564-4463	gallion.lynette@epa.gov
Deborah Hoover	U.S. EPA–Region 4 61 Forsyth Street, S.W. Atlanta, GA 30303-8960	(404) 562-8373	hoover.deborah@epa.gov
OAQPS			
WAM, National PEP Project Leader Dennis Crumpler	U.S. EPA Office of Air Quality Planning and Standards MQAG (C304-06) Research Triangle Park, NC 27711	(919) 541-0871	crumpler.dennis@epa.gov
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Mark Shanis		(919) 541-1323	shanis.mark@epa.gov
Field Instrument Consultant Jeff Lantz	U.S. EPA Office of Radiation and Indoor Air, Radiation & Indoor Environments National Laboratory P.O. Box 98517 Las Vegas, NV 89193-8517	(702) 784-8275	lantz.jeff@epa.gov

Name	Address	Phone Number	E-mail
REGIONS			
Region 1 **TOPO** Mary Jane Cuzzupe **Regional Project Officer (RPO)** Pat Svetaka	U.S. EPA–Region 1 New England Regional Laboratory Office of Environmental Measurement and Evaluation 11 Technology Dr. (ECA) North Chelmsford, MA 01863	(617) 918-8383 (617) 918-8396	cuzzupe.maryjane@epa.gov svetaka.pat@epa.gov
Region 2 **TOPO** Mark Winter **RPO** Yolanda Guess	U.S EPA–Region 2 Raritan Depot (220MS220) 2890 Woodbridge Ave. Edison, NJ 08837-3679 ** Same as above ** (Mail Code: 215MS215)	(732) 321-4360 (732) 906-6875	winter.mark@epa.gov guess.yolanda@epa.gov
Region 3 **TOPO** Cathleen Kennedy **RPO** Khin-Cho Thaung	U.S. EPA–Region 3 1650 Arch. St. (3AP22) Philadelphia, PA 19103-2029 U.S. EPA–Region 3 Environmental Science Center 701 Mapes Rd. (3ES20) Fort Meade, MD 20755-5350	(215) 814-2746 (410) 305-2743	kennedy.cathleen@epa.gov thaung.khin-cho@epa.gov
Region 4 **TOPO** Greg Noah **RPO** Sandra Sims	U.S. EPA–Region 4 Science and Ecosystem Support Division 980 College Station Rd. Athens, GA 30605-2720 U.S. EPA–Region 4 Atlanta Federal Center 61 Forsyth St., SW Atlanta, GA 30303-8960	(706) 355-8635 (706) 355-8772	noah.greg@epa.gov sims.sandra@epa.gov
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REGIONS (continued)			
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Region 9 **TOPO** Mathew Plate **RPO** Rose Fong	U.S. EPA–Region 9 75 Hawthorne St. (MTS-3) San Francisco, CA 94105 ** Same as above ** (Mail Code: MTS-3)	 (415) 972-3799 (415) 972-3812	 plate.mathew@epa.gov fong.rose@epa.gov
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RTI			
PEP Support **Work Assignment** **Leader** Jennifer Lloyd **Project Manager** James Flanagan	RTI International 3040 Cornwallis Rd. P.O. Box 12194 Research Triangle Park, NC 27709	 (919) 541-5942 (919) 990-8649	 jml@rti.org jamesf@rti.org

It is likely the individuals who are listed in Table 3-1 will not be associated with the program indefinitely; therefore, updates to the PEP contact list will be made available on the Internet through the Ambient Monitoring Technology Information Center's (AMTIC's) Bulletin Board under the quality assurance (QA) area of the $PM_{2.5}$ Monitoring Information (available at http://www.epa.gov/ttn/amtic/pmpep.html).

4.0 Project/Task Organization

This element will provide the U.S. Environmental Protection Agency (EPA) and other involved parties with a clear understanding of the role that each party plays in the PEP and will provide the lines of authority and reporting for the project.

The degree of complexity and the number of agencies that are involved with the PEP requires that the flow of information and associated communications be structured to optimize the collective resources. The deployment and operation of this network is a shared responsibility among all of the involved organizations. The purposes of the following role descriptions are to facilitate communications and to outline basic responsibilities. Figure 4-1 provides a basic diagram of the organization and the lines of communication. Table 3-1 in Element 3.0, *Distribution*, lists the primary personnel who are involved in the PEP.

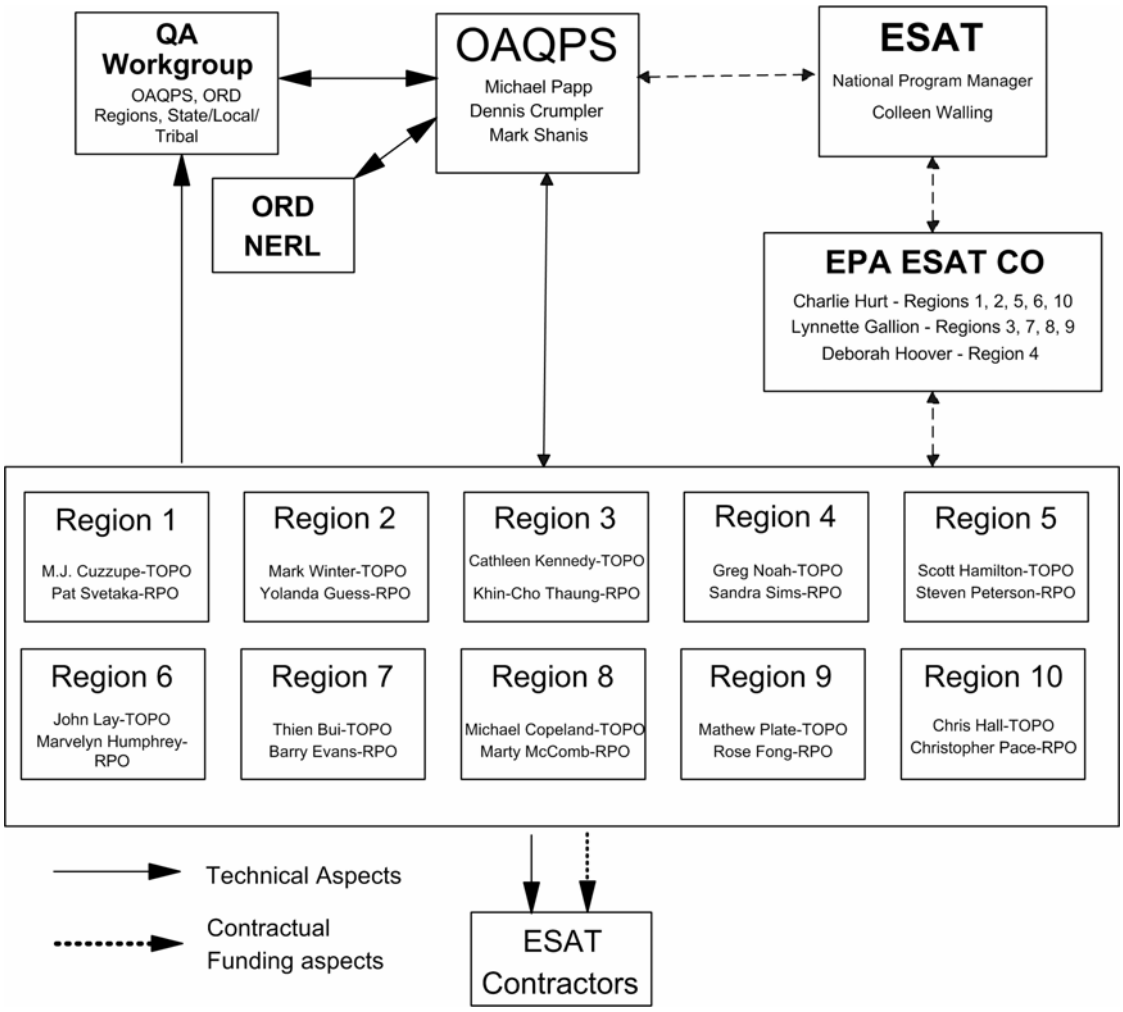


Figure 4.1. Organizational chart of the technical and contractual aspects of the PEP.

4.1 The PEP Workgroup (Previously the $PM_{2.5}$ QA Workgroup)

The $PM_{2.5}$ QA Workgroup was originally formed in 1988 to address the QA aspects of the $PM_{2.5}$ Monitoring Program during the deployment of the $PM_{2.5}$ ambient monitoring network and the PEP. Members of this workgroup included personnel from EPA's Office of Air Quality Planning and Standards (OAQPS), EPA Regions, EPA's Office of Research and Development (ORD), the National Exposure Research Laboratory (NERL), and State, local, and Tribal (SLT) air monitoring organizations. That workgroup has evolved into a more overarching "National Ambient Monitoring QA Strategy Workgroup" for all ambient monitoring and meteorological measurements.

The PEP has formed an ad hoc workgroup, the PEP Workgroup, which consists of the EPA Regional WAMs, TOPOs, and DOPOs for the ESAT contract; and 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 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's Office of Air Quality Planning and Standards

OAQPS, which has oversight for ensuring the quality of the nation's ambient air data, has developed specific regulations for the development of a quality system as found in 40 *Code of Federal Regulations* (CFR) Part 58, Appendix A. One specific element of this quality system is the PEP. OAQPS has the following responsibilities to ensure the continued success of this program:

- Coordinating and overseeing the PEP
- Providing a contractual vehicle for the acquisition and distribution of the Federal Reference Method (FRM) portable evaluation samplers
- Developing a memorandum of understanding with the ESAT office
- Working with the EPA Regions to determine which SLT organizations will use the federally implemented PEP
- Transferring the necessary funds through the EPA Regional offices to the EPA ESAT Contracts Management Division (CMD) to support the PEP and to the Region 4 office for laboratory equipment and consumables
- Procuring the majority of the field capital equipment and facilitating major repairs
- Distributing filters to the national weighing laboratory

- Developing the PEP Implementation Plan, the statement of work for the PEP in the ESAT contract language, SOPs, and the PEP QAPP
- Developing the field and laboratory personnel requirements
- Developing the field and laboratory training activities, participating in training, and securing national experts to answer specific technical questions
- Developing and maintaining the Performance Evaluation Database (PED)
- Assessing the concentration information uploaded into EPA's Air Quality System (AQS) database and assisting in reconciling significant differences between site and audit data
- Initiating and instituting a communications network and serving as a liaison to groups that are working on the PEP
- Interacting with regional, SLT organization personnel about the setup, operation, and data results of the performance evaluations (PEs)
- Ensuring the program's success by performing various assessment activities, such as Regional management systems reviews (MSRs) and technical systems audits (TSAs).

OAQPS provides oversight for the program through the National PEP Project Leader. 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 implementing the PEP and this QAPP, most technical components (with support from ORD, Regional offices, and SLT organizations), and the resource estimates underlying program implementation. Resource guidance necessary for the State and Tribal Assistance Grants (STAG) distribution is coordinated through the Planning, Resources, and Regional Management staff within OAQPS. In addition, the National Air Data Group, within the Outreach and Information Division, is responsible for maintaining the AQS database.

4.3 ESAT Organization

Since the PEP's inception in 1999, the PEP field operators and laboratory technicians have been secured through EPA ESAT's contractors[1] In 2006–2007, the support was dispersed among 10 new contracts, one for each region. EPA's oversight of ESAT consists of Contracting Officers (COs), Contracting Specialists (CSs), Project Officers (POs), and Regional Project Officers (RPOs). Table 4-1 provides information about the regions and important contacts within them. Additional information about ESAT and these contacts is available at http://www.epa.gov/superfund/policy/contracts/12esat.htm.

[1] Currently, ESAT is providing all field operations for the federally implemented PEP. If for some reason an ESAT contractor is unable to provide the capacity that is required for the PEP, EPA may issue contracts to other organizations to fulfill these needs. An example might be in case of a national disaster. Such contractors would be expected to have similar roles and responsibilities as described for the ESAT organization in this QAPP.

Table 4-1. ESAT Oversight

Colleen Walling—ESAT Program Manager		
Region	**Contracting Officer**	**Regional Project Officers**
1	Charlie Hurt	Pat Svetaka
2	Charlie Hurt	Yolanda Guess
3	Lynette Gallion	Khin-Cho Thaung
4	Deborah Hoover	Sandra Sims
5	Charlie Hurt	Steven Peterson
6	Charlie Hurt	Marvelyn Humphrey and Melvin Ritter
7	Lynette Gallion	Barry Evans
8	Lynette Gallion	Marty McComb
9	Lynette Gallion	Rose Fong
10	Charlie Hurt	Christopher Pace

Some important aspects of the ESAT contract include the following:

- Only the WAM/TOPO/DOPO, the RPO/PO, and the CO/CS 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.
- WAM/TOPO/DOPOs and RPO/POs will prepare the work assignments/task orders/delivery orders and are effective only upon approval by the CO.

The EPA Contracts Manual describes the roles and responsibilities of COs, CSs and POs, which do not need to be explained here. The important roles and responsibilities for the 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 that contract activities fall within ESAT's scope of work
- Approve work assignments, task orders, and delivery orders.

Contracting Specialists

- Work with OAQPS or Regional ESAT WAM/TOPO/DOPOs 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 a Regional liaison between the RPO and the CO
- Provide contract-wide administration
- Develop a memorandum of understanding with OAQPS.

Regional Project Officers

- Provide overall management and oversees performance of respective Regional teams
- Review Region-specific invoices with input from WAMs, TOPOs, and DOPOs
- Prepare (with WAM/TOPO/DOPO) PEP work assignments, task orders, and delivery orders
- Assist in developing ESAT work assignments, task orders, and delivery orders
- Ensure that there are qualified contractual personnel available to implement the PEP
- Provide administrative and logistical support for the ESAT contract
- Oversee the performance of the required activities of the contractor
- Regularly communicate with program participants (e.g., OAQPS, Region).

Work Assignment Managers, Task Order Project Officers, and Delivery Order Project Officers

In most cases, the WAM/TOPO/DOPO will serve as a technical person from the regional air program branch or division. He or she will be responsible for assisting in the technical implementation of the program. Some of the WAM/TOPO/DOPO's activities may include the activities listed in Section 4.4; however, the primary responsibilities related to the ESAT contract are the following:

- Communicating with the National PEP Project Leader about the current status of funding for the federally implemented PEP
- Preparing (with RPO) PEP work assignments, task orders, and delivery orders
- Setting up a file system that contains 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 PEP
- Reviewing the contractor's work plan and preparing findings on proposed tasks, labor hours skill mix, and materials and quantities
- Monitoring contract and QAPP compliance
- Tracking the dollars and hours, providing technical direction (in accordance with the terms of the contract), and reviewing monthly technical and financial reports

- Verifying contractor representations of deliverables received and accepted and/or progress
- Communicating contractor performance, budgetary, and administrative/logistical issues to the RPO and to the National PEP Project Leader
- Validating and accepting data.

4.4 EPA Regional Offices

The EPA Regional offices are the major communication link with SLT organizations in terms of communicating the needs and concerns of states to EPA Headquarters offices and in communicating to the SLT organizations the objectives and guidance that are often developed by OAQPS. This role is vital for the development of effective policies and programs. For the PEP, the Regional offices have the following specific responsibilities:

All Regions:

- Assist, through QA workgroup activities, in the development of all pertinent PEP guidance documents
- Review and approve the work plans submitted by the ESAT contractors
- Provide a WAM/TOPO/DOPO to oversee the technical aspects of field activities that are performed by the ESAT contractors
- Train and certify ESAT field personnel (if the Regional trainer is certified by EPA to do so)
- Provide technical oversight of the field activities by performing TSAs of the PEP field or support laboratory operations
- Provide oversight of PEP activities for SLT organizations that have assumed the field and/or laboratory operations for PEP in their jurisdictions
- Work with SLT organizations to develop a yearly schedule of site evaluations
- Provide a yearly schedule of site evaluations for the ESAT contractors
- Inform SLT organizations of an upcoming PE
- Evaluate the PE data, forward that data to the SLT organizations, and inform them of significant differences between the PEP and their FRM/Federal Equivalent Method (FEM) monitors
- Participate in training and certification activities, including multi-state conferences, EPA satellite broadcasts, and other training vehicles
- Attend conference calls and meetings about PE activities.

Region 4 (including items previously listed):

- Provide a WAM/TOPO/DOPO to oversee the technical aspects of laboratory activities that are performed by the ESAT contractors
- Develops the primary laboratories for this program with respect to logistical, technical, and analytical support, including providing the necessary facilities to store, condition, weigh, distribute, and archive filters and the distribution of filters (including coolers, ice packs, and other supplies) to the Regions
- Trains and certifies ESAT laboratory personnel (if a Regional trainer is certified by EPA to do so)
- Provides technical oversight of the laboratory activities by performing TSAs of these activities
- Validates data before they are uploaded into the AQS.

4.5 ESAT Contractors

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

- Developing a work plan and cost estimates for each work assignment, task order, or delivery order
- Staffing appropriately to meet the contract requirements
- Successfully implementing the activities described in the work plan and work assignment/task order/delivery order
- Receiving training and certification(s) to perform field and laboratory PEP activities, as appropriate
- Understanding 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 $PM_{2.5}$ Monitoring Program; as well as for optimizing the data quality. Conversely, the PEP provides an invaluable QA/QC function on the overall performance of the network and often isolates unique sampler or site problems. It is imperative that SLT organizations work with the EPA Regional offices to make every PEP audit event successful. They should identify problems that will impede the mission of the PEP as early as possible and help find solutions. The SLT organizations have the following specific responsibilities:

General monitoring site accommodations:

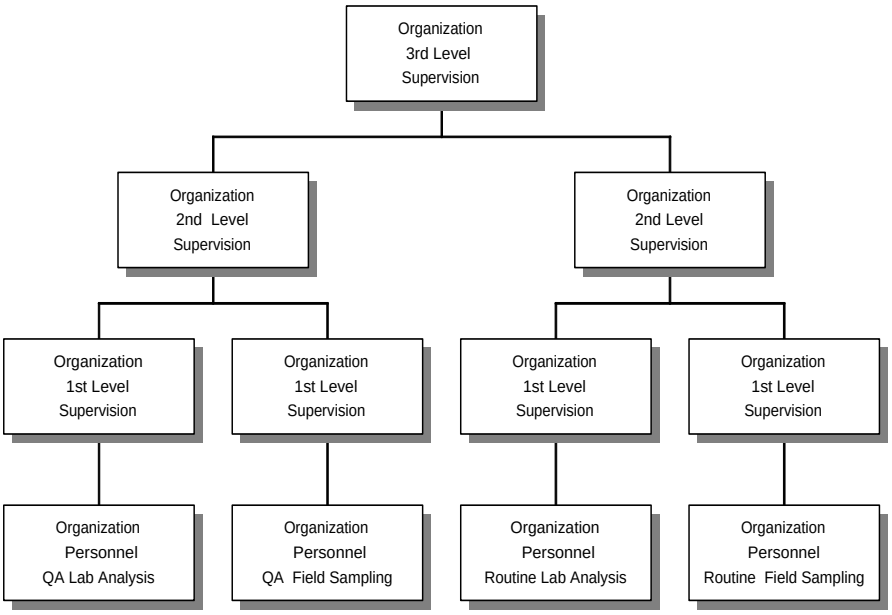
- Ensure that there is sufficient space for a collocated audit monitor within 1 to 4 meters of the primary monitor, while still meeting CFR siting requirements
- Ensure that the collocated audit monitor can be placed within 1 meter vertically of the primary monitor
- Ensure that each site is accessible for a PEP sampling (may be an issue for some continuous potential "FEM" sites.)
- 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 PEP samplers.

If not using the federal PEP:

- Implements a comparable or equivalent PEP at the frequency prescribed by the federal regulations in 40 CFR Part 58, Appendix A
- Adheres to the definition of independent assessment (see Figure 4-2)
- Participates in similar training and certification activities
- Procures necessary equipment and consumables
- Develops the necessary SOPs and QA procedures into their respective QAPPs
- Participates in semi-annual collocation precision studies of the SLT and federally deployed PEP samplers
- Transmits data to the AQS according the schedule outlined in the monitoring QA regulations and procedures provided by EPA
- Selects the sites for evaluation
- If using a third-party laboratory, requires that laboratory to participate in an annual gravimetric round-robin PE administered by EPA's Office of Radiation and Indoor Air– National Air and Radiation Environmental Laboratory (ORIA-NAREL), in Montgomery, AL. This is not required if the SLT PEP uses EPA's PEP weighing laboratory for its filter weighing
- Prepares a weighing laboratory annual report in an EPA-specified format and submits it to EPA. This is not required if the SLT PEP uses EPA's PEP weighing laboratory for its filter weighing
- Submits to an annual TSA of their PEP activities by the EPA Regional PEP Leader or QA Manager.

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 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 pre- and post-sample weighing of audit filters must be performed 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 4-2. Definition of an independent assessment.

If using the federal PEP:

- Operates the routine $PM_{2.5}$ FRM/FEM monitoring network according to the established regulations and guidelines, including proper siting, operations, and QA procedures
- Creates an accurate list of State and Local Ambient Monitoring Station (SLAMS) or Tribal sites with addresses, AQS IDs, makes and models of routine sampling equipment, and sampling schedules
- Assists, through $PM_{2.5}$ QA 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 $PM_{2.5}$ FRM/FEM monitoring network for PEs and the associated sampling schedules
- Ensures that an Agency representative is onsite when the PEP Field Scientist (FS) arrives and performs the evaluation. This 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
- 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 Participating Entities

EPA Office of Research and Development

The ORD's primary role in the implementation of the PEP will be to serve as a technical consultant, advisor, and arbiter of technical issues. This action will be primarily through the NERL, which provides many of the applied research elements for the program. ORD also has the overall responsibility for designating all air monitors as FRM/FEM. The FRM/FEM portable audit sampler must be designated by ORD through its Federal Reference and Equivalency Program (40 CFR Part 53). This overall responsibility includes the following:

- Designating $PM_{2.5}$ samplers as FRM/FEM and providing technical support
- Providing technical support for the national monitor procurement contracts
- Arbitrating PEP technical issues
- Providing guidance for field and analytical activities (*QA Hand Book Guidance Document 2.12).*

EPA Contracts Management Division Responsibilities

The CMD, within the Office of Acquisition Management (OAM), 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 COs and other contracting support for national procurements of contract support for federal implementation of the PEP, major equipment repairs, and equipment upgrades.

5.0 Problem Definition/Background

The background information provided in this element will place the problem in historical perspective, giving readers and users of the QAPP a sense of the project's purpose and position relative to the Ambient Air Quality 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 [PM_{10}, $PM_{2.5}$], sulfur dioxide [SO_2], carbon monoxide, nitrogen dioxide [NO_2], ozone [O_3], and lead) are regulated. The CAA requires SLT organizations to monitor these criteria pollutants through the Ambient Air Quality Surveillance Program as defined in 40 CFR Part 58.

The criteria pollutant defined as particulate matter (PM) is a general term used to describe a broad class of substances that exist as liquid or solid particles over a wide range of sizes. As a part of the Ambient Air Monitoring Program, two particle size fractions will be measured: those less than or equal to 10 micrometers (PM_{10}) and those less than or equal to 2.5 micrometers ($PM_{2.5}$). This QAPP focuses on one QA activity, the PEP, which is associated with $PM_{2.5}$ monitoring.

The background and rationale for the implementation of the $PM_{2.5}$ FRM/FEM monitoring network can be found in *Air Quality Criteria for Particulate Matter*, which is available at http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=87903. In general, some of the findings include the following:

- The characteristics, sources, and potential health effects of larger or "coarse" particles (from 2.5–10 micrometers in diameter) and smaller or "fine" particles (smaller than 2.5 micrometers in diameter) are very different.
- Coarse particles come from sources such as windblown dust from the desert or agricultural fields and dust that is circulated on unpaved roads from vehicle traffic.
- Fine particles are generally emitted from activities such as industrial and residential combustion and from vehicle exhaust. Fine particles are also formed in the atmosphere from gases, such as SO_2, nitrogen oxides, and volatile organic compounds, that are emitted from combustion activities, and then become particles as a result of chemical transformations in the air.
- Coarse particles can deposit in the respiratory system and contribute to adverse health effects, such as aggravating asthma. EPA's *Air Quality Criteria for Particulate Matter* concluded that fine particles, which also deposit deeply in the lungs, are more likely than coarse particles to contribute to the adverse health effects (e.g., premature mortality and hospital admissions) found in many published community epidemiological studies.

- Community studies found that adverse public health effects are associated with exposure to particles at levels well below the current PM standards for both short-term (e.g., less than 1 day to up to 5 days) and long-term (generally 1 year to several years) periods.
- These adverse health effects included premature death and increased hospital admissions and emergency room visits (primarily among the elderly and individuals with cardiopulmonary disease); increased respiratory symptoms and disease (among children and individuals with respiratory disease, such as asthma); decreased lung function (particularly in children and individuals with asthma); and alterations in lung tissue and structure and in respiratory tract defense mechanisms.

One goal of EPA's $PM_{2.5}$ program was to establish a $PM_{2.5}$ monitoring network by December 31, 1999.

Air quality samples are generally collected for one or more of the following purposes:

- To judge compliance with and/or progress made towards meeting the National Ambient Air Quality Standards (NAAQS)
- To develop, modify, or activate control strategies that prevent or alleviate air pollution episodes
- To observe pollution trends throughout the Region, including non-urban areas
- To provide a database for research and evaluation of effects.

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 Ambient Air Quality Monitoring Network consists of four major categories of monitoring stations that measure the criteria pollutants. These stations are described below.

The SLAMS network consists of approximately 3,500 monitoring stations whose size and distribution are largely determined by the needs of SLT air pollution control agencies to meet their respective State Implementation Plan (SIP) requirements.

The National Core (NCore) network multipollutant monitoring stations are part of an overall strategy to integrate multiple monitoring networks and measurements. These are a subset of SLAMS. Monitors at NCore multipollutant sites will measure particles ($PM_{2.5}$, speciated $PM_{2.5}$, $PM_{10-2.5}$), O_3, SO_2, carbon monoxide, nitrogen oxides ($NO/NO_2/NO_y$), and provide basic meteorology. Monitors for all of the gases, except for O_3, would be more sensitive than standard FRM/FEM monitors, so they could accurately report concentrations that are well below the respective NAAQS but that can be important in the formation of O_3 and PM. EPA expects that each state would have from one to three NCore sites, and EPA will collaborate with states individually and through multistate organizations on site selection. The objective is to locate sites in broadly representative urban (approximately 55 sites) and rural (approximately 20 sites) locations throughout the country to help characterize regional and urban patterns of air pollution. In many cases, states will likely collocate these new stations with the Photochemical Assessment Monitoring Station (PAMS) sites that are already measuring O_3 precursors and/or National Air Toxics Trend Station (NATTS) sites that are measuring air toxics. By combining these monitoring programs at a single location, EPA and its partners can maximize the multipollutant information.

The PAMS network is required to measure O_3 precursors in each O_3 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 to 90 sites and is likely to change.

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

Note: This QAPP only focuses on the QA activities of the SLAMS and NCore networks and the objectives of these networks, which include any $PM_{2.5}$ samplers 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 data and therefore may be responsible for activities such as setting and making comparisons to the NAAQS and evaluating trends. Because there are more than one objective for this data and more than one decision maker, the quality of the data will be based on the highest priority objective, which was identified as determining the attainment of the NAAQS.

Because the data for the FRM/FEM monitors in the SLAMS and NCore networks are used for NAAQS comparisons, the quality of these data is very important. A quality system has been developed to control and evaluate the quality of data to make NAAQS determinations within an acceptable level of confidence. During the development of the $PM_{2.5}$ NAAQS, EPA used the

Data Quality Objective (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 (10% coefficient of variation [CV]) and bias requirement (±10%) are based on total measurement uncertainty, which incorporates errors from all phases (e.g., field sampling, handling, analysis) of the measurement process. The collocated samples provide adequate estimates of precision. If properly implemented, the FRM/FEM PE can provide an evaluation of bias.

The PEP is a QA activity that is used to independently evaluate the measurement system bias of the $PM_{2.5}$ FRM/FEM monitoring network, which includes measurement uncertainties from field and laboratory activities. The pertinent regulations for this PE are outlined in 40 CFR Part 58, Appendix A, Section 3.2.7. The strategy is for an independent PEP Auditor to collocate a portable FRM/FEM $PM_{2.5}$ air sampling instrument within 1–4 meters of a routine SLAMS/NCore air monitoring instrument. Both monitors operate simultaneously as required in the FRM/FEM and SOPs. The PEP filter is analyzed by an independent gravimetric laboratory. The gravimetric results that are derived from the two samplers are compared.

Implementing the FRM/FEM PE is a SLT responsibility; however, due to many comments made during the review period for the December 13, 1996 $PM_{2.5}$ NAAQS Proposal, EPA made the following revisions:

- Modified the system to include an independent FRM/FEM PE
- Reduced the burden of this program by changing the audit frequency from all sites to 25% of the $PM_{2.5}$ sites
- Made allowances to shift the implementation burden from the SLT organizations to the federal government.

During August through October 1997, EPA discussed the possibility of federal implementation with EPA Regions and various SLT organizations (e.g., NESCAUM, MARAMA, WESTAR, and individual organizations). The majority of the responses from these organizations favored federal implementation of the PEP.

EPA evaluated potential contracting mechanisms to assist in the implementation of this activity, and it decided to use the ESAT contract, currently in place in each Region, to provide the necessary field and laboratory activities. Each EPA Region is responsible for implementing the field component of the PEP. Regions 4 and 10 operated the laboratory component from the beginning of the program through 2006. Region 4 assumed all responsibility for laboratory operations in 2006.

In October 2006, 40 CFR Part 58, Appendix A, Section 3.2.7 was amended to require the following:

- For primary quality assurance organizations (PQAOs) with less than or equal to five monitoring sites, five valid PE audits must be collected and reported each year.
- For PQAOs with greater than five monitoring sites, eight valid PE audits must be collected and reported each year.
- A valid PE audit means that both the primary monitor and PEP audit concentrations have not been invalidated and are greater than 3 micrograms per cubic meter ($\mu g/m^3$).

Additionally, each year, every designated FRM or FEM within a PQAO must have

- Each method designation evaluated each year; and
- All FRM or FEM samplers subjected to a PEP audit at least once every 6 years; which equates to approximately 15% of the monitoring sites audited each year.

Prior to 2007, only the State of Illinois chose to fully-implement its own PEP, which included the field and gravimetric laboratory support. In response to the 2006 regulatory revisions, a few more states and some Tribal organizations opted to partially self-implement the program in 2007. These SLTs that have chosen to partially self-implement the PEP are essentially providing the same service that the ESAT contractors provide at the Regional level (i.e., they conduct and perform all of the necessary field activities). All SLTs that have chosen to partially self-implement the PEP have agreed that a central service laboratory is the better alternative to individual SLTs running their own independent service laboratory or contracting with an independent laboratory. An important consideration is that the fully self-implementing organization must ensure that its resulting PEP data are entered into the AQS as prescribed in 40 CFR Part 58.16, which states, "The data and information reported for each reporting period must contain all data and information gathered during the reporting period, and be received in the AQS within 90 days after the end of the quarterly reporting period."

References

1. U.S. EPA (Environmental Protection Agency). 2004. Air Quality Criteria for Particulate Matter. U.S. Environmental Protection Agency, Washington, DC, EPA 600/P-99/002aF-bF, October.
2. U.S. EPA (Environmental Protection Agency). 2006. Revisions to Ambient Air Monitoring Regulations. 40 CFR Parts 53 and 58. Federal Register 71(200):61235–61328. October 17.
3. U.S. EPA (Environmental Protection Agency). 2008. *PEP Program Adequacy and Independence Criteria: Monitoring Rule Requirements and Implementing Instructions*. Revised July 23, 2008.

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/quality control (QC) goals, procedures, and timetables for collecting the measurements.

6.1 Description of Work to be Performed

In general, the measurement goal of the $PM_{2.5}$ PEP is to estimate the bias of SLT routine $PM_{2.5}$ FRM/FEM monitors as compared to PEP monitors, which represent the best measurement of $PM_{2.5}$ currently available. It is accomplished by measuring the concentration, in units of $\mu g/m^3$, of particulates less than or equal to 2.5 μm that have been collected on a 46.2-mm Teflon™ (polytetrafluoroethylene [PTFE]) filter and comparing these values against the data from a SLT routine $PM_{2.5}$ FRM/FEM monitor with the collocation of the PEP monitor. The applicable regulations for this activity can be found in 40 CFR Part 58, Appendix A, Section 3.5.3.

The following sections will describe the measurements required for the routine field and laboratory activities for the $PM_{2.5}$ PEP.

The PE can be segregated into field and laboratory components. The following information briefly describes these activities. Detailed SOPs have been developed for all field and laboratory activities and have been distributed to all field and laboratory personnel and all personnel who appear on the distribution list in Element 3.0, *Distribution*. Figure 6-1 provides a basic description of the PEP in the following steps:

- EPA will send filters to the weighing laboratory, where they will be inventoried, inspected, equilibrated, weighed, and prepared for the field.
- The weighing laboratory will ship or deliver the filter cassettes and accompanying Chain-of-Custody (COC) forms to all Regions.
- The FSs will take the filter cassettes, Field Data Sheets (FDSs), and COC forms to the field and operate the portable FRM monitor.
- The FS will send the filter cassettes, data storage media, FDSs, and COC forms back to the weighing laboratory (as well as filing the data and records at the field office).
- The weighing laboratory will receive, equilibrate, inspect, and post-weigh the filters. Data will be validated and uploaded into the AQS database.

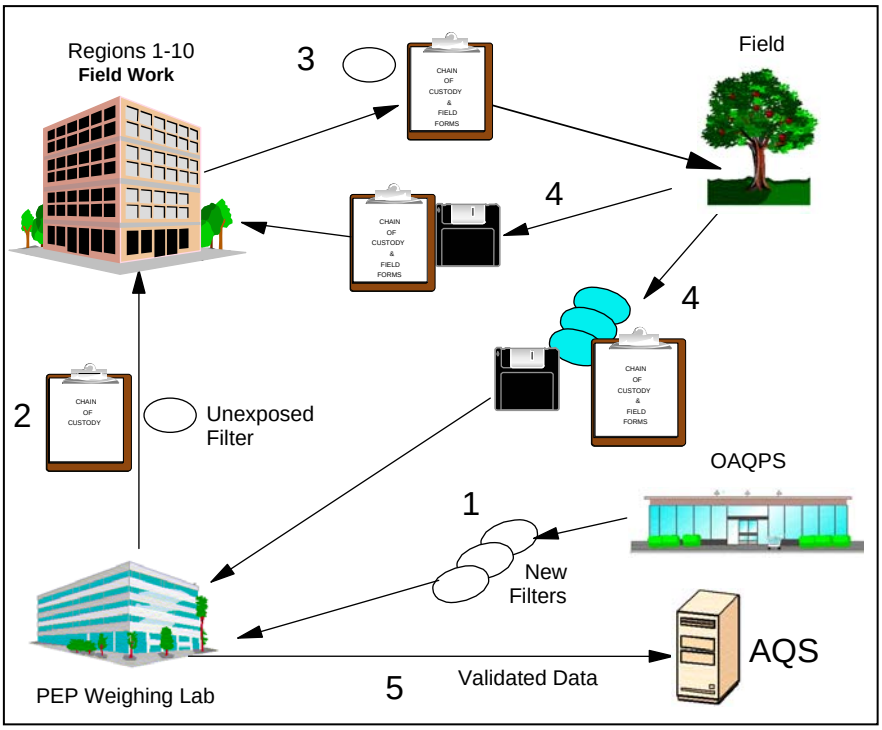


Figure 6-1. PEP overview.

6.2 Field Activities

The portable audit samplers are used in a collocated manner to perform the PEs. These samplers have been approved by EPA as FRM samplers and are designed to be durable, rugged, and capable of frequent transport. These samplers are constructed in sections, with each section weighing no more than 40 pounds and a total weight that does not exceed 120 pounds. To optimize the consistency of PEP measurements nationwide, the BGI PQ200A portable sampler will be used for PEP audits at all monitoring site locations with elevations under 7,000 feet. At elevations higher than 7,000 feet, the Andersen RAAS 200 portable sampler or the Rupprecht & Patashnick (R&P) 2000 portable sampler will be used. There are also some locations where electromagnetic field interference can only be mitigated by the Andersen or R&P samplers. Although these samplers have been specifically designed to perform these PEs, precautions must still be taken to ensure data quality. Basic instructions are found in this PEP QAPP, and specific instructions are detailed in the PEP Field SOPs (see http://www.epa.gov/ttn/amtic/pmpep.html).

The following steps must be observed to ensure data quality:

- The samplers must be operated in adherence to the vendor's instruction manual, which discusses the proper transport, assembly, calibration, operation, and maintenance.
- Samples must be taken in adherence with the guidance outlined in *QA Guidance Document 2.12 Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods*, except that shipping procedures will adhere to those specified in this

QAPP and in the PEP Field SOPs, which are more rigorous than the current regulations specify.

- All activities must adhere to the PEP Field SOPs.
- In addition to adhering to the standards, principles, and practices outlined in the PEP QAPP, activities and procedures must adhere to specific site QAPPs for the identified sites. An example would be where a sampler is not properly sited, but the SLT organization has an approved waiver from the EPA Regional Ambient Air Monitoring Program.
- Personnel must complete EPA's federally implemented training and certification program annually.

6.2.1 Field Activity Summary

The following activities are outlined in the PEP Field SOPs:

- The FS will transport a portable $PM_{2.5}$ FRM PE sampling device to an established $PM_{2.5}$ site as agreed upon by the SLT organization and its respective EPA Region.
- The FS will assemble the instrument; collocate the sampler; perform time, barometric pressure, temperature, and flow verifications; install a filter cassette; and operate the instrument from midnight to midnight on the same scheduled sampling day as the SLT's primary sampler.
- If scheduling permits, the operator will leave this location to set up additional PEP audits at other routine sampling locations. If the schedule does not allow for another setup, the operator will perform additional activities, such as scheduling subsequent audits, reviewing and verifying data from previous PEP audits, and completing associated paperwork.
- The FS will return to each site within a specified time following the 24-hour sampling time, review the run data, download the stored electronic monitoring data, remove and properly store the filter cassette for transport, and disassemble the instrument.
- The FS will properly package the filter cassette(s) for shipment to the weighing laboratory. Samples will be shipped in coolers with ice packs to maintain filter temperatures at $4^{o}C$.

The performance requirements of the PEP air sampler are specified in 40 CFR Part 50, Appendix L. Required recovery times and shipping schedule are discussed 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
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 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
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
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 air samplers will be purchased, distributed, and certified by EPA as meeting the requirements specified in the *Federal Register*; therefore, the PEP assumes that the instruments are adequate for sampling $PM_{2.5}$. However, the PEP is responsible for certifying the performance parameters of the $PM_{2.5}$ samplers after assuming custodianship of these samplers. Routine verifications (every sampling event) and quarterly audits of sampler performance specifications are conducted thereafter. Element 15.0, *Instrument/Equipment Testing, Inspection, and*

Maintenance Requirements, lists all the primary operational equipment requirements for the PEP $PM_{2.5}$ data collection operations. Additional support equipment are listed in the PEP Field SOPs.

6.2.2 Critical Field Measurements

Table 6-2, which is based on Table L-1 of Appendix L in the *Federal Register*, represents the field measurements that must be collected. These measurements are made by the air sampler and are stored in the instrument for downloading by the FS during routine visits.

Table 6-2. Field Measurement Requirements

Information to be Provided	Appendix L Section Reference	Availability				Format	
		Anytime[a]	End of Period[b]	Visual Display[c]	Data Output[d]	Digital Reading[e]	Units
Flow rate, 30-second maximum interval	7.4.5.1	✔	—	✔	✱	XX.X	L/min
Flow rate, average for the sample period	7.4.5.2	✱	✔	✱	✔	XX.X	L/min
Flow rate, coefficient of variation for the sample period	7.4.5.2	✱	✔	✱	✔ •	XX.X	%
Flow rate, 5-minute average out of specification[f]	7.4.5.2	✔	✔	✔	✔ •	On/off	
Sample volume, total	7.4.5.2	✱	✔	✔	✔ •	XX.X	m^3
Temperature, ambient, 30-second interval	7.4.8	✔	—	✔	—	XX.X	°C
Temperature, ambient, minimum, maximum, average for the sample period	7.4.8	✱	✔	✔	✔ •	XX.X	°C
Barometric pressure, ambient, 30-second interval	7.4.9	✔	—	✔	—	XXX	mm Hg
Barometric pressure, ambient, minimum, maximum, average for the sample period	7.4.9	✱	✔	✔	✔ •	XXX	mm Hg
Filter temperature, 30-second interval	7.4.11	✔	—	✔	—	XX.X	°C
Filter temperature, differential, 30-minute interval, out of specification[f]	7.4.11	✱	✔	✔	✔ •	On/off	
Filter temperature, maximum differential from ambient, date, time of occurrence	7.4.11	✱	✱	✱	✱	X.X, YY/MM/DD HH:mm	°C, Yr/mo/day hr min
Date and time	7.4.12	✔	—	✔	—	YY/MM/DD HH:mm	Yr/mo/day hr min
Sample start and stop time settings	7.4.12	✔	✔	✔	✔	YY/MM/DD HH:mm	Yr/mo/day hr min

Information to be Provided	Appendix L Section Reference	Availability				Format	
		Anytime[a]	End of Period[b]	Visual Display[c]	Data Output[d]	Digital Reading[e]	Units
Sample period start time	7.4.12	—	✔	✔	✔ ●	YYYY/MM/DD HH:mm	Yr/mo/day hr min
Elapsed sample time	7.4.13	✱	✔	✔	✔ ●	HH:mm	Hr min
Elapsed sample time out of specification[f]	7.4.13	—	✔	✔	✔ ●	On/off	
Power interruptions >1 min, start time of first 10 power interruptions	7.4.15.5	✱	✔	✱	✔	1HH:mm, 2HH:mm, etc.	Hr min
User-entered information, such as sampler and site identification	7.4.16	✔	✔	✔	✔ ●	As entered	

✔ Provision of this information is required.
— Not applicable.
✱ Provision of this information is optional. If information related to the entire sample period is optionally provided before the end of the sample period, then the value provided should be the value calculated for the portion of the sampler period completed up to the time the information is provided.
● Indicates that this information is also required to be provided to the AQS database.
[a] Information must be available to the operator at any time the sampler is operating.
[b] Information relates to the entire sampler period and must be provided following the end of the sample period until the operator 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 operator 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 operator 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 in this table.
[f] Flag warnings may be displayed to the operator 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 PEP Field SOPs and help to identify the samples, ensure proper COC, holding times, and data quality. The values are recorded on the COC Form and the FDS.

6.3 Laboratory Activities

The PEP also requires extensive laboratory activities, including filter handling, inspection, equilibration, weighing, data entry/management, and archiving. Region 4 is currently responsible for laboratory activities for this program. Detailed Laboratory SOPs have been developed. In addition, Good Laboratory Practices must be followed. The PEP laboratory must conform to the following:

- Microbalance operation and calibration must be in accordance with the vendor's instructions manual with the requirements for gravimetric analyses provided in 40 CFR 50, Appendix L, and with the *QA Guidance Document 2.12 Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods.*
- Activities must adhere to the PEP Laboratory SOPs.
- Activities must adhere to the standards, principles, and practices outlined in the PEP QAPP.
- Personnel must complete EPA's federally implemented training and certification program annually.

The following information summarizes the laboratory activities, in general chronological order, that are detailed in the laboratory SOPs.

Pre-sampling weighing will include the following:

- Filters will be received from EPA and examined for integrity.
- Filters will be enumerated for data entry.
- Filters will be equilibrated and weighed.
- Filters will be prepared for field activities or stored.
- The laboratory will develop and maintain shipping/receiving requirements, which would apply to containers, cold packs, minimum/maximum thermometers, and COC requirements/documentation.

Post-sampling weighing will include the following:

- Filters will be received in the laboratory, checked for integrity (e.g., damage, temperature), and logged in.
- Filters will be archived (cold storage) until they are ready for weighing.
- Filters will be brought into the weighing facility and equilibrated for 24 hours.
- Filters will be weighed, and gravimetric data will be entered in the database to calculate a concentration.
- Field data will be entered into the database.
- Filters will be archived in cold storage for the rest of the calendar year, for the next full calendar year, and will remain at room temperature for 3 additional years. As an example, a filter sampled on March 1, 2007, would be kept in cold storage until December 31, 2008, and not disposed of until after December 31, 2011.
- Required data will be submitted to the AQS database.

The details for these activities are included in various sections of this document, as well as in laboratory SOPs. Table 6-3 provides the performance specifications of the laboratory environment and equipment.

Table 6-3. Laboratory Performance Specifications

Equipment	Acceptance Criteria
Microbalance	Resolution of 1 μg, repeatability of 1 μg.
Microbalance environment	Climate-controlled draft-free room, chamber, or equivalent. Mean relative humidity between 30% and 40%, with a target of 35% and variability of not more than ± 5% over 24 hours; with minimums and maximums never to fall out of the range of 25%–45%. Mean temperature should be held between 20°C and 23°C, with a variability of not more than ± 2°C over 24 hours, with minimums and maximums never to fall out of the range of 18°C–25°C.
Mass reference standards	Standards will bracket the expected weight of filter, and the individual (Class 1) standard's tolerance will be within ± 25 μg, annual certified mass.

6.3.1 Critical Laboratory Measurements

Filter pre-weights (unexposed) and post-weights (exposed) are the most critical measurements in the laboratory. The difference between these two measurements provides the net weight of particles in micrograms (μg) that when divided by the air volume in cubic meters (m^3) pulled through the filter, provides a final concentration ($\mu g/m^3$). In addition to these critical measurements, supporting laboratory data will also be collected to help identify the samples and ensure proper COC, holding times, and data quality. These additional parameters are described in more detail in Element 13.0, *Analytical Methods Requirements*, and in the PEP Laboratory SOPs.

6.4 Schedule of Activities

The PEP consists of laboratory and field activities, which must be coordinated and completed in a timely, efficient manner for the program to be successful. This includes activities such as acquiring equipment and supplies, developing sampling schedules, shipping and receiving prepared filter cassettes, conducting site visits, weighing filters, and performing QC checks. The sections below describe some of the time-critical components of conducting PEP audits. Additional detail is provided in the PEP Field and Laboratory SOPs. The laboratory must also ensure that its operating calibration standards and independent internal audit standards are certified annually as National Institute of Standards and Technology (NIST) traceable.

6.4.1 PEP Audit Frequency

The sampling design has been codified in 40 CFR Part 58, Appendix A, Section 3.2.7, as follows.

The PEP is an independent assessment used to estimate total measurement system bias. These evaluations will be performed under the PM PEP (40 CFR Part 58, Appendix A, Section 2.4) or a comparable program. PEs will be performed on the SLAMS monitors annually within each PQAO. For PQAOs with more than five monitoring sites, eight valid PE audits must be collected and reported each year. A valid PE audit (for the purposes of calculating network bias and precision as required by the regulations) means that both the primary monitor and PEP audit

concentrations have not been invalidated and are greater than 3 $\mu g/m^3$. Additionally, each year, every designated FRM or FEM sampler within a PQAO must have

- Each method designation evaluated each year
- All FRM or FEM samplers subjected to a PEP audit at least once every 6 years. This equates to approximately 15% of monitoring sites audited per year.

A limited number of "make-up" PEs are included in the annual budget by OAQPS. Scheduling is the responsibility of the Regional WAM/TOPO/DOPO and the SLT.

NOTE: Sites that have seasonally low concentrations should be sampled during times when concentrations are expected to be greater than 3 $\mu g/m^3$. EPA recognizes that it may be difficult or impossible to obtain valid audits at sites where the concentration rarely exceeds 3 $\mu g/m^3$. EPA is currently considering ways to evaluate such sites. Audits that are otherwise valid, but do not meet the "greater than 3 $\mu g/m^3$" criteria, are still useful to evaluate sampler operation, even if such audit data may not be used in the calculations for sampler bias.

6.4.2 PEP Sampling Schedule

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

- CFR requirements for audit frequency
- Meeting the same monitoring schedule as the routine sampler being evaluated
- Site proximity (the sites that are closest in proximity to each other can be visited within the same day or week).

PEs should be implemented on a normal sampling day so that they do not create additional work for the SLT organizations. Thus, for sites that only sample 1 day in 3 or 1 day in 6, this schedule must be taken into account when scheduling a PE site visit. However, if the SLT agency is amenable to perform a PE on a day other than a routine sampling day and is willing to post the result to AQS, then the visit can be scheduled. Accurate reporting of alternate sampling days is critical.

6.4.3 General Time Line for PEP Activities

Below is a list of activities, in general chronological order, that are performed by PEP laboratory and field personnel when conducting an FRM PE:

1. A field equipment list is developed, and the equipment is acquired.
2. The EPA WAM/TOPO/DOPO and SLT organization determine the annual PEP sampling schedule.
3. The WAM/TOPO/DOPO, FS, and SLT organization schedule site visits.

4. The FS attempts to identify any issues with the site prior to audit; the WAM/TOPO/DOPO resolves issues with the SLT organization.
5. The FS and site operators confirm the scheduled PE.
6. The FS sends an order for filters to the weighing laboratory.
7. The PEP weighing laboratory activities commence.
   a. The weighing laboratory receives filter shipments from EPA.
   b. The weighing laboratory checks, equilibrates, and weighs filters.
   c. The weighing laboratory loads the filters into cassettes and ships them with their accompanying COC forms to the EPA Regions/FS office.
8. The FS receives the filter cassettes, FDSs, and COC forms and completes as much of these sheets and forms as possible at the field office.
9. The FS transports the PEP audit sampler to the site and evaluates the site for set up.
10. The FS assembles the sampler, sets the date/time, and then performs leak checks and barometric pressure, temperature, and flow rate verifications.
11. The FS performs a field blank exercise if needed.
12. The FS installs the sampling filter cassette.
13. The FS sets the controller to run during a 24-hour sampling event (midnight to midnight).
14. The sampler collects PM on the filter during the scheduled event.
15. The FS recovers the filter cassette and downloads recorded sampling event parametric summary data.
16. The FS disassembles the sampler.
17. The FS packages recovered cassette(s) and ships them along with data (e.g., diskette or other portable media), FDSs, and COC forms back to the weighing laboratory.
18. The PEP weighing laboratory will post-equilibrate and weigh filters.
19. The PEP weighing laboratory performs data validation activities, including FS review of transcribed field data.
20. The EPA WAM/TOPO/DOPO for the PEP weighing laboratory approves data that are to be loaded into the AQS.
21. EPA OAQPS (contractor) loads data into the AQS.

6.4.4 Implementation Time Lines

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

One time-critical aspect of the implementation process is the filter holding time. As illustrated in Figure 6-2 and as stipulated in the CFR, filters must be used within 30 days of pre-sampling weighing, or they must be reconditioned and pre-weighed again. Therefore, it is critical that the weighing laboratory develop a schedule to provide the FSs with filters that will be used in the appropriate time frame.

Figure 6-2 indicates that for best practice, the FS will collect the filters within 24 hours of the end of the sample exposure period. Filters collected after 48 hours will be assigned a minor flag by the weighing laboratory, which may contribute to an invalidation depending upon the result of other QC checks. The critical recovery time, beyond which filters will be automatically invalidated, is 96 hours.

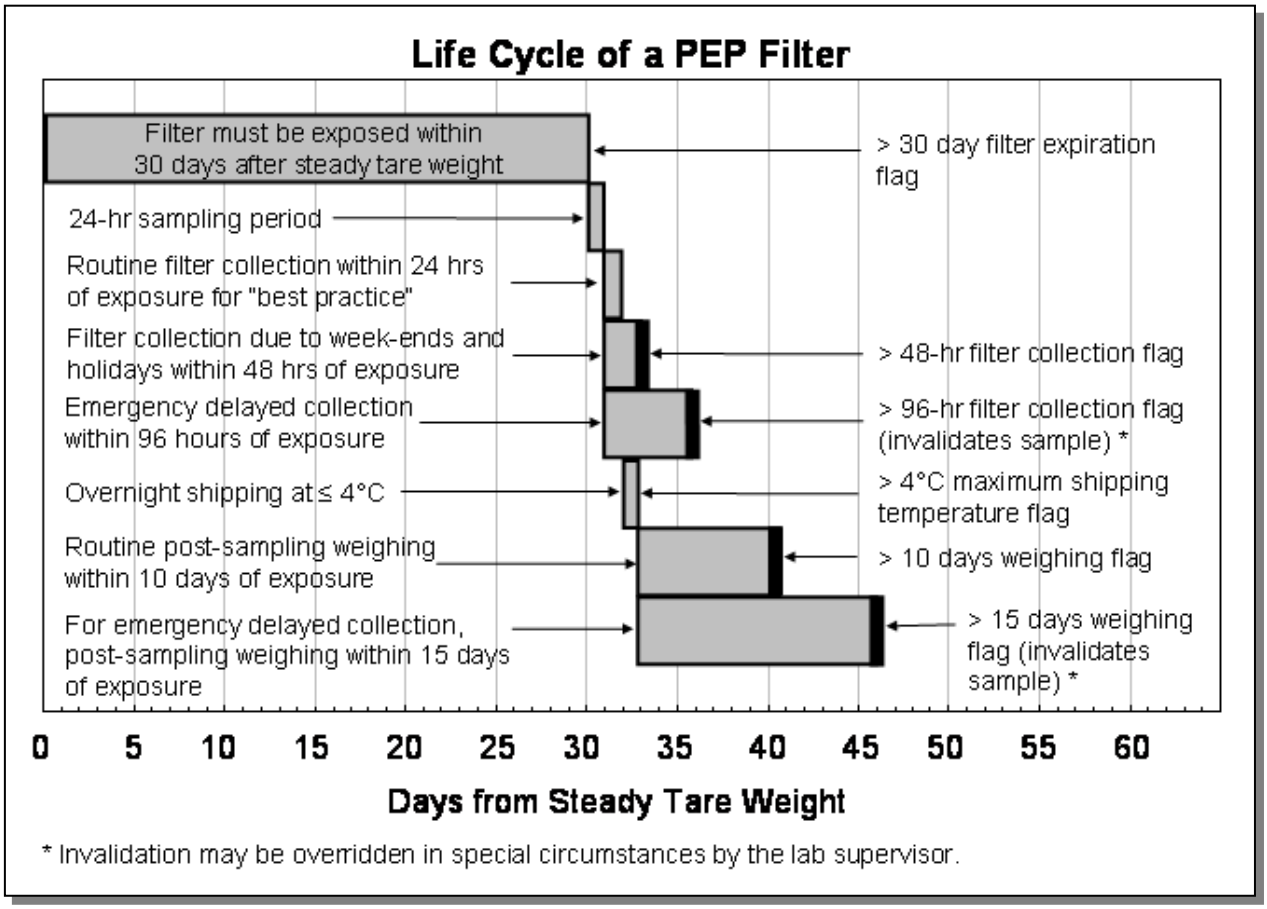


Figure 6-2. Critical filter-holding times.

Ideally, samples will be sent the day of removal to the appropriate laboratory via next-day delivery. The FS should ship the exposed filters within 8 hours of recovery on Monday through Thursday and as soon as possible if recovery occurs on a Friday. If an issue arises in which shipment cannot occur within these guidelines, then the FS must store the filters at less than or equal to 4°C until the next available shipping day. The weighing laboratory must be notified of the delayed shipment date because the post-sample weighing must occur within 10 days of exposure to avoid a data validation flag. Data will be immediately downloaded from the portable sampler and stored on the computer's hard drive and two portable storage media (e.g., diskette, CD, or USB drive). One copy of these data will be shipped with the sample. Data may also be transmitted electronically (e.g., via e-mail) if necessary to the weighing laboratory. Table 6-4 provides a summary of the key activities previously discussed.

Table 6-4. Implementation Summary

Activity	Holding Time	From	To
Laboratory tares the filters	As needed	Filter box	Stable tare weight
Laboratory ships the filters to the FS (best practice)[a]	≤7 days	Stable tare weight	Shipment
FS loads the filter into the sampler[b]	<30 days from pre-weigh	Received from the laboratory	Mounting in sampler
Filter exposure	1 day	Mounting in sampler	End of sampling period
Filter collection[c]	24 (48) (96) hrs	End of sampling period	Recovery
Shipped to laboratory (best practice)[d]	≤8 hrs	Recovery	Shipment
Laboratory equilibrates and weighs the filter[e]	≤10 (15) (30) days	End of sampling period	Stable post-sampling gravimetric mass
The maximum life for a PEP audit filter is 46 days.			

[a] The PEP QAPP states that the filter must be loaded into sampler or used as a blank within 30 days after the tare weight stabilizes. Best practice dictates that the laboratory ship tared filters as soon as possible, usually within 1 week.

[b] Refer to the "use by" date on the PEP COC Form.

[c] PEP filters should be routinely recovered within 24 hours after conclusion of exposure. Note that 48-hour collection is permissible due to holidays and weekends if the site is inaccessible. These filters receive a 48-hour collection flag. Up to 96-hour collection is permissible, but only in the case of an emergency (e.g., sickness, accident). If the collection time is > 96 hours, the sample will receive an invalidation flag.

[d] The FS will always transport exposed filters and blanks with chilled cold packs. The PEP requires 8-hour packaging and shipping after filter recovery. However, if the sample is recovered on a Friday, then it should be stored at a temperature ≤4°C until the next available shipping day. The laboratory must be notified of the delay because the sample must be weighed within 10 days after exposure to avoid a validation flag, which in conjunction with another flag may invalidate the sample.

[e] Filters received from the field are to be equilibrated and post-weighed within 10 days after exposure. Exceptional events, such as Thursday sampling events followed by a Monday holiday or collection between 48 and 96 hours (resulting from emergencies), will permit 15-day post-sampling weighing periods. **NOTE:** Samples weighed after 15 days will be considered invalid unless additional QA evaluation is performed by the laboratory's QA Officer. Based on review and acceptance of the sample's consistency with historical CV data (comparing differences between PEP and routine site sample data), the validation flag may be overridden by the QA Officer. However, any PEP sample that cannot be weighed within 30 days from exposure shall not be overridden and should therefore not be post-weighed.

6.4.5 Assessment Time Lines

6.4.5.1 Data Availability

The PEP weighing laboratory should complete data validation within 60 days of the sample end date. The laboratory should submit its validated data to OAQPS (or authorized contractor) monthly for data assessment purposes. Submitting routine sampler data as soon as possible is encouraged to ensure that data assessment occurs in a timely manner.

PEP audit results are posted to the AQS as data pairs. A data pair consists of the PEP audit and site's measured values. SLAMS sites are required to post their site data to the AQS within 90

days after the end of the quarter. Because posting PEP data requires first obtaining the site's measured value from the AQS, PEP data cannot normally be posted until after the due dates listed in Table 6-5. In cases where the site data have been uploaded into the AQS and validated on or before the due date, the PEP audit data should be available through the AQS within 30 days after the due date (to allow enough time for processing and review). Data submitted after the due date will be available within 30 days after the end of the next reporting period.

Table 6-5. Data Reporting Schedule for the 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 Assessments of PEP Data

The Region 4 ESAT Contractor is tasked to provide Level 0 and Level 1 assessments of the PEP data. Refer to Element 22.0 for a discussion of PEP data review, validation, and verification requirements, which incorporate these levels of assessment. Following the SLT agencies' submittals of quarterly $PM_{2.5}$ FRM/FEM data, OAQPS (via the support contractor) will load the PEP data into the AQS. The PEP Laboratory Manager, Regional (Laboratory) WAM/TOPO/DOPO, and the OAQPS contractor(s) will review the PEP data. They will report to the PEP Workgroup significant operations issues of the PEP that are reflected by the data. After both routine data and PE data for a site are in the AQS database, OAQPS, EPA Regions, and SLT organizations can use the AQS data evaluation programs, based on data quality assessment techniques, to assess this information.

6.4.6 OAQPS Reporting Time Lines

6.4.6.1 QA Reports

As mentioned in Element 3.0, *Distribution*, OAQPS plans to develop and distribute Annual QA Summary Reports and interpretive 3-year QA Reports per the distribution list in Element 3.0 and to other interested parties, such as ESAT contractors. The Annual QA Summary Report will be based on a calendar year, and it should be completed 6 months from the last valid entry of routine data by the SLT organizations. This report will include basic statistics of the data, including completeness; PEP results versus FRM/FEM results; results of collocation studies for precision of PEP samplers, both aggregated and by the Region; QC charts for the weighing laboratory; and PEP sampler performance versus acceptance criteria, PEP TSA findings, and a summary of yearly standard certifications. The 3-year QA Report should be generated 9 months after the last valid entry of routine data by the SLT organizations for the final year. This report is a composite of the annual reports, but with a more narrative interpretation and evaluation of longer term trends with respect to PEP sampler and operational performance. In the year that a 3-year QA Report is generated, the Annual QA Summary Report is not required.

6.4.6.2 Assessment Reports

Each EPA Region, ORIA and OAQPS will perform TSAs of the PEP ESAT contractors and PEP activities as specified in Table 6-6 below. 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 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, MSR, peer review, inspection, or surveillance. Definitions for each of these activities can be found in the glossary (Appendix A). Element 20.0, *Assessments and Response Actions*, discusses the details of the assessments. Table 6-6 provides information on the organizations that implement the assessment and the frequency of these assessments.

Table 6-6. Assessment Schedule

Assessment Type	Assessment Agency	Frequency
TSA of FS and field operations	EPA Regional office	One per year
Surveillance of FSs' operations	OAQPS at annual recertification of FSs or by the EPA Regional office as needed	One per year unless there is a need for additional Regional surveillance
TSA of the gravimetric laboratory and laboratory operations	OAQPS or the EPA Regional office if the SLT organization runs its own PEP laboratory	One per year
PE of weighing lab(s)	ORIA	Two per year, approximately every 6 months
Management systems review of Regional conduct of the PEP	OAQPS	Two Regions per year
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 $PM_{2.5}$ information. Information about 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	State Implementation Plan 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 QC 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 $PM_{2.5}$ data Data management systems
QA	Good Laboratory Practices Network reviews Control charts Data Quality Assessments QA reports System audits Response/corrective action reports Site audits

References

1. U.S. EPA (Environmental Protection Agency). 2006. National Ambient Air Quality Standards for Particulate Matter—Final Rule. 40 CFR Part 50. *Federal Register* 71(200):61144–61233. October 17.

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 to generate 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 $PM_{2.5}$, EPA guards against committing resources to data collection efforts that do not support a defensible decision. The DQO process was implemented for the $PM_{2.5}$ PEP in 1997. The DQOs were based on the ability of the decision maker(s) to make NAAQS comparisons within an acceptable probability of decision errors. Based upon the acceptable decision error of 5%, the DQO for acceptable precision (10% CV) and bias (± 10%) were identified. These precision and bias values will be used as goals from which to evaluate and control measurement uncertainty. The PEP provides the measurements upon which the bias component of the DQO is evaluated and is, in essence, a network-scale QC check. 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 particles into a $PM_{2.5}$ FRM/FEM sampler, the PEP was developed to serve, as closely as possible, as a reference standard by which a relative network bias can be determined (and in a gross sense, the relative accuracy of a local monitor).

The data collected under the PEP are to be used to determine whether there is bias in the measurement system used to measure $PM_{2.5}$ for comparison to the $PM_{2.5}$ NAAQS. It is important to control the repeatability of the measurements from each PEP sampler. It is also important to be sure there is a statistically significant amount of data on which to make a decision about the presence of bias. The more samples used in the analysis, the larger the confidence; however, it is important not to waste resources by collecting too many samples.

The minimum number of samples needed to detect a bias of ± 10% depends on the precision (CV) of $PM_{2.5}$ measurements and the actual bias, which were not well characterized at the beginning of the PEP. Initially, based on a statistical review, the audit frequency was set at 25% of the national $PM_{2.5}$ FRM/FEM network each year; each selected sampler was audited four times during the specified year. This frequency was shown to be adequate to evaluate bias for a typical reporting organization, assuming initial estimates of sampler CV of less than 10% and allowing for a 10% decision error.

In 2005, the minimum sampling frequencies that were needed to detect a 10% bias over 3 years were re-evaluated using actual network data to get a better estimate of CV and typical bias levels. A paper that provides more details on this re-evaluation is provided as Appendix B,

Support Data Quality Objectives. Using the updated estimates, it was determined that approximately 24 audits over a 3-year period (i.e., 8 per year) would be adequate to evaluate a ± 10% bias for a reporting organization. Recent changes to the regulations (40 CFR Part 58, Appendix A, Section 3.2.7) now require all organizations with five or fewer sites to collect at least five valid PE audits per year and organizations with more than five sites to collect at least eight valid PE audits per year (see Section 6.4.1 for additional discussion on audit frequency). These sampling frequencies are consistent with the frequencies described in Appendix B, *Documents to Support Data Quality Objectives*, to meet the DQOs of the PEP for the national $PM_{2.5}$ FRM network. The data will be evaluated year by year and cumulatively every third year.

7.2 Measurement Quality Objectives

After 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. Measurement Quality Objectives (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:

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 will be determined by estimating the positive and negative deviations from the true value as a percentage of the true 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.

"*Accuracy*" is 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. The PEP attempts to apportion measurement uncertainties into precision and bias components.

For each of these attributes, acceptance criteria were developed for various phases of the EDO. Various parts of 40 CFR have identified acceptance criteria for some of these attributes, as well as *Guidance Document 2.12*. In theory, if these MQOs are met, then measurement uncertainty should be controlled to the levels required by the DQO. It should be noted that some MQOs for PEP are more stringent than routine $PM_{2.5}$ FRM MQOs. Table 7-1 lists the MQOs for the PEP. 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 Field and Laboratory SOPs.

References

1. U.S. EPA (Environmental Protection Agency). 1998. EPA Guidance for Quality Assurance Project Plans. EPA QA/G-5, EPA/600/R-98/018. February.
2. U.S. EPA (Environmental Protection Agency). 1998. *Quality Assurance Guidance Document 2.12: Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods*. December.

Table 7-1. Measurement Quality Objectives—Parameter $PM_{2.5}$

Requirement	Frequency	Acceptance Criteria	40 CFR Reference	Lab/Field SOP Reference
Filter Holding Times				
Pre-sampling weighing	All filters	≤30 days before sampling	Part 50, Appendix L, Section 8.3	Lab SOP, Section 4
Post-sampling weighing	All filters	≤10 days stored at 4°C from sample end date[a]	Part 50, Appendix L, Section 8.3	Lab SOP, Section 4
Reporting Units				
Reporting units	All data	$\mu g/m^3$	Part 50.3	
Detection Limit				
Lower detection limit	All data	2 $\mu g/m^3$	Part 50, Appendix L, Section 3.1	
Upper concentration limit	All data	200 $\mu g/m^3$	Part 50, Appendix L, Section 3.2	
Data Completeness				
Data completeness	5 or 8 sites with 24-hr collocated filter collection	100%	Part 58, Appendix A, Section 3.2.7	
Filter				
Visual defect check	All filters	See reference	Part 50, Appendix L, Section 6.0	Lab SOP, Section 5
Exposure lot blanks	3 filters from each of the 3 boxes in lot (9 filters total)	≤15 μg change between weighings	Not described	Lab SOP, Section 6
Filter Conditioning Environment				
Pre-sample equilibration	All filters	24 hrs minimum in weighing room; ≤5 μg change between sequential weighings of each filter	Part 50, Appendix L, Section 8.2	Lab SOP, Section 6
Post-sample equilibration	All filters	24 hrs minimum in weighing room; ≤15 μg between sequential weighings for 2 of 3 filters in each filter batch	Part 50, Appendix L, Section 8.2	Lab SOP, Section 6
Temperature range	All filters	24-hr mean 20°C–23°C; 18°C minimum, 25°C maximum	Part 50, Appendix L, Section 8.2.1	Lab SOP, Section 6
Temperature control	All filters	± 2°C over 24 hr	Part 50, Appendix L, Section 8.2.2	Lab SOP, Section 6

Requirement	Frequency	Acceptance Criteria	40 CFR Reference	Lab/Field SOP Reference
Relative humidity range	All filters	24-hr mean 30%–40%; 25% minimum, 45% maximum	Part 50, Appendix L, Section 8.2.3	Lab SOP, Section 6
Relative humidity control	All filters	± 5% over 24 hr	Part 50, Appendix L, Section 8.2.4	Lab SOP, Section 6
Laboratory Quality Control Check				
Field filter blank[b]	1 per audit (for programs <2 years old) or 1 per FS per trip (for all other programs)	± 30 μg change between weighings	Part 50, Appendix L, Section 8.3.7	Lab SOP, Section 8 and Field SOP, Section 6
Laboratory filter blank	10% or 1 per weighing session	± 15 μg change between weighings	Part 50, Appendix L, Section 8.3.7	Lab SOP, Section 8
Trip filter blank[c]	10% of all filters	± 30 μg change between weighings	Not described	Lab SOP, Section 8 and Field SOP, Section 6
Balance check	Beginning/end of weighing session and one after approximately every 15 samples or fewer, per recommendations of balance manufacturer	$\leq$3 μg of working mass standard	Part 50, Appendix L, Section 8.3	Lab SOP, Section 8
Duplicate filter weighing	1 per weighing session; one carried over to next session	± 15 μg change between weighings	Part 50, Appendix L, Section 8.3	Lab SOP, Section 8
Field Calibration/Verification				
Clock/timer verification	Every sampling event	± 1.0 min/mo	Part 50, Appendix L, Section 7.4.12	Field SOP, Section 5
External leak check	Every sampling event	<80 mL/min	Part 50, Appendix L, Section 7.4.6.1	Field SOP, Section 5
Internal leak check	Upon failure of external leak check	<80 mL/min	Part 50, Appendix L, Section 7.4.6.2	Field SOP, Section 5
One-point barometric pressure verification	Every sampling event and following every calibration	± 10 mmHg	Part 50, Appendix L, Sections 7.4.9 and 9.3	Field SOP, Section 5
Barometric pressure calibration[d]	Upon failure of single-point verification	± 10 mmHg	Part 50, Appendix L, Sections 7.4.9 and 9.3	Field SOP, Section 10
Single-point temperature verification	Every sampling event and following every calibration	± 2°C of working standard	Part 50, Appendix L, Sections 7.4.8 and 9.3	Field SOP, Section 5
Temperature calibration[d]	Upon failure of single-point verification	± 0.1°C of calibration standard	Part 50, Appendix L, Sections 7.4.8 and 9.3	Field SOP, Section 10

Requirement	Frequency	Acceptance Criteria	40 CFR Reference	Lab/Field SOP Reference
Single-point flow rate verification	Every sampling event	± 4% of working standard or ± 4% of design flow (16.67 Lpm)	Part 50, Appendix L, Section 9.2.5	Field SOP, Section 5
Flow rate calibration[d]	Upon failure of single-point verification	± 2% of calibration standard at design flow (16.67 Lpm)	Part 50, Appendix L, Sections 7.4.1 and 9.2.6	Field SOP, Section 10
Post-calibration single-point flow rate verification	Following every calibration	±2% of design flow (16.67 Lpm)	Part 50, Appendix L, Section 9.2.6	Field SOP, Section 10
Laboratory Calibration/Verification				
Balance calibration	When routine QC checks indicate calibration is needed and upon approval	Manufacturer's specification	Not described	Lab SOP, Section 7
Laboratory temperature verification	1/quarter	± 2°C	Not described	Lab SOP, Section 7
Laboratory humidity verification	1/quarter	±2 % relative humidity	Not described	Lab SOP, Section 7
Accuracy				
Flow rate audit	4/yr (manual)	± 4% of calibration standard at design flow (16.67 Lpm)	Part 58, Appendix A, Section 3.5.1	Field SOP, Section 8
External leak check	4/yr	<80 mL/min	Part 50, Appendix L, Section 7.4.6	Field SOP, Section 8
Internal leak check	4/yr (if external leak check fails)	<80 mL/min	Part 50, Appendix L, Section 7.4.6	Field SOP, Section 8
Temperature audit	4/yr	± 2°C of calibration standard	Part 50, Appendix L, Section 9.3	Field SOP, Section 8
Barometric pressure audit	4/yr	± 10 mmHg of calibration standard	Part 50, Appendix L, Section 7.4	Field SOP, Section 8
Balance audit (PE)	2/yr	± 20 μg of NIST-traceable standard, ± 15 μg for unexposed filters	Not described	Lab SOP, Section 11
Precision (Using Collocated Samplers)[e]				
All samplers (mandatory)	2/year (semi-annual)	CV ≤10%	Part 50, Appendix L, Section 5.0	Field SOP, Section 8
Calibration and Check Standards				
Flow rate transfer standard	1/yr	± 2% of NIST-traceable standard	Part 50, Appendix L, Sections 9.1 and 9.2	Field SOP, Section 8

Requirement	Frequency	Acceptance Criteria	40 CFR Reference	Lab/Field SOP Reference
Field thermometer	1/yr	± 0.1°C resolution ± 0.5°C accuracy	Not described Not described	Field SOP, Section 8
Field barometer	1/yr	±1 mmHg resolution ±5 mmHg accuracy	Not described Not described	Field SOP, Section 8
Working mass standards	3–6 mo	0.025 mg	Not described	Lab SOP, Section 7
Primary mass standards	1/yr	0.025 mg	Not described	Lab SOP, Section 7
Representativeness				
Method designation (sampler type) in reporting organization	Each method designation audited yearly	Primary and PEP audit concentrations are valid and >3.0 $\mu g/m^3$	Part 58, Appendix A, Section 3.2.7	
Samplers in reporting organization	Each sampler audited at least once every 6 years	Primary and PEP audit concentrations are valid and >3.0 $\mu g/m^3$	Part 58, Appendix A, Section 3.2.7	

[a] The PEP requirement is more stringent than regulation (see Element 6.0, *Project/Task Description*, Table 6-4 for exceptions).

[b] For a new SLT program (i.e., less than 2-years old), the frequency for field blanks is one per FRM/FEM audit. For all others, one field blank should be performed per FS per trip. A trip may include audits for more than one FRM/FEM sampler. It is up to the FS to determine the site where the field blank audit will be performed, unless otherwise directed by his or her Regional WAM/TOPO/DOPO (such as when a problem is identified at a particular site).

[c] Trip blanks will be performed at a frequency of 10% of all filters, as determined by the weighing laboratory (i.e., 1 per every 10 filters shipped out, rounded up). So if the laboratory sends out 1 to 10 filters, then 1 trip blank should be included in the shipment. If the laboratory ships out 11 to 20 filters, then 2 trip blanks should be included. The FS will determine with which trip to use the trip blank filter(s), in a manner similar to the field blanks. However, if the FS receives more than one trip blank in a shipment, then he or she must make sure that only one trip blank is carried per trip.

[d] The BGI PQ200A is not capable of performing multipoint verifications. If the BGI PQ200A fails a single-point verification, then a calibration should be performed next.

[e] Twice per year, all of the PEP samplers used by the Region (and any SLT organizations that are running their own PEP) must be collocated and run at the same location over the same time period. These are often referred to as "parking lot collocations." In 2007, this frequency was reduced from monthly and quarterly collocation scenarios because the historical performance shows that the precision does not seem to vary significantly. Semi-annual precision checks are justified.

8.0 Special Training Requirements/Certification

The purpose of this element is to ensure that any specialized or unusual training requirements to conduct the 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 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 Quality Monitoring Network and the principles and operation of the PEP and the QA procedures. This phase of training is ongoing and includes the following:

- National-level conferences and training workshops
- Regional training events
- 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 PEP training are posted on AMTIC's Bulletin Board at http://www.epa.gov/ttn/amtic/pmpep.html.

In the future, EPA will be developing and implementing the following:

- National broadcasts of the Web-based PEP training sessions with an interactive component
- Training videos for complete courses that consist of individual modules for each subject matter topic needed to attain full certification.

The second phase of training specifically focuses on the PEP and includes the following:

- Specific, extensive hands-on field and laboratory training sessions, which are sponsored and developed by OAQPS, involve the ESAT contractors, Regional personnel, and SLT 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, OAQPS, and ORIA (Las Vegas, NV), has multiple training facilities, which provide the capacity to

- Develop internal expertise in fine PM monitoring and gravimetric analysis

- Provide monitoring equipment that is readily accessible to EPA staff for investigating operational questions and concerns
- Perform field and laboratory training for personnel at EPA, Regional, SLT 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 PEP training program will involve the following four phases:

- **Classroom lecture.** This will include an overall review of the $PM_{2.5}$ program and the consequential importance of the PEP. Classroom lectures will also be implemented for each training module (as described below). Revisions to the training modules and SOPs are made based on suggestions from PEP auditors and a subsequent annual evaluation and consensus of the EPA PEP WAM/TOPO/DOPOs and the PEP 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 C contains PE forms for this review.

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

8.3 Field Training

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

Annual 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 each year. Additional training may be arranged at the discretion of OAQPS. This may include training conducted by EPA-certified Regional WAM/TOPO/DOPOs within their respective Regions. When this occurs, the WAM/TOPO/DOPO is responsible for submitting a record of training and certification results to OAQPS.

Field training for full certification is expected to last 3 full days. Trainers may be required to be available a fourth day for any individual trainees requiring more instruction.

Field training will include the following topics:

- Introduction to the PEP
- Planning and preparation
- Cassette receipt, storage, and handling
- Sampler transport, placement, and assembly
- System checks
- Programming the run
- Filter exposure and concluding the sampling event
- Using the COC Form
- Using the FDS
- QA/QC and information retention
- Troubleshooting in the field: When to perform calibrations (not typically performed in the field).

8.4 Laboratory Training

Annual laboratory training/recertification for the routine PEP filter preparation and weighing activities will be conducted at an EPA PEP weighing laboratory designated by OAQPS. Additional training may be arranged at the discretion of OAQPS.

Laboratory personnel will be trained on the following topics:

- General laboratory preparation
- Communications
- Filter conditioning
- Filter weighing
- Using the COC Form
- Using the FDS
- QA/QC
- Equipment inventory and maintenance
- Filter handling
- Calibrations
- Filter shipping
- Data entry and data transfer
- Storage and archiving

8.5 Certification

EPA requires certification for FSs, LAs, and the Project Leaders (including WAM/TOPO/DOPOs) to help ensure that personnel are sufficiently trained to perform the necessary PEP activities at a level that does not compromise data quality and also inspires confidence in the PEP by the SLT organizations.

8.5.1 Certification of Field Scientists and Laboratory Analysts

Both a written exam and a performance review are considered part of the certification requirements for FSs and LAs. The written exam is gauged to review the more critical aspects of the 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 C 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 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, then 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, then the ESAT WAM/TOPO/DOPOs and RPOs will be notified to initiate remedial action.

8.5.2 Certification of Regional Project Leaders

Because Regional Project Leaders (including WAM/TOPO/DOPOs) conduct TSAs and may be authorized to train staff on behalf of EPA, annual recertification is necessary to maintain their knowledge of current issues and changes in equipment and procedures. They must meet the following certification requirements:

- At a minimum, they must successfully complete the initial 3½-day PEP training course
- At least every 2 years, they must participate in the "hands-on" PEP annual certification event conducted by OAQPS. In alternate years, they may fulfill their annual certification requirement by participating in OAQPS-led Web-based training events.

8.6 Additional PEP Field and Laboratory Training

Annual certifications and recertifications will be arranged and conducted by OAQPS. Personnel turnover is expected among PEP contractor and SLT organizations. Occasionally, the 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 extraordinary circumstances:

- EPA-certified Regional WAM/TOPO/DOPOs or Project Leaders may train additional ESAT personnel with authorization by the National PEP Project Leader.
- Individual training may be arranged at the discretion of OAQPS at its air training facility in Research Triangle Park, NC.

OAQPS will work with the Regional 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 who support the Ambient Air Quality 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:

- OAQPS, AAMG
- 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 (OEI) (http://www.epa.gov/quality/trcourse.html)
- EPA AQAD (http://www.epa.gov/air/oaqps/organization/aqad/io.html)
- EPA Regional offices.

Table 8-1 presents a sequence of core ambient air monitoring and QA courses for ambient air monitoring staff and QAMs (*marked with an asterisk*). The suggested course sequences assume little or no experience in QA/QC or air monitoring.

Table 8-1. Core Ambient Air Training Courses

Sequence	Course Title (Self Instructional [SI])	Number	Source
1*	Air Pollution Control Orientation Course, SI-422	422	APTI
2*	Principles and Practices of Air Pollution Control, 452	452	APTI
3*	Introduction to EPA Quality System Requirements	—	OEI
4*	Introduction to Ambient Air Monitoring, SI-434	434	APTI
5*	General Quality Assurance Considerations for Ambient Air Monitoring (under revision), SI-471	471	APTI
6*	Quality Assurance for Air Pollution Measurement Systems (under revision), 470	470	APTI
7*	Introduction to Data Quality Objectives	—	OEI
8*	Introduction to Quality Assurance Project Plans	—	OEI
9	Atmospheric Sampling, 435	435	APTI
10	Analytical Methods for Air Quality Standards, 464	464	APTI
11	Chain-of-Custody Procedures for Samples and Data, SI-443	443	APTI
*	Introduction to Data Quality Assessment	—	OEI
*	Introduction to Data Quality Indicators	—	OEI
*	Assessing Quality Systems	—	OEI
*	Detecting Improper Laboratory Practices	—	OEI
*	Beginning Environmental Statistical Techniques, SI-473A	473	APTI
*	Introduction to Environmental Statistics, SI-473B	473B	APTI
*	Interpreting Monitoring Data	—	OEI
*	Interpreting Multivariate Analysis	—	OEI
*	Quality Audits for Improved Performance	QA6	AWMA
	Air Quality System (AQS) Training	—**	OAQPS
*	Federal Reference Method Performance Evaluation Program Training (field/laboratory)	QA7	OAQPS
*	$PM_{2.5}$ Monitoring Implementation (video)	PM1	OAQPS

* Courses recommended for QAMs

** Information about AQS training is available on EPA's Technology Transfer Network Web site for the AQS. Materials used in past AQS training classes are also posted on the Web site at http://www.epa.gov/ttn/airs/airsaqs/training/training.htm

9.0 Documentation and Records

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

For the Ambient Air Monitoring Program, there are many documents and records that need to be retained. A document, from a records management perspective, is a volume that contains information, which 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 PEP. In EPA's QAPP regulation and guidance, EPA uses the term "*reporting package*," which is 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 PEP.

9.1 Information Included in the Reporting Package

9.1.1 Data Reporting Package Format and Document Control

The 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 it is key to a successful records management program. It can help you complete the following:

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

The PEP records management system uses the Agency File Codes (AFCs) to facilitate easy retrieval of information during EPA TSAs and reviews. The PEP records management system 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). For more information on EPA records schedules, see http://www.epa.gov/records/policy/schedule (the Web site is searchable by AFC function code and schedule number).

Table 9-1 includes the documents and records that will be filed according to the statute of limitations discussed in Section 9.3. To archive the information as a cohesive unit, all of the PEP $PM_{2.5}$ information will be filed under the major code "PEP," followed by the AFC function code and schedule numbers listed in Table 9-1. For example, PEP project plans would be filed under the heading "PEP/301-093-006.1," and COC forms would be filed under "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. $PM_{2.5}$ 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 EPA and how the Regions and ESAT contractors fit into running the PEP • Organizational structure for the support contractors • PEP project plans and subsequent revisions • Quality Management Plan
	006.2	Monitoring site information	• Site characterization file (Site Data Sheets) • Site maps • Site pictures • SLT site contact information
	006.3	Field operations and data acquisition (by EPA Regional staff or contractors on behalf of EPA)	• QAPPs • SOPs • Field logbooks and communications • Sample handling/COC forms • Documentation of instrument inspection and maintenance • Field testing of PEP equipment
	006.4	Communications (contractor technical project activity)	• Telephone record and e-mail between the ESAT contractor and SLT organizations • Telephone record and e-mail between the ESAT contractor and the Contract Officer's Representative (COR)

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 SLT 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 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 FSs and Laboratory Analysts (LAs) for 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 QC data), including data entry forms • Data algorithms • Documentation of PEP database (PED) (national/Regional level) • $PM_{2.5}$ PED data • FDSs 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

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 PEP QA reports • 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	• WAM/TOPO/DOPO training certifications • Certification as a PEP FS and/or LA • Certification as a PEP FS trainer and/or LA trainer

9.1.2 Notebooks

The following types of notebooks will be issued to field and laboratory personnel:

Field/Laboratory Notebooks. The PEP will issue notebooks to each FS and Laboratory Analyst (LA). Each notebook will be uniquely numbered and associated with the individual and the 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 will 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, which will be issued to each FS and LA, will contain the appropriate data forms for routine operations, as well as inspection and maintenance forms and SOPs.

Sample Shipping/Receipt. One notebook, which will be issued to each field and laboratory shipping and receiving facility, will be uniquely numbered and associated with the $PM_{2.5}$ PEP. It will include standard forms and areas for free-form notes.

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 $PM_{2.5}$ 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 Table 6-2 (found in Element 6.0, *Project/Task Description*) will be collected electronically, along with the laboratory pre- and post-sampling weights. Therefore, 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 PED 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 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

There will be many data forms that will be entered by hand. These 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

As of April 2007, the EPA implemented a new record-handling system for e-mail and associated attachments. ESAT and other contractors who use EPA's in-house e-mail will be expected to use the record-handling system as soon as guidelines for the PEP and user training are available. Instructions on use for PEP e-mail and attachments are currently being developed and will be issued as a quality directive to EPA and ESAT personnel.

9.2 Reports to Management

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

9.2.1 Laboratory Weekly Report

The LA will provide the WAM/TOPO/DOPO with a written progress report every Friday or the last day of the scheduled work week. The LA will maintain a complete record of the laboratory weekly progress reports (PEP Laboratory SOP, Form COM-2) in a three-ring binder and will include an updated Filter Inventory and Tracking Form (PEP Laboratory SOP, Form COC-1). The PEP Laboratory SOP, Section 4 contains the details of this report, which will be filed according to the records schedule outlined in Table 9-1. The WAM/TOPO/DOPO may request more information to be included in the weekly reports if he or she deems that it is necessary.

9.2.2 Field Monthly Report

The FS will provide a written progress report to the WAM/TOPO/DOPO each month (the deadline is the 15th calendar day of the following month unless otherwise specified by the WAM/TOPO/DOPO). See the PEP Field SOP, Section 2 for more details about this report. This monthly report will be filed according to the schedule outlined in Table 9-1.

The monthly progress report (PEP Field SOP, Form COM-2) 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—Necessary to resolve issues, including the person(s) responsible for resolving them and the anticipated dates when they will be resolved
- Extra purchases.

The WAM/TOPO/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 1999 will be archived until 12/31/2002). Upon reaching the 4-year archival date, the ESAT contractor will inform OAQPS 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 PEP, 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

Section 6.4 (found in Element 6.0, *Project/Task Description*) details the critical time lines and activities for the 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 3.2.7, as described below.

The PEP is an independent assessment used to estimate total measurement system bias. These evaluations will be performed under the $PM_{2.5}$ PEP (40 CFR Part 58, Appendix A, Section 2.4,) or a comparable program. PEs will be performed on the SLAMS monitors annually within each PQAO. For PQAOs with less than or equal to five monitoring sites, five valid PE audits must be collected and reported each year. For PQAOs with more than five monitoring sites, eight valid PE audits must be collected and reported each year. A valid PE audit means that both the primary monitor and PEP audit concentrations have not been invalidated and are greater than 3 $\mu g/m^3$. To achieve this, sites that have seasonally low concentrations should be sampled during times when concentrations are expected to be greater than 3 $\mu g/m^3$. EPA recognizes that it may be difficult or impossible to obtain valid audits at sites where the concentration rarely exceeds 3 $\mu g/m^3$. EPA is currently considering ways to evaluate such sites. Audits that are otherwise valid, but do not meet the greater than 3 $\mu g/m^3$ criteria are still useful to evaluate sampler operation, even if such audit data may not be used in the calculations for sampler bias (see Section 6.4.1 for additional information about audit frequency).

Additionally, each year, every designated FRM or FEM sampler within a PQAO must have

- Each method designation evaluated each year
- All FRM or FEM samplers subjected to a PEP audit at least once every 6 years. This equates to approximately 15% of monitoring sites audited per year.

SLT organizations will be asked to select the sites that they feel meet the previously mentioned criteria and provide a list of sites for the PEs 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 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 PEP data to be statistically evaluated at various levels of aggregation to determine whether the DQOs have been attained. Data Quality Assessments (DQAs) will be aggregated at the following three levels:

- **Monitor.** Monitor/method designation
- **Reporting Organization.** Monitors in a method designation, all monitors
- **National.** Monitors in a method designation, all monitors.

OAQPS believes it 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. After 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 PEP is based on how the NAAQS for $PM_{2.5}$ is determined. It is based on 3 years of data from individual monitors; therefore, it is important to assess the PE data against the DQO at the same frequency and level of aggregation. Because the audit frequency of the PEP is 15%, any one monitor would receive a PEP audit at least once every 6 years. The PEP data is suitable for the actual assessment of the particular monitor type but has limited use at the unique monitor level of aggregation. At the PQAO and national levels of aggregation, a sufficient amount of PEP data will be available to evaluate bias. The uncertainty of the 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 PEP design attempts to represent parameter variations at a sampling point by locating the PEP sampler within 1–4 meters of the primary routine sampler (inlets within 1 meter of the vertical height) and by operating the PEP sampler on the same sampling schedule as the routine sampler. In addition, the PEP ensures representativeness of sampling within the SLAMS network by evaluating all method designations within a PQAO annually and by evaluating all samplers over a 6-year period (100% sampling).

Appendix L of 40 CFR Part 50 also provides the following summary of the measurement principle:

> An electrically powered air sampler draws ambient air at a constant volumetric flow rate into a specially shaped inlet and through an inertial particle size separator (impactor) where the suspended particulate matter in the $PM_{2.5}$ size range is separated for collection on a PTFE filter over the specified sampling period. The air sampler and other aspects of this reference method are specified either explicitly in this appendix or generally with reference to other applicable regulations or QA guidance.

Because all PE samplers must meet the requirements of 40 CFR Part 50 and be designated by EPA as an FRM sampler, it is assumed that they collect a representative sample of suspended PM in the $PM_{2.5}$ size range, similar to the primary sampler at the site.

10.3.2 Homogeneity

The PE sampler must be placed within 1–4 meters of the primary routine sampler to which it is being compared. The assumption is that the air within this 1–4-meter area is homogenous; therefore, both monitors will sample the same $PM_{2.5}$ load. Historical information on PM_{10} collocation data and preliminary $PM_{2.5}$ data indicates this assumption is correct.

10.4 Procedure for Locating and Selecting Environmental Samples

Sections 10.2 and 10.3 explain the following:

- **Frequency** (15% of the samplers with a method designation each year).
- **Location (**1–4 meters from monitor to be evaluated; inlets within 1 meter of the vertical height). The physical location of the routine monitor is the responsibility of the SLT organizations and does not affect the intent of the PE. Site locational information is entered by the SLT organization into the AQS database. The critical piece of information is the AQS site ID (state, county, unit, pollution 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 develop 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 (e.g., SLAMS)*
- Reporting organization*
- Reporting organization contact
- Street address*
- Directions to the site (from the Regional office)
- Directions to and 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 $PM_{2.5}$ site
- Second closest $PM_{2.5}$ site

* *Items marked with an asterisk (*) are available in the AQS. These data are publicly available through EPA's Web site; in the Web browser, enter http://www.epa.gov/aqspubl1/site.htm and go to Monitor Data Queries. The criteria pollutant code for $PM_{2.5}$ is 88101.*

The information previously listed 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 or she cannot transport or set up the monitor without jeopardizing his or her personnel safety. The FS will document the occurrence of any unsafe conditions so that mechanisms can be instituted to make the platform safely accessible for a PE. 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 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 PEP is deploying only FRM samplers and will be operating these samplers according to the established SOPs, there will not be any non-standard measurements. Also, because the PEP will be sending its filters to a certified laboratory for weighing, there will not be any non-standard measurements from the analysis of the filters; therefore, all sampling and analysis measurements will be standard.

11.0 Sampling Methods Requirements

The PEP provides for measurement of the mass concentration of $PM_{2.5}$ in ambient air over a 24-hour period. The measurement process is considered to be non-destructive, and the $PM_{2.5}$ sample obtained can be subjected to subsequent physical or chemical analyses. A set of SOPs for field sampling (*Field Standard Operating Procedures for the Federal $PM_{2.5}$ Performance Evaluation Program)* has been developed for the 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

Portable FRM monitors are used for collecting $PM_{2.5}$ samples for the PEP. Three models are available: the BGI™ PQ200A, the Andersen™ RAAS2.5-200, and the R&P Partisol®. Because the goal is to provide comparable results across the nation, using one make and model of a portable monitor to evaluate all of the routine monitors is advantageous because it reduces the chances that bias and imprecision among the different portable instrument models will confound the routine monitor comparisons. Because the BGI was the only portable instrument to be granted FRM designation before January 1999, it was selected as the primary instrument; therefore, the Field SOPs have been written based on this instrument. The other two instruments have been purchased and used as back-up instruments or used in areas where they have advantages due to their design. It should be noted that Thermo Fisher Scientific currently owns the Andersen and R&P sampler lines. Thermo Fisher Scientific has discontinued active production and technical support for the Andersen RAAS line of samplers, so parts will likely become unavailable in the future. PEP FSs may continue to use the Andersen RAAS or R&P samplers in their limited roles as long as the samplers are serviceable and they are included in semiannual collocation evaluations.

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 on-hand based upon the number of sites to be visited. At least one spare portable monitor and one set of calibration equipment will be available. Filters will be selected and stored appropriately (per SOPs) for transport to the sites. Filter COC forms will be started, and the filter expiration dates will be checked to ensure they have not exceeded their 30-day pre-sampling time period. Site Data Sheets, which contains information on site characteristics for each site, and blank FDSs, which are used to record field information for the PE audit, should 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 PEP FSs will review the site schedule to be sure that they understand which tasks will be implemented at the sites they are visiting that week.

Shipping the filters back to the laboratories will require FSs to use ice substitutes, which must be kept frozen until use. During transport to/from the sites, the ice substitutes will be placed in a cooler to minimize heat gain.

11.1.2 Field Sample Collection

FSs will travel to the sites and meet the person (typically the Site Operator) who will allow them access to the monitoring site. The portable FRM monitors will be transported to within 1–4 meters of the routine monitor, and then set up and calibrated per the PEP Field SOPs. Filter cassettes will be installed and the monitor will be set to run on a midnight-to-midnight 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, then the ESAT FS will contact the affected SLT 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 cassette, 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 portable laptop and a data logger (or another mechanism to download sampler data) provided by the portable sampler manufacturers. In 2006, BGI discontinued support for its DataTrans® data loggers. Currently, functioning instruments may be used until they are no longer serviceable. BGI may decide to develop another instrument in the future. If a new instrument is developed, it will be evaluated and placed in service if it appears to be reliable. Laptops should be used as a first option to acquire the data from the samples. When safety or precipitation prevents the use of a laptop, a data logger may be used or these data may be downloaded later. A portable media device (e.g., diskette, CD, or USB flash drive) of the downloaded data must be sent to the laboratory along with the filters.

11.1.3 Filter Transportation

It is important that the filters be properly stored and transported to the weighing laboratory as soon as possible. Ideally, filter cassettes will be shipped the same day that they are removed from the monitors via next-day delivery. Filter cassettes, ice packs, maximum/minimum thermometers, copies of the COC forms and FDSs, and a field data diskette/CD/USB flash drive containing the monitor information will be included in the shipment. The FS will keep a copy of the FDS and the COC Form (to file under PEP/301-093-006.3) and will record the number of containers shipped and the air bill number in the field notebook. On the day of shipping, the FS will contact the weighing laboratory to make its personnel aware of the shipment and to provide the laboratory with the number of containers 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, ensure that all equipment and consumables are properly stored, and determine if ordering supplies or performing equipment maintenance are required. A second copy of the week's field data will be stored at the field office and provided to the EPA Regional WAM/TOPO/DOPO upon request.

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 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 more information about this.

11.2 Support Facilities for Sampling Methods

The analytical support facilities for the federally implemented PEP will be provided by the Region 4 gravimetric laboratory in Athens, GA. This laboratory has been developed to meet the measurement quality objectives described in Table 7-1. In case of emergency, several back-up laboratories have been arranged: EPA's facility in Research Triangle Park, NC; EPA's ORIA–NAREL in Montgomery, AL; EPA's ORIA's Office of Radiation and Indoor Environments (OR&IE) Laboratory in Las Vegas, NV; and EPA's Region 2 Environmental Laboratory in Edison, NJ.

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 PEP 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 PEP Workgroup, a new SOP 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 WAM/TOPO/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 PEP Workgroup, 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 PEP 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:

_____
$PM_{2.5}$ 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. Quality Bulletin.

11.3.2 Data Operations

Corrective action measures in the 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 PEP.

Table 11-1. Field Corrective Action

Item	Problem	Action	Notification
Pre-Sampling Event Activities			
Filter inspection	Pinhole(s) or tear(s)	1. If additional filters have been brought to the site, use one of them. Void filters with pinholes or tears 2. Use a new field blank filter as a sample filter 3. Obtain a new filter from the laboratory	1. Document on the FDS 2. Document on the FDS 3. Notify the Regional WAM/TOPO/DOPO
WINS impactor	Heavily loaded with coarse particulate matter. Will be obvious due to a "cone" shape on the impactor well	Clean downtube and WINS impactor. Load new impactor oil into the WINS impactor well	Document in a log book
Leak test	Leak outside acceptable tolerance (80 mL/min)	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	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

Item	Problem	Action	Notification
Ambient pressure verification	Out of specification (± 10 mm Hg)	1. Make sure pressure sensors are each 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
Ambient temperature range during sampling event	<−30°C or >45°C	Reschedule another audit[a]	Document on the FDS; notify the Regional WAM/TOPO/DOPO
Ambient temperature verification and filter temperature verification	Out of specification (± 2°C of standard)	1. Make sure that thermocouples are immersed in the same liquid at same point without touching the sides or bottom of the container 2. Use ice bath or warm water bath to check a different temperature. If the temperature is acceptable, perform the ambient temperature verification again 3. Connect a new thermocouple 4. Check the ambient temperature with another NIST-traceable thermometer	1. Document on the FDS 2. Document on the FDS 3. Document on the FDS; notify the Regional WAM/TOPO/ DOPO 4. Document on the FDS; notify the Regional WAM/TOPO/ DOPO

Item	Problem	Action	Notification
Sample flow rate verification	Out of specification (indicated flow rate ± 4% of transfer standard and ± 4% of design flow rate [16.67 Lpm])	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. Check the flow rate at 16.67 Lpm	3. Document on the FDS; notify the Regional WAM/TOPO/ DOPO
		4. Recalibrate the flow rate	4. Document on the FDS; notify the Regional WAM/TOPO/ DOPO
		5. Verify it again; flow rate must be within ±2% of design flow rate (16.67 Lpm)	5. Document on the FDS
Sample flow rate	Consistently low flows 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
		3. Inspect the in-line filter downstream of 46.2-mm filter location, and replace it as necessary	3. Document in the log book
Sample flow rate	24-hr CV >2%	1. Inspect 5-minute CVs during sampler performance download; determine if the exceedance is associated with external stimuli, such as power loss	1. Document in the log book
		2. If the exceedance is not justifiable, retest sampler in a laboratory, troubleshoot, and repair as necessary	2. Document in the log book

Post-Sampling Event Activities			
Elapsed sample time	Out of specification (1 min/mo)	Check programming; verify power outages	Notify the Regional WAM/ TOPO/DOPO
Elapsed sample time	Sample did not run	1. Check programming 2. Try programming the sample run to start while the operator is at the site; ensure the transport filter is in the unit	1. Document on the FDS; notify the Regional WAM/TOPO/ DOPO 2. Document in the log book; notify the Regional WAM/ TOPO/DOPO
Power	Power interruptions	Check line voltage	Notify the Regional WAM/ TOPO/DOPO
Power	Liquid crystal display (LCD) panel is on, but the sample is not working	Check the circuit breaker (some samplers have a battery backup for data, but it will not work without AC power)	Document in the log book
Filter inspection	Torn filter or otherwise suspect particulate matter on the 46.2-mm filter	1. Inspect area downstream of where filter rests in the sampler and determine if particulate matter has been bypassing filter 2. Inspect the in-line filter before the sample pump and determine if excessive loading has occurred; replace as necessary	1. Document on the FDS 2. Document in the log book
Data down-loading	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 micro-processor	Notify the Regional WAM/ TOPO/DOPO

[a] Contingent on the SLT monitoring agency invalidating its FRM results for the sampling event or other PEP sampler performance anomalies such as flow CVs that fall outside of acceptable ranges.

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, how to protect the sample from contamination, 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 PEP has rigid requirements for preventing sample contamination. Powder-free, antistatic gloves are worn while handling filter cassettes in the laboratory. After the filter cassette has been removed from the weigh room, it must never be opened because the 46.2-mm Teflon filter could become damaged. Filter cassettes will be stored in protective containers. After samples have been pre-weighed, they are to be stored with the particulate collection side up, capped with metal caps, and individually stored in static-resistant zip-top plastic bags.

11.4.2 Sample Volume

The volume of air to be sampled is specified in 40 CFR Part 50, Appendix L. Sample flow rate of air is 16.67 Lpm. The total sample of air collected will be 24 m^3 based on a 24-hour sample. Sampling time is expected to be 24 hours (midnight to midnight); however, a shorter sampling period may be necessary in some cases. This shorter sampling period should not be less than 23 hours. If a sample period is less than 23 hours or greater than 25 hours, then the sample will be flagged and the Regional WAM/TOPO/DOPO will be notified.

11.4.3 Temperature Preservation Requirements

The temperature requirements for FRM $PM_{2.5}$ sample collection are explicitly detailed in 40 CFR Part 50, Appendix L. During transport from the laboratory to the sampling location, there are no specific requirements for temperature control; however, the filters will remain in their protective container and in the transport container. Excessive heat must be avoided (e.g., do not leave in direct sunlight or in a closed car during summer). During the 24-hour sampling period, the filters will be subjected to ambient temperatures and shall not exceed the ambient temperature by more than 5°C for more than 30 minutes. Upon retrieval of the sample, the filter temperature will be modified to cool them as soon as possible to ≤4°C (see PEP Field SOP, Section 6). The filter temperature requirements are detailed in Table 11-2.

Table 11-2. Filter Temperature Requirements

Item	Temperature Requirement	Reference
Filter temperature control during sampling and until recovery	No more than 5°C above ambient temperature	40 CFR Part 50, Appendix L, Section 7.4.10
Filter temperature control from time of recovery to the start of conditioning.	4°C or less[a]	40 CFR Part 50, Appendix L, Section 10.13
Post-sample transport	4°C or less[a]	40 CFR Part 50, Appendix L, Section 8.3.6

[a] PEP requirement is more stringent than regulations for FRM design.

11.4.4 Permissible Holding Times

The permissible holding times for the routine FRM network $PM_{2.5}$ sample are clearly detailed in both 40 CFR Part 50, Appendix L, and *Quality Assurance Guidance Document 2.12*. The holding times for the PEP are provided in Table 11-3. Note that in some steps, PEP requirements are more stringent than the FRM network regulations.

Table 11-3. Holding Times

Item	Holding Time	From	To	Reference
Pre-sampling weighed filter	≤30 days	Date of pre-weighing	Date of sampling event	40 CFR Part 50, Appendix L, Section 8.3.5
Recovery of filter	≤24 hours[a, b]	Completion of sampling event	Time of sample recovery	40 CFR Part 50, Appendix L, Section 10.10
Shipped to laboratory	≤8 hours (ideally)[a, b]	Time of recovery	Time of shipment	40 CFR Part 50, Appendix L, Section 10.13
Post-sampling filter stored at ≤4°C	≤10 days[a, b]	Sample end date/time	Date of post-weighing	40 CFR Part 50, Appendix L, Section 8.3.6

[a] PEP requirement is more stringent than regulations for FRM design.

[b] See Table 6-4 (found in Element 6.0, *Project/Task Description*) for exceptions.

12.0 Sample Handling and Custody

Due to the potential use of the $PM_{2.5}$ data for comparison to the NAAQS and the requirement for extreme care in handling the sample collection filters, sample COC procedures will be followed. The PEP Laboratory SOP (Sections 5 and 9) and the PEP Field SOP (Sections 3 and 7) provide detailed instruction on filter-handling and COC procedures, which will not be included in this section.

Due to the small 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. Filter cassettes should be handled in a manner to prevent the filters they contain from being damaged or contaminated. Similarly, rough handling of exposed filters should be avoided because this may dislodge collected PM on the filters. Care should be taken to avoid inadequate conditioning of filters or excessive delays between sample retrieval and sample weighing because this may lead to positive or negative weight changes and, thus, to inaccurate $PM_{2.5}$ concentration measurements.

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 for all stages 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 (found in Element 6.0, *Project/Task Description*) the three-part carbonless COC Form starts at the weighing laboratory, proceeds through field activities, and then it is sent back to the laboratory. Later, the information is entered into the weighing laboratory's sample tracking system, where an electronic record will be kept.

13.0 Analytical Methods Requirements

The analytical methods described below provide for gravimetric analyses of filters used in the PEP. The net weight gain of a sample filter is calculated by subtracting the initial weight (pre-sampling) from the final weight (post-sampling). The net weight gain is divided by the total flow volume passed through a filter (derived from the field data) to calculate the concentration. This PEP-derived concentration may be compared to the concentration derived in the same manner from a primary routine monitor.

All analytical methods are included in the document entitled *Quality Assurance Guidance Document Method Compendium Laboratory Standard Operating Procedure for the $PM_{2.5}$ Performance Evaluation Program*. The PEP weighing laboratory will be responsible for implementing these analytical procedures. The following sections summarize the information in the PEP Laboratory SOP; however, it is important to note that these summaries do not replace the SOP.

13.1 Preparation of Sample Filters

Upon delivery of 46.2-mm Teflon filters to the laboratory, the receipt is documented and the filters are stored in the conditioning/weighing room/laboratory. Storing filters in the laboratory makes it easier to maximize the amount of time available for conditioning. Upon receipt, cases of filters will be labeled with the date of receipt, they will be opened one at a time, and they will be used completely before opening another case. All filters in a lot will be used before a case containing another lot is opened. When more than one case is available to open, the "First In–First Out" rule will apply.

Filters will be visually inspected according to the FRM criteria to determine compliance. Filters will then be stored in the filter conditioning compartment in unmarked Petri dishes.

13.2 Analysis Method

13.2.1 Analytical Equipment and Method

A complete listing of the analytical equipment is found in the PEP Laboratory SOP and in Element 17.0, *Inspection/Acceptance for Supplies and Consumables*.

The analytical instrument used for gravimetric analysis in the FRM method (gravimetric analysis) is the microbalance. The PEP weighing laboratory currently uses the Sartorius® MC-5, which has a readability of 1 μg and a repeatability of 1 μg. The microbalance is calibrated twice yearly by a technician under a service agreement between the weighing laboratory and the vendor.

As Figure 13-1 indicates, the method of analysis consists of pre-sampling and post-sampling stages. Figure 13.1 also indicates the section number where detailed procedures can be found in the PEP Laboratory SOP.

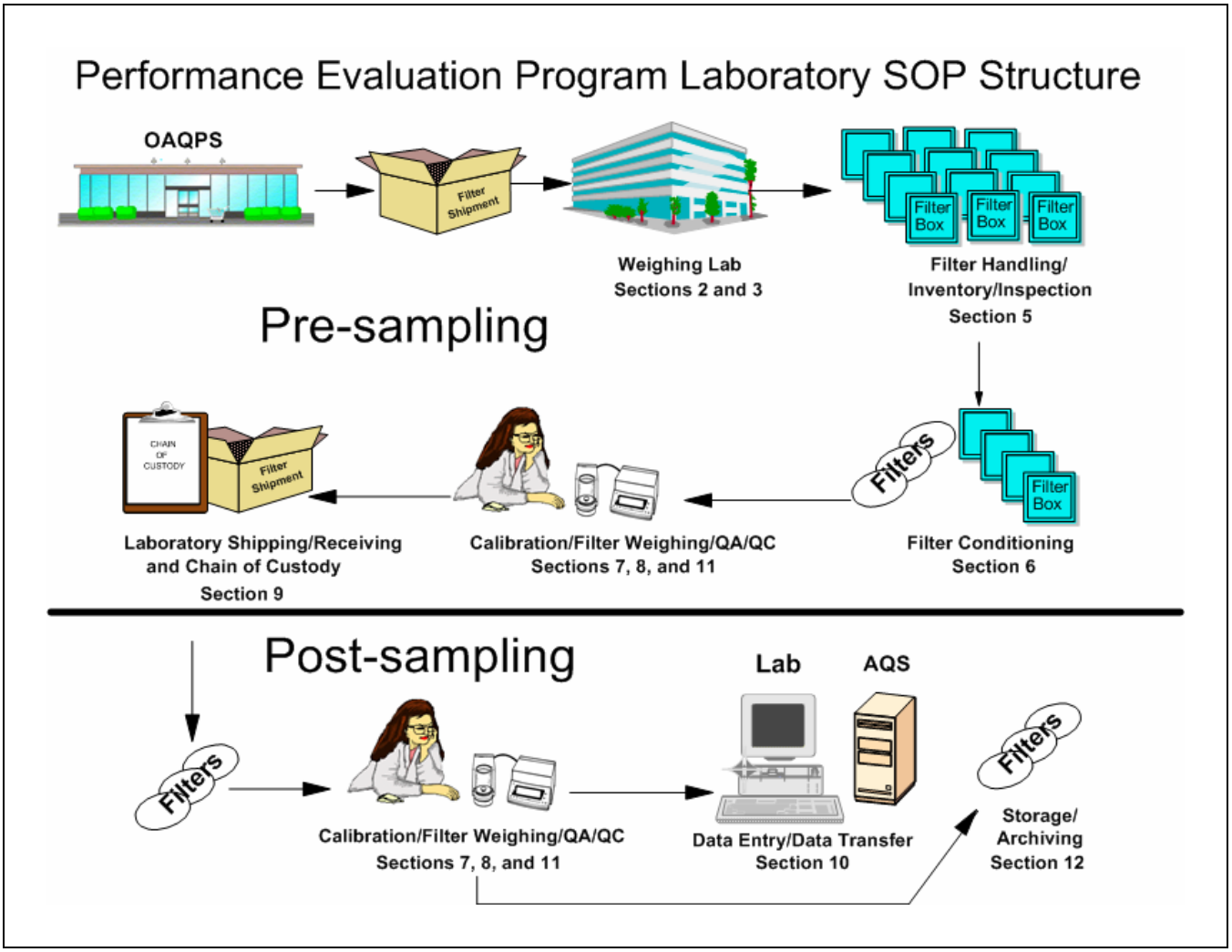


Figure 13-1. Laboratory activities.

Pre-sampling Stage

- Filters are received from EPA, logged in, and examined for integrity.
- A proportion of filters are conditioned for use in the field.
- Filters are equilibrated, weighed, and enumerated.
- Filters are prepared for field activities and shipped to the appropriate Regions.

Post-sampling Stage

The post-sampling stage consists of the following steps (in chronological order):

Step 1. Filters are received in the weighing laboratory, checked for integrity (e.g., damage, temperature), and logged in.

Step 2. Filters are archived (in cold storage) until ready for weighing.

Step 3. Filters are brought into the weighing laboratory and equilibrated for 24 hours.

Step 4. Filters are weighed, and then the gravimetric results are entered into the data entry system.

Step 5. Field data are entered into the data entry system to calculate a concentration.

Step 6. Data are verified and validated.

Step 7. Filters are archived in cold storage for the remainder of the calendar year and for one full calendar year afterwards. Filters are then stored at room temperature for an additional three calendar years. For example, a filter sampled on March 1, 2007 will be kept in refrigerated storage until December 31, 2008 and not disposed of until after December 31, 2011.

Step 8. Required data are submitted to the AQS database.

13.2.2 Conditioning and Weighing Room

The primary support facility for the $PM_{2.5}$ analysis is the weighing laboratory. Facility space is dedicated for long-term archiving of the filter. This weighing room is used for both sample conditioning and pre- and post-sampling weighings of each $PM_{2.5}$ filter sample. The laboratory facilities have been constructed to minimize contamination from dust or other potential contaminants (using High-Efficiency Particulate Air [HEPA] filters and sticky mats) and will have restricted access to LAs who will wear appropriate laboratory attire at all times.

Specific requirements for environmental control of the weighing room are detailed in 40 CFR Part 50, Appendix L. Mean relative humidity is controlled between 30% and 40%, with a target of 35% and variability of not more than ± 5% over 24 hours, with minimums and maximums never to fall out of the 25%–45% range. Mean temperature should be held between 20°C and 23°C, with a variability of not more than ± 2°C over 24 hours, with minimums and maximums never to fall out of the 18°C–25°C range. Temperature and relative humidity are measured and recorded continuously during equilibration. The balance is located on a vibration-free table and is protected from or located out of the path of any sources of drafts. Filters are conditioned before the pre- and post-sampling weighing sessions. Filters must be conditioned for at least 24 hours to allow their weights to stabilize before being weighed.

13.3 Internal QC and Corrective Action for Measurement System

13.3.1 Corrections to the SOP

The ESAT contractors are responsible for implementing this QAPP and the PEP Laboratory SOP, 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 PEP Laboratory SOP or QAPP, the ESAT contractor will notify the Regional WAM/TOPO/DOPO in writing. The WAM/TOPO/DOPO will then convey the issue(s) to the PEP Workgroup, which will review the changes and attempt to classify them according to the effect the changes would have on the data. The required procedure for changes to the PEP Field SOP is discussed in Element 11.0, *Sampling Methods Requirements*.

13.3.2 Data Operations

A QC notebook or database (with disk backups) will be maintained and will contain QC data and entry forms, calibration and maintenance information, routine internal QC checks of mass reference standards, laboratory and field filter blanks, and external QA audits. Control charts will be maintained for each microbalance and it will be included in this notebook. These charts may allow for the discovery of excess drift that could signal an instrument malfunction.

QC checks will be used to assist the LAs in controlling and evaluating the quality of data during a weighing session. These QC checks include the following:

- Mass working standards weighed at the beginning and at the end of each weighing session, and one after approximately every 15 samples or fewer, per the recommendations of the balance manufacturer
- Blanks (both field and laboratory) that will be used to determine contamination
- Duplicate routine weights to determine repeatability and filter stability of the instrument within and between the weighing sessions.

The acceptance requirements for these QC checks can be found in Table 7-1, in the SOP, and in more detail in Element 14.0, *Quality Control Requirements*.

Corrective action measures in the PEP will be taken to ensure data of adequate quality. There is the potential for many types of sampling and measurement system corrective actions. Tables 13-1 (organized by laboratory support equipment) and 13-2 (organized by laboratory support activity) list potential problems and corrective actions needed to support the PEP. Filter weighing will be delayed until corrective actions are satisfactorily implemented.

Table 13-1. Potential Problems/Corrective Action for Laboratory Support Equipment

System	Item	Problem	Action	Notification
Weigh room	Relative humidity	Out of specification	Check the heating, ventilation, and air conditioning (HVAC) system	PEP Laboratory Manager
Weigh room	Temperature	Out of specification	Check the HVAC system	PEP Laboratory Manager
Balance	Internal calibration	Unstable	Retry internal calibration	PEP Laboratory Manager
Balance	Zero	Unstable	Retry zero and check for drafts; check that draft guard is sealed	PEP Laboratory Manager
Balance	Working standards	Out of specification	1. Check the temperature and relative humidity and check the working standard 2. Recalibrate and check the working standard 3. Check with primary standards	Document, PEP Laboratory Manager
Balance	Filter weighing	Unstable	Check laboratory blank filters	Document in a log book

Table 13-2. Filter Preparation and Analysis Checks

Activity	Method and Frequency	Requirements	Action If the Requirements Are Not Met
Microbalance use	1 per year to establish instrument detection limit (IDL)	Resolution of 1 μg, repeatability of 1 μg	Obtain proper microbalance
Control of balance environment	5-minute values of temperature and relative humidity averaged for 24 hours	Climate-controlled draft-free room or chamber or equivalent	Modify the environment
Use of mass reference standards	Working standards checked every 3 months against the laboratory primary standards	Standards bracket weight of filter, an individual standard's tolerance less than 25 μg, and handle with smooth, nonmetallic forceps	Obtain new working standards
Filter handling	Observe handling procedures	Use powder-free and antistatic gloves and smooth forceps; replace Polonium-210 antistatic strips every 6 months	Discard the mishandled filter or the old antistatic strip
Filter integrity check	Visually inspect each filter	No pinholes, separation, chaff, loose material, discoloration, or filter non-uniformity	Discard defective filter
Filter identification	Write the filter number on the COC Form, the cassette number on the protective container, and both numbers in the database and/or on a laboratory data form in permanent ink	Make sure the numbers are written legibly	Replace label or correct the form

Activity	Method and Frequency	Requirements	Action If the Requirements Are Not Met
Filter lot stability	Determine the correct equilibration conditions and period (at least 24 hours) for each new lot of filters	Check for stability of lot exposure blank filter weights; weight changes must be ≤15 μg on successive weighings of lot exposure blanks	Revise the equilibration conditions and period; repeat the equilibration
Pre-sampling filter equilibration	Equilibrate filters for at least 24 hours in weighing room; observe and record the equilibration chamber relative humidity and temperature; enter into the database and/or on the laboratory data form	Mean relative humidity between 30% and 40%, with a target of 35% and variability of not more than ± 5% over 24 hours, with minimums and maximums never to fall out of the 25%–45% range; mean temperature should be held between 20°C and 23°C, with a variability of not more than ± 2°C over 24 hours, with minimums and maximums never to fall out of the 18°C–25°C range	Revise the equilibration conditions and period; repeat the equilibration
Initial filter weighing	Observe all weighing procedures; perform all QC checks	Neutralize electrostatic charge on filters; wait until the balance indicates a stable reading	Repeat weighing
Internal QC	1. After approximately every 15th filter (or fewer, per recommendations from the balance manufacturer), reweigh the two working standards 2. Weigh laboratory filter blanks 3. Reweigh the first filter as the last routine weight with each sample batch (duplicate weighing) 4. For post-sampling weighing sessions only, keep the filter used for duplicate weighing and place it with the next batch; do not make this filter one of the first three filters in the next batch (previous batch duplicate)	1. Working standard measurements must agree to within 3 μg of the certified values 2. Blank measurements must agree to within 15 μg 3. First and last filter reweigh measurements must agree to within 15 μg 4. Filter reweigh measurements between adjacent weigh sessions must agree to within 15 μg	1. Stop weighing and troubleshoot 2. Flag values for validation activities 3. Flag; reweigh 2nd and 3rd filters; if failure, then recondition all sample in run and reweigh
Post-sampling inspection, documentation, and verification	Examine the filter and FDSs for correct and complete entries; if sample was shipped in a cooled container, verify that a low temperature was maintained	No damage to filter; FDS complete; sampler worked OK	Notify the PEP Laboratory Manager; flag filters

Activity	Method and Frequency	Requirements	Action If the Requirements Are Not Met
Post-sampling filter equilibration	Equilibrate filters for at least 24 hours in weighing room; observe and record the equilibration chamber relative humidity and temperature; enter into the database and/or on the laboratory data form (must be within ± 5% relative humidity of pre-sampling weighing conditions)	Mean relative humidity between 30% and 40%, with a target of 35% and variability of not more than ±5% over 24 hours; with minimums and maximums never to fall out of the 25–45% range; mean temperature should be held between 20°C and 23°C, with a variability of not more than ±2°C over 24 hours, with minimums and maximums never to fall out of the 18–25°C range	Repeat equilibration
Post-sampling filter weighing	Observe all weighing procedures; perform all QC checks	Neutralize electrostatic charge on filters; wait 30 to 60 seconds after balance indicates a stable reading before recording data	Repeat weighing

13.4 Filter Sample Contamination Prevention, Preservation, and Holding Time Requirements

This section details the requirements needed to prevent and protect the sample from contamination, the temperature requirements for sample preservation, and the permissible holding times to ensure against degradation of sample integrity.

13.4.1 Sample Contamination Prevention

The analytical support component of the PEP has rigid requirements for preventing sample contamination. Filters are equilibrated/conditioned and stored in the same room where they were weighed and will be protected in Petri dishes. The weighing room is controlled for climate and contamination (see Section 13.2.2). Powder-free and antistatic gloves are worn while handling filters, and filters are only contacted with smooth, non-serrated forceps. Upon determining a pre-sampling weight, the filter is placed in its cassette, filter caps are placed on the cassette, and then the capped cassette is placed in a plastic, antistatic shipping bag. The shipping bag and capped cassette are only opened when the filter is being installed in a monitor. After the filter has been removed from the weighing room, it will never leave the cassette until it is back in the weighing room (during post-sampling).

13.4.2 Temperature Preservation Requirements

The temperature requirements of the $PM_{2.5}$ FRM network are explicitly detailed in 40 CFR Part 50, Appendix L. The PEP requirements will be more stringent. In the weighing room laboratory, the filters must be conditioned for a minimum of 24 hours before pre-weighing; although, a longer period of conditioning may be required. The mean weighing room laboratory temperature must be maintained between 20°C and 23°C, with no more than a ± 2°C change over the 24-hour period before weighing the filters. Minimums and maximums should never fall out of the

18°C–25°C range. During transport from the weighing room to the sample location, there are no specific temperature control requirements; however, the filters will be in their protective container, and temperature extremes (excessive heat or cold) will be avoided. Temperature requirements for the sampling and post-sampling periods are detailed in 40 CFR Part 50, Appendix L, Section 7.4.10. These requirements state that the temperature of the filter cassette during sampler operation and in the period from the end of sampling to the time of sample recovery shall not exceed that of the ambient temperature by more than 5°C for more than 30 minutes.

The specifics of temperature preservation requirements are clearly detailed in 40 CFR Part 50, Appendix L.[1] These requirements pertain to sample media before collection, as well as the sample media and sample after a sample has been collected. During the sample collection, there are also temperature control requirements, which are detailed in Table 13-3.

Table 13-3. Temperature Control Requirements

Item	Temperature Requirement	Reference
Weighing room	Mean temperature should be held between 20°C and 23°C, with a variability of not more than ± 2°C over 24 hours, with minimums and maximums never to fall out of the18°C–25°C range[a]	40 CFR Part 50, Appendix L, Section 8.2
Filter temperature control during sampling and until recovery	No more than 5°C above ambient temperature	40 CFR Part 50, Appendix L, Section 7.4.10
Post-sample transport	≤4°C[a]	40 CFR Part 50, Appendix L, Section 8.3.6

[a] PEP requirement is more stringent than regulations for FRM design.

13.4.3 Permissible Holding Times

The permissible holding times for the $PM_{2.5}$ sample are clearly detailed in both 40 CFR Part 50[1] and Section 2.12 of the U.S. EPA QA Handbook[2]. A summary of these holding times is provided in Table 11-3, which is found in Element 11.0, *Sampling Methods Requirements*.

References

The following documents were used to develop this element:

1. U.S. EPA (Environmental Protection Agency). 2006. National Ambient Air Quality Standards for Particulate Matter—Final Rule. 40 CFR Part 50. *Federal Register 71*(200):61144–61233. October 17.

2. U.S. EPA (Environmental Protection Agency). 1998. *U.S. EPA Quality Assurance Guidance Document 2.12: Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods*. March.

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 of a given monitoring system, the better will be 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 PEP, 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. Figure 14-1 represents many QC activities that help to evaluate and control data quality for the $PM_{2.5}$ PEP. The activities in this figure are implemented by the PEP and are discussed in the appropriate elements of this QAPP.

14.1 QC Procedures

Day-to-day QC is implemented through various check samples or instruments that are used for comparison. The MQOs table (Table 7-1) 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 $PM_{2.5}$ PEP. The procedures for implementing the QC samples are included in the PEP Field and Laboratory SOPs, respectively. As Figure 14-1 illustrates, various types of QC samples have been inserted at phases of the data operation to assess and control measurement uncertainties. Tables 14-1 and 14-2 contain summaries of all the field and laboratory QC samples. 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.

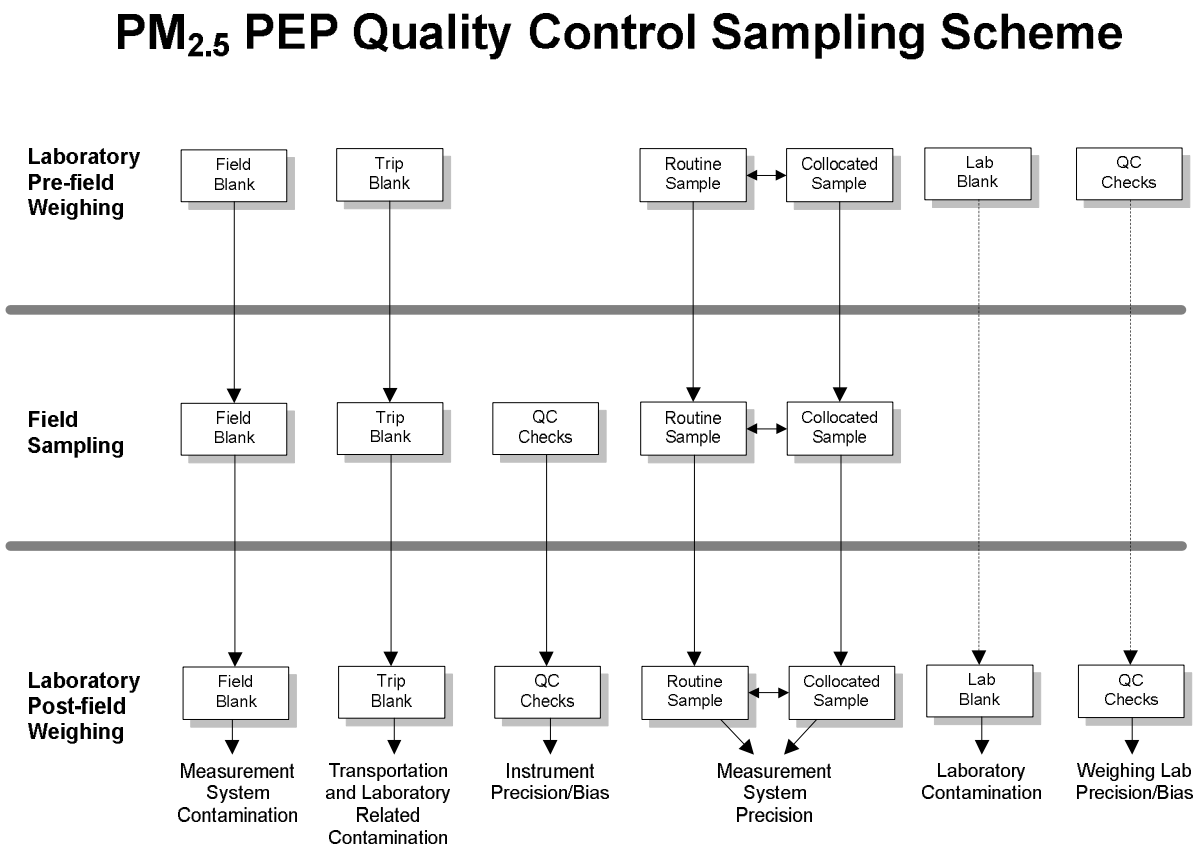


Figure 14-1. PEP QC scheme.

Table 14-1. Field QC Checks

Requirement	Frequency	Acceptance Criteria	CFR Reference	SOP Reference	Information Provided
Calibration Standards					
Flow rate transfer standard or primary standard	1/yr	± 2% of NIST-traceable standard	Part 50, Appendix L, Section 9.2.2	Field SOP, Section 8	Certification of traceability
Field thermometer	1/yr	± 0.1°C resolution ± 0.5°C accuracy	Not described Not described		Certification of traceability
Field barometer	1/yr	± 1 mm Hg resolution ± 5 mm Hg accuracy	Not described Not described		Certification of traceability
Calibration/Verification					
Single-point flow rate verification	Every sampling event	± 4% of working standard or ± 4% of design flow (16.67 Lpm)	Part 50, Appendix L, Section 9.2.5	Field SOP, Section 5	Calibration drift and memory effects
Multipoint flow rate verification[a]	1/yr or upon failure of single-point verification	± 2% of calibration standard	Part 50, Appendix L, Section 9.2.5	Field SOP, Section 10	Calibration drift and memory effects
Flow rate calibration	Upon failure of multipoint verification	± 2% of calibration standard at design flow (16.67 Lpm)	Part 50, Appendix L, Section 9.2.6	Field SOP, Section 10	Calibration drift and memory effects
Single-point flow rate verification	Following every calibration	± 2% of design flow (16.67 Lpm)	Part 50, Appendix L, Section 9.2.6	Field SOP, Section 10	Calibration drift and memory effects
External leak check	Every sampling event	<80 mL/min	Part 50, Appendix L, Section 7.4.6	Field SOP, Section 5	Sampler function
Internal leak check	Upon failure of external leak check	<80 mL/min	Part 50, Appendix L, Section 7.4.6	Field SOP, Section 5	Sampler function
Single-point temperature verification	Every sampling event and following every calibration	± 2°C of working standard	Part 50, Appendix L, Section 9.3	Field SOP, Section 5	Calibration drift and memory effects
Temperature multipoint verification	1/yr or upon failure of single-point verification	± 2°C of calibration standard	Part 50, Appendix L, Section 9.3	Field SOP, Section 10	Calibration drift and memory effects
Temperature calibration	Upon failure of multipoint verification	± 0.1°C of calibration standard	Part 50, Appendix L, Section 9.3	Field SOP, Section 10	Calibration drift and memory effects

Requirement	Frequency	Acceptance Criteria	CFR Reference	SOP Reference	Information Provided
Single-point barometric pressure verification	Every sampling event and following every calibration	± 10 mm Hg	Part 50, Appendix L, Section 9.3	Field SOP, Section 5	Calibration drift and memory effects
Multipoint barometric pressure verification	1/yr or upon failure of single-point verification	± 10 mm Hg	Part 50, Appendix L, Section 9.3	Field SOP, Section 10	Calibration drift and memory effects
Barometric pressure calibration	Upon failure of multipoint verification	± 10 mm Hg	Part 50, Appendix L, Section 9.3	Field SOP, Section 10	Calibration drift and memory effects
Clock/timer verification	Every sampling event	1 min/mo	Part 50, Appendix L, Section 7.4.12	Field SOP, Section 5	Verification of to assure proper function
Blanks					
Field filter blank[b]	One/audit (for programs <2 years old) One/FS per trip (for all others)	± 30 μg change between weighings	Part 50, Appendix L, Section 8.2	Field SOP, Section 8	Measurement system contamination
Trip filter blank[c]	10% of all filters	± 30 μg change between weighings	Not described	Lab SOP, Section 8 and Field SOP, Section 6	Measurement system contamination
Precision (Using Collocated Samplers)[d]					
All samplers (mandatory)	2/yr (semi-annual)	Coefficient of variance ≤10%	Not described	Field SOP, Section 8	Measurement system precision
Accuracy (Using Independent Verification Devices)					
Flow rate audit	4/yr (manual)	± 4% of calibration standard at design flow (16.67 Lpm)	Part 58, Appendix A, Section 3.5.1	Field SOP, Section 5	Instrument bias/accuracy
External leak check	4/yr	<80 mL/min	Part 50, Appendix L, Section 7.4.6	Field SOP, Section 5	Sampler function
Internal leak check	4/yr (if external leak check fails)	<80 mL/min	Part 50, Appendix L, Section 7.4.6	Field SOP, Section 5	Sampler function

Requirement	Frequency	Acceptance Criteria	CFR Reference	SOP Reference	Information Provided
Temperature audit	4/yr	± 2°C of calibration standard	Part 50, Appendix L, Section 9.3	Field SOP, Section 5	Calibration drift and memory effects
Barometric pressure audit	4/yr	± 10 mm Hg of calibration standard	Part 50, Appendix L, Section 7.4	Field SOP, Section 5	Calibration drift and memory effects
Technical Systems Audits*					
Flow rate audit	1/yr	± 4% of calibration standard at design flow (16.67 Lpm)	Part 58, Appendix A, Section 3.5.1	Field SOP, Section 5	External verification bias/ accuracy
External leak check	1/yr	<80 mL/min	Part 50, Appendix L, Section 7.4.6	Field SOP, Section 5	Sampler function
Internal leak check	1/yr (if external leak check fails)	<80 mL/min	Part 50, Appendix L, Section 7.4.6	Field SOP, Section 5	Sampler function
Temperature audit	1/yr	± 2°C of transfer standard	Part 50, Appendix L, Section 9.3	Field SOP, Section 5	Calibration drift and memory effects
Barometric pressure audit	1/yr	± 10 mm Hg of transfer standard	Part 50, Appendix L, Section 7.4	Field SOP, Section 5	Calibration drift and memory effects

[a] The BGI PQ200A is not capable of performing a multipoint verification for flow rate. If the BGI PQ200A fails a single-point verification for flow, then a single-point calibration should be performed next.

[b] For a new SLT program (i.e., <2 years old), the frequency for field blanks is one per FRM/FEM audit. For all others, one field blank should be performed per FS per trip. A trip may include audits for more than one FRM/FEM sampler. It is up to the FS to determine the site where the field blank audit will be performed, unless otherwise directed by his or her Regional WAM/TOPO/DOPO (e.g., when a problem is identified at a particular site).

[c] Trip blanks will be performed at a frequency of 10% of all filters, as determined by the weighing laboratory (i.e., one per every 10 filters shipped out, rounded up). So if the laboratory sends out one to 10 filters, then one trip blank should be included in the shipment. If the laboratory ships 11 to 20 filters, then two trip blanks should be included. The FS will determine with which trip to use the trip blank filter(s), in a manner similar to the field blanks; however, if the FS receives more than one trip blank in a shipment, then he or she must make sure that only one trip blank is carried per trip.

[d] Twice per year, all of the PEP samplers used by the Region (and any SLT organizations that are running their own PEP) must be collocated and run at the same location over the same time period. These are often referred to as "parking lot collocations." In 2007, the monthly and quarterly frequency was replaced by semi-annual collocation scenarios because the historical performance shows that the precision does not seem to vary significantly.

* All of the annual technical assessments may be performed in conjunction with one of the semi-annual parking lot studies. It will involve the Regional WAM/DOPO/TOPO or the National PEP Project Leader who will observe the FS when the sampler audits are performed.

Table 14-2. Laboratory QC

Requirement	Frequency	Acceptance Criteria	SOP Reference	Information Provided
Blanks				
Lot exposure	3 filters from each of 3 boxes in lot (9 filters total)	± 15 μg change between weighings	Lab SOP, Section 6	Filter stabilization/ equilibrium
Laboratory filter	10% or 1 per weighing session	± 15 μg change between weighings	Lab SOP, Section 8	Laboratory contamination
Trip filter	10% of all filters	± 30 μg change between weighings	Lab SOP, Section 8	Transportation and laboratory contamination
Calibration/Verification				
Balance calibration	When routine QC checks indicate calibration is needed and upon approval	Manufacturer's specification	Lab SOP, Section 7	Verification of equipment operation
Laboratory temperature verification	1/quarter	± 2°C	Lab SOP, Section 7	Verification of equipment operation
Laboratory humidity verification	1/quarter	± 2% relative humidity	Lab SOP, Section 7	Verification of equipment operation
Accuracy				
Balance audit (PE)	2/yr	± 20 μg of NIST-traceable standard, ± 15 μg for unexposed filters	Lab SOP, Section 11	LA operation
Balance check	Beginning/end of the weighing session and one after approximately every 15 samples or fewer, per the balance manufacturer's recommendations	≤3 μg of working mass standard	Lab SOP, Section 8	Balance accuracy/stability
Calibration Standards				
Working mass standards	3–6 months	0.025 mg	Lab SOP, Section 7	Standards verification
Primary mass standards	1/yr	0.025 mg	Lab SOP, Section 7	Primary standards verification
Precision				
Duplicate filter weighings	One per weighing session, one carried over to next session	± 15 μg change between weighings	Lab SOP, Section 8	Weighing repeatability/ filter stability
Interlaboratory comparisons[a]	1/yr	Advisory limits set by NAREL	Lab SOP, Section 11	Between laboratory repeatability

[a] NAREL administers inter-laboratory comparisons. EPA reports results annually in the *Laboratory Comparison Study of Gravimetric Laboratories Performing $PM_{2.5}$ Filter Weighing for the $PM_{2.5}$ Performance Evaluation Program and Tribal Air Monitoring Support* (available at http://www.epa.gov/ttn/amtic/pmpep.html). The advisory limits are three sigma limits that were derived from previous gravimetric PE studies administered by NAREL.

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 PEP calibration also ensures that the bias in flow rate among the PEP sampler is minimized.

For the 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 14-1 and 14-2, respectively; the details of the calibration methods are included in Element 16.0, *Instrument Calibration and Frequency*, and in the PEP Field and Laboratory SOPs.

14.1.1.1 Calibration Evaluation

Calibration data will be compared against actual standards acceptance.

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

$$d_i = \frac{measured - audit}{audit} \times 100$$

Corrective action. The PEP Field and Laboratory SOPs are very prescriptive about corrective action for verifications and calibrations. In general, sampling or analysis will not be implemented unless verifications meet acceptance criteria. If the instrument fails to meet acceptance criteria, then troubleshooting and corrective action will take place and the verification/calibration will be performed again. If the instrument flow rate acceptance criteria cannot be met, then a spare sampler may be used. If a field situation arises where a spare sampler is not available, then the PEP audit will be postponed.

14.1.1.2 Blanks

Blank samples are used to determine contamination that arises principally from the following sources: the environments from which the sample was collected, transported, and weighed; the equipment used for collecting and weighing the sample; and the FS or LA who handled the PE sample. The following five types of blanks will be implemented in the PEP:

Lot blanks. A shipment of 46.2-mm filters will be sent from EPA to the weighing laboratory. The shipment may contain many filter lots, which are labeled on each filter box (box of 50 filters). A representative number of filters in each lot must be tested to determine the length of time that it takes for the lot to stabilize. Three filter boxes will be randomly selected from the lot, and three filter lot blanks will be randomly chosen from each box (nine filters total). These lot blanks will be subjected to the conditioning/pre-sampling weighing procedures. The blanks will be weighed every 24 hours for a minimum of 1 week to determine the length of time that it takes to condition filters (see PEP Laboratory SOP, Section 6).

Lot exposure blanks. Similar to lot blanks, lot exposure blanks are used to determine whether a specific set of filters scheduled to be conditioned at one time are stable for pre-weighing (see PEP Laboratory SOP, Section 6).

Field blanks. 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. For a new SLT program (i.e., <2 years old), the frequency for field blanks is one per FRM/FEM audit. For all others, one field blank should be performed per FS per trip. A trip may include audits for more than one FRM/FEM sampler. The FS will determine the site where the field blank audit will be performed, unless otherwise directed by his or her Regional WAM/TOPO/DOPO (such as when a problem is identified at a particular site). Details about using field blanks can be found in PEP Field SOP, Section 6.

Trip blanks. These are used to measure the possible contamination to filters during transportation to and from sampling locations. Trip blanks provide a frame of reference in case field blanks exhibit a mass gain that is higher than the tolerance levels. Trip blanks will be performed at a frequency of 10% of all filters, as determined by the weighing laboratory (i.e., 1 per every 10 filters shipped out, rounded up). So if the laboratory sends out 1 to 10 filters, then one trip blank should be included in the shipment. If the laboratory ships out 11 to 20 filters, then two trip blanks should be included. The FS will determine with which trip to use the trip blank filter(s), in a manner similar to the field blanks. However, if the FS receives more than one trip blank in a shipment, then he or she must make sure that only one trip blank is carried per trip. Details about using the trip blanks can be found in PEP Field SOP, Section 6.

Laboratory blanks. These provide an estimate of contamination occurring at the weighing facility. Laboratory blanks should be performed at a frequency of one per post-sampling weighing session. The LA must weigh an adequate amount of filters during the pre-sampling weighing sessions to allow for the post-sampling weighing requirement. Details about using the laboratory blanks can be found in PEP Laboratory SOP, Section 8.

14.1.1.3 Blank Evaluation

The PEP will include, at a minimum, one field and one laboratory blank in each weighing session sample batch. When the shipment of trip blanks and audit event filters arrive at the weighing laboratory, they will be post-weighed. A batch is defined in Section 14.2. The following statistics will be generated for data evaluation purposes:

Difference for a single check *(d).* The difference, d, for each check is calculated using the following equation, where X represents the mass of the original pristine filter (pre-sampling), and Y represents the mass of the blank filter upon return to the laboratory (post-sampling).

$$d = |Y - X|$$

Percent difference for a single check (d_i). The percent difference, d_i, for each check is calculated using the following equation, where X_i represents the original mass, and Y_i represents the mass reported for the blank upon return to the laboratory.

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

NOTE: The d or d_i can be converted to a concentration for comparing with the average concentration for the sampling event by dividing the difference in mass by 24 m^3.

Mean difference for batch (d_z). The mean difference d_z for both field and laboratory blanks within a weighing session batch is calculated using the following equation, where d_1 through d_n represent individual differences, and n represents the number of blanks in the batch.

$$d_z = \frac{d_1 + d_2 + d_3 ..... d_n}{n}$$

NOTE: For routine PEP events n will equal one, although aggregate trip and field blank values can be determined at the EPA Regional and National PEP levels. For laboratory blanks, there will typically be one blank per batch, but again these blanks can be aggregated for specified time periods.

Corrective action. The acceptance criteria for field blanks is a 30-μg difference (d), whereas lot and laboratory blanks have criteria of a 15-μg difference. However, the mean difference (d_z) will be used for comparison against the acceptance criteria. If the mean difference of either the field or laboratory blanks is >30 μg or 15 μg, respectively, then all of the samples in the weighing session will be reweighed. Before reweighing, the laboratory balance will be checked for proper operation. If the mean differences of either the field or laboratory blanks are still out of the acceptance criteria, all samples within the weighing session will be flagged with the appropriate flag (failed field blank [FFB] or failed laboratory blank [FLB]), and efforts will be made to

determine the source of contamination. In theory, field blanks would be expected to contain more contamination than laboratory blanks; therefore, if the field blanks are outside of the criteria but the laboratory blanks are acceptable, then weighing can continue on the next batch of samples while field contamination sources are investigated. If the mean difference of the laboratory blanks is >20 μg and two or more of the individual differences were >15 μg, then the laboratory weighing of PEP filters will be suspended until the source of the instability is identified and corrected. If the resolution requires more than 2 weeks, then the back-up laboratories will be notified and operations will be temporarily shifted to the back-up laboratory until the issue is satisfactorily resolved. The LA will alert the PEP Laboratory Manager about the problem. The problem and solution will be reported and appropriately filed under response and corrective action reports (PEP/108-025-01-01-237.1, see Element 9.0, *Documentation and Records*).

Contamination of trip blanks would be expected to fall between those of laboratory blanks and field blanks. If a trip blank acquires a mass gain that is >30 μg, then the filter should be compared to the mass gain of the coincident field blank to determine if there was some unique problem in transportation. If the field blanks are low (≤30 μg), then the shipping and transportation are suspect and should be investigated for possible invalidation of all events associated with filters that were shipped with the trip blank. If the field blanks are high (>30 μg), then further investigation is necessary to determine the source of the problem. A problem may exist with sample handling. After investigation, the appropriate sample may be flagged (failed trip blank [FTB] or FFB).

Laboratory, trip, and field blanks will be control charted (see Section 14.3). The percent difference calculation (d_i) is used for control-charting purposes and can be used to determine equilibrium status.

14.1.2 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 PEP must ensure the entire measurement process is within statistical control. The following two types of precision measurements, which are further discussed in the following sections, will be made in the $PM_{2.5}$ PEP:

- Collocated monitoring
- Filter duplicates.

14.1.2.1 Collocated Monitoring

To evaluate the total measurement precision of the PEP fleet of samplers, collocated monitoring will be implemented. Twice per year (semi-annually), all of the PEP samplers used by a single FS or Region must be collocated and run at the same location over the same time period. These are often referred to as “parking lot collocations.” These data will also be analyzed to identify

individual samplers that habitually operate outside of the performance parameters that are demonstrated by the bulk of the Regional PEP fleet of which it is associated (see Section 14.1.3.1 for more information). SLT agencies that conduct their PEP field operations will also bring their samplers and participate in at least one of the semi-annual events. If an SLT agency chooses to participate in only one collocation event with the EPA Region in a year, then it must conduct one other collocation event that involves at least four samplers and meets all other collocation criteria such as the number of sampling days, sampling time, and sampler spacing. These data will be reported to the PEP data support contractor for inclusion into the PEP's QA/QC analyses and reports.

Evaluation of collocated data. Collocated measurement pairs are selected for use in the precision calculations only when both measurements are at least 3 $\mu g/m^3$. The following algorithms will be used to evaluate collocated data.

Percent difference for a single check (d_i). The percent difference, d_i, for each check is calculated by using 40 CFR Part 58 Appendix A, Equation 10 (the following equation), where X_i represents the concentration produced from the primary sampler, and Y_i represents the concentration reported from the target audit sampler (as opposed to all the others in the collocation study).

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

Precision of a single sampler—semi-annual basis ($CV_{j,q}$). For particulate sampler j, the individual coefficients of variation ($CV_{j,q}$) during the semi-annual collocation study are pooled using 40 CFR Part 58 Appendix A, Equation 11 (the following equation), where n is the number of measurement pairs from collocated samplers. The coefficient of variation (CV) is the precision estimator for PEP regional "parking lot" collocation studies, and $X^2_{0.1,n-1}$ is the 10th percentile of a chi-squared distribution with $n-1$ degrees of freedom. The factor of two in the denominator adjusts for the fact that each d_i is calculated from two values with error.

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

In a classical sense, the precision of a single sampler cannot be estimated without the ability to introduce a known concentration in a controlled environmental testing chamber in which the sampler could make multiple measurements. Consequently the PEP relies upon its collocation studies to characterize the relative precision, relative accuracy, and relative bias of a single sampler compared to the other samplers in the same studies. The latter two are discussed in Section 14.1.3.

Precision of a single sampler—semi-annual basis. For PEP sampler *j*, the individual CV values (represented by CV_i) that are produced during a semi-annual collocation study are aggregated using the following equation, where n_j is the number of CV calculations for that particular sampler made during the collocation study.

$$CV_j = \sqrt{\frac{\sum_{i=1}^{n_j} CV_i^2}{n_j}}$$

Corrective action: Single monitor. A sampler with a CV >10% will be flagged (failed collocated sample [FCS]) and reweighed. If the calculated CV is 10%–20%, then the FS will be alerted to the problem. If the CV is >20%, then all the primary sampler data will be flagged (FCS) from the last precision check and corrective action will be initiated. CVs and percent differences will be control charted to determine trends (Section 14.2). The LA will alert the PEP Laboratory Manager and the EPA Regional WAM/TOPO/DOPO about the problem as soon as possible. The report will be appropriately filed under response and corrective action reports (PEP/108-025-01-01-237.1, see Element 9.0, *Documentation and Records*).

14.1.2.2 Duplicate Laboratory Measurements

During laboratory pre- and post-weighing sessions, the first routine sample filter will be weighed a second time at the end of the weighing session (see PEP Laboratory SOP, Section 8). The difference (d) and percent difference (d_i) will be calculated from these measurements. The difference in the weights of the filter must be ≤15 μg. Failure may be due to transcription errors, microbalance malfunction, or that the routine samples have not reached equilibrium. Other QC checks (balance standards and laboratory blanks) may be used to eliminate microbalance malfunction. If the duplicate does not meet the criteria, then the second and third routine samples will be selected and reweighed as second and third duplicate checks. If either of these samples fails the acceptance criteria and the possibility of balance malfunction and transcription errors have been eliminated, all samples in the batch will be equilibrated for another 12 hours and reweighed. Corrective actions will continue until duplicate weights for the batch meet acceptance criteria.

After a post-weighing session is completed, the routine sample used as the batch duplicate is placed with the next batch. This filter should not be weighed as one of the first three filters in the next batch. These are sometimes referred to as “previous batch duplicates” and serve as indicators for the stability of the conditioning environments and the consistency of the microbalances between weighing sessions. The difference between these filter weights must be ≤15 μg. If the difference is >15 μg, then select two additional routine filters from the previous batch and reweigh those. If there continues to be a problem, then review the weighing session QC checks and consult with the PEP Laboratory Manager.

14.1.3 Relative Accuracy and Relative Bias

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 PEP:

- Collocated monitors
- Flow rate audits
- Balance checks.

14.1.3.1 Collocated Monitors

Although the collocated PEP monitors are primarily used for evaluating and controlling precision, the practice can also be used to determine relative accuracy or relative bias among different models of PEP samplers. Beginning in 2008, EPA mandated that each Region will collocate its entire fleet of samplers for a series of three sequential sampling events on a semi-annual basis. In this way, each sampler's performance will compared to every other sampler. By using 40 CFR Part 58, Appendix A, Equation 10, to determine the relative percent difference (d_i), trends or bias of a single instrument can be tracked without knowing the true value.

The PEP now uses the BGI PQ200A as the only sampler to run side-by-side with FRM/FEM samplers, except at altitudes >7,000 feet. EPA is aware that that the BGI PQ200A is incapable of performing satisfactorily at altitudes >7,000 feet. EPA Regions 8, 9, and 10 contain monitoring sites with elevations where this issue may arise. A limited number of sites exist or may be up-fitted for $PM_{2.5}$ FRM/FEM sampling in the future. The portable versions of the Andersen RAAS 100 and the R&P Partisol Model 2000 $PM_{2.5}$ FEM audit sampler have been successfully used at higher altitudes throughout the PEP's history. A potentially serious issue exists because both manufacturers no longer support these models. To the extent that the PEP can maintain the serviceability of these models, these samplers will be used to conduct high-altitude PEP audits and included in the Regional collocation studies. EPA acknowledges that the collocations will only characterize performance at lower elevations, but the small number of high-altitude sites does not warrant the expense of developing additional high-altitude samplers at this time. Regions that use these samplers will include them in routine parking lot collocations for bias and precision evaluations at lower elevations.

Relative bias of a single sampler—semi-annual basis. Several QA criteria will be used to screen anomalous measurements, as compared to the other data obtained from each sampling event during a collocation study (see Appendix B). Normalized paired differences ($N_{i,j,d}$) will then be calculated for all samplers that participate in a Regional collocation study using the following equation, where n is the number of monitors in the collocation study, i and j represent different individual monitors in the study, d represents a specific day in a collocation event, $D_{i,j}$ represents the paired differences among monitors for each day during the event, and $\bar{x}_d$ is the

daily mean. After normalization, the differences are considered comparable among individual studies conducted under differing atmospheric conditions.

$$N_{i,j,d} = \frac{abs(D_{i,j})}{\bar{x}_d}$$

$$where\ D_{i,j} = \sum_{i=1}^{n-1} \sum_{j=i+1}^{n} x_i - x_j$$

The collocation study data will be evaluated to determine the relative bias of individual samplers when compared to all samplers in a study. Histograms of the resulting normalized paired differences can be used to infer the expected among-monitor precision, which is based on historical data collected within the PEP. As discussed in Section 14.1.2.1, the "true" precision of any given monitor is unachievable. However, the among-monitor precision of the samplers that participate in a collocation study provides for a programmatic review of the general tendencies, or relative bias, of the reference monitors to obtain consistent results.

Corrective action. Individual samplers that have been identified as having notable differences will be investigated. If it appears that there is a significant problem with a particular sampler, then corrective action will be initiated. The process will include eliminating uncertainties that may be occurring during the filter handling, transport, and laboratory stages to determine that the cause of bias is truly the instrument. Corrective actions taken on the instrument will include temperature and flow rate verifications, additional trial runs where the sampler's flow CV is strip-charted for indications of controller problems, as well as complete maintenance activities. Additional corrective action could include a request for vendor servicing.

If the findings of the investigation reveal potential error in historical audit results, then the sample results will be flagged in the PED, and any data posted to the AQS will be nullified. If possible, additional PEs may be scheduled to meet PEP completeness requirements. The EPA National PEP Project Leader and the EPA Regional WAM/TOPO/DOPOs will be notified of the problem as soon as possible. Corrective action reports will be appropriately filed under the heading "PEP/108-025-01-01-237.1" (see Element 9.0, *Documentation and Records*).

14.1.3.2 Flow Rate

The PEP FS will implement a flow rate verification with each setup. Details of the implementation aspects of the audit are included in PEP Field SOP, Section 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 percent difference, d_i, for a single flow rate audit, *i,* is calculated using 40 CFR Part 58, Appendix A, Equation 1 (the following equation), where *audit* represents the audit standard flow rate (known), and *measured* represents the indicated flow rate by the sampler.

$$d_i = \frac{measured - audit}{audit} \times 100$$

Bias of a single sampler—quarterly basis (D_j). For an individual PEP sampler *j*, the average (D_j) of the individual percent differences (d_i) from the past two and the past four quarters is calculated using 40 CFR Part 58, Appendix A, Equation 4 (the following equation), where n_j is the number of individual percent differences produced for sampler *j* during the selected period.

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

Corrective action. Because flow rate is verified prior to conducting each sampling event, if the verification violates the acceptance criteria (± 4% of the flow measured by a transfer standard and ± 4% of design flow), then the sampler must be recalibrated before it can be used for a PEP audit. Any follow-up action occurs during the routine conduct of the PEP Field SOP; however, the mean bias (D_j) can be used to identify a systematic drift in a sampler's performance. If a systematic drift is noted, then the sampler may need to be recalibrated more frequently.

14.1.3.3 Balance Checks

Balance checks are frequent challenges of the balance that uses of the 100-mg and 200-mg working standards. This helps to ensure that the balance performs within acceptance criteria throughout the pre- and post-sampling weighing sessions. The PEP will use ASTM Class 1 or Class 0 weights for its primary and secondary (working) standards. Both working standards will be measured at the beginning and end of a weighing session. Results will be control charted (see Section 14.3). The following algorithm will be used to evaluate the balance checks.

Difference for a single check (d_y). The difference, d_y, for each check is calculated using the equation below, where *X* represents the certified mass weight, and *Y* represents the reported weight.

$$d_y = Y - X$$

Corrective action. The absolute value of the difference among the reported weight and the certified weight must be ≤3 μg (control charting should allow for negative values to identify drifts in either direction). Because this is the first check before any pre- or post-sampling weighings, corrective action will be initiated if the acceptance criteria are not met. Corrective action may be as simple as allowing the balance to perform internal calibrations or sufficiently

warm up and may require checking the balance weights many times. If the acceptance criteria are still not met, the LA will be required to verify the working standards against the primary standards. Finally, if it is established that the balance does not meet acceptance criteria for both the working and primary standards and other troubleshooting techniques fail, the vendor service technician (see Element 15.0, *Instrument/Equipment Testing, Inspection, and Maintenance Requirements*) will be called to perform corrective action.

If the balance check fails acceptance criteria during a weighing session, then the QC check samples will be reweighed. If the balance check continues to fail, then troubleshooting, as previously discussed, will be initiated. The filter weights from the sample batch will be recorded and flagged (failed internal standard [FIS]); however, the filters will remain in the conditioning environment to be reweighed when the balance meets the acceptance criteria. The data acquisition system will flag any balance check outside the acceptance criteria as FIS.

14.2 Sample Batching—QC Sample Distribution

To ensure that the PEP includes all types of QC samples within a weighing session, the PEP will use the concept of sample batches, which will consist of balance checks, field blanks, laboratory blanks, trip blanks (if available), batch duplicates, and previous batch duplicates, as indicated in Figure 14-2.

14.2.1 Sample Distribution

QC samples need to be interspersed within the batch to provide data quality information throughout the batch weighing session.

PEP Filter Weighing Data Entry Form

Batch Type (circle): PRE POST Batch No.: _____

Date: _____ Analyst Initials: _____

Mean Temperature for the past 24 hours: _____SD: _____
Mean Relative Humidity for the past 24 hours: _____SD: _____

Sample	Filter ID	Filter Type RO/LB/FB CO/BD/PD	Cassette ID	Weight 1 xxx.xxx mg	Weight 2 xxx.xxx mg	Flag
QC1	100 mg					
QC2	200 mg					
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Routine filter						
Duplicate 1		BD				
Duplicate 2		DU				
Duplicate 3		DU				
QC1	100 mg					
QC2	200 mg					
BAT-01						

Figure 14-2. PEP Filter Weighing Data Entry Form

14.3 Control Charts

Control charts will be used extensively in the PEP because they provide a graphical means of determining whether various phases of the measurement process are within control limits. The PEP will use property charts, which graph single measurements of a standard or a mean of several measurements. Table 14-3 indicates which QC data will be control charted. The control charts will be used as an "early warning system" to evaluate trends in precision and bias. These charts will be discussed in the annual and 3-year PEP QA reports (Elements 6.0, *Project/Task Description*, and 21.0, *Reports to Management*, respectively). They will be appropriately filed (PEP/108-025-01-01-237.1).

Table 14-3. Control Charts

QC Check	Plotting Technique
Laboratory conditioning environment (temperature and relative humidity)	Daily mean and standard deviation
Lot, laboratory, field, and trip blanks	Difference of pre- and post-weighed values
Batch stability (post-sample)	Individual weight differences from pre- and post-weighing sessions; also, days between weighings
Duplicate filter weighings (batch duplicates and previous batch duplicates)	Percent difference each pair
Balance checks (100-mg and 200-mg standards)	Individual weight differences between balance and certified weights
Leak check	Difference between ending pressure and beginning pressure
Barometric pressure check	Difference between standard and sampler
Ambient temperature check	Difference between standard and sampler
Filter temperature check	Difference between standard and sampler
Flow rate check	Percent difference between standard and sampler
Collocated monitoring	CV of all samplers per semi-annual basis (aggregated at the regional and national levels) Median of normalized paired differences (aggregated at regional and national levels)

References

1. Taylor, J.K. 1987. *Quality Assurance of Chemical Measurements*. Lewis Publishers: Chelsea, MI. Pp. 328.

2. U.S. EPA. 2006. Revisions to Ambient Air Monitoring Regulations. 40 CFR Parts 53 and 58. *Federal Register 71*(200):61236–61327. October 17.

15.0 Instrument/Equipment Testing, Inspection, and Maintenance Requirements

The purpose of this element in the 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 PEP/301-093-006.3. See Element 9.0, *Documentation and Records*, for document filing and record details.

15.1 Testing

All $PM_{2.5}$ samplers used in the 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.[1] 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 external and internal leak checks, as well as temperature, time, pressure, and flow rate single-point verification checks. If any of these checks are out of specification (see Table 14-1 in Element 14.0, *Quality Control Requirements*), then the FS or WAM/TOPO/DOPO will initiate troubleshooting procedures (see Field SOP Section 5). If the problem cannot be located and the sampler continues to fail the verification checks, then the sampler cannot be used for the PE. The FS should use an alternate sampler, and the sampler should be returned 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 PEP, then it should be subject to a collocation with at least two other samplers that are believed to be performing satisfactorily. The results should comply with acceptance criteria for a routine collocation study. If new upgraded FRM sampler hardware is introduced for service (e.g., a very sharp-cut cyclone replaces the WINS impactor), the same type of testing will be conducted. A more detailed testing protocol will be furnished by the National PEP Project Leader. These tests will be properly documented and filed under PEP/301-093-006.3.

15.2 Inspection

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

15.2.1 Inspection in Weighing Room

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

Table 15-1. Inspections in the Weigh Room Laboratory

Item	Inspection Frequency	Inspection Parameter	Action If Item Fails Inspection	Documentation Requirement
Weighing room temperature	Daily	20°C–23°C	1. Check heating, ventilation, and air conditioning (HVAC) system 2. Call service provider that holds maintenance agreement	1. Document in the weighing room log book 2. Notify the PEP Laboratory Manager
Weighing room relative humidity	Daily	30%–40%	1. Check HVAC system 2. Call service provider that holds maintenance agreement	1. Document in the weighing room log book 2. Notify the PEP Laboratory Manager
Dust in weighing room	Monthly	Use glove and visually inspect	Clean weigh room	1. Document in weighing room log book

15.2.2 Inspection of Field Items

There are several FRM sampler parts and filter cassette parts to inspect in the field operation's maintenance area and in the field before and after a $PM_{2.5}$ sample has been taken. 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
Sample downtube	Every site visit	Visible particulate	Clean with a clean dry cloth	Document in the log book
WINS impactor well	Every site visit	"Cone" shape of particulate on impactor well	Replace impactor well filter (including new impactor oil)	Document in the log book
Very sharp-cut cyclone	Every 10 sampling events or after a dust storm or heavy air pollution episode	Collection reservoir laden with particulate matter >2.5 μm	Clean reservoir	Document in the log book
Rain collector	Every site visit	Condensate of sufficient volume to pour	Empty	Document in the log book
O-rings	Every site visit	Any damage	Replace	Document in the log book

Item	Inspection Frequency	Inspection Parameter	Action If Item Fails Inspection	Documentation Requirement
Filter cassettes	After each sample run	Visible particulate matter	Check downtube and WINS impactor	Document in the log book
Cassette seals	Each sample	Clean and smooth	Clean with a clean dry cloth or replace as needed	Document when replaced
Battery	Every 6 months	Decrease in voltage	Replace	Document in the log book

15.3 Maintenance

There are many items that need maintenance attention in the PEP. This section describes those items according to whether they are weighing room items or field items.

15.3.1 Weighing Room Maintenance Items

The successful execution of a preventive maintenance program for the weighing laboratory will go a long way towards the success of the PEP. Weigh laboratory preventive maintenance is handled through the use of service agreements. The weighing laboratory has entered into maintenance agreements with the vendors who developed the heating, ventilation, and air conditioning (HVAC) system. Similarly, preventive maintenance for the microbalances is performed by the vendor's service technician (e.g., Sartorius) and is scheduled to occur at initial setup and every 6 months thereafter. In the event that there is a problem with a microbalance that cannot be resolved within the laboratory, the service technician can be paged. The laboratory will maintain a spare microbalance in case the balance in use should fail.

Service agreements for both the HVAC and microbalance will be renewed each year. In the event either company's service agreement is not renewed, a new service provider will be selected and contract will be put in place.

Table 15-3 details the weighing laboratory maintenance items, how frequently they will be replaced, and who will be responsible for performing the maintenance.

Table 15-3. Preventive Maintenance in Weighing Laboratories

Item	Responsibility	Frequency
General Laboratory Maintenance/Cleaning		
Table cleaning	LA	Every day
Overall laboratory	LA	Once a month
Cassette ethanol wiping/washing	LA	After each use
Adhesive-coated floor mats	LA	Weekly or when soiled to a point of non-performance
HEPA filter change	LA	Once a month
Polonium-210 strip change	LA	Every 6 months
Polonium-210 strip cleaning	LA	Monthly or as shown by blank data
Microbalance		
Cleaning	LA	Every 6 months
Service cleaning/calibration	Service provider	Twice a year
Calibration/verification	LA	Every sample weighing
Temperature/Humidity Readers		
Calibration/verification	LA	Once every 3 months
Laboratory Computers		
Computer backup	LA	Weekly, at minimum; automated daily backup is preferred
Computer virus check	LA	Weekly, with automated on-access scans and on-delivery e-mail scans
PEP database compaction	LA	Monthly
Computer system preventive maintenance (e.g., archive old files, compress hard drive, inspect)	PC support personnel	Yearly

Maintenance (e.g., backup) of network file shares used to store the PED is performed by EPA contractor(s) according to policies established by EPA's 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. Table 15-4 details the appropriate maintenance checks of the $PM_{2.5}$ samplers and their frequency. Field SOP Section 6 provides procedures for cleaning some of the more important pieces of field equipment.

Table 15-4. Preventive Maintenance of Field Items

Frequency	Maintenance Item
Every visit	1. Inspect and, if necessary, empty water collector bottle 2. Clean and/or change-out WINS impactor well 3. Inspect visible O-rings in the flow path
Every 10 sampling events or as needed	1. Clean very sharp-cut cyclone (this requirement may be fulfilled by a quarterly cleaning)
Quarterly (every 3 months)	1. Clean sampler inlet surfaces 2. Clean main (first stage) size-selective inlet (PM_{10} head) 3. Clean impactor housing (if applicable) and impactor jet surfaces 4. Clean interior of sampler unit 5. Clean very sharp-cut cyclone 6. Check condition of sampler transport containers 7. Clean sampler downtube 8. Inspect cooling air intake fan(s) and filter; replace if necessary 9. Inspect all O-rings, visible and hidden, and reapply vacuum grease as needed 10. Inspect vacuum tubing, tube fittings, and other connections to pump and electrical components; service if necessary

References

The following document was used in the development of this element:

1. U.S. EPA. 1997. National Ambient Air Quality Standards for Particulate Matter—Final Rule. 40 CFR Part 53. *Federal Register 62*(138):38651–38760. July 18.

16.0 Instrument Calibration and Frequency

This element of the PEP QAPP discusses the calibration procedures that will be used for instruments involved in the environmental measurements. Table 16-1 lists the instruments that require verification and calibration, the required frequencies of these activities, the acceptance criteria for these activities, and the PEP Field and Laboratory SOPs that describe the procedures and all calibration activities.

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

- Single-point verification—These verifications ensure that the calibration is within acceptance limits by performing frequent single-point verifications that do not include instrument adjustments.
- Calibration—This occurs when there is a failure of a single-point verification. Instrument adjustment occurs at this point and is followed by a subsequent single-point verification.

Table 16-1. Instrument Calibrations

Type	Frequency	Acceptance Criteria	PEP SOP
Laboratory Verification			
Mass standards verification	1/quarter	± 2 μg	Lab SOP, Section 7
Microbalance verification	Every weigh session	Manufacturer's specifications	Lab SOP, Section 7
Temperature verification	1/quarter	± 2°C of standard	Lab SOP, Section 7
Relative humidity verification	1/quarter	± 2% of standard	Lab SOP, Section 7
Laboratory Calibration			
Mass standards calibration	1/yr	± 2 μg	Lab SOP, Section 7
Microbalance calibration	At least 2/yr	Manufacturer's specifications	Lab SOP, Section 7
Temperature calibration	1/yr	± 2°C of standard	Lab SOP, Section 7
Relative humidity calibration	1/yr	± 2% of standard	Lab SOP, Section 7
Field Calibration/Verification			
Clock/timer verification	Every sampling event	1 min/mo	Field SOP, Section 5
Single-point flow rate verification	Every sampling event	± 4% of working standard or ± 4% of design flow (16.67 Lpm)	Field SOP, Section 5
Flow rate calibration	Upon failure of single-point verification	± 2% of calibration standard at design flow (16.67 Lpm)	Field SOP, Section 10
Post-calibration single-point flow rate verification	Following every calibration	± 2% of design flow (16.67 Lpm)	Field SOP, Section 10
Single-point barometric pressure verification	Every sampling event and following every calibration	± 10 mm Hg	Field SOP, Section 5
Barometric pressure calibration	Upon failure of multipoint verification	± 10 mm Hg	Field SOP, Section 10
Single-point temperature verification	Every sampling event and following every calibration	± 2°C of working standard	Field SOP, Section 5

Type	Frequency	Acceptance Criteria	PEP SOP
Temperature calibration	Upon failure of single-point verification	Adjust to within ± 0.1°C of calibration standard	Field SOP, Section 10
Standards Recertifications			
Flow rate transfer standard	1/yr	±2% of NIST-traceable standard	Field SOP, Section 8
Field thermometer	1/yr	± 0.1°C resolution ± 0.5°C accuracy	Field SOP, Section 8
Field barometer	1/yr	± 1 mm Hg resolution ± 5 mm Hg accuracy	Field SOP, Section 8
Working mass standards	3−6 mo	0.025 mg	Lab SOP, Section 7
Primary mass standards	1/yr	0.025 mg	Lab SOP, Section 7

16.1 Instrumentation Requiring Calibration

16.1.1 Laboratory Equipment

16.1.1.1 Laboratory Microbalance

The laboratory support for the PEP includes calibration of the Sartorius MC-5 microbalance. As indicated in Element 13.0, *Analytical Methods Requirements*, the balance is calibrated (and the mass standard check weights are recertified) regularly (twice per year) under a service agreement and additionally when routine QC checks indicate that the microbalance may be out of calibration and when the PEP Laboratory Manager grants permission. The service technician performs routine maintenance and makes any balance response adjustments that the calibration shows to be necessary. During the visit by the service technician, both the in-house primary and secondary (working) standards are checked against the service technician's standards to ensure acceptability. All of these actions are documented in the service technician's report a copy of which is provided to the PEP Laboratory Manager. After review, the report is appropriately filed under PEP/301-093-006.6 (see Element 9.0, *Documentation and Records*).

16.1.1.2 Laboratory Temperature and Relative Humidity Recorders

The laboratory reference, Vaisala™ HMT330 NIST-Traceable Hygrometer/Thermometer, is placed inside the conditioning environment and operated with the following specifications. Mean relative humidity is controlled between 30% and 40%, with a target of 35% and variability of not more than ± 5% over 24 hours, with minimums and maximums never to fall out of the 25%–45% range. Mean temperature should be held between 20°C and 23°C, with a variability of not more than ± 2°C over 24 hours, with minimums and maximums never to fall out of the 18°C–25°C range. The responses of the reference instrument's combination probe are compared with the responses of the conditioning environment control system's recording thermometer and recording hygrometer. Daily mean and standard deviation are calculated from the recorded responses. The mean is compared to the operating range and must be within it. The standard deviation is compared to the control limits and must be within them.

16.1.2 Field Equipment—the $PM_{2.5}$ Portable Sampler

Upon receipt of a new portable sampler, single-point verifications will be performed as indicated in Table 16-1. Calibrations typically occur at the field office or laboratory.

NOTE: Experience has shown that multipoint verifications do not indicate the accuracy of the BGI sampler at its required design flow rate. Multipoint verifications may be useful for troubleshooting.

The following verifications are routinely performed in the field:

- The sampler's internal clock against a timepiece.
- The sampler's barometric pressure against the working pressure standard
- The sampler's temperature probes against the working temperature standard
- The sampler's volumetric flow rate meter against the working flow standard.

16.1.2.1 Time Standard

The FS will use an atomic clock, which can be found on the Internet at http://www.time.gov or through a known time standard (e.g., cell phone), to verify that the sampler's time matches the time standard. 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.

16.1.2.2 Barometric Pressure

A NIST-traceable verification device (e.g., BGI Delta-Cal or BGI Tri-Cal) will be used in the field for single-point verifications of the portable sampler's pressure sensor during each sampling event. If a sampler fails the single-point verification for barometric pressure, then a different NIST-traceable verification/calibration device will later be used in the field office as a primary standard to perform a single-point calibration for barometric pressure. Each time the sampler is calibrated for barometric pressure, a subsequent single-point barometric pressure verification must follow.

16.1.2.3 Temperature Probes

The portable sampler has ambient and internal temperature probes. At every sampling event, the FSs will perform single-point field verifications of both sensors using a digital NIST-traceable temperature probe (e.g., BGI Delta-Cal or BGI Tri-Cal). A single-point temperature calibration is usually performed at the laboratory after there has been a single-point temperature verification failure. Each time the sampler is calibrated for temperature, a subsequent single-point temperature verification must follow.

16.1.2.4 Flow Rate

Before every sampling event and after leak checks, temperature verifications, and barometric pressure verifications are performed, a single-point flow rate verification will be performed using a NIST-traceable calibration device (e.g., BGI Delta-Cal or BGI Tri-Cal). If the verification result is outside the acceptable tolerance, then the sampler may need to be calibrated. A different NIST-traceable verification/calibration device will be used in the field office as a primary standard to perform a single-point calibration after there has been a verification failure. The single-point verification must be repeated after any calibration procedure to ensure the sampler operates at the design flow rate of 16.67 Lpm.

16.2 Calibration Method That Will Be Used for Each Instrument

As shown in Table 16-1, the calibration methods are described in the PEP Field and Laboratory SOPs.

16.3 Calibration Standard Materials and Apparatus

Table 16-2 presents a summary of the specific standard materials and apparatus used in calibrating measurement systems for parameters necessary to generate the $PM_{2.5}$ data required in 40 CFR Part 50, Appendix L, and 40 CFR Part 58. Table 16-1 presents the acceptance requirements of each of the standards used in the program; whereas Table 16-2 presents the accuracy and resolution of each standard. All of the standards meet the acceptance requirements in Table 7-1 and will be NIST-traceable. Traceability will be established each year through service agreements with vendors from which the instruments were purchased.

Table 16-2. Calibration Standards and/or Apparatus for $PM_{2.5}$ Calibration

Parameter	Standard (S) or Apparatus (A)	Description	Accuracy or Resolution	Manufacturer's Name	Model Number
Mass					
Primary and working	S	Class 1 weights	Weight tolerance 0.010 mg	Rice Lake	100-mg, 200-mg, and 5-g weights
Temperature					
Calibration (laboratory) and working (field)	A	Multi-parameter calibrator	Accuracy ±0.2°C Resolution 0.1°C	BGI Delta-Cal BGI Tri-Cal	DC-1 TC-12
Barometric Pressure					
Calibration (laboratory) and working (field)	A	Multi-parameter calibrator	Accuracy ± 0.1% Resolution 0.01 psig	BGI Delta-Cal BGI Tri-Cal	DC-1 TC-12
Flow Rate					
Calibration (laboratory) and working (field)	A	Multi-parameter calibrator	Accuracy ± 2% Resolution 20 mL/min	BGI Delta-Cal BGI Delta-Cal	DC-1 TC-12

Parameter	Standard (S) or Apparatus (A)	Description	Accuracy or Resolution	Manufacturer's Name	Model Number
Laboratory Temperature/Relative Humidity					
Laboratory temperature/ relative humidity	A	Hygrometer/ thermometer	Temperature Accuracy ± 0.2°C Resolution 0.01°C Relative humidity Accuracy ± 1.5% Resolution 0.01%	Vaisala	HMT330

16.4 Calibration Frequency

See Table 16-1 for a summary of calibration frequencies.

All calibration events, as well as sampler and calibration equipment maintenance, will be documented in field data records and notebooks and annotated with the flags as required by Appendix L of 40 CFR Part 50, the manufacturer's operating instruction manual, and any others indicated in the PEP 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 PEP/301-093-006.6 (see Element 9.0, *Documentation and Records*).

16.5 Standards Recertifications

All primary/calibration and working standards will be certified every year as NIST-traceable. Agreements with vendors will be set up to provide this certification activity. OAQPS will work with the Regional offices to find an appropriate time frame to achieve recertifications.

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 PEP data. The 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 and consumables, their acceptance criteria, and the required documentation for tracking this process.

Many forms will be discussed in the following sections. These forms can be found in the PEP 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 describes the needed supplies for the PEP and includes items for the weighing laboratory and the field. Generally, critical field and laboratory equipment has been selected by the PEP organizers based on the required performance specifications of resolution, accuracy, and ease of use.

17.2.1 Laboratory Supplies

OAQPS has developed a list of the critical laboratory equipment, which are listed in Table 17-1. Equipment that is not deemed critical (affecting data quality) has been left to the PEP Laboratory Manager to select. To maintain consistency in the PEP, 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 the Field/ Laboratory Inventory Form (INV-01), which is shown in Figure 17-1.

Table 17-1. Weighing Laboratory Equipment

Quantity	Units	Item	Vendor	Model Number
2	Each	Microbalance	Sartorius	MC-5
2	Sets	ASTM Class 1 weights	Rice Lake Weighing Systems	11909
2	Each	Balance table	Thermo Fisher Scientific	HM019945
2	Each	Computer	Dell	
2	Each	Barcode reader		
1	Each	Relative humidity/temperature monitor	Vaisala	E-37510-02
1	Each	Relative humidity/temperature standard	Thermo Fisher Scientific	11-661-78
1	Each	NIST-traceable thermometer	Thermo Fisher Scientific	15-041A
1	Each	Tacky mat plastic frame	Thermo Fisher Scientific	06-528A
1	Each	Uninterruptible power supply	Cole-Parmer	E-05158-60
1	Each	Refrigerator		
1	Each	Freezer		
1	Each	Dishwasher		
2	Each	Antifatigue floor mat	Richmond	19-61-763
2	Each	Equilibration rack		
1	Each	Laser printer		
1	Each	Dehumidifier		
1	Each	Light table		
1	Each	Microsoft Access 2000 or later		077-00370
2	Each	SartoWedge software for Sartorius balances	Sartorius	YSW01
1	Each	Barcode-printing software	Cole-Parmer	E-21190-10
24	Each	HVAC filters		
1	Case of 1,000	Powder-free antistatic gloves	Thermo Fisher Scientific	11-393-85A
12	Each	Polonium-210 strips	NRD	2U500
7	Pack of 100	Petri slides	Gelman	7231
1	Case of 12 bottles	Staticide	Cole-Parmer	E-33672-00
1	Case of 15 packs	Low-lint wipes (Kimwipes)	Kimberly-Clark	34155
1	Each	HVAC service contract		
1	Each	Microbalance service contract (two scheduled visits per year)	Sartorius	
6	Sets	Chart paper and pens		
1		Cleaning supplies		
2	Each	Worklon antistatic laboratory coats	Thermo Fisher Scientific	01-352-69B
2	Each	Forceps (stainless steel with plastic tips)	VWR	25672-100
1	Case	Antistatic 3" x 5" reclosable bags (for cassettes)	Consolidated Plastics	90202KH
1	Box	Barcode stickers		
1	Case of 1,000	Alcohol swipes	Thermo Fisher Scientific	14-819-2
20	Each	Coolers (6-pack size)		
4	Case of 24	Reusable U-Tek refrigerant packs (−1ºC)	Thermo Fisher Scientific	03-528B

Quantity	Units	Item	Vendor	Model Number
1	Case	Antistatic 9" x 12" reclosable bags (for data sheet)	Consolidated Plastics	90210KH
4	Each	Log books		
20	Each	Minimum/maximum thermometers (various digital ones available)	Sentry	4121
3	120 sheets	Hard surface tacky mat (moderate tack)	Thermo Fisher Scientific	06-527-2

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 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 WAM/TOPO/DOPO. The PEP Laboratory Manager will report any equipment changes that could affect the results of sampling events to the National PEP Project Leader. 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 PEP Laboratory Manager and the laboratory services ESAT WAM/TOPO/DOPO.
- File PRO-01 under AFC "PEP/301-093-006.6."

17.2.2 Field Equipment and Supplies

To ensure consistency and to meet the DQOs, OAQPS purchases all equipment and consumables, as listed in Table 17-2, for the field activities. Quantities for 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

Quantity	PEP Field Equipment and Supplies	Vendor/Catalog Number	Make/Model Number
	Monitoring Equipment and Supplies		
	Transport cases for loose equipment/consumables	Forestry Suppliers/31113	Collapsible crate
	Backpack frame for carrying samplers	Forestry Suppliers/35913	
	Portable FRM $PM_{2.5}$ sampler(s) with carrying case	BGI	BGI PQ200A
	Very sharp cut cyclone (VSCC)	BGI	VSCCB
	Pre-weighed 46.2-mm diameter filters in the proper cassette	Supplied by the weighing laboratory	

Quantity	PEP Field Equipment and Supplies	Vendor/Catalog Number	Make/Model Number
	COC Form for each filter cassette		
	Impactor oil and dropper (NOTE: Dow 704 has been found to solidify when sustained at 4°C for long periods.)	SPI Supplies	Octoil®-S (SPI#00031)
	Impactor filters (37-mm diameter glass fiber)	BGI (preferred)	
	Teflon-coated tweezers (for handling impactor filters)		
	Sample shipping containers (coolers)		
	Custody seals (tape or stickers)		
	Minimum/maximum thermometers	Daigger/AX24081B	Sentry
	Cold packs (ice substitutes), 36 per box	Daigger	EF2592D
	Electric transport cooler with 12 volt to AC transformer	Globe Mart/5615-807	Coleman 16 quart
	Filter transport coolers (6 quart)	Rubbermaid Web site	Rubbermaid 6 pack
	Bubble wrap	Consolidated Plastics	87604
	PEP FRM Sampler Operations Manual		
	Field notebook(s)		
	Clipboard (8" x 14")	Forestry Suppliers/53283	Cruiser mate
	Grip binders	Office Depot/501-627	Presstex
	Data storage media (e.g., diskette, CD, or USB card)		
	Silicone grease for O-rings (e.g., vacuum grease)	Daigger/AX23061A	
	PEP Field SOP		
	Field Data Sheets, preprinted		
	Laptop computer with PQ200A job-control software		
	Datatrans™ to download data; BGI upgraded version 2006	BGI/DC201	
	Cables for connecting the data-download device to the portable FRM sampler		
	Magnetic compass or other means of determining site orientation	Forestry Suppliers/37177	Suunto Partner II
	Tape measure (metric)	Forestry Suppliers/39651	Lufkin/ W 9210ME
	Cellular phone		
	Mechanical pencils Markers (indelible)	Skilcraft Sharpie	9 mm Ultra-fine
	Mounting Equipment and Tools		
	Ladder and a rope for hoisting equipment		
	Hand truck or cart with wheels and straps for transporting equipment		
	Bubble level for checking the portable FRM sampler	Mayes (torpedo)	10198
	Wooden shims or other means for leveling the portable FRM sampler		
	Tool box with basic tools, including the following:		
	Allen wrenches (metric and standard)		
	Micro screwdriver set		

Quantity	PEP Field Equipment and Supplies	Vendor/Catalog Number	Make/Model Number
	Pliers (multiple sizes and types)		
	Screwdrivers (standard straight and Phillips head)		
	Wire cutters		
	Small synchs ties		
	Electrical tape		
	Soldering gun/solder		
	Hemostat (for flow rate troubleshooting)		
	Flashlight with spare batteries		
	Heavy-duty, grounded, weatherproof electrical extension cord with multiple outlets (25' length) Heavy-duty, grounded, weatherproof electrical extension cord with multiple outlets (12' length)	Unicor Unicor	Style3 Class2 Series2 Style3 Class2 Series2
	Tie-down cables, anchors, plywood sheet, and bungee cords to anchor and stabilize the portable FRM sampler and to dampen vibration (optional)		
	Masking tape Packaging tape Strapping tape	GSA-7510-00-283-0612 GSA-7510-00-079-7906 GSA-7510-00-159-4450	
	Calibration/Verification Standards and Related Equipment		
	Downtube flow rate adapter		
	Temperature, pressure, and flow verification device with external temperature probe	BGI Delta-Cal BGI Tri-Cal	DC-1 TC-12
	Temperature verification/calibration standard (NIST-traceable) with probe (optional)	VWR	61220-601
	Styrofoam cup and deionized ice water for temperature calibrations		
	Flow-check filter in transport cassette		
	Impermeable “filter” disk for internal leak checks		
	Accurately set timepiece (cell phone)		
	Hand calculator (scientific)	Office Depot/397-554	Casio
	Spare Parts and Optional Equipment		
	Spare O-rings for the portable FRM sampler		
	Spare batteries (for all battery-powered equipment)		
	Fuses, as required by all equipment used		
	Spare in-line filters (if required by the portable FRM sampler)		
	Voltmeter/ammeter/ohmmeter for troubleshooting		
	Spare impactor(s)		
	Ground fault circuit interrupter (GFCI) tester		
	Portable GFCI device		
	Camera (digital) for site pictures		

Quantity	PEP Field Equipment and Supplies	Vendor/Catalog Number	Make/Model Number
	Cleaning Supplies and Equipment		
	Low-lint laboratory wipes for cleaning WINS and other sampling equipment (Kimwipes)	Kimberly-Clark	
	Disposable paper towels		Kay-Pees disposable paper towels
	Large, locking plastic bag for cleanup of debris and wipes		
	Soft brush		
	Supply of deionized water for cleaning and rinsing equipment		
	Isopropyl alcohol to aid in removal of grease and dirt		
	Alcohol wipes for preloading hand wipe	Nearest drug store	
	Penetrating oil (silicone oil or 3-in-1™)		
	Lint-free pipe cleaners		
	Safety pin/dental pick		
	Lint-free cotton-tipped swabs		
	Wooden dowel and cloth wads to clean downtube		
	Spray bottle		
	Gloves (powder-free, nitrile)		

Initial quantities will be worked out with the WAM/TOPO/DOPO 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 WAM/TOPO/DOPO suggests a different item because of its improved quality, reduction in contamination, increased ease of use, or lower cost (without sacrificing quality). The WAM/TOPO/DOPO will report any equipment changes that could affect the results of sampling events to the EPA National PEP Project Leader. The FS will perform the following required procedures:

- 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 Regional WAM/TOPO/DOPO.
- File PRO-01 under AFC “PEP/301-093-006.6.”

17.3 Acceptance Criteria

The major pieces of capital equipment are namely the following:

Laboratory

- Microbalances
- Calibration equipment (see Element 16.0, *Instrument Calibration and Frequency*)
- Mass weights
- Temperature recorder
- Humidity recorder

Field

- Portable samplers
- Calibration equipment (see Element 16.0, *Instrument Calibration and Frequency*)

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 previously listed 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 and to 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) (Figure 17-1), which lists each equipment item and 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 is the need for the purchasing department to accurately track goods received so that payment or credit of invoices can be approved. The following procedures address these issues by outlining the proper tracking and documentation process 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. Pull the appropriate purchase order for the incoming items from the files
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 AFC "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 WAM/TOPO/DOPO
6. Call the vendor to report the problem with the package and/or 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.

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

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

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

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

Field/Laboratory Equipment/Consumable Receiving Report Form (REC-01) Date: _____				
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:				

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

18.0 Data Acquisition Requirements

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

18.1 Acquisition of Non-Direct Measurement Data

The PEP relies on data that are generated through field and laboratory operations; however, some data are obtained from sources outside the PEP. This element lists these data and addresses quality issues related to the 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 PEP Project Leader. The following sources may be used in the PEP without prior approval:

- NIST
- International Organization for Standardization (ISO), International Union of Pure and Applied Chemistry (IUPAC), American National Standards Institute (ANSI), and other widely recognized national and international standards organizations
- EPA
- The current edition of certain standard handbooks may be used without prior approval from the National PEP Project Leader. Two that are relevant to the fine particulate monitoring program are CRC Press' *Handbook of Chemistry and Physics* and *Lange's Handbook of Chemistry*.

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. 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, the FSs will compare physical and chemical constants in the operator's manuals to those given in the sources previously listed. If discrepancies are found, then the FS may raise these issues during 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 or her by the SLT monitoring agency and included in the site file and on each FDS. This will include the following parameters:

- AQS Site ID
- Monitor type
- Method designation (routine instrument)
- Reporting organization.

These values should be available in the AQS database and can be double-checked for their accuracy before proceeding to a site.

18.1.4 External Monitoring Databases

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

Data from EPA's AQS database may be used in published reports with appropriate caution. Care must be taken when reviewing and using any data that contain flags or data qualifiers. If data are flagged, such data shall not be used unless it is clear that these data still meet critical QA/QC requirements. It is impossible to assure that a database, such as the AQS, is completely free from errors, including outliers and biases, so caution and skepticism are called for when 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 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, that pertain to $PM_{2.5}$ measurements for the PEP. This includes an overview of the mathematical operations and analyses performed on raw ("as-collected") $PM_{2.5}$ data.

Data processing procedures for PEP $PM_{2.5}$ data are summarized in Figure 19-1. A data management system (called the PED) has been developed to collect the critical information that must be uploaded into the AQS database and is required to calculate $PM_{2.5}$ concentrations. As time and resources allow, system features will be added to automate and electronically store other important information. The PED is set up so that as a default, all information can be manually recorded. The critical data values are entered into the PED and processed using a set of programs written in Microsoft Access. The PED user application resides on PCs running in the weighing laboratory (the back-end to the database may reside on a network server in another location). This local copy of the database is shown in the upper left of Figure 19-1. In essence, data for the PEP can be seen as accumulating during the following three stages:

- **Pre-sampling filter weighing.** At this stage, the filters are assigned a unique Filter ID/Cassette ID combination, and a pre-sampling weight value is recorded.
- **Field.** The Filter Cassette is installed, and the sampler is operated by providing many values that are automatically downloaded from the sampler to a data logger, laptop, and data storage device (e.g., diskette, CD, or USB drive). In particular, the critical measurement value collected in the field is the air volume sampled during the filter exposure.
- **Post-sampling filter weighing.** At this stage, the exposed filter cassette is returned to the laboratory where the filter is equilibrated and weighed again. The difference between the initial pre- and post-sampling weights is the particulate load on the filter, which is a critical value.

During these stages, additional data, including COC data, calibration data, and laboratory atmospheric data (temperature/RH), are collected, recorded in hard copy and/or electronic form, and appropriately stored to ensure the quality of the critical values.

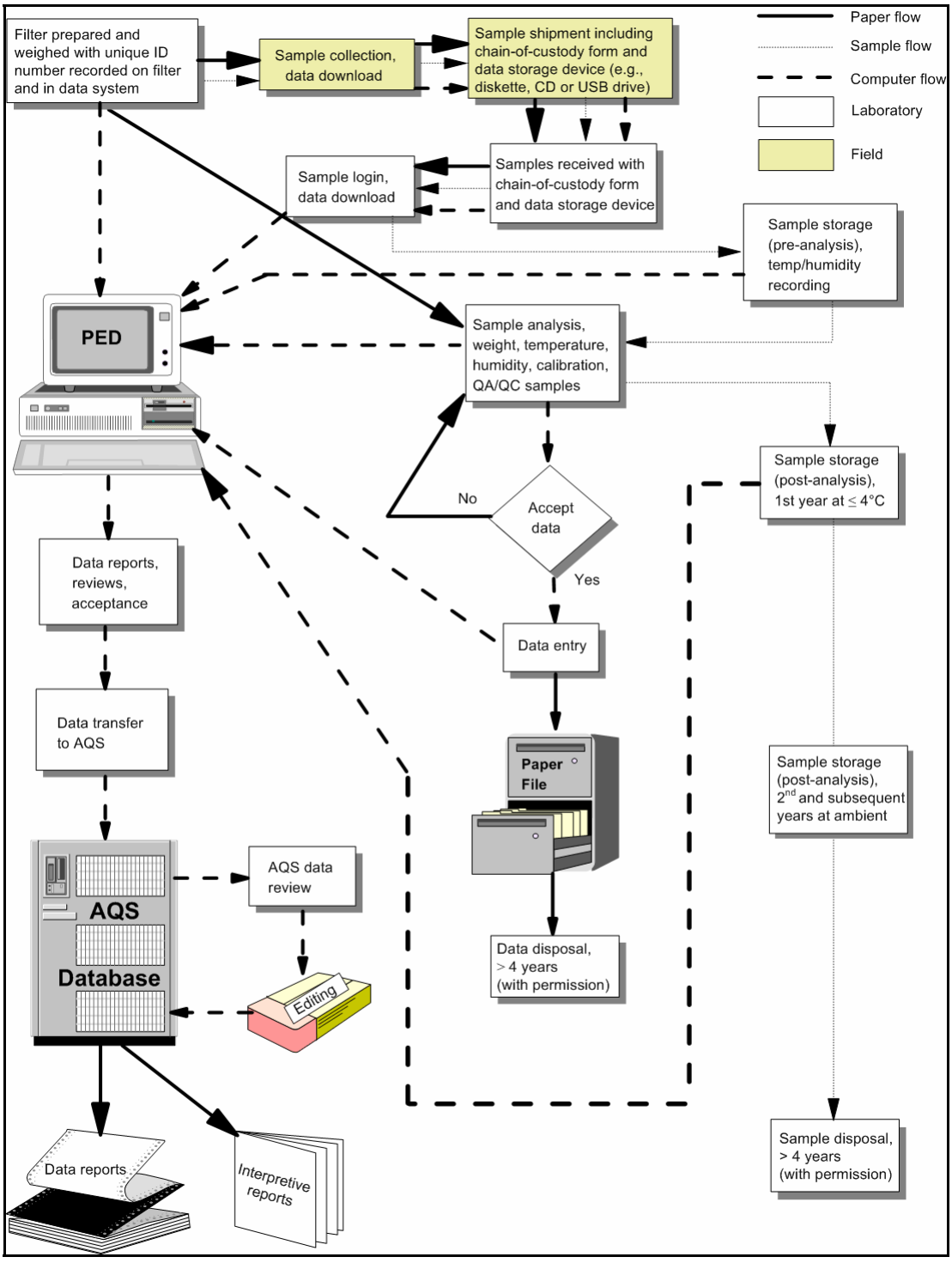


Figure 19-1. PEP information management flow.

19.1.1 Information Management Security

The PED is maintained on an EPA file share, and access is restricted to authorized personnel. Data can only be released with the express permission of the National PEP Project Leader. PE results should not be released for events that have not been posted by the Reporting Organization to AQS. Only validated, approved data are loaded into the AQS, where the information becomes public domain. In addition, hard copies of all weighing logs and routine back-up copies of the PED are archived. A comparison of the archived PED copies with the current PED allows unauthorized or altered entries to be detected in the current PED.

19.2 Data Recording

Each method that generates information in the PEP will have a data form available for hand recording this information. These forms are found at the end of the particular PEP Field or Laboratory SOP that describes the data collection activity, as summarized in Table 19-1.

Table 19-1. List of PEP Data Processing Operations for Critical Values

Reference	Title	Description (Data Related)
Lab SOP, Section 8	*Filter Weighing*	Describes the procedure for pre- and post-sample weighings of the filter and for recording data
Lab SOP, Section 9	*Chain of Custody (COC) and Shipping*	Describes the laboratory procedure for starting a COC Form and for processing the same form when it returns from the field
Field SOP, Section 6	*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 how to acquire data from the portable sampler
Field SOP, Section 7	*COC Form and Field Data Sheet*	Describes the field procedure for completing the field portions of the COC Form
Not applicable	*Performance Evaluation Database (PED) User's Manual*	Describes data entry forms and procedures for using the PED
Not applicable	*AQS Data Coding Manual (AQ2)*[a]	Describes the coding of air quality data transactions; describes the various transactions used to create, update, or delete data in the AQS
Not applicable	*AQS User Guide*[a]	Describes the installation of AQS software, accounts, data input (batch and online), maintenance, and data retrievals (standard reports)

[a] AQS reference documents can be found at http://www.epa.gov/ttn/airs/airsaqs/manuals

19.3 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. After 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 PED are never internally overwritten by condition flags. Flags that denote 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 PED to ensure the quality of data entry and data processing operations:

- **100% data review.** Filter weight reports, FDSs, and COC forms are subjected to a 100% data review by the LA and random reviews once a month by the PEP Laboratory Manager or designated Laboratory QA Officer.
- **Range checks.** Simple range checks are performed by the PED 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, the summer temperatures in most Regions should be between 10°C and 50°C. Because these range limits for data input are not regulatory requirements, the 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, filter weigh dates, 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 PED. For example, the end time of a filter must be later 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 4 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 1 calendar year at ≤4°C. After the first year, the filters may be kept at ambient temperature. At the end of the 4th calendar year, the LA may request instructions from OAQPS on the disposition of archived sample filters.

  NOTE: 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. Data

validation is the process in which raw data are screened and assessed before inclusion into 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 that contain too many flags would be rerun and/or invalidated.

Table 19-2 summarizes the validation checks applicable to the PEP data.

Table 19-2. 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 $PM_{2.5}$ 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 PEP Laboratory Manager or a designated Laboratory QA Officer will inspect the results of collocated sampling during each batch validation activity. These data will be evaluated as early in the process as possible, so that potential operational problems can be addressed. An objective of the PEP will be to optimize the performance of its $PM_{2.5}$ 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.

19.4 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 19-3 pertain to $PM_{2.5}$ monitoring:

Table 19-3. Raw Data Calculations

Parameter	Units	Type of Conversion	Equation
Filter volume (V)*	m^3	Calculated from average flow rate (Q_{ave}) in L/min and total elapsed time (t) in minutes multiplied by the unit conversion (m^3/L)	$V = Q_{ave} \times t \times 10^{-3}$
Mass on filter ($M_{2.5}$)	μg	Calculated from filter post-weight (M_f) in mg and filter pre-weight (M_i) in mg multiplied by the unit conversion (μg/mg)	$M_{2.5} = \left(M_f - M_i\right) \times 10^3$
$PM_{2.5}$ concentration	$\mu g/m^3$	Calculated from gravimetric mass and sampler volume	$PM_{2.5} = \frac{M_{2.5}}{V}$

* FRM instruments will provide this value.

19.5 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 1) submission of downloaded instrument data files saved on a portable storage device for subsequent upload into a data entry system and 2) transcription of raw data from a notebook into an electronic data entry system. Table 19-4 summarizes data transfer operations.

Table 19-4. Data Transfer Operations

Description of Data Transfer	Originator	Recipient	QA Measures Applied
Keying weighing data into the PED	LA (hand-written data form)	LA	100% review; random checks by the PEP Laboratory Manager or by a designated Laboratory QA Officer
Electronic data transfer	(Between computers or over network)	–	Parity checking; transmission protocols
Filter receiving, COC forms, and FDSs	FS	LA	Filter numbers are automatically verified; reports indicate missing filters and/or incorrect data entries; FS checks data entry with 100% review
Verification/calibration and audit data	Auditor or Field Supervisor	LA	Entries are checked by the LA and the PEP Laboratory Manager or by a designated Laboratory QA Officer
AQS data	LA	AQS (EPA)	Data transfer is checked by the technical support contractor for the AQS

The PEP will report all $PM_{2.5}$ ambient air quality data and information specified by the AQS Data Coding Manual (http://www.epa.gov/ttn/airs/airsaqs/manuals), in the required format for the 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 AQS format, and in accordance with the quarterly schedule. PEP audit results are posted to the AQS as data pairs. The data pair consists of the PEP audit measured value and the site's measured value. SLAMS and NCore sites are required to post their site data to the AQS on the schedule shown in Table 19-5. Because posting the PEP data requires first obtaining the site's measured value from AQS, PEP data cannot normally be posted until after the due dates listed in Table 19-5. In cases where the site data have been uploaded to the AQS and validated on or before the due date, the PEP audit data should be available within 30 days after the due date (to allow time for processing and review). Data submitted after the due date will be available within 30 days after the end of the next reporting period.

Table 19-5. 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

19.6 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 $PM_{2.5}$ monitoring regulations require certain summary data to be computed and reported regularly to EPA. Examples of data summaries include the following:

- Average $PM_{2.5}$ concentration
- Accuracy, bias, and precision statistics based on accumulated FRM/FEM data
- Data completeness reports based on the numbers of valid samples collected during a specified period.

The integrity of PEP data reduction can be verified by independent review of the data and algorithms used. Verification of data integrity requires that 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 PEP Laboratory SOP, which requires archiving of hard-copy records for important data (e.g., weighing session 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, the PEP Laboratory SOP requires that regular copies of the PED 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 matched the data on hard-copy records.

19.7 Data Analysis

The PEP is currently implementing the data summary and analysis requirements contained in 40 CFR Part 58, Appendix A. It is anticipated that as the $PM_{2.5}$ Monitoring Program develops, additional data analysis procedures may evolve. The following specific summary statistics will be tracked and reported for the PEP:

- Single sampler bias (when the Anderson or R&P samplers are included in collocation studies) or accuracy (based on internal 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 and internal flow rate performance audits)
- Data completeness.

Equations used in these analyses are provided in the Table 19-6.

Table 19-6. Data Assessment Equations

Criterion	Equation	Reference
Percent difference (d_i)—Single-point check to compare audit concentration or value (flow rate) to the concentration/value measured by the sampler; *i* represents a unique pair of audit and measured values for a particular audit site and sampling date. For determining network bias, the data pair will only be used when both concentrations are >3 $\mu g/m^3$.	$d_i = \frac{measured - audit}{audit} \times 100$	40 CFR Part 58, Appendix A, Section 4.1.1
Mean (D)—Averages the individual biases (d_i) between sampler and audit value for various levels of aggregation; *n* is the number of sampler/audit pairs in the aggregation.	$D = \frac{1}{n} \times \sum_{i=1}^{n} d_i$	40 CFR Part 58, Appendix A, Section 4.3.2
Standard deviation (S)—An estimate of the variability of the average bias.	$S = \sqrt{\frac{\sum_{i=1}^{n} (d_i - D)^2}{(n-1)}}$	40 CFR Part 58, Appendix A, Section 4.3.2
Confidence intervals for the average bias estimates—$D_{U=90\%}$ is the upper 90% confidence interval; $D_{L=90\%}$ is the lower 90% confidence interval; $t_{0.95, n-1}$ is the 95th quantile of a *t* distribution with *n-1* degrees of freedom.	$D_{U=90\%} = D + t_{0.95,n-1} \times \frac{S}{\sqrt{n}}$ $D_{L=90\%} = D - t_{0.95,n-1} \times \frac{S}{\sqrt{n}}$	40 CFR Part 58, Appendix A, Section 4.3.2

Criterion	Equation	Reference
Relative percent difference for PEP collocation study data (i.e., "parking lot events") (d_i)—X_i and Y_i are concentrations from two different PEP samplers on a selected sampling day.	$$d_i = \frac{Y_i - X_i}{(Y_i + X_i)/2} \times 100$$	40 CFR Part 58, Appendix A, Section 4.2.1
Coefficient of variation (CV)—Precision estimate for PEP regional "parking lot" collocation studies; $X^2_{0.1,n-1}$ is the 10th percentile of a chi-squared distribution with $n-1$ degrees of freedom.	$$CV = \sqrt{\frac{n \times \sum_{i=1}^{n} d_i^2 - \left(\sum_{i=1}^{n} d_i\right)^2}{2n(n-1)}} \times \sqrt{\frac{n-1}{X^2_{0.1,n-1}}}$$	40 CFR Part 58, Appendix A, Section 4.2.1
Normalized paired differences ($N_{i,j,d}$)—Evaluation of collocation study data to determine bias of individual samplers when compared to all samplers in a study; n is the number of monitors in the collocation study; i and j represent different individual monitors in the study; d represents a specific day in a collocation event; $D_{i,j}$ represents the paired differences among monitors for each day during the event; $\bar{x}_d$ is the daily mean.	$$N_{i,j,d} = \frac{abs(D_{i,j})}{\bar{x}_d}$$ $$where\ D_{i,j} = \sum_{i=1}^{n-1} \sum_{j=i+1}^{n} x_i - x_j$$	Not described
Completeness of mandatory PEP audits—A comparison of the number of valid audits to the number that are expected based on the size of the PQAO; data are aggregated at the PQAO level, regionally, and nationally.	$$Completeness = \frac{N_{valid}}{N_{theoretical}} \times 100$$	Audit frequency described in 40 CFR Part 58, Appendix A, Section 3.2.7

19.8 Data Flagging—Sample Qualifiers

A sample qualifier or a result qualifier consists of three alphanumeric characters, which indicate the fact and the reason why that 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
- 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. Some flags will be generated by the sampling instrument (see Table 6-2). Appendix D contains a complete list of the data qualifiers and flags 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 PED 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 whether to validate or invalidate individual samples or batches of data.

19.9 Data Tracking

The PED 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 filter receipt (by lot)
- Laboratory filter pre-sampling equilibration (individual Filter ID first enters the system)
- Laboratory filter pre-sampling weighing
- Laboratory loads filters into cassettes (Filter IDs associated with Cassette IDs are recorded)
- Filter packaged for the field (Cassette IDs in each package are recorded)
- Shipping (package numbers are entered for both sending and receiving)
- Laboratory package receipt (package is opened and Cassette IDs are logged in)
- Laboratory filter post-sampling equilibration
- Laboratory filter post-sampling weighing
- Laboratory filter storage/archival.

Tracking reports may be generated by any personnel who have access to the PED. The following tracking reports are available:

- List of all filters in the filter archive
- List of all filters that have been received but have not been post-weighed
- Ad hoc reports (generated using Microsoft Access queries).

Although not currently in the PED, other reports could be added, if needed, such as the following:

- Location of any filter (by Filter ID)
- List of all filters sent to a specified site that have not been returned
- List of all filters that have not been returned and are more than 30 days past the initial weighing date.

The PEP Laboratory Manager or designee is responsible for tracking filter status at least twice per week and for following up on anomalies such as excessive holding time in the laboratory before reweighing.

19.10 Data Storage and Retrieval

Table 19-7 shows archival policies for the $PM_{2.5}$ data.

Table 19-7. Data Archive Policies

Data Type	Medium	Location	Retention Time	Final Disposition
Weighing records; COC forms	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
PED (excluding audit trail records)	Electronic (online)	Air Quality Division	Indefinite	Back-up media retained indefinitely
PED audit trail records	Electronic (back-up tapes)	Air Quality Division	4 years	Discarded, with permission from OAQPS
Filters	Filters	Laboratory	4 years; 1 full calendar year at 4°C, and then 3 additional calendar years at ambient temperature	Discarded, with permission from OAQPS

The $PM_{2.5}$ data reside on a Microsoft Windows-compatible computer in the PEP weighing laboratory. The security of data in the PED 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.

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 PEP data quality are required to be reported to EPA. However, the selection and extent of the QA and QC activities used by the PEP depend on many 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 PEP will be subject to the following assessments:

- Management systems reviews (MSRs)
- Technical system audits (TSAs)
- Surveillance
- Audits of data quality (ADQs)
- Data quality assessments (DQAs)
- Peer review.

20.1 Assessment Activities and Project Planning

20.1.1 Management Systems Review

An MSR is a qualitative assessment of data collection operations and/or organization(s) to establish whether the quality management structure, policies, practices, and procedures are adequate to ensure that the desired quality of data needed are met. An MSR is used to determine the effectiveness of and adherence to the QA program and the adequacy of resources and personnel provided to achieve and ensure quality in all activities. A review of the PEP is just one part of an MSR performed on an EPA Region's monitoring program. OAQPS has a goal of conducting two to three MSRs per year.

The MSR includes reviews of

- Procedures for developing DQOs
- Procedures for developing and approving QAPPs
- The quality of existing QAPP guidance and QAPPs
- Procedures for developing and approving SOPs
- Procedures and criteria for designing and conducting audits
- Tracking systems for assuring that the QA program is operating and that corrective actions disclosed by audits have been taken
- The degree of management support
- Responsibilities and authorities of the various line managers and the QA Program Manager for carrying out the QA program.

20.1.2 Technical Systems Audit

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 SLT organizations that implement PEP activities. The PEP Region 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 PEP laboratory and data management operations will be conducted annually by OAQPS; TSAs of the field operations will be conducted annually by the Regional WAM/TOPO/DOPOs. This will include any SLT-run PEP. It is possible that OAQPS would team with the Region during the TSAs of SLT-run PEPs. TSAs may be conducted coincident with the recertification of FSs, where appropriate.

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

- **Field.** Filter receipt, instrument setup, sampling, and shipping
- **Laboratory.** Pre-sampling weighing, shipping, receiving, post-sampling weighing, archiving, and associated QA/QC
- **Data management.** Information collection, flagging, data editing, security, and upload.

The audit activities are illustrated in Figure 20-1. To increase uniformity of the TSA, an audit form will be used (see Appendix E, *Technical Systems Audit Forms*).

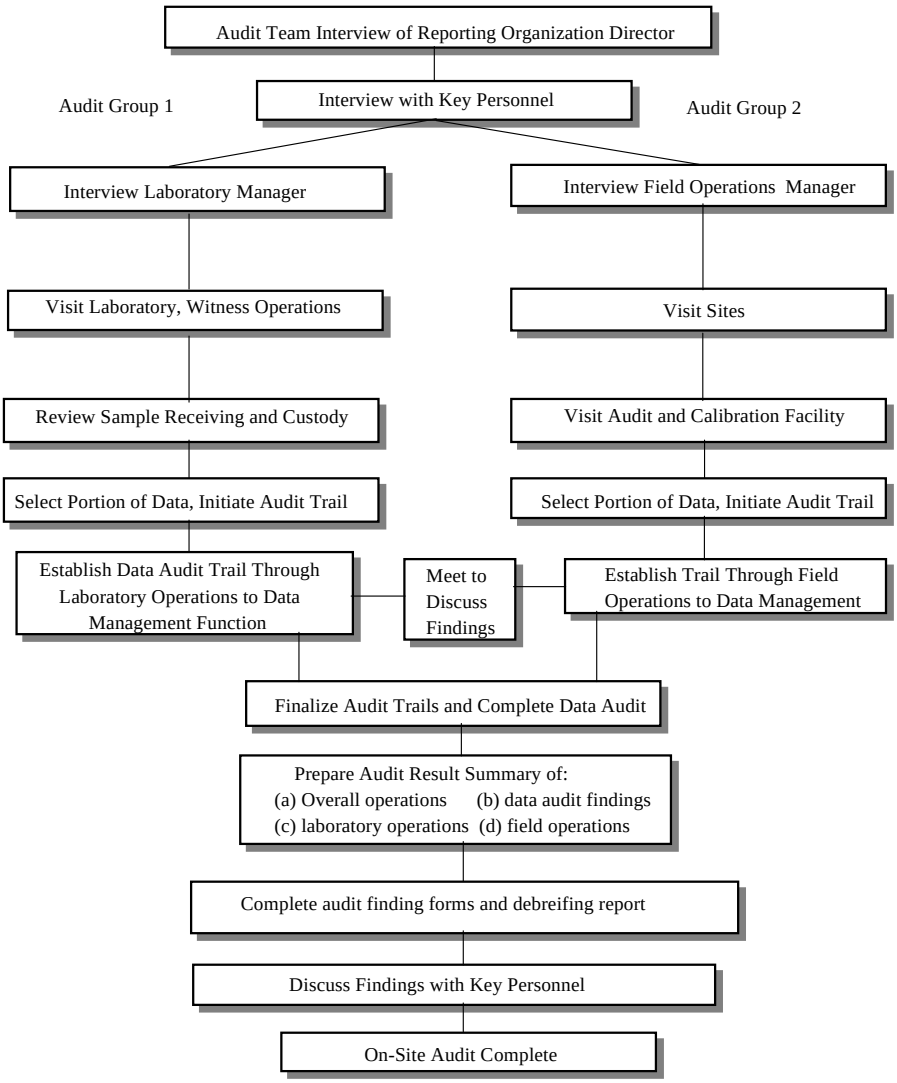


Figure 20-1. Audit activities.

The TSA team will prepare a brief 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 audit findings on the Audit Finding Form (Figure 20-2).

Audit Finding Form

Audit Title: _____ Audit Number: _____
Finding Number: _____

_____

Finding:

_____

Discussion:

QA Lead Signature: _____ Date: _____

Audited Agency
Signature: _____ Date: _____

Figure 20-2. Audit Finding Form.

By design, an Audit Finding Form should be completed for each major deficiency that requires formal corrective action. This form should include information such as the finding impact, estimated time period of deficiency, site(s) affected, and reason for action. The Audit 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 are 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, then 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. These forms are filed under the AFC heading "PEP/108-025-01-01-237.1" (see Element 9.0, *Documentation and Records*).

20.1.2.1 Post-Audit Activities

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

- Audit title, number, and any other identifying information
- Audit team leaders, audit team participants, and audit participants
- Background information about the project, purpose of the audit, dates of the audit, particular measurement phase or parameters that were audited, and a brief description of the audit process
- Summary and conclusions of the audit and corrective action required
- Attachments or appendices that include all audit evaluations and audit 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 audit findings are reviewed in detail. Within 30 calendar days of the completion of the audit, a draft audit report will be prepared and submitted. The TSA report will be submitted to the appropriate ESAT personnel and appropriately filed under the AFC heading "PEP/108-025-01-01-237.1."

If the ESAT organization has written comments or questions about the TSA report, then the TSA team will review and incorporate them as appropriate and will 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 Audit Finding Response Form (Figure 20-3) will be generated by the assessed organization for each Audit Finding Form submitted by the TSA team. In addition, ESAT will include corrective action in either its weekly (laboratory) or monthly (field) progress reports. The Audit Finding Response Form will be signed by the assessed organization, and then it will be sent to the ESAT WAM/TOPO/DOPO, who reviews and accepts the corrective action. The Audit Finding Response Form will be completed by the assessed organization within 30 days of acceptance of the audit report. Audit Finding Response forms are filed under the AFC heading "PEP/108-025-01-01-237.1."

Audit Finding Response Form

Audited Division: _____

Audit Title: _____ **Audit Number:** _____
Finding Number:_____

_____

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 Audit Finding Closed? _____ **When?** _____

File with Official Audit Records. Send a Copy to the Audited Organization.

Figure 20-3. Audit Finding Response Form.

20.1.3 Surveillance

"*Surveillance*" is defined as continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled. Surveillance is similar to a TSA except that it serves as a more frequent review of certain important phases of the measurement system (i.e., calibrations and run setup) rather than a review of the entire implementation process. Because the PEP has matured, surveillance is limited to specific issues that might be identified by OAQPS, the ESAT WAM/TOPO/DOPOs, or the PEP Laboratory Manager. A Surveillance Report Form (Figure 20-4) will be used for documentation and filed under AFC heading "PEP/108-025-01-01-237.1."

Surveillance Report Form

Reviewer _____ Date of Review: _____

Personnel Reviewed: _____

Activity Monitored	Acceptable Performance	
	YES	NO

Notes:

Signature: _____ Date: _____

Figure 20-4. Surveillance Report Form.

20.1.4 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 their 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**.**

20.1.5 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 *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, Regions, and laboratories and will be aggregated to all monitors.

20.1.6 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 informal $PM_{2.5}$ QA Strategy workgroup (facilitated by AAMG). This workgroup will serve as a peer reviewer. OAQPS will post the resulting document in draft on AMTIC's Web site and will announce its availability for public review through a Monitoring List Server Notice. 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 previously discussed.

Table 20-1. Assessment Summary

Assessment Activity	Frequency	Personnel Responsible	Report Completion	Resolution
MSRs	2 to 3 per yr	OAQPS	30 days after the activity	Regional Air Program Managers
TSAs	1/yr	OAQPS and Regional WAM/TOPO/DOPO	30 days after the activity	ESAT or SLT
Surveillance	As needed	OAQPS and Regional WAM/TOPO/DOPO	30 days after the activity	ESAT or SLT
ADQs	1/yr	OAQPS (National PEP Project Leader)	30 days after the activity	WAM/TOPO/DOPOs
DQAs	1/yr	OAQPS and EPA Regions	120 days after the end of the calendar year	EPA Regions and SLT

21.0 Reports to Management

This element describes the quality-related reports and communications to management necessary to support the 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 $PM_{2.5}$ PEP. Figure 21-1 represents the principal communication pathways.

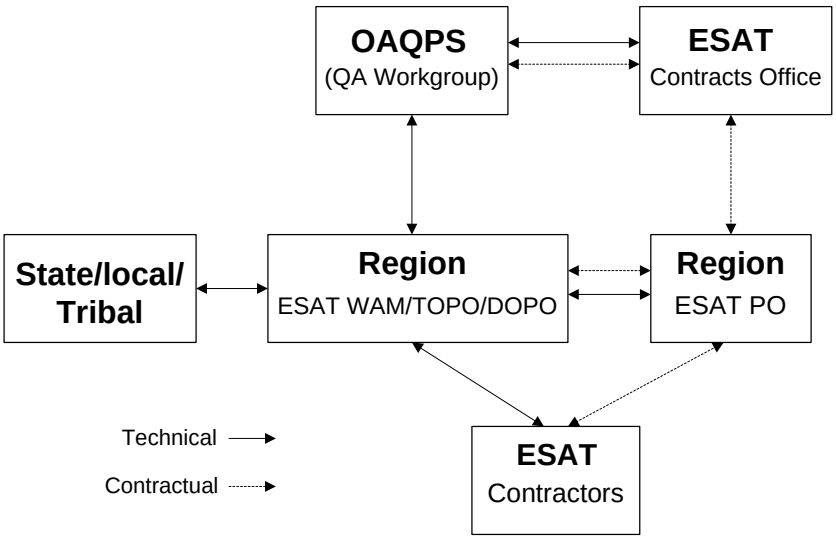


Figure 21-1. Lines of communication.

In general, ESAT contractors will be responsible for informing the PEP Laboratory Manager, the Regional WAM/TOPO/DOPO, and the POs about technical progress, issues, and contractual obligations. On the technical side, the Regional WAM/TOPO/DOPO(s) will be responsible for communicating with SLT agencies and for informing OAQPS about issues that require technical attention. Contractual issues will be conveyed from the ESAT contractor through POs to the ESAT CMD and, if necessary, to OAQPS. Table 21-1 lists key EPA ESAT contacts.

The ESAT contractors will frequently communicate with the PEP Laboratory Manager and the Regional WAM/TOPO/DOPO on the progress of their activities and any problems and issues associated with them. Resolution of these issues should take place in the Regions unless the issue could affect the implementation of the PEP at a national level. In those cases, it can be discussed and resolved through the communications between the National PEP Program Leader, the Regional WAM/TOPO/DOPOs, and, if needed, the ESAT Project and Contract Officers.

Communications among various participants in the PEP will be critical to the success of the program. The PEP Field SOP (Section 2) and PEP Laboratory SOP (Section 4) contain procedures for required communication and for documenting this information.

Table 21-1. Communications Summary

Person	Communicates to	Communication Function
PEP Laboratory Manager	Regional (Laboratory) WAM/TOPO/DOPO and LA	Contract performance issues Review of deliverables Review of data Corrective action Schedule changes
Regional WAM/TOPO/DOPO	OAQPS	Funding and resource needs Bulk filter shipments
	Regional Project Officer	Contract performance issues
	FS	Audit site selection and scheduling
LA	PEP Laboratory Manager and Regional (Laboratory) WAM/TOPO/DOPO	Laboratory progress Problems and issues Scheduling
	FS	Out-going filter/equipment shipment Filter shipment receipt from field Field procedure issues
	OAQPS or approved contractor(s)	Database management and 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	Regional (Laboratory) WAM/TOPO/DOPO	Requests for PEP data Data transfer to the AQS database Data quality issues
National PEP Project Leader	Regional WAM/TOPO/DOPOs	Funding and resource needs Contract performance issues

21.1.1 Field Communication

Field communications can take place by phone or by e-mail. Phone messages or conversations will be recorded using the Phone Communication Form (COM-1) in the field communications notebook. All PEP-related communication should be logged. 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, then these actions will be included in the monthly progress reports (see Element 9.0, *Problem Definition/Background*, Section 9.2.2). 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 PEP activities. The Regional WAM/TOPO/DOPO should also identify alternates to receive field communications when he or she is not in the office.

21.1.1.1 Filter Shipment Receipt

Upon request from the FS, the LA will ship the filters to the field offices. On the day of receipt, the FS will contact the LA and provide the following information:

- Date of receipt
- Number of filter cassettes in shipment
- Number of boxes in shipment
- Airbill number.

21.1.1.2 Equipment Shipment Receipt

Once a month, the laboratory will ship coolers, maximum/minimum thermometers, and gel packs back to the field offices. On the day of receipt, the FS will contact the LA and will provide the following information:

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

21.1.1.3 PEP Conference Calls

The FS may be asked to participate in PEP conference calls to discuss progress or resolution of issues. The Regional WAM/TOPO/DOPO will inform the FS of information that needs to be prepared for the call at least 3 days before the call. During this call, the FS will 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.

21.1.1.4 Communicating with Reporting Organizations and Site Operators

Dates for the FRM PE visits 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 on-site visit. 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 site visit. Contact must be made by phone if it is within 30 days of the site visit, but e-mail is sufficient otherwise.
- Approximately 1 week before the actual evaluation, the FS will call the site operator to confirm that the PE visit 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 Filter Shipment

Twice monthly, filters will be shipped to the field offices by Federal Express (FedEx) or another approved courier. On the day of shipment, the LA will communicate with the FS and will provide the following information:

- Date of shipment
- Number of filter cassettes in shipment
- Number of boxes in shipment
- Airbill number.

The LA will also send the FS an e-mail that contains this information.

21.1.2.2 Equipment Shipment

Once a month or as needed, the laboratory will ship coolers, maximum/minimum thermometers, and ice substitutes back to the Regional offices by FedEx. 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 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 monthly (PEP Field SOP, Section 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 dates that are covered in the report
- **Reporter.** Person writing the reports
- **Progress.** Progress on field activities, including evaluations scheduled and conducted within a reporting date
- **Issues.** Old issues reported in earlier reports that have not been resolved and new issues arising within a reporting date
- **Actions.** The 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 PEP Laboratory Manager and the Regional (Laboratory) WAM/TOPO/DOPO every Friday or on the last day of the scheduled work week (PEP Laboratory SOP, Section 4). Progress Report Form (COM-2) will be used to convey the following information:

- **Reporting date.** Beginning and end dates that are covered in the report
- **Reporter.** Person writing the reports
- **Progress.** Progress on field activities
  - **Pre-sampling processing.** Filters prepared within a reporting date
  - **Post-sampling processing.** Filters weighed within a reporting date and data submitted to the AQS
  - **Shipments.** Shipments made to each Region within a reporting date
  - **Receipt.** Total number of filters received 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.

In addition, an updated Filter Inventory and Tracking Form (COC-1) will be included with the weekly progress report. 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 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 performed annually to determine if data are of the right type, quality, and quantity to support their intended use. The 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).

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. OAQPS will be responsible for generating these reports through the AQS.

Assessment reports. TSAs will be on file at EPA's Regional offices and OAQPS.

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 because 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 PEP and its resultant data quality.

The Annual QA Summary Reports will include the following information:

- 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 (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 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 an assessment finding. 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 (field or laboratory) WAM/TOPO/DOPO, and the National 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 PEP 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 PEP Laboratory Manager (laboratory instruments) and the Regional WAM/TOPO/DOPOs. 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.

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 the AQS within 25 days of receiving the filter from the field. The required reporting periods and due dates for SLAMS and NCore sites are listed in Table 21-2.

Table 21-2. Quarterly SLAMS/NCore Reporting Schedule

Reporting period	Due on or before
January 1–March 31	June 30
April 1–June 30	September 30
July 1–September 30	December 31
October 1–December 31	March 31 (following year)

PEP audit results are posted to the AQS as paired data. The data pair comprises the 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 applicable sampler (POC). Because both measured values are needed to report PEP audits to the AQS, the PEP audit results

will not be available until approximately 30 days after the dates listed in Table 21-2 (to allow time for processing and data approvals).

In cases where the PEP audit results are available, but the routine measurements are not available before the deadlines in Table 21-2, the PEP audit results will not be posted until the next quarter's posting. For example, for a routine sample collected on March 31st and posted by the state on or before June 30th, the associated PEP audit results should be posted to the AQS by approximately July 31st. If the same routine sample's result were not available in the AQS until September 1st, then the PEP audit results would not be posted until approximately January 31st.

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* (available at http://www.epa.gov/ttn/airs/airsaqs/manuals).

Table 21-3. Report Summary

Report Type	Frequency	Reporting Organization	Distribution
Field progress	Monthly	ESAT contractor	Regional WAM/TOPO/DOPO
Laboratory progress	Weekly	ESAT contractor	PEP Laboratory Manager, Regional (Laboratory) WAM/TOPO/DOPO
DQA	1/yr	OAQPS and EPA Regions	ESAT contractor, Regional WAM/TOPO/DOPO, AMTIC
PEP audit results	Quarterly	OAQPS and authorized contractor	AQS
PEP P&A (collocation study results)	2/yr	National PEP Project Leader	FS, Regional WAM/TOPO/DOPO, AMTIC
TSA (of SLT agencies or ESAT)	1/yr	EPA Region	ESAT contractor, assessed agency, National PEP Project Leader
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 PEP Project Leader

22.0 Data Review, Validation, and Verification Requirements

This element describes how the 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 of the 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 many of the important data collection phases. Earlier elements of this QAPP and the 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 PEP will use various qualitative assessments (e.g., TSAs, 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 PEP. It covers the number of PEs required for each reporting organization and method designation, as well as the frequency of data collection. These requirements have been described in the CFR; however, it is the responsibility of PEP to ensure that the intent of the regulations are properly administered and performed.

22.1.1 Sampling Design Verification

SLT 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, which 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 PE)
- Site proximity (the sites that are closest in proximity to each other can be visited within the same day or week).

The PEP implementation plan can then be reviewed and compared to the AQS data of active SLAMS and NCore sites aggregated by reporting organization and method designation. This can

ensure that the 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 PEP Field SOP 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.

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 PEP Field and Laboratory SOPs. Deviations from the sample collection activity will be noted in Audit 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 PEP Field SOP (Section 3) and PEP Laboratory SOP (Section 5), 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. Due to the size of the filters and the nature of the collected particles, 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 previously mentioned, 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, laboratory, trip, and lot 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 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 handling activities that would require corrective action.

22.4 Analytical Procedures

Element 13.0, *Analytical Methods Requirements*, details the requirements for the analytical methods, which include the pre-sampling and post-sampling weighing activities. Pre-sampling weighing activities give each sample a unique identification, establish an initial weight, and prepare the sample for the field. The post-sampling weighing activities provide the mass net weight and the final concentration calculations. The PEP Laboratory SOP, specifically Section 8, provides the actual procedures. 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 each sample's deviation from the procedure.

22.4.1 Verification of Analytical Procedures

As previously mentioned, 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 Audit 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, laboratory records for temperature and relative humidity devices, the Filter Inventory and Tracking Form (COC-1), and other laboratory QC activities described in Element 14.0 (*Quality Control Requirements*), Element 16.0 (*Instrument Calibration and Frequency*), and in the PEP Laboratory SOP. Acceptable precision and bias in these samples or control of the laboratory's temperature and relative humidity conditions 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 that would require 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 PEP Field and Laboratory SOPs.

22.5.1 Verification of Quality Control Procedures

As previously mentioned, 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 that are 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 PEP. The PEP Field SOP (Section 10) and the PEP Laboratory SOP (Section 7) provide detailed calibration techniques.

22.6.1 Verification of Calibration Procedures

As previously mentioned, TSAs and surveillance will be performed to ensure that the calibration specifications and corrective actions mentioned in the QAPP are being followed. Deviations from the calibration procedures will be noted in Audit 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 that would require 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 previously mentioned, 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

As part of the ADQ discussed in Element 20.0, *Assessments and Response Actions*, many randomly chosen Sample IDs will be identified. All raw data files, including those that contain the following will be selected:

- Pre-sampling-weighing activity (e.g., lot testing)
- Pre-sampling weighing
- Sampling (sampler download information)
- Calibration (information represented from that sampling period)
- Sample handling/custody
- Post-sampling weighing
- Corrective action

- Data reduction.

These raw data will be reviewed and final concentrations will be calculated independently of the PEP database to determine if the final values submitted to the AQS are comparable to the independent calculations. The data will also be reviewed to ensure that flags or any other data qualifiers have been appropriately associated with the PE database reports and that appropriate corrective actions were taken.

23.0 Validation and Verification Methods

Many of the processes for verifying and validating the measurement phases of the 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, then the PEP should obtain the necessary data quality to permit comparison of 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 about problems that affect the integrity of data is identified in the form of flags (see Appendix D). It is important to determine how these failures affect the routine data. The review of these 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 Sample Batches

After a sample batch is completed, a thorough review of these data will be conducted for completeness and data entry accuracy. Data used in PED audit calculations or used for evaluating critical validation criteria that are recorded on data sheets by hand will be 100% verified. After these data are entered into the PED, the system will review the data for routine data outliers and data outside of acceptance criteria or ranges. These data will be flagged appropriately. All flagged data will be "re-verified" to ensure that the values are correctly entered. Details of these activities are discussed in Element 19.0, *Data Management*. The data qualifiers or flags can be found in Appendix D.

23.1.2 Validation

Validation of measurement data can occur at the following different levels: at the single sample level, on a group of samples that are related (either to a single instrument, operator, or a pre- or post-weighing session), or at the sample batch level. Validation at these three levels is discussed below.

The PED contains automated procedures to assist in the validation process. For instance, the PED performs automated QC checks for many of the criteria defined in the CFR, as well as the more stringent QC checks required by the PEP. These checks are illustrated in the PEP Validation Matrix (Figure 23-1). The PED produces a PE Summary Report, which details all of the relevant data associated with a particular PE along with the pass/fail status of the automated checks. During validation review, the LA has the ability to override the pass/fail status (with a note documenting reasons for the override). All overrides must be approved by the PEP Laboratory QA Officer.

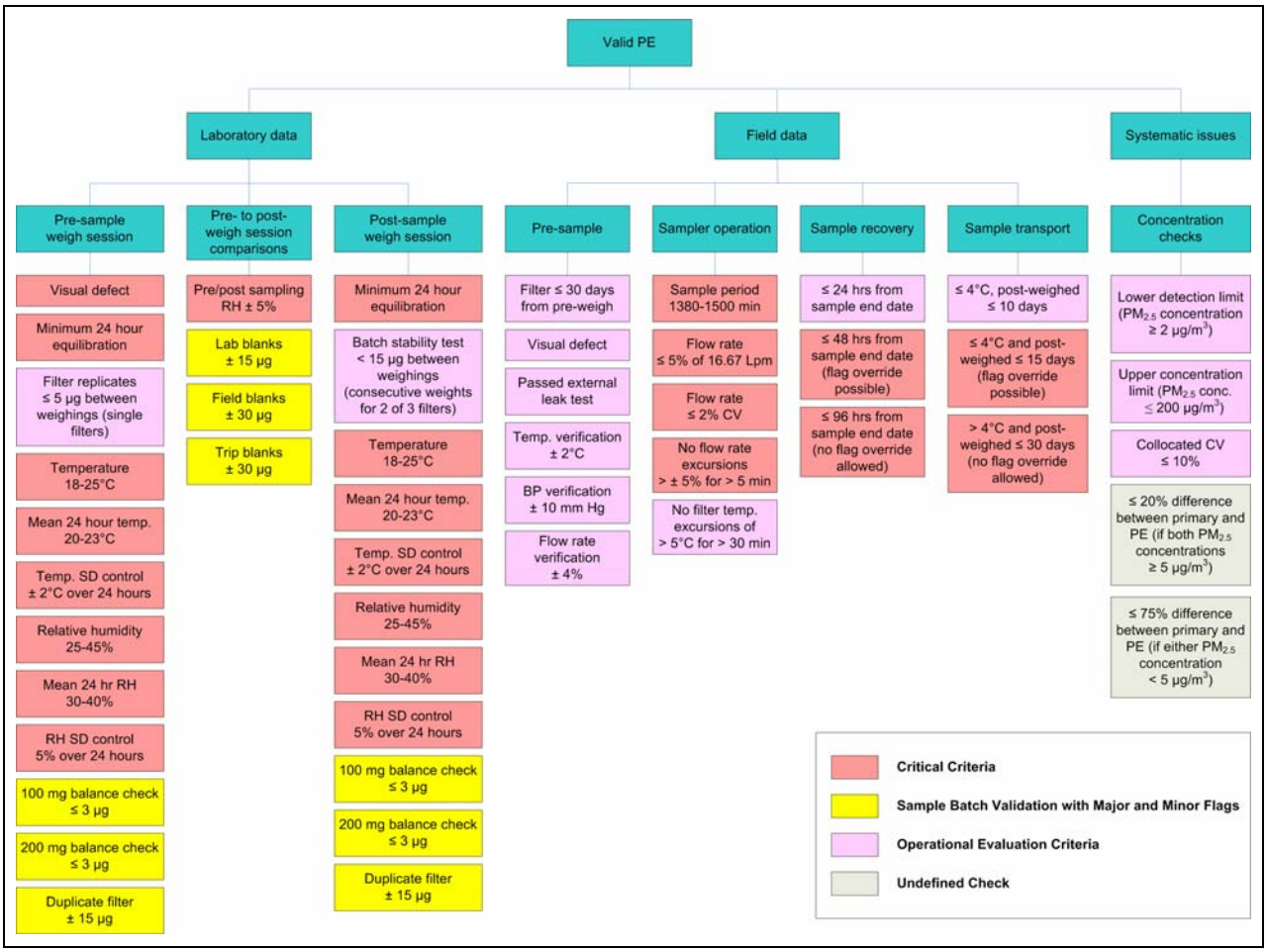


Figure 23-1. PEP validation matrix.

At least one flag will be associated with an invalid sample. The flag "INV" will be used to signify that a sample is invalid or the "NAR" flag will be used when no analysis result is reported. Additional flags will usually be associated with the NAR or INV flags to help describe the reason(s) for these flags. In addition, free-form notes from the FS or LA are often associated with the sample to further describe the reason(s) for these flags.

Records of all invalid samples will be filed by the LA. Information will include a brief summary of why the sample was invalidated, along with the associated flags. This record will be available from the PED because all filters that were pre-weighed will be recorded.

23.1.2.1 Validation of Single Samples or Groups of Samples

The PEP validation criteria are based upon the CFR criteria and the judgment of the PEP Workgroup. These criteria will be used to validate a sample or groups of samples. The flags listed in Appendix D will be used to assist in the validation activities.

Samples flagged in the field will always be returned to the weighing laboratory for further examination. When the LA reviews the FDS and COC Form, he or she will look for flag values. Filters that have flags related to obvious contamination (CON), filter damage (DAM), or field accidents (FAC) will be immediately examined. Upon concurrence with the PEP Laboratory QA Officer, these samples will be invalidated. The flag for no analysis result (NAR) will be applied to this sample, along with the other associated flags.

A single sample may be invalidated based on many criteria, such as known or suspected field or laboratory contamination, field or laboratory accidents, or failure of CFR acceptance criteria. Table 23-1 lists the cases where single samples or groups of samples may be invalidated based on failure of any one acceptance criteria (i.e., critical criteria).

Flags may be used in combination to invalidate samples. Table 23-2 identifies the operational evaluation criteria that can be used in combination to invalidate single samples or groups of samples. Because the possible flag combinations are overwhelming and cannot be anticipated, the PEP will review the flags associated with single values or groups of samples and determine invalidation criteria. The PEP will keep a record of the combination of flags that result in invalidation. These combinations will be listed and used by the weighing laboratory to ensure that the PEP evaluates and invalidates data consistently. The PEP anticipates the use of a scoring system (under development) to further ensure consistency in validation decisions. As previously mentioned, all data invalidation will be documented.

Table 23-1. Validation Template Where Failure of Any One Criteria Would Invalidate a Sample or a Group of Samples

CRITERIA DEFINED IN CFR—SAMPLES OR GROUPS OF SAMPLES INVALIDATED FOR ANY FAILED CRITERIA					
Requirement	**Type**	**Frequency**	**Acceptance Criteria**	**40 CFR Reference**	**Flag Value**
Filter Holding Times					
Sample recovery	**S**	All filters	≤48 hours from sample end date (override permissible)	Not described	HTE
	S	All filters	≤96 hours from sample end date (cannot be overridden)	Part 50, Appendix L, Section 10.10	HTE
Post-sampling weighing	**S**	All filters	≤15 days at 4°C from sample end date (override permissible)	Not described	HTE
	S	All filters	≤30 days at 4°C from sample end date (cannot be overridden)	Not described	HTE
Sampling Period					
Sampling period	**S**	All data	1,380–1,500 min	Part 50, Appendix L, Section 3.3	EST
Sampling Instrument					
Flow rate	**S**	Every 24 hours of operation	≤4% of design flow (16.67 Lpm)	Part 50, Appendix L, Section 7.4	FLR
	S	Every 24 hours of operation	≤2% CV	Part 50, Appendix L, Section 7.4.3.2	FLR
	S	Every 24 hours of operation	No flow rate excursions > ± 5% for > 5 min	Part 50, Appendix L, Section 7.4.3.1	FVL
Filter					
Visual defect check	**S**	All filters	See reference	Part 50, Appendix L, Section 6.0	DAM
Filter Conditioning Environment					
Equilibration	**G**	All filters	24 hours minimum in weighing room	Part 50, Appendix L, Section 8.2	ISP

CRITERIA DEFINED IN CFR—SAMPLES OR GROUPS OF SAMPLES INVALIDATED FOR ANY FAILED CRITERIA					
Requirement	**Type**	**Frequency**	**Acceptance Criteria**	**40 CFR Reference**	**Flag Value**
Temperature range	**G**	All filters	24-hr mean 20°C–23°C	Part 50, Appendix L, Section 8.2	ISP
	G	All filters	18°C minimum, 25°C maximum	Not described	ISP
Temperature control	**G**	All filters	± 2°C SD[a] over 24 hr	Part 50, Appendix L, Section 8.2	ISP
Relative humidity range	**G**	All filters	24-hr mean 30%–40% relative humidity	Part 50, Appendix L, Section 8.2	ISP
	G	All filters	25% relative humidity minimum, 45% relative humidity maximum	Not described	ISP
Relative humidity control	**G**	All filters	± 5% SD[a] over 24 hr	Part 50, Appendix L, Section 8.2	ISP
Pre-/post-sampling relative humidity	**S/G**	All filters	± 5% relative humidity		ISP

NOTE: S = single filter; G = group of filters (i.e., batch); G1 = group of filters from one instrument

[a] Variability estimate not defined in CFR

Table 23-2 Validation Template Where Certain Combinations of Failure May Be Used to Invalidate a Sample or Group of Samples

OPERATIONAL EVALUATIONS					
Requirement	**Type**	**Frequency**	**Acceptance Criteria**	**40 CFR Reference**	**Flag Value**
Filter Checks					
Lot exposure blanks	**G**	3 filters from each of 3boxes in lot (9 filters total)	± 15 μg change between weighings	Not described	
Filter integrity (exposed)	**S**	Each filter	No visual defects	Part 50, Appendix L, Section 10.2	CON, DAM
Filter Holding Times					
Pre-sampling[a]	**S**	All filters	<30 days from pre-weigh to sampling	Part 50, Appendix L, Section 8.3	HTE
Sample recovery	**S**	All filters	≤24 hours from sample end date	Not described	HTE
Post-sampling weighing	**S**	All filters	≤10 days at 4°C from sample end date	Not described	HTE
Detection Limit					
Lower detection limit	**G/G1**	All data	2 $\mu g/m^3$	Part 50, Appendix L, Section 3.1	BDL
Upper concentration limit	**G/G1**	All data	200 $\mu g/m^3$	Part 50, Appendix L, Section 3.2	NA
Laboratory QC Checks					
Field filter blank[a]	**G/G1**	1/audit (for programs <2 yrs old) 1/FS per trip (for all others)[b]	± 30 μg change between weighings	Part 50, Appendix L, Section 8.3	FFB
Laboratory filter blank[a]	**G**	10% or 1/weighing session	± 15 μg change between weighings	Part 50, Appendix L, Section 8.3	FLB
Trip filter blank	**G**	10% of all filters[c]	± 30 μg change between weighings	Not described	FTB
Balance check	**G**	Beginning/end of weighing session and 1 after approximately every 15 samples or fewer, per recommendations of the balance's manufacturer	≤3 μg	Part 50, Appendix L, Section 8.3	FQC

OPERATIONAL EVALUATIONS					
Requirement	**Type**	**Frequency**	**Acceptance Criteria**	**40 CFR Reference**	**Flag Value**
Duplicate filter weighing	**G**	1/weighing session, 1 carried over to next session	± 15 μg change between weighings	Part 50, Appendix L, Section 8.3	FLD
Sampling Instrument					
Filter temperature sensor	**S**	Every 24 hours of operation	No excursions of >5°C lasting longer than 30 min	Part 50, Appendix L, Section 7.4	FLT
Accuracy					
Flow rate audit[a]	**G1**	4/yr (manual)	± 4% of calibration standard at design flow (16.67 Lpm)	Part 58, Appendix A, Section 3.5.1	FQC
External leak check[a]	**G1**	4/yr	<80 mL/min	Part 50, Appendix L, Section 7.4.6	FQC
Internal leak check[a]	**G1**	4/yr (if external leak check fails)	<80 mL/min	Part 50, Appendix L, Section 7.4.6	FQC
Temperature audit[a]	**G1**	4/yr	± 2°C of calibration standard	Part 50, Appendix L, Section 9.3	FQC
Barometric pressure audit[a]	**G1**	4/yr	± 10 mm Hg of calibration standard	Part 50, Appendix L, Section 7.4	FQC
Balance audit (PE)	**G**	2/yr	± 20 μg of NIST-traceable standard ± 15 μg for unexposed filters	Not described	FQC
Precision (using collocated samplers) [d]					
All samplers (mandatory)	**G**	2/year (semi-annual)	CV ≤10%	Part 58, Appendix A, Sections 3.5 and 5.5	FCS
Verification					
Single-point flow rate verification	**G1**	Every sampling event	± 4% of working standard or 4% of design flow (16.67 Lpm)[a]	Part 50, Appendix L, Section 9.2.5	FSC
External leak check	**G1**	Every sampling event	<80 mL/min[a]	Part 50, Appendix L, Section 7.4	LEK
Internal leak check	**G1**	Upon failure of external leak check	<80 mL/min[a]	Part 50, Appendix L, Section 7.4	LEK
Single-point temperature verification[a]	**G1**	Every sampling event and following every calibration	± 2°C of working standard	Part 50, Appendix L, Section 9.3	FSC

OPERATIONAL EVALUATIONS					
Requirement	**Type**	**Frequency**	**Acceptance Criteria**	**40 CFR Reference**	**Flag Value**
Single-point barometric pressure verification[a]	**G1**	Every sampling event and following every calibration	± 10 mm Hg	Part 50, Appendix L, Section 7.4	FSC
Clock/timer verification	**G1**	Every sampling event	1 min/mo	Part 50, Appendix L, Section 7.4.12	NA
Laboratory temperature verification	**G**	1/quarter	± 2°C	Not described	FLT
Laboratory relative humidity verification		1/quarter	± 2% relative humidity	Not described	FLH

NOTE: S = single filter; G = group of filters (i.e., batch); G1 = group of filters from one instrument

[a] Identified in the CFR

[b] For a new SLT program (i.e., <2 years old), the frequency for field blanks is one per FRM/FEM audit. For all others, one field blank should be performed per FS per trip. A trip may include audits for more than one FRM/FEM sampler. It is up to the FS to determine which site to perform the field blank audit, unless otherwise directed by their Regional WAM/TOPO/DOPO (such as when a problem is identified at a particular site).

[c] Trip blanks will be performed at a frequency of 10% of all filters, as determined by the weighing laboratory (i.e., 1 per every 10 filters shipped out, rounded up). So if the laboratory sends out 1 to 10 filters, then one trip blank should be included in the shipment. If the laboratory ships out 11 to 20 filters, then two trip blanks should be included. The FS will determine with which trip to use the trip blank filter(s), in a manner similar to the field blanks. However, if the FS receives more than one trip blank in a shipment, then he or she must make sure that only one trip blank is carried per trip.

[d] Twice per year, all of the PEP samplers used by the Region (and any SLT organizations that are running their own PEP) must be collocated and run at the same location over the same time period. These are often referred to as "parking lot collocations."

23.1.2.2 Validation of Sample Batches

Due to the nature and holding times of the routine samples, it is critical that the PEP minimize the amount of data that is invalidated; therefore, the PEP will validate data on sample batches as described in Element 14.0, *Quality Control Requirements*. Based on the types of QC samples that are included in the batch and on the field and laboratory conditions that are reported along with the batch (field/laboratory flags), the PEP has developed a validation template that will be used to determine when PE data will be invalidated and when major corrective actions must be instituted. Table 23-3 represents the sample batch validation template.

Table 23-3. Sample Batch Validation Template

Requirement	Number Per Batch	Audit Acceptance Criteria	Major[a]	Minor[b]	Flag
Blanks					
Field blanks	1	≤ ± 30 μg	Blank ≥ ± 40 μg	One blank > ± 30 μg	FFB
	>1	Mean ≤ ± 30 μg	Mean ≥ ± 30 μg		FFB
Laboratory blanks	1	≤ ± 15 μg	Blank ≥ ± 17 μg	Blank > ± 15 μg	FLB
	>1	Mean ≤ ± 15 μg	Mean ≥ ± 15 μg		FLB
Trip blanks	1	≤ ± 30 μg	Blank ≥ ± 40 μg	One blank > ± 30 μg	FTB
	>1	Mean ≤ ± 15 μg	Mean ≥ ± 30 μg		FTB
Precision Checks					
Filter duplicates	1	≤ ± 15 μg	Duplicate > ± 17 μg	Duplicate > ± 15 μg	FLD
Accuracy					
Balance checks	4	≤ ± 3 μg	Four checks > ± 3 μg	Two checks > ± 3 μg	FIS

[a] If two majors occur, data are invalidated.
[b] If four minors occur, data are invalidated. Two minors equal one major.

Based on the number of major and minor flags associated with the batch, it may be invalidated. Either the PED or the LAs will evaluate the batch and generate a report based on the results described in the validation template. If the report describes invalidating the batch of data, then the batch will be re-analyzed. Prior to re-analysis, all efforts will be made to take corrective actions and, depending on the type of QC checks that were outside of acceptance criteria, to correct the problem. If the batch remains outside the criteria, then the routine samples will be flagged invalid (INV).

23.1.3 Validation Acceptance and Reporting

All efforts will be made to produce adequate results. Any data flagged as invalid, with the exception of obvious filter damage or accidents, will be re-analyzed.

The PEP Laboratory QA Officer will be responsible for determining that data have been validated before submittal to the AQS. A summary report of all data that were invalidated, along

with explanations for batch failures, will be submitted to the PEP Laboratory Manager and the Regional (Laboratory) WAM/TOPO/DOPO each week.

Invalidated PEP audit events cannot be posted to the AQS because there is currently no provision in the AQS precision data record format ("RP" transaction type), for adding null value codes or data qualifiers.

24.0 Reconciliation with Data Quality Objectives

The DQOs for the PEP are prescribed in the QA provisions of the Federal Monitoring Regulations at 40 CFR Part 58, Appendix A, most recently revised on October 17, 2006. They are described in this QAPP in Element 7.0, *Data Quality Objectives and Criteria for Measurement*. This element of the QAPP outlines the procedures that the 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 $PM_{2.5}$ FRM/FEM network (i.e., to ensure that the PEP is meeting its DQOs).

The underlying premise for using the data from the PEP to estimate the bias associated with the National $PM_{2.5}$ FRM/FEM network is that the PEP represents the most precise and least biased measurements of $PM_{2.5}$ using the FRM. Therefore, the promulgated DQOs are not static goals with respect to data quality, but they are actually goals that may be periodically revised to reflect progressive scientific developments and experience. Improvements in the precision and bias of the PEP-generated data are constant goals. To this end, the PEP has instituted many QC procedures and tests and internal evaluations of sampler and the operators and LAs. The control limits for the many MQOs that are associated with the PEP are discussed in other elements of this QAPP. It follows that a variety of mathematical and statistical tools are employed to analyze these QC data that are generated. Occasionally, a new or different tool will be evaluated for new or different insights into PEP data.

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, then 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 each Region.

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

Twice per year (semi-annually), all of the PEP samplers used by a single FS or Region 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 is to determine whether one of the samplers is biased, relative to the performance of the other samplers (of both same and different FRM make or model) and to estimate the repeatability (or between-monitor precision) of the instruments. Estimates of the repeatability can be used to evaluate the certainty with which the bias of the SLT program within each Region can be estimated. Statistical methods will be used to determine the between-sampler precision and identify individual samplers that yield aberrant results. Samplers that produce aberrant results will be reported to their respective Regional users. In each case, the sampler will be quarantined from use in the PEP until a subsequent investigation is performed and its issues have been resolved.

24.3 National Level Evaluation of Data Collected While All PEP Samplers Are Collocated

A major goal of the national review of the data from the collocation of all the PEP samplers is to determine if the repeatability of the samplers varies greatly by Region or by laboratory. OAQPS will check for equal variances across all Regions or laboratories 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).[1, 2] EPA will apply additional methods for data evaluation as deemed appropriate by OAQPS. New analytical methods will be reviewed by the PEP Workgroup. 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.

References

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

2. 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.

Appendix A

Glossary

The following glossary contains terms commonly used in the PEP. All terms listed may not actually be used in this document.

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Glossary

Acceptance criteria—Specified limits that are placed on the characteristics of an item, process, or service defined in requirements documents (American Society of Quality Control definition).

Accuracy—This term refers to a measure of the closeness of an individual measurement or the average of a number of measurements to the true value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; the U.S. Environmental Protection Agency (EPA) recommends using the terms "*precision*" and "*bias,*" rather than "*accuracy*," to convey the information usually associated with accuracy.

Activity—This all-inclusive term describes a specific set of operations of related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication) that, in total, result in a product or service.

Aerometric Information Retrieval System (AIRS)—See the Air Quality System (AQS).

Air Quality System (AQS)—The AQS, which is EPA's repository of ambient air quality data, stores data from more than 10,000 monitors, 5,000 of which are currently active. State, local, and Tribal agencies collect monitoring data and submit it to the AQS periodically. The AQS was formerly the Air Quality Subsystem of the AIRS, which also contained an Air Facility System (AFS) that stored information on pollution sources. After the AFS was separated from AIRS, the terms AIRS and AQS became frequently used as synonyms to refer to the ambient air quality database.

American National Standards Institute (ANSI)—ANSI is the administrator and coordinator of the U.S. private-sector voluntary standardization system.

American Society for Testing and Materials (ASTM)—The ASTM is a professional organization that develops and distributes protocols for testing and provides reference standards.

Analyst—An analyst is a staff member who weighs the new and used filters and computes the concentration of $PM_{2.5}$ in $\mu g/m^3$.

ANSI/ASTM Class 1 and 2 standards—These are the standards for weighing operations with a microbalance that is certified by their manufacturer as being in conformance with ASTM's standard specification for laboratory weights and precision mass standards (E 617-9), particularly the Class 1 and 2 specifications. These standards are traceable to the National Institute of Standards and Technology (NIST).

AQS Monitor ID—This is a 10-digit combination of the AIRS Site ID and POC (see each in this glossary) that together uniquely defines a specific air sampling monitor for a given pollutant. Some forms and dialog boxes may refer to this as an AIRS ID or 10-digit AIRS ID.

AQS Site ID—This is a unique identifier for an AQS sampling site. The AQS Site ID is frequently combined with the Parameter Occurrence Code (POC) (see POC in this glossary) to provide a unique 10-digit monitor ID. The first nine digits uniquely identify each air monitoring site (two-digit state code, three-digit county code, and four-digit site code). The tenth digit (POC) identifies the monitor at that site.

The state and county codes are Federal Information Processing Standard (FIPS) codes. The four-digit site codes are assigned by the local agency, which may allocate them in any way it chooses, as long as there is no duplication in the county. AQS Site IDs are associated with a specific physical location and address. Any significant change in location will typically require a new site ID.

Assessment—This term refers to the evaluation process that was used to measure the performance or effectiveness of a system and its elements. As used here, "*assessment*" is an all-inclusive term that is used to denote any of the following: an audit, a Performance Evaluation (PE), a management systems review (MSR), peer review, inspection, or surveillance.

Audit (quality)—A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Audit of Data Quality (ADQ)—A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

Authenticate—The act of establishing an item as genuine, valid, or authoritative.

Bias—The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Blank—A sample that is intended to contain none of the analytes of interest and is subjected to the usual analytical or measurement process to establish a zero baseline or background value. A blank is sometimes used to adjust or correct routine analytical results. A blank is used to detect contamination during sample handling preparation and/or analysis.

Calibration drift—The deviation in instrument response from a reference value over a period of time before recalibration.

Calibration—A comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

Cassette—A device that is supplied with $PM_{2.5}$ samplers to allow a weighed Teflon® filter to be held in place in the sampler and manipulated before and after sampling without touching the filter and to minimize damage to the filter and/or sample during such activities.

Certification—The process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.

Chain of custody—An unbroken trail of accountability that ensures the physical security of samples, data, and records.

Characteristic—Any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

Check standard—A standard that is prepared independently of the calibration standards and analyzed exactly like the samples. Check standard results are used to estimate analytical precision and to indicate the presence of bias due to the calibration of the analytical system.

Collocated samples—Two or more portions collected at the same point in time and space, so as to be considered identical. These samples are also known as "*field replicates*" and should be identified as such.

Comparability—A measure of the confidence with which one data set or method can be compared to another.

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.

Computer program—A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution. A computer program may be stored on magnetic media and referred to as "software," or it may be stored permanently on computer chips, referred to as "firmware." Computer programs covered in a Quality Assurance Project Plan (QAPP) are those used for design analysis, data acquisition, data reduction, data storage (databases), operation or control, and database or document control registers when used as the controlled source of quality information.

Conditioning environment—A specific range of temperature and relative humidity values in which unexposed and exposed filters are to be conditioned for at least 24 hours immediately preceding their gravimetric analysis.

Confidence interval—The numerical interval constructed around a point estimate of a population parameter, combined with a probability statement (the confidence coefficient) linking it to the population's true parameter value. If the same confidence interval construction technique and assumptions are used to calculate future intervals, then they will include the unknown population parameter with the same specified probability.

Confidentiality procedure—A procedure that is used to protect confidential business information (including proprietary data and personnel records) from unauthorized access.

Configuration—The functional, physical, and procedural characteristics of an item, experiment, or document.

Conformance—An affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting the requirements.

Consensus standard—A standard established by a group representing a cross section of a particular industry or trade, or a part thereof.

Contract Officer's Representative (COR)—The EPA Contract Officer designates this person as the responsible party for managing the work. Depending on the contract, the COR could be the Delivery Order Project Officer (DOPO), the Task Order Project Officer (TOPO), or the Work Assignment Manager (WAM).

Contractor—Any organization or individual contracting to furnish services or items or to perform work.

Control chart—A graphical presentation of quality control (QC) information over a period of time. If a procedure is "in control," the results usually fall within established control limits. The chart is useful in detecting defective performance and abnormal trends or cycles, which can then be corrected promptly.

Corrective action—Any measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

Correlation coefficient—A number between −1 and 1 that indicates the degree of linearity between two variables or sets of numbers. The closer to −1 or +1, the stronger the linear relationship between the two (i.e., the better the correlation). Values close to zero suggest no correlation between the two variables. The most common correlation coefficient is the product–moment, which is a measure of the degree of linear relationship between two variables.

Data of known quality—Data that have the qualitative and quantitative components associated with their derivation documented appropriately for their intended use; documentation is verifiable and defensible.

Data Quality Assessment (DQA)—The scientific and statistical evaluation of data to determine if data obtained from environmental operations are of the right type, quality, and quantity to support their intended use. The five steps of the DQA process include: 1) reviewing the Data Quality Objectives (DQOs) and sampling design, 2) conducting a preliminary data review, 3) selecting the statistical test, 4) verifying the assumptions of the statistical test, and 5) drawing conclusions from the data.

Data Quality Indicators (DQIs)—The quantitative statistics and qualitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are bias, precision, and accuracy (bias is preferred); comparability; completeness; and representativeness.

Data Quality Objectives (DQO) Process—A systematic planning tool to facilitate the planning of environmental data collection activities. DQOs are the qualitative and quantitative outputs from the DQO process.

Data Quality Objectives (DQOs)—The qualitative and quantitative statements derived from the DQO process that clarify a study's technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data reduction—The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors and collating them into a more useful form. Data reduction is irreversible and generally results in a reduced data set and an associated loss of detail.

Data usability—The process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Deficiency—An unauthorized deviation from acceptable procedures or practices or a defect in an item.

Demonstrated capability—The capability to meet a procurement's technical and quality specifications through evidence presented by the supplier to substantiate its claims and in a manner defined by the customer.

Design change—Any revision or alteration of the technical requirements defined by approved and issued design output documents and by approved and issued changes thereto.

Design review—A documented evaluation by a team, including personnel such as the responsible designers, the client for whom the work or product is being designed, and a quality assurance (QA) representative, but excluding the original designers, to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Design—The design refers to specifications, drawings, design criteria, and performance requirements, as well as the result of deliberate planning, analysis, mathematical manipulations, and design processes.

Detection limit (DL)—A measure of the capability of an analytical method to distinguish samples that do not contain a specific analyte from samples that contain low concentrations of the analyte; the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated level of probability. DLs are analyte and matrix specific and may be laboratory dependent.

Distribution—This term refers to 1) the appointment of an environmental contaminant at a point over time, over an area, or within a volume; and 2) a probability function (density function, mass function, or distribution function) used to describe a set of observations (statistical sample) or a population from which the observations are generated.

Document control—The policies and procedures used by an organization to ensure that its documents and their revisions are proposed, reviewed, approved for release, inventoried, distributed, archived, stored, and retrieved in accordance with the organization's requirements.

Document—Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Dry-bulb temperature—The actual temperature of the air, which is used for comparison with the wet-bulb temperature.

Duplicate samples—Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method, including sampling and analysis (see also *collocated samples*).

Electrostatic charge buildup—A buildup of static electrical charge on an item, such as the $PM_{2.5}$ filter, which makes it difficult to handle, attracts or repels particles, and can influence its proper weighing.

Environmental conditions—The description of a physical medium (e.g., air, water, soil, sediment) or a biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

Environmental data operations—Any work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental data—Any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes, conditions, and effects of pollutants on human health and the environment, including results from laboratory analyses or from experimental systems representing such processes and conditions.

Environmental monitoring—The process of measuring or collecting environmental data.

Environmental processes—Any manufactured or natural processes that produce discharges to, or that impact, the ambient environment.

Environmental programs—An all-inclusive term that pertains to any work or activities involving the environment, including but not limited to, the characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

Environmental technology—An all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be used to remove pollutants or contaminants from, or to prevent them from entering, the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it can also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Equilibration chamber—A clean chamber that is usually constructed of plastic or glass, held at near constant temperature and relative humidity, and is used to store and condition $PM_{2.5}$ filters until they and their collected particulate sample (if the filters have been exposed) have reached a steady state of moisture equilibration.

Estimate—A characteristic from the sample from which inferences on parameters can be made.

Evidentiary records—Any records identified as part of litigation and subject to restricted access, custody, use, and disposal.

Expedited change—An abbreviated method of revising a document at the work location where the document is used when the normal change process would cause unnecessary or intolerable delay in the work.

Field (matrix) spike—A sample prepared at the sampling point (i.e., in the field) by adding a known mass of the target analyte to a specified amount of the sample. Field matrix spikes are used, for example, to determine the effect of the sample preservation, shipment, storage, and preparation on analyte recovery efficiency (the analytical bias).

Field blank filter—New, randomly selected filters that are weighed at the same time that presampling weights are determined for a set of $PM_{2.5}$ filters and used for QA purposes. These field blank filters are

transported to the sampling site in the same manner as the filter(s) intended for sampling, installed in the sampler, removed from the sampler without sampling, stored in their protective containers inside the sampler's case at the sampling site until the corresponding exposed filter(s) is (are) retrieved, and returned for postsampling weighing in the laboratory, where they are handled in the same way as an actual sample filter and reweighed as a QC check to detect weight changes due to filter handling.

Field blank—A blank that provides information about contaminants that may be introduced during sample collection, storage, and transport. A clean sample is carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample.

Field split samples—Two or more representative portions taken from the same sample and submitted for analysis to different laboratories to estimate inter-laboratory precision.

File plan—A file plan lists the records in your office, and describes how they are organized and maintained. For more information about EPA's File Plan Guide, see http://www.epa.gov/records/tools/toolkits/filecode (see also *records schedule*).
Filter chamber assembly—As shown in Figures 5.6 and 5.7 in this Performance Evaluation Program (PEP) Field Standard Operating Procedure (SOP), this is referencing the mechanism in the interior of the BGI main unit. This assembly contains the WINS impactor assembly in the upper half and the filter cassette or holder assembly in the lower half.

Financial assistance—The process by which funds are provided by one organization (usually governmental) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and governmental interagency agreements.

Finding—An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative, and is normally accompanied by specific examples of the observed condition.

Goodness-of-fit test—The application of the chi square distribution in comparing the frequency distribution of a statistic observed in a sample with the expected frequency distribution based on some theoretical model.

Graded approach—The process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results (see also *Data Quality Objectives (DQO) Process*).

Grade—The category or rank given to entities having the same functional use but different requirements for quality.

Guidance—A suggested practice that is not mandatory; it is intended to be an aid or example in complying with a standard or requirement.

Guideline—A suggested practice that is not mandatory in programs intended to comply with a standard.

Hazardous waste—Any waste material that satisfies the definition of hazardous waste given in 40 CFR 261, *Identification and Listing of Hazardous Waste*.

High-efficiency particulate air (HEPA) filter—A HEPA filter is an extended-media, dry-type filter with a minimum collection efficiency of 99.97% when tested with an aerosol of essentially monodisperse 0.3-μm particles.

Holding time—The period of time a sample may be stored prior to its required analysis. Although exceeding the holding time does not necessarily negate the veracity of analytical results, it causes the qualifying or "flagging" of any data not meeting all of the specified acceptance criteria.

Hygrothermograph—An instrument that results from the combination of a thermograph and a hygrograph and furnishing, on the same chart, simultaneous time recording of ambient temperature and relative humidity.

Identification error—The misidentification of an analyte. In this error type, the contaminant of concern is unidentified and the measured concentration is incorrectly assigned to another contaminant.

Independent assessment—An assessment that is performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

Inspection—The examination or measurement of an item or activity to verify conformance to specific requirements.

Internal standard—A standard added to a test portion of a sample in a known amount and carried through the entire determination procedure as a reference for calibrating and controlling the precision and bias of the applied analytical method.

Item—An all-inclusive term that is used in place of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

Laboratory analyst—The generic term used to describe the Environmental Sampling and Assistance Team (ESAT) contractor(s) responsible for the activities described in the PEP SOPs.

Laboratory blank filters—New filters that are weighed at the time of determination of the presampling (tare) weight of each set of $PM_{2.5}$ filters intended for field use. These laboratory blank filters remain in the laboratory in protective containers during the field sampling and are reweighed in each weighing session as a QC check.

Laboratory split samples—Two or more representative portions taken from the same sample and analyzed by different laboratories to estimate the inter-laboratory precision or variability and the data comparability.

Limit of quantitation—The minimum concentration of an analyte or category of analytes in a specific matrix that can be identified and quantified above the method detection limit and within specified limits of precision and bias during routine analytical operating conditions.

Local Standard Time—The time used in the geographic location of the sample site that is set to standard time. Standard time is used in the Federal Reference Method (FRM) program to match continuous

instruments to filter-based instruments. During the winter months, all areas of the country use standard time; however, in the summer months, some areas may go to Daylight Saving Time (1 hour ahead of standard time).

Management system—A structured, nontechnical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management Systems Review (MSR)—The qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

Management—Those individuals who are directly responsible and accountable for planning, implementing, and assessing work.

Mass reference standard—The NIST-traceable weighing standards, generally in the range of weights expected for the filters.

Matrix spike—A sample that is prepared by adding a known mass of a target analyte to a specified amount of matrix sample for which an independent estimate of the target analyte concentration is available. Spiked samples are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

May—When used in a sentence, this term denotes permission but not a necessity.

Mean (arithmetic)—The sum of all the values of a set of measurements divided by the number of values in the set; a measure of central tendency.

Mean squared error—A statistical term for variance added to the square of the bias.

Measurement and Testing Equipment (M&TE)—Tools, gauges, instruments, sampling devices, or systems used to calibrate, measure, test, or inspect to control or acquire data to verify conformance to specified requirements.

Memory effects error—The effect that a relatively high concentration sample has on the measurement of a lower concentration sample of the same analyte when the higher concentration sample precedes the lower concentration sample in the same analytical instrument.

Method blank—A blank that is prepared to represent the sample matrix as closely as possible and analyzed exactly like the calibration standards, samples, and QC samples. Results of method blanks provide an estimate of the within-batch variability of the blank response and an indication of bias introduced by the analytical procedure.

Method—A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

Microbalance—A type of analytical balance that can weigh to the nearest 0.001 μg (i.e., one microgram, or one-millionth of a gram).

Mid-range check—A standard used to establish whether the middle of a measurement method's calibrated range is still within specifications.

Mixed waste—A hazardous waste material as defined by 40 CFR 261 and the Resource Conservation and Recovery Act (RCRA) and mixed with radioactive waste subject to the requirements of the Atomic Energy Act.

Must—When used in a sentence, this term denotes a requirement that has to be met.

Nonconformance—A deficiency in a characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

Objective evidence—Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Observation—An assessment conclusion that identifies a condition (either positive or negative) that does not represent a significant impact on an item or activity. An observation may identify a condition that has not yet caused a degradation of quality.

Organization structure—The responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions.

Organization—A company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

Outlier—An extreme observation that is shown to have a low probability of belonging to a specified data population.

Parameter—A quantity, usually unknown, such as a mean or a standard deviation characterizing a population. Commonly misused for "*variable*," "*characteristic*," or "*property*."

Peer review—A documented, critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. Conducted by qualified individuals (or an organization) who are independent of those who performed the work but collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. Peer reviews are conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. An in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation (PE)—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 an analyst or laboratory.

$PM_{2.5}$—Particulate matter (suspended in the atmosphere) having an aerodynamic diameter less than or equal to a nominal 2.5 μm, as measured by a reference method based on 40 CFR Part 50, Appendix L, and designated in accordance with 40 CFR Part 53.

$PM_{2.5}$ sampler—A sampler that is used for monitoring $PM_{2.5}$ in the atmosphere that collects a sample of particulate matter from the air based on principles of inertial separation and filtration. The sampler also maintains a constant sample flow rate and may record the actual flow rate and the total volume sampled. $PM_{2.5}$ mass concentration is calculated as the weight of the filter catch divided by the sampled volume. A sampler cannot calculate $PM_{2.5}$ concentration directly.

POC (Parameter Occurrence Code)—A one-digit identifier used in AIRS/AQS (see both defined in this glossary) to distinguish between multiple monitors at the same site that are measuring the same parameter (e.g., pollutant). For example, if two different samplers both measure $PM_{2.5}$, then one may be assigned a POC of 1 and the other a POC of 2. Note that replacement samplers are typically given the POC of the sampler that they replaced, even if the replacement is of a different model or type.

Pollution prevention—An organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge into the environment.

Polonium-210 (^{210}Po) antistatic strip—A device that contains a small amount of ^{210}Po that emits α particles (He^{2+}) that neutralize the static charge on filters, making them easier to handle and their weights more accurate.

Polytetrafluoroethylene (PTFE)—Also known as Teflon, this is a polymer that is used to manufacture the 46.2-mm diameter filters for $PM_{2.5}$ FRM and Federal Equivalent Method (FEM) samplers.

Population—The totality of items or units of material under consideration or study.

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

Procedure—A specified way to perform an activity.

Process—A set of interrelated resources and activities that transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Project—An organized set of activities within a program.

Qualified data—Any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Qualified services—An indication that suppliers providing services have been evaluated and determined to meet the technical and quality requirements of the client as provided by approved procurement documents and demonstrated by the supplier to the client's satisfaction.

Quality Assurance (QA) Supervisor or Coordinator—A staff member who assists in preparation of the reporting organization's quality plan, makes recommendations to management on quality issues (including training), oversees the quality system's control and audit components, and reports the results.

Quality assurance (QA)—An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Assurance Program Description/Plan—See *Quality Management Plan*.

Quality Assurance Project Plan (QAPP)—A formal document that describes in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QAPP components are divided into the following four classes: 1) Project Management, 2) Measurement/Data Acquisition, 3) Assessment/Oversight, and 4) Data Validation and Usability. Guidance and requirements on preparation of QAPPs can be found in *EPA, Requirements for Quality Assurance Project Plans, EPA QA/R-5* and *Guidance for Quality Assurance Project Plans, EPA QA/G-5*.

Quality control (QC) sample—An uncontaminated sample matrix that is spiked with known amounts of analytes from a source independent of the calibration standards. This type of sample is generally used to establish intra-laboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system.

Quality control (QC)—The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality. The system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring the results are of acceptable quality.

Quality improvement—A management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality Management Plan (QMP)—A formal document that describes the quality system in terms of the organization's structure, the functional responsibilities of management and staff, the lines of authority, and the required interfaces for those planning, implementing, and assessing all activities conducted.

Quality management—That aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality system—A structured and documented management system that describes the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

Quality—The totality of features and characteristics of a product or service that bears on its ability to meet the stated or implied needs and expectations of the user.

Radioactive waste—This refers to waste material that contains or is contaminated by radionuclides and is subject to the requirements of the Atomic Energy Act.

Readability—The smallest difference between two measured values that can be read on the microbalance display. The term "*resolution*" is a commonly used synonym.

Readiness review—A systematic, documented review of the readiness for the startup or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Record (quality)—A document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

Records schedule—This schedule constitutes EPA's official policy on how long to keep Agency records (retention) and what to do with them afterwards (disposition). For more information, refer to http://www.epa.gov/records/policy/schedule on EPA's Web site or see *file plan*.

Recovery—The act of determining whether the methodology measures all of the analyte contained in a sample.

Remediation—The process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

Repeatability—This refers to a measure of the ability of a microbalance to display the same result in repetitive weighings of the same mass under the same measurement conditions. The term "*precision*" is sometimes used as a synonym. Repeatability also refers to the degree of agreement between independent test results produced by the same analyst, using the same test method and equipment on random aliquots of the same sample within a short time period.

Reporting limit—The lowest concentration or amount of the target analyte required to be reported from a data collection project. Reporting limits are generally greater than detection limits and are usually not associated with a probability level.

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

Reproducibility—The precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

Requirement—A formal statement of a need and the expected manner in which it is to be met.

Research (applied)—A process, the objective of which is to gain the knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

Research (basic)—A process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

Research development/demonstration—The systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

Round-robin study—A method validation study involving a predetermined number of laboratories or analysts, all analyzing the same sample(s) by the same method. In a round-robin study, all results are compared and used to develop summary statistics such as inter-laboratory precision and method bias or recovery efficiency.

Ruggedness study—The carefully ordered testing of an analytical method while making slight variations in test conditions (as might be expected in routine use) to determine how such variations affect test results. If a variation affects the results significantly, the method restrictions are tightened to minimize this variability.

Scientific method—The principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

Self-assessment—The assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Sensitivity—The capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest.

Service—The result generated by activities at the interface between the supplier and the customer, and the supplier internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and/or field analysis, repair, and installation.

Shall—A term that denotes a requirement is mandatory whenever the criterion for conformance with the specification permits no deviation. This term does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

Should—A term that denotes a guideline or recommendation whenever noncompliance with the specification is permissible.

Significant condition—Any state, status, incident, or situation of an environmental process or condition, or environmental technology in which the work being performed will be adversely affected sufficiently to require corrective action to satisfy quality objectives or specifications and safety requirements.

Software life cycle—The period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirement phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

Source reduction—Any practice that reduces the quantity of hazardous substances, contaminants, or pollutants.

Span check—A standard used to establish that a measurement method is not deviating from its calibrated range.

Specification—A document that states requirements and refers to or includes drawings or other relevant documents. Specifications should indicate the means and criteria for determining conformance.

Spike—A substance that is added to an environmental sample to increase the concentration of target analytes by known amounts. Spikes are used to assess measurement accuracy (spike recovery), whereas spike duplicates are used to assess measurement precision.

Split samples—Two or more representative portions taken from one sample in the field or in the laboratory and analyzed by different analysts or laboratories. Split samples are QC samples that are used to assess analytical variability and comparability.

Standard deviation—A measure of the dispersion or imprecision of a sample or population distribution expressed as the positive square root of the variance and having the same unit of measurement as the mean.

Standard Operating Procedure (SOP)—A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps and that is officially approved as the method for performing certain routine or repetitive tasks.

Supplier—Any individual or organization furnishing items or services or performing work according to a procurement document or a financial assistance agreement. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surrogate spike or analyte—A pure substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them to establish that the analytical method has been performed properly.

Surveillance (quality)—Continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

Technical review—A documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements have been satisfied.

Technical Systems Audit (TSA)—A thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of a system.

Traceability—This term refers to the ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. This term also refers to the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties. Many QA programs demand traceability of standards to a national standard. In most cases this can be achieved through a standard traceable to NIST.

Trip blank—A clean sample of a matrix that is taken to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures.

Validation—Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. In design and development, validation refers to the process of examining a product or result to determine conformance to user needs.

Variance (statistical)—A measure or dispersion of a sample or population distribution. Population variance is the sum of squares of deviation from the mean divided by the population size (number of elements). Sample variance is the sum of squares of deviations from the mean divided by the degrees of freedom (number of observations minus one).

Verification—Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification refers to the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

Wet-bulb temperature—The temperature of the wet-bulb thermometer at equilibrium with a constant flow of ambient air at a rate of from 2.5 meters to 10.0 meters per second.

Wet-bulb thermometer—A thermometer with a muslin-covered bulb, which is moistened and used to measure the wet-bulb temperature.

Appendix B

Documents to Support Data Quality Objectives

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Review of the Potential to Reduce or Provide a More Cost Efficient Means to Implement the $PM_{2.5}$ Performance Evaluation Program

DRAFT

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December 2005

Intent of Paper

During the June 2, 2005 Ambient Air Monitoring Steering Committee Meeting, OAQPS was asked to look at whether the costs associated with the $PM_{2.5}$ Performance Evaluation Program (PEP) could be reduced, either through a reduction in the number of audits or by providing a different implementation scheme that would reduce implementation costs. This paper provides a description of the process OAQPS used to evaluate the question of reducing the number of PEP audits and provides a few options and recommendations for the steering committee to consider.

Background

Unlike the gaseous criteria pollutants, where one can use a standard of known concentration to estimate precision and bias and perform this at every site, the particulate matter pollutants rely on a representative sample of sites for estimates of both precision and bias. Precision is estimated using collocated sampling; bias is estimated using the PEP. Since only a portion of the monitoring sites are represented, the precision and bias estimates are assessed at the reporting organization level. In order to provide an adequate level of confidence in our estimates of precision and bias, an adequate number of collocation and PEP samples must be collected.

The PEP is a quality assurance activity which is used to evaluate measurement system bias of the fine particle ($PM_{2.5}$) monitoring network. The pertinent regulations for this performance evaluation are found in 40 CFR Part 58, Appendix A. The strategy is to collocate a portable FRM $PM_{2.5}$ air sampling instrument with an established primary sampler at a routine air monitoring site, operate both samplers in the same manner, and then compare the results. In the original promulgation, the performance evaluation was required at every site at a frequency of six times per year. EPA believed this would have allowed an adequate assessment of bias at the site level. However, due to criticism of the burden of this requirement, the PEP was revised to its current form of 25 percent of the monitors within each reporting organization network at a frequency of four times per year. The data from the routine monitors and PEP monitors are compared for each reporting organization in order to determine whether the bias estimate for the reporting organization is within the data quality objective of +/- 10%.

Approach

First, the study question was restated:

> "Can the $PM_{2.5}$ PEP audits be reduced without adversely affecting the confidence in the 3-year bias estimate at the reporting organization level?"

Since our data quality objectives are based upon assessments of precision and bias at a 3-year level of aggregation per reporting organization, we need to have enough representative data at this level of aggregation to make a reasonable assessment of bias.

Over the past few years, the QA Strategy Workgroup has been reviewing and revising the Ambient Air Monitoring Program Quality System requirements found in 40 CFR Part 58 Appendix A. The planned revisions have included the statistics used in our estimates of precision and bias and the move towards using confidence limits rather than simple averages over various time periods (quarters/years). One advantage of the new statistics is that it provides monitoring organizations some flexibility in choosing how frequently the quality control checks need to be performed. In the report that was generated to

explain the new statistics[1] a matrix table was developed to demonstrate how one could determine how many QC samples, such as the biweekly one-point QC check, were needed to ensure that the DQO would be met. The following is an excerpt from this document.

> *For ozone and other gases, the proposed precision and bias estimates are both made from the biweekly checks. Table 1 shows how many of those checks are needed to confidently (90%) establish that both the precision and bias are less than 10%. In this way, one knows that both the precision and the bias are controlled to at most 10%, provided the sample size is at least the number shown in Table 1. For Table 1, one-sided 90% confidence limits about the precision estimate were assumed. This statistic matches the current use for the $PM_{2.5}$ precision estimates in CFR.*

Table 1. Conservative Number of Precision and Bias Checks Needed to Yield Both an Absolute Bias Upper Bound of at Most 10% and an Upper bound of at most 10% for the Precision.

Minimum sample size		Precision Point Estimate				
		5%	6%	7%	8%	9%
Bias Pt. Est.	5%	8	8	12	24	87
	6%	12	12	12	24	87
	7%	20	20	20	24	87
	8%	43	43	43	43	87
	9%	166	166	166	166	166

This sample size matrix approach was used to answer our study question. This was accomplished by:

1. **Developing a matrix table with precision and bias ranges of 15% and 9.5%, respectively.** Since the DQO for bias (provided by the PEP) is +/-10%, the bias side of the matrix table could not exceed 10% since it is impossible to determine how many samples are needed to control a bias estimate to 10% if the current estimate is over 10%. Table 2 represents the matrix table that was used for this evaluation.

2. **Data aggregation/data reduction-** Precision and bias data from the calendar years 2002-2004 were used to provide appropriate reporting organization estimates. Any precision and bias data were excluded if their concentrations were < 3 ug/m^3. In addition, bias outliers for each reporting organization were identified using a univariate outlier test and removed prior to data evaluation.

3. **Providing 3-year precision and bias estimates at the reporting organization level.** Statistics used in the precision and bias estimates are provided in Appendix A.

4. **Determination of number of PEP pairs necessary for assessment purposes.** The matrix table was used to identify the required number of PEP visits over a 3-year period needed to obtain 90% confidence that the bias DQO of +/-10% is being met.

Table 2. PEP Sample Size Requirements Based on Reporting Organization

[1] Proposal: A New Method for Estimating Precision and Bias for Gaseous Automated Methods for the Ambient Air Monitoring Program

Precision and Bias Estimates

		BIAS															
		2	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**	**5.5**	**6**	**6.5**	**7**	**7.5**	**8**	**8.5**	**9**	**9.5**
	1													3	3	4	9
	1.5											3	3	3	4	6	17
	2									3	3	3	3	4	5	9	28
P	**2.5**							3	3	3	3	3	4	5	7	12	43
R	**3**				3	3	3	3	3	3	3	4	4	6	9	17	61
E	**3.5**		3	3	3	3	3	3	3	3	4	4	5	7	11	22	82
C	**4**	3	3	3	3	3	3	3	3	4	4	5	6	9	14	28	107
I	**4.5**	3	3	3	3	3	3	3	4	4	5	6	7	10	17	35	135
S	**5**	3	3	3	3	3	3	4	4	5	5	7	9	12	20	43	166
I	**5.5**	3	3	3	3	3	4	4	5	5	6	7	10	14	24	52	201
O	**6**	3	3	3	4	4	4	4	5	6	7	9	11	17	28	61	238
N	**6.5**	3	3	4	4	4	4	5	5	6	8	10	13	19	33	71	279
	7	3	4	4	4	4	5	5	6	7	9	11	15	22	38	82	324
C	**7.5**	4	4	4	4	5	5	6	7	8	9	12	17	25	43	94	371
V	**8**	4	4	4	5	5	5	6	7	9	10	14	19	28	49	107	422
	8.5	4	4	4	5	5	6	7	8	9	12	15	21	32	55	120	476
U	**9**	4	4	5	5	6	6	7	9	10	13	17	23	35	61	135	534
P	**9.5**	4	5	5	6	6	7	8	9	11	14	18	26	39	68	150	595
P	**10**	5	5	5	6	7	7	9	10	12	15	20	28	43	75	166	659
E	**10.5**	5	5	6	6	7	8	9	11	13	17	22	31	47	82	183	726
R	**11**	5	6	6	7	7	9	10	12	14	18	24	34	52	90	201	797
	11.5	5	6	6	7	8	9	11	13	15	20	26	37	56	98	219	871
B	**12**	6	6	7	8	9	10	11	14	17	21	28	40	61	107	238	948
O	**12.5**	6	7	7	8	9	10	12	15	18	23	30	43	66	116	258	1028
U	**13**	6	7	8	9	10	11	13	16	19	25	33	46	71	125	279	1112
N	**13.5**	7	7	8	9	10	12	14	17	21	26	35	50	77	135	301	1199
D	**14**	7	8	9	10	11	13	15	18	22	28	38	53	82	145	324	1289
	14.5	7	8	9	10	11	13	16	19	23	30	40	57	88	155	347	1383
	15	8	9	9	11	12	14	17	20	25	32	43	61	94	166	371	1480

Statistical Background

Generation of Matrix Table

For the purpose of calculating optimal sample sizes, a sample size matrix was iteratively generated to yield a statistically calculated sample size given a specific precision and bias scenario. The matrix indicates the smallest sample size needed to assure that the upper confidence limit on bias will be below 10% given the current estimate of precision and bias for a reporting organization.

The sample size matrix is generated using an algorithm in SAS and creates various potential precision and bias scenarios. The precision and bias scenarios begin at a minimum of 1% and 2%, respectively, and increase to values of 15% and 9.5%. Possible sample sizes range from 3 to 1480. The algorithm used to create the matrix iteratively increases the sample size by one through each loop and calculates upper confidence limits for the current sample size and one sample size smaller for a specific precision and bias scenario. For each precision and bias scenario, the sample size begins at 3 and is increased by one until the 90% upper confidence limit calculated by sample size 'n' is below 10% and the 90% upper confidence limit calculated by a sample size 'n-1' is above 10%. This assures that the matrix sample size 'n' is the smallest sample size that can be used where the 90% upper confidence limit is still below 10%.

Given a specific reporting organization precision and bias estimate, one can use this matrix as a guide to approximate sample size, **assuming that the bias estimate is already less than 10%.** As the reporting organization precision and bias estimates get closer to 15% or 10% respectively, more samples are required to ensure that 90% of the time the bias estimate is below 10%. When the bias estimate is greater than 10%, the sample matrix cannot be used since the initial estimate is already above 10%.

The matrix is generated using the following equations:

The 90% upper confidence limit on the bias for sample size 'n' is calculated by Equation 1a:

$$bias\_1_{UCL} = m + t_{0.90,(n-1)} \cdot \frac{s_d}{\sqrt{n}} \qquad \textbf{Equation 1a}$$

The 90% upper confidence limit on the bias for sample size 'n-1' is calculated by Equation 1b:

$$bias\_2_{UCL} = m + t_{0.90,(n-2)} \cdot \frac{s_d}{\sqrt{(n-1)}} \qquad \textbf{Equation 1b}$$

Both Equation 1a and 1b use a standard deviation of the percent differences, d_i, calculated in Equation 2 below:

$$s_d = \sqrt{\frac{n \cdot \sum_{i=1}^{n} d_i^{\,2} - \left(\sum_{i=1}^{n} d_i\right)^2}{(n-1) \cdot n}} \qquad \textbf{Equation 2}$$

where the percent difference (or individual bias), d_i, is described in Equation 5 in Appendix A

When $bias\_1_{UCL}$ is under 10% and $bias\_2_{UCL}$ is above 10%, one can be 90% confident that the bias value that is under 10% is at most 10% when using a sample size of n.

Precision and Bias Estimates

The precision value that feeds into the sample size matrix above is based on the proposed precision upper bound statistic, while the bias value is based on the mean absolute value of the individual bias estimates. The relevant precision and bias equations can be found in Appendix A of this document. For this study, precision and bias sample pairs are considered valid when both paired value concentrations are greater than 3ug/m^3. In addition, a univariate outlier test was run on the individual bias estimates for each reporting organization. Outliers were located and filtered out if data points were a certain distance away from the interquartile range (bulk of the data). Any outlier identified from the test was excluded from the reporting organization bias estimate. Table 3 identifies the frequency of excluded outliers within a reporting organization.

Data Evaluation

Table 3 provides the estimates of precision and bias for the CY 2002-2004 $PM_{2.5}$ data. Definitions for the columns are provided below:

k	Variable	Comment
1	Rep Org	Reporting Organization
2	State	State
3	Sites 02-04	Number of SLAMS sites active in 2002-2004
4	Req PEP Checks	Required PEP checks in a 3 year period (25% of sites*4/year*3 years)
5	PEP Checks	Valid PEP audits performed in the 3 year period
6	Outlier	Number of individual bias estimates (percent difference >$\pm$50) that were removed from the dataset at a reporting organization level.
7	Prec Checks	Number of collocated precision checks in the 3-year period
8	Mean Abs Bias	Mean absolute bias
9	CV_ub	Precision coefficient of variation 90% upper confidence bound.
10	Matrix	Number of PEP audits required based on the sampling matrix
11	Diff	Difference between the matrix value and the PEP requirement (Matrix - REQ PEP Check=Diff)
12	Matrix >	A value of 1 signifying when matrix value was greater than the required PEP number
13	Matrix <	A value of 1 signifying when matrix value was less than the required PEP number

Since we are using confidence limits, we made a decision not to evaluate any reporting organization that did not have at least 7 valid PEP/routine pairs after outliers and values < 3 ug/m^3 were removed. The 23 unevaluated reporting organizations are highlighted in green in Table 3. Additionally, there were 2 reporting organizations (see Table 3) with > 7 PEP/routine pairs that did not report precision data to AQS and therefore could not be used in the evaluation.

For each reporting organization, the CV_ub and the mean absolute bias values were used in the matrix table to determine the number of PEP audits needed to ensure, with 90% confidence, the DQO will be met. Example:

> For the first site with 7 valid PEP/routine pairs in Table 3 (Rep. Org. 0012), the intersection of the bias value of 3.09% and the precision value of 4.08% on the matrix yields a value of 3 audit pairs to ensure that 90% of the time the bias estimate of 3.09 % will be less than 10%. For reporting organizations that had either the precision or bias estimates beyond the matrix table, the extreme value for that row or column was used.

For example, if the reporting organization had a bias estimate of 6.5% and a precision estimate of 16%, the matrix estimate for that reporting organization would be 32 samples which relates to the intersection of 6.5 (bias) and 15 (precision).

The "Diff" column in Table 3 provides the difference based on the subtraction of the number of required PEP checks from the matrix estimate for each reporting organization. A positive value indicates where the matrix has required more PEP audits than the current requirement (a value of "1" is placed in the "Matrix >" column); a negative value indicates that the matrix required less PEP audits than the current requirement (a value of "1" is placed in the "Matrix <" column). In the case described above (Rep. Org. 0012), the matrix required 6 fewer samples then the current PEP requirement. The next two columns ("Matrix >" and "Matrix <") are used to summarize the number of sites where more or less audits than the current required PEP checks are needed.

Upon evaluation of the data, a number of observations can be made:

- For reporting organizations with greater than 7 valid PEP/routine pairs and reported both precision and bias values, 32 needed more audits than the current PEP requirement, 50 required fewer and 2 sites had the same number of audits for the matrix and PEP requirement. If we went strictly by what the matrix required, in total, many more audits would be required then are currently implemented.
- We noticed that at around 20 PEP audits, there was a tendency for the matrix to require less audits then the PEP requirement. For reporting organizations with > 20 PEP audits, 11 reporting organizations needed more audits and 31 required fewer audits than the PEP requirement. This observation may infer that around 20 valid audits may be appropriate to provide bias 3-year estimates with satisfactory confidence.

Next Step—Finding an Appropriate and Consistent Sample Size

Our evaluation of the sample size matrix (Table 2) information suggested that selecting a consistent sample size for reporting organizations could ensure more statistically sound bias assessments while reducing program costs. In answering the study question, two objectives remained critical: 1) that the sample size is adequate to provide an appropriate level of confidence in the bias estimate, and 2) ensuring the bias estimate is representative of the reporting organization.

In order to select an appropriate sample size, we evaluated the 2002-2004 $PM_{2.5}$ data base used to generate Table 3. To get an idea of the national bias average, averaging the mean absolute value of the bias estimates from the filtered data for each reporting organization provided us with a national average bias of ~7.6%. Since individual reporting organizations bias estimates values can change quarterly and yearly, and our DQOs are based on national estimates, we felt using this national estimate was justified. We then posed the question:

- How many samples would it take to ensure that 90% of the time, a bias estimate 7.6% would not be >10%?

In order to answer this question we needed to have a variability parameter to feed into the confidence limit width equation that varies by reporting organization. Since we had much more collocated precision data at our disposal, we used this data to generate our confidence limits with the assumption that the uncertainty between collocated routine samplers is indicative of the uncertainty between the two samplers used to assess bias (PEP/routine sampler). The widths of confidence limits were calculated for each bias value using this assumption and are shown in Table 4 in the column labeled "CLimit". We generated 90% confidence limit CLimits by varying samples sizes until we came to the sample size number where the

national average CLimit was 2.4 or less. This sample size would ensure that 90% of the time, the national bias estimate of 7.6% would not be >10%. A sample size of 24 samples produced the appropriate CLimit. Considering a reporting organization with 24 samples and a national mean bias value of ~7.60 %, we can be sure that this bias value in reality lies somewhere between 5.2% and 10%. 24 samples equate to 8 PEP audits each year per reporting organization over the 3-year period. However, in order to allow for incomplete data, we propose 9 PEP audits a year or 27 over a three year period. The sample size of 27 would be allocated across the sites in the reporting organization in a manner that takes into account the logistical costs of implementation but must also be accomplished in a manner that provides for adequate spatial and temporal representation of the reporting organization. This paper does not address this issue but believes that 27 audits could be implemented in a manner that would achieve the representativeness objective.

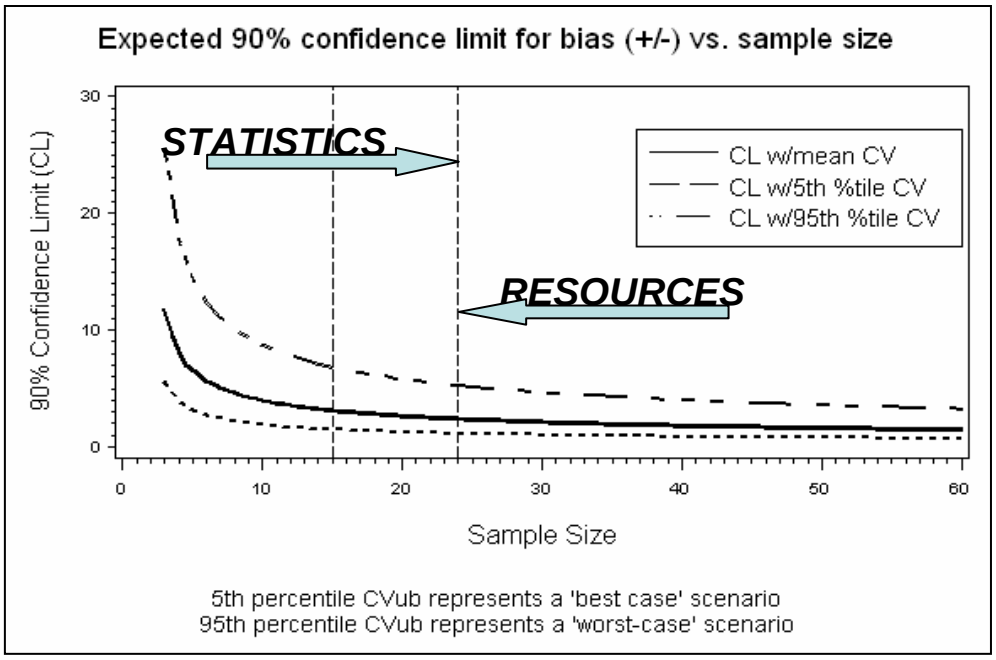

Figure 1. $PM_{2.5}$ Bias uncertainty based on sample size.

Figure 1 provides a representation of the confidence one might have in the bias estimates based on sample size. The three lines graphed in the figure use the CLimits generated in Table 3. The upper line represents a worse case scenario (estimate from the 95th percentile) CLimit of the reporting organization data. The middle line is based on the mean CLimit (which was used in the evaluation above), and the lower line presents the best case scenario (the 5th percentile of the data). Using the national mean bias estimate (7.6%), the intersection of 24 samples (PEP audits) would yield a confidence limit of $\pm$ 2.4%. The idea behind the graph is to find an area away from the inflection point which yields reasonable and acceptable confidence while not wasting resources by taking more samples with little return as far as improving the confidence of the bias estimate. We feel that 24 PEP audits per reporting organization provide a good balance between data adequacy and cost efficiency.

Last Step—A Sample Size for Smaller Monitoring Organizations

The proposed 27 audit sample approach provides an adequate compromise for representativeness and sample frequency. When a reporting organization only has a few monitoring sites, providing a representative estimate of bias it not as significant. Taking this to the extreme, a reporting organization with 1 site would have to take 24 valid samples at that site over a three year period. We propose that monitoring organizations with fewer than 5 sites perform a minimum of 15 audits. In order to account for incompleteness, as described in the 24 audit scenario, we propose planning for 18 audits. Plotting a sample size of 15 on Figure 1 puts us close to the inflection of the middle curve but is considered a

reasonable risk for smaller reporting organizations in lieu of more complete sampling representation at each site.

Allowing for one data loss event each year while requiring one more audit than actually needed allows reporting organizations to have one audit credit per year in case it is needed in the future. This audit credit acts as a "spare" to be used to compensate for unexpected data loss events without increasing the resources already allocated to each reporting organization. Using this "18/27"approach we can reduce the PEP from the current required audits of 3237 (over 3 years) to about 2466. This relates to a 24% audit reduction (~ 250) a year and which equate to a cost savings of between 400-450K (accounting for some static infrastructure costs).

Conclusions

$PM_{2.5}$ precision and bias are estimated at the reporting organization level. The data evaluation suggests that we could provide better estimates of reporting organization bias with a more consistent distribution of auditing across reporting organizations. The data evaluation revealed an anticipated pattern: large reporting organizations can reduce their sampling and small reporting organizations need to sample more.

Our discussions of the proposed PEP sampling reformation yielded the issue of discrepant representativeness within a reporting organization. To perform a successful assessment, one must be confident that the data collected is representative of the target population. By increasing our samples within a small reporting organization, we are improving representativeness within the target population. However, representativeness is compromised for larger reporting organizations when reductions in sampling occur. It is also important to note that these larger reporting organizations also tend to be more heterogeneous across a larger area. An optimized sampling design for large reporting organizations may involve stratification by design value and consideration of important spatial and geographic characteristics. Discussions regarding the most appropriate sampling design for assessing bias across a large reporting organization are in progress.

Recommendations (CY2007)

Revise PEP requirement to the "18/27" audit scheme. This would allow for one extra audit to accommodate historically-documented data incompleteness issues within the PEP and routine monitoring programs. Every 3 years, precision and bias data will be evaluated to determine whether adjustments in the sampling scheme are needed.

Select appropriate sites to represent the reporting organizations. Since we do not use concentrations < 3 ug/m^3, we will only select sites that have a good chance of providing a concentration above this value. Since we have plenty of routine concentration data from all sites within a reporting organization, we can appropriately select the sites that will provide the best opportunity to be representative of the reporting organization.

Consolidation of reporting organizations. Some states would benefit by consolidating their networks into one or fewer reporting organizations. The states of Ohio, Florida, and California may be good candidates for consolidation. Some years ago the term reporting organization started to be used by monitoring organizations to identify the organization responsible for reporting data to AQS and therefore lost its original meaning. The revision in CFR to add the term **primary quality assurance organization** was developed in order to restore its original meaning. This new term uses the old definition and gives the monitoring organizations another opportunity for consolidation which would reduce the PEP audit requirements.

Provide a better implementation scheme to reduce travel costs. OAQPS will look at ways to implement the program more efficiently, taking into account representative needs of a reporting organization from a spatial, temporal, and concentration context. For example, for large reporting organizations the PEP may be able to reduce travel expenses by performing audits at a specific geographic area one year, and then moving to a different geographic area the next. This scheme is beyond the scope of this paper, but could be presented upon further evaluation.

The proposed sampling technique for the PEP program strengthens our assessments of bias while providing for an overall reduction in the audit requirements. By implementing the program as proposed, PEP audits can be reduced without adversely affecting the confidence in the 3-year bias estimate at the reporting organization level. In strengthening our bias assessments, we are strengthening the PEP program and its mission.

Table 3. 2002–2004 $PM_{2.5}$ Reporting Organization Precision and Bias Estimates for Sites with > 7 Valid PEP Audits

Rep_Org	State	Sites 02-04	Req PEP Checks	PEP checks	Outlier	Prec checks	Mean Abs bias	CV_ub	Matrix	Diff	Matrix >	Matrix <
0121	FL	3	9	0	0							
0274	FL	2	6	0	0							
0394	FL	1	3	0	0							
0779	NC	1	3	0	0							
0833	FL	2	6	0	0							
561	MO	4	12	1	0	65	8.33	4.10				
1124	VI	2	6	1	0		22.92					
709	CA	1	3	3	0	75	5.49	18.23				
1224	FL	2	6	3	0	186	9.36	4.87				
170	TN	1	3	4	0	301	6.63	2.96				
300	AL	1	3	4	0	169	7.07	2.69				
391	FL	1	3	4	0	164	10.34	9.34				
393	FL	1	3	4	0	185	10.73	5.07				
549	KY	3	9	4	0	506	3.12	7.16				
581	TN	4	12	4	0	142	2.01	6.26				
809	OH	4	12	4	0	131	2.90	7.11				
951	FL	1	3	4	0	147	19.20	8.23				
1226	FL	1	3	4	0	128	11.55	5.18				
220	OH	3	9	5	1	150	4.02	8.45				
595	OH	1	3	5	1	150	1.77	6.08				
151	OH	2	6	6	0	158	3.38	5.54				
458	CA	2	6	6	1	36	1.78	10.11				
880	OH	2	6	6	0	148	4.49	8.90				
12	OH	3	9	7	1	169	3.09	4.08	3	-6		1
395	FL	2	6	7	0	159	7.54	8.96	23	17	1	
403	NC	3	9	7	0	249	2.27	5.05	3	-6		1
805	OH	5	15	7	1	160	4.20	15.44	12	-3	1	
820	NC	2	6	7	0	142	9.06	5.37	52	46	1	
867	FL	3	9	7	0	186	10.20	5.33	201	192	1	
544	FL	2	6	8	0	136	6.75	4.41	6	0		
550	AL	4	12	8	0	370	4.31	3.98	4	-8		1
682	TN	3	9	8	0	151	6.54	6.86	11	2	1	
874	IA	4	12	8	0	224	6.86	5.54	7	-5		1
986	MO	1	3	8	1	179	7.05	3.96	5	2	1	
491	FL	2	6	9	3	159	6.25	5.53	5	-1		1
0017	NM	2	6	10	0		17.24					
807	OH	2	6	10	0	129	8.13	7.31	25	19	1	
864	AZ	2	6	10	1	142	9.54	17.44	1480	1474	1	
258	IL	9	27	11	0	468	7.61	9.34	26	-1		1
861	PA	5	15	11	1	149	8.67	8.87	61	46	1	
1150	WV	6	18	11	2	327	2.27	2.94	3	-15		1
1188	WY	5	15	11	2	169	8.74	5.05	20	5	1	
0350	DC	3	9	12	1		2.16					
392	FL	3	9	12	1	172	9.26	5.72	52	43	1	
396	FL	6	18	12	0	167	4.31	6.66	4	-14		1
481	HI	6	18	12	0	149	12.91	15.04	1480	1462	1	

Rep_Org	State	Sites 02-04	Req PEP Checks	PEP checks	Outlier	Prec checks	Mean Abs bias	CV_ub	Matrix	Diff	Matrix >	Matrix <
669	NC	3	9	12	0	154	4.00	4.83	3	-6		1
812	OK	5	15	12	0	61	10.64	5.98	238	223	1	
990	MO	3	9	12	0	766	8.52	3.68	11	2	1	
1025	TN	7	21	12	0	451	10.36	6.26	279	258	1	
1138	NV	1	3	12	0	174	6.74	2.20	3	0		
15	AK	7	21	13	2	327	4.68	10.35	8	-13		1
53	AZ	7	21	13	1	250	14.84	18.99	1480	1459	1	
226	NV	6	18	13	0	99	4.35	12.88	11	-7		1
634	OH	3	9	13	1	161	4.16	3.82	3	-6		1
287	OH	5	15	14	1	149	4.69	5.28	4	-11		1
523	IN	7	21	14	0	231	4.60	5.15	4	-17		1
635	ME	6	18	14	0	306	22.47	5.64	201	183	1	
992	MO	3	9	14	0	158	7.31	4.29	7	-2		1
1119	VT	6	18	14	2	311	2.78	4.03	3	-15		1
673	TN	5	15	15	0	144	10.34	7.44	371	356	1	
613	IA	3	9	16	1	221	11.68	4.59	135	126	1	
782	ND	8	24	16	0	81	12.60	5.86	238	214	1	
816	NE	3	9	17	2	257	7.24	12.67	30	21	1	
1151	WV	5	15	18	2	349	4.07	4.44	3	-12		1
730	MT	10	30	19	1	272	7.60	7.95	19	-11		1
1259	OH	11	33	19	0	453	5.84	3.01	3	-30		1
229	OH	9	27	20	2	307	5.15	7.69	6	-21		1
762	NH	12	36	20	1	351	5.21	7.58	6	-30		1
907	RI	8	24	20	1	206	7.58	12.70	43	19	1	
294	DE	7	21	21	0	148	3.91	5.19	3	-18		1
942	CA	11	33	21	1	213	7.54	5.23	9	-24		1
889	PR	15	45	22	0	229	20.33	13.24	1112	1067	1	
251	CT	12	36	24	2	341	7.54	6.81	15	-21		1
973	SD	12	36	24	3	496	24.74	10.12	659	623	1	
752	NE	11	33	25	1	264	10.48	8.52	476	443	1	
1175	WI	25	75	26	3	571	4.44	4.05	3	-72		1
21	PA	8	24	27	2	418	5.51	3.92	3	-21		1
513	IL	28	84	27	0	757	11.14	8.56	476	392	1	
511	ID/WA	12	36	28	2	385	7.15	6.23	9	-27		1
700	MN	25	75	29	3	578	6.52	8.09	10	-65		1
1118	CA	15	45	29	2	457	4.02	6.61	4	-41		1
240	CO	14	42	30	2	392	7.36	9.70	26	-16		1
588	MO	14	42	34	0	796	5.24	3.32	3	-39		1
13	AL	13	39	35	3	476	4.51	4.89	3	-36		1
584	KY	17	51	36	4	568	6.90	6.34	10	-41		1
764	NJ	21	63	41	3	441	8.46	7.12	38	-25		1
971	SC	14	42	42	5	723	4.13	4.11	3	-39		1
972	CA	17	51	42	4	596	4.62	4.51	3	-48		1
1113	UT	17	51	42	2	611	8.40	8.22	49	-2		1
1127	VA	21	63	42	1	929	5.16	7.58	6	-57		1
55	AR	24	72	43	7	462	8.42	2.14	5	-67		1
86	CA	15	45	44	1	240	6.21	4.95	5	-40		1
660	MA	24	72	44	3	995	9.23	14.93	371	299	1	
703	MS	17	51	44	0	483	8.04	7.04	22	-29		1

Rep_Org	State	Sites 02-04	Req PEP Checks	PEP checks	Outlier	Prec checks	Mean Abs bias	CV_ub	Matrix	Diff	Matrix >	Matrix <
1001	LA	25	75	44	3	645	12.39	5.92	238	163	1	
145	CA	30	90	45	2	646	8.85	10.53	183	93	1	
1136	WA	22	66	45	4	603	5.37	4.48	4	-62		1
685	MI	28	84	48	10	678	6.50	6.27	8	-76		1
437	GA	23	69	49	5	444	3.51	4.88	3	-66		1
563	KS	13	39	49	5	616	8.48	8.73	55	16	1	
776	NC	23	69	50	2	815	7.80	8.30	32	-37		1
1080	IA	15	45	54	1	861	9.64	6.55	279	234	1	
1002	MD	20	60	58	5	437	7.62	5.51	10	-50		1
520	IN	34	102	64	7	765	5.38	4.26	4	-98		1
851	PA	25	75	71	6	772	4.03	4.66	3	-72		1
821	OR	32	96	81	2	721	7.62	4.09	6	-90		1
1035	TX	56	168	87	1	1354	7.78	7.97	28	-140		1
768	NY	53	159	99	5	647	9.75	5.62	201	42	1	
Summary		**1079**	**3237**	**2313**	**146**	**35809**	**7.62**	**6.93**	**10969**	**7882**	**32**	**50**

Table 4. 2002–04 $PM_{2.5}$ Summary of Potential Reduction Based on Proposed Equitable Allocation

Rep_Org	State	Sites 02-04	Req PEP Checks	PEP checks	Mean Abs bias	CV_ub	Climit 24 90%
0121	FL	3	9	0			
0274	FL	2	6	0			
0394	FL	1	3	0			
0779	NC	1	3	0			
0833	FL	2	6	0			
561	MO	4	12	1	8.33	4.10	1.43
1124	VI	2	6	1	22.92		
709	CA	1	3	3	5.49	18.23	6.38
1224	FL	2	6	3	9.36	4.87	1.70
170	TN	1	3	4	6.63	2.96	1.04
300	AL	1	3	4	7.07	2.69	0.94
391	FL	1	3	4	10.34	9.34	3.27
393	FL	1	3	4	10.73	5.07	1.77
549	KY	3	9	4	3.12	7.16	2.51
581	TN	4	12	4	2.01	6.26	2.19
809	OH	4	12	4	2.90	7.11	2.49
951	FL	1	3	4	19.20	8.23	2.88
1226	FL	1	3	4	11.55	5.18	1.81
220	OH	3	9	5	4.02	8.45	2.96
595	OH	1	3	5	1.77	6.08	2.13
151	OH	2	6	6	3.38	5.54	1.94
458	CA	2	6	6	1.78	10.11	3.54
880	OH	2	6	6	4.49	8.90	3.11
12	OH	3	9	7	3.09	4.08	1.43
395	FL	2	6	7	7.54	8.96	3.13
403	NC	3	9	7	2.27	5.05	1.77
805	OH	5	15	7	4.20	15.44	5.40
820	NC	2	6	7	9.06	5.37	1.88
867	FL	3	9	7	10.20	5.33	1.87
544	FL	2	6	8	6.75	4.41	1.54
550	AL	4	12	8	4.31	3.98	1.39
682	TN	3	9	8	6.54	6.86	2.40
874	IA	4	12	8	6.86	5.54	1.94
986	MO	1	3	8	7.05	3.96	1.38
491	FL	2	6	9	6.25	5.53	1.94
0017	NM	2	6	10	17.24		
807	OH	2	6	10	8.13	7.31	2.56
864	AZ	2	6	10	9.54	17.44	6.10
258	IL	9	27	11	7.61	9.34	3.27
861	PA	5	15	11	8.67	8.87	3.10
1150	WV	6	18	11	2.27	2.94	1.03
1188	WY	5	15	11	8.74	5.05	1.77
0350	DC	3	9	12	2.16		

Rep_Org	State	Sites 02-04	Req PEP Checks	PEP checks	Mean Abs bias	CV_ub	Climit 24 90%
392	FL	3	9	12	9.26	5.72	2.00
396	FL	6	18	12	4.31	6.66	2.33
481	HI	6	18	12	12.91	15.04	5.26
669	NC	3	9	12	4.00	4.83	1.69
812	OK	5	15	12	10.64	5.98	2.09
990	MO	3	9	12	8.52	3.68	1.29
1025	TN	7	21	12	10.36	6.26	2.19
1138	NV	1	3	12	6.74	2.20	0.77
15	AK	7	21	13	4.68	10.35	3.62
53	AZ	7	21	13	14.84	18.99	6.64
226	NV	6	18	13	4.35	12.88	4.51
634	OH	3	9	13	4.16	3.82	1.34
287	OH	5	15	14	4.69	5.28	1.85
523	IN	7	21	14	4.60	5.15	1.80
635	ME	6	18	14	22.47	5.64	1.97
992	MO	3	9	14	7.31	4.29	1.50
1119	VT	6	18	14	2.78	4.03	1.41
673	TN	5	15	15	10.34	7.44	2.60
613	IA	3	9	16	11.68	4.59	1.61
782	ND	8	24	16	12.60	5.86	2.05
816	NE	3	9	17	7.24	12.67	4.43
1151	WV	5	15	18	4.07	4.44	1.55
730	MT	10	30	19	7.60	7.95	2.78
1259	OH	11	33	19	5.84	3.01	1.05
229	OH	9	27	20	5.15	7.69	2.69
762	NH	12	36	20	5.21	7.58	2.65
907	RI	8	24	20	7.58	12.70	4.44
294	DE	7	21	21	3.91	5.19	1.82
942	CA	11	33	21	7.54	5.23	1.83
889	PR	15	45	22	20.33	13.24	4.63
251	CT	12	36	24	7.54	6.81	2.38
973	SD	12	36	24	24.74	10.12	3.54
752	NE	11	33	25	10.48	8.52	2.98
1175	WI	25	75	26	4.44	4.05	1.42
21	PA	8	24	27	5.51	3.92	1.37
513	IL	28	84	27	11.14	8.56	2.99
511	ID/WA	12	36	28	7.15	6.23	2.18
700	MN	25	75	29	6.52	8.09	2.83
1118	CA	15	45	29	4.02	6.61	2.31
240	CO	14	42	30	7.36	9.70	3.39
588	MO	14	42	34	5.24	3.32	1.16
13	AL	13	39	35	4.51	4.89	1.71
584	KY	17	51	36	6.90	6.34	2.22
764	NJ	21	63	41	8.46	7.12	2.49
971	SC	14	42	42	4.13	4.11	1.44

Rep_Org	State	Sites 02-04	Req PEP Checks	PEP checks	Mean Abs bias	CV_ub	Climit 24 90%
972	CA	17	51	42	4.62	4.51	1.58
1113	UT	17	51	42	8.40	8.22	2.87
1127	VA	21	63	42	5.16	7.58	2.65
55	AR	24	72	43	8.42	2.14	0.75
86	CA	15	45	44	6.21	4.95	1.73
660	MA	24	72	44	9.23	14.93	5.22
703	MS	17	51	44	8.04	7.04	2.46
1001	LA	25	75	44	12.39	5.92	2.07
145	CA	30	90	45	8.85	10.53	3.68
1136	WA	22	66	45	5.37	4.48	1.57
685	MI	28	84	48	6.50	6.27	2.19
437	GA	23	69	49	3.51	4.88	1.71
563	KS	13	39	49	8.48	8.73	3.05
776	NC	23	69	50	7.80	8.30	2.90
1080	IA	15	45	54	9.64	6.55	2.29
1002	MD	20	60	58	7.62	5.51	1.93
520	IN	34	102	64	5.38	4.26	1.49
851	PA	25	75	71	4.03	4.66	1.63
821	OR	32	96	81	7.62	4.09	1.43
1035	TX	56	168	87	7.78	7.97	2.79
768	NY	53	159	99	9.75	5.62	1.97
Summary		**1079**	**3237**	**2313**	**7.62**	**6.93**	**2.42**

Appendix A

Precision and Bias Statistical Calculations

Precision

Precision is estimated via duplicate measurements from collocated samplers of the same type. Precision is aggregated at the reporting organization level quarterly, annually, and at the 3-year level. For each collocated data pair, the relative percent difference, d_i, is calculated by Equation 3.

$$d_i = \frac{X_i - Y_i}{\left(X_i + Y_i\right)/2} \cdot 100 \qquad \text{Equation 3}$$

where X_i is the concentration of the primary sampler and Y_i is the concentration value from the audit sampler

The precision upper bound statistic, CV_{ub}, is a standard deviation with a 90% upper confidence limit (Equation 4).

$$CV_{ub} = \sqrt{\frac{n \cdot \sum_{i=1}^{n} d_i^{\,2} - \left(\sum_{i=1}^{n} d_i\right)^2}{(n-1) \cdot n}} \cdot \sqrt{\frac{n-1}{\chi^2_{0.10,(n-1)}}} \qquad \text{Equation 4}$$

Bias

PEP audits are performed by a PEP audit sampler to find measurement bias in the routine sampler relative to the audit sampler. This is calculated below as a percent difference or individual bias, d_i, where i represents a specific sampler (Equation 5).

$$d_i = \frac{Y_i - X_i}{X_i} \cdot 100 \qquad \text{Equation 5}$$

where X_i represents the audit sampler and Y_i represents the routine sampler

The bias value is based on the average individual bias and is calculated as m in equation 6 below:

$$m = \frac{1}{n} \cdot \sum_{i=1}^{n} d_i \qquad \text{Equation 6}$$

Decision Framework for $PM_{2.5}$ Performance Evaluation Program (PEP) Collocation Study Data

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January 2009 *(DRAFT)*

Introduction

Historically, evaluating the precision and bias of $PM_{2.5}$ Federal Reference Method (FRM) samplers measuring low concentrations (i.e., less than 6 µg/m^3) has been somewhat problematic. Previous methods to evaluate collocated samplers involved comparisons of paired sampler results (X_i and Y_i) using calculations based on relative percent difference (d_i):

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

Prior to the 2006 update to 40 CFR Part 58, Appendix A, the PEP utilized a non-traditional coefficient of variation (CV) for flagging parking lot collocated sampler results as one of the sampler performance test criteria. The "CV" was calculated using the relative percent difference (d_i) for each single check (i.e., pair of collocated sample results):

$$"CV" = \frac{d_i}{\sqrt{2}}$$

For the majority of the historical data, this did not present a problem. However, at low concentrations, the percent difference could appear unacceptably large, when the true difference between values was reasonably small. Less problematic but with similar consequence, percent differences based on higher concentrations may have indicated that the results were consistent when the true difference was unacceptably large.

Figure 1 presents precision data from 2005 for the FRM Network; State, local, and Tribal (SLT) samplers are collocated with other SLT samplers. This graph shows that as the average $PM_{2.5}$ concentration decreases, then the range (or scatter) of relative percent differences increases. This large dataset convincingly illustrates the problem described above.

Figures 2 and 3 present the PEP collocation study results for 1999-2007. **Figure 2** shows the difference in concentration from each pair of collocated samplers against the mean concentration for entire sampling day. **Figure 3** shows the "CV" (described above) plotted against the daily mean concentration. (Note: In order to illustrate the effects on individual collocation studies, three different studies were highlighted using different graph symbols to set them apart from the full data set.) These graphs again illustrate that at lower concentrations, the scatter of values based on a relative percent difference increases.

This type of analysis does not provide an adequate tool for identifying PEP samplers that do not perform in a manner consistent with the fleet, especially at low concentrations. As a result, EPA is adopting a different approach for identifying the nonconforming PEP samplers.

Data Sets

EPA utilized two different data sets in this evaluation. The first was the "parking lot" collocation results from the Performance Evaluation Program (PEP) for years 1999 to 2007 (later narrowed to 2002-2007). The second data set was obtained from EPA's AQS database and consisted of $PM_{2.5}$ results for SLT routine FRM samples paired with the coincident PEP audit results for years 2002-2007.

Analytical Approach

Normalized paired differences for all valid parking lot studies were calculated using the following equations:

$$N_{i,j,d} = \frac{abs(D_{i,j})}{\bar{x}_d}$$

$$\text{where, } D_{i,j} = \sum_{i=1}^{n-1} \sum_{j=i+1}^{n} x_i - x_j$$

There are *n* samplers evaluated for a specific day, *d*, during the testing period. The absolute value of the differences ($D_{i,j}$) for all available pairings (*i, j*) among samplers are computed for each day during the study. For each day of a testing period, these differences are then normalized and turned into a percentage ($N_{i,j,d}$ * *100*) by dividing each *i, j* pair by the daily mean, $\bar{x}_d$, and multiplying by 100. After normalization, the differences are considered comparable among individual studies conducted under differing atmospheric conditions.

Normalization also serves to dampen the effects of an increased percent difference at lower concentrations (see **Figure 4**). However, the mathematical characteristics of the dataset are still present (i.e., the normalized percentages calculated from low concentrations still tend to be inflated relative to those calculated from higher concentrations). The normalized data lends itself to a more sensitive analysis of the collocation study results and an associated tiered decision framework for identifying more subtle deviations in sampler performance.

Histograms of the Normalized Data Sets

Histograms of the resulting normalized percent differences can be used to infer the expected among-sampler precision based on historical data collected within the PEP. The true accuracy of any given sampler can only be approximated; a reference gas with a known $PM_{2.5}$ concentration is not readily available for challenging samplers. However, the among-sampler precision of the PEP collocated samplers provides a programmatic review of the general tendencies of the reference samplers to obtain consistent results.

Figure 5 shows the distribution of normalized differences (%) for all available concentration data generated during the parking lot studies. **Figure 6** presents the same information for the 2002 – 2007 time periods. The histogram shown in the figures represents the empirical data. Three theoretical distributions, calibrated from the empirical data, are shown on each plot. The Beta and lognormal distributions are reasonable choices, with each distribution limited to values greater than zero. The normal distribution is only displayed for reference, and is generally inappropriate for these data (not limited to normalized

values greater than zero). A few (less than 1%) of the normalized values are greater than 50%, and are not shown in the graphic. As shown, the distributions are positively skewed with a median value of approximately 4.5% to 4.6%.

For the 2002 – 2007 data subset (**Figure 6**), 95% of the observations have a normalized difference less than 16.3%, 90% of the observations are less than 10.6%, and 75% of the observations are less than 5.8%.

Figures 7 – 9 present the data and distributions aggregated by EPA Region. Examination of the figures indicates that the shapes of the distributions among Regions are similar, with the median values ranging from 2.27% to 4.12%. The distributions provide empirical evidence that the results among EPA Regions are reasonably consistent.

Figure 10 presents the normalized differences for the FRM data set. Differences between a SLT FRM sampler and corresponding PEP audit sampler for all observations in the data set during the period 2002 – 2007 are calculated and plotted. The median value is 6.95%. Examination of the figure illustrates that the FRM distribution has a larger variance than found in the parking lot studies.

For the FRM data in **Figure 10**, 95% of the observations have a normalized difference less than 47.4%, 90% of the observations are less than 29.4%, and 75% of the observations are less than 15.0%.

Figures 11 – 13 present the FRM normalized differences by Region. Unlike the parking lot study data, the distributions among EPA Regions are inconsistent. In general, a larger probability mass in the tail is seen than would be expected if the data were associated with a traditional lognormal distribution. The medians among Regions range from 5.1% to 10.65%. Regions with larger variation in results include Regions 2, 8, and 6.

The historical data described above can be used to establish reasonable quality assurance criteria and decision-frameworks for identifying samplers that may be generating inaccurate results. A tiered decision framework that does not rely on classic hypothesis testing has several advantages, including the following: (1) hypothesis testing results are difficult to interpret and the available methods can easily provide conflicting answers, (2) empirical decision-frameworks using historical information on a program-wide basis can provide useful information reflecting among-sampler variation leading to quality assurance criteria and decision pathways, (3) tiered decision frameworks can be designed to provide QA officers with information that can be lead to a final decision concerning sampler performance, and (4) simplified numerical methods typically found in tiered decision frameworks can be programmed into most software systems.

Evaluation of Decision Methods

Several QA criteria for isolating samplers with anomalous measurements relative to other samplers were evaluated using the historical PEP data. The number of samplers found to be inconsistent within each collocation study was recorded. The steps in the QA decision-framework, and the approach to simulating candidate QA criteria, are described below. Results of the simulation follow in the next section.

Step 1. Reasonable measured concentrations – The measured $PM_{2.5}$ concentrations are first screened for reasonableness. The maximum detection limit stipulated by the CFR is 200 $\mu g/m^3$. Therefore, on any study day, if a sampler measures a $PM_{2.5}$ concentration >200 $\mu g/m^3$, the measurements associated with the sampler are dropped from consideration
(i.e., all measurements from the sampler are discarded during evaluation of the data collected during the multiple-day study period). The sampler cannot be used for PEP audits without a thorough engineering evaluation. If more than one sampler measures a $PM_{2.5}$ concentration
>200 $\mu g/m^3$ on a given day, then the entire collocation study warrants closer examination before judgments on sampler bias can be made. Field scientists are advised that if an atmospheric condition caused by an event (such as a nearby wild fire) occurs, then the collocation study should be rescheduled.

Step 2. Notable differences – Based on the examination of the histograms displaying the distribution of normalized percent differences (**Figures 5 – 13**), QA criteria cutoffs of (a) >10%, (b) >15%, and (c) >20% were evaluated. Considerations included all the factors that might have biased the data for those sampling events. EPA also considered the numbers of samplers which might require further investigation and possible maintenance (to avoid overburdening the program). EPA has decided that normalized percent differences ≤15% will be accepted as within the expected normal range of within-sampler precision historically observed within the PEP. Normalized percent differences >15% will be flagged as "notable differences."

Step 3. Relevance of notable differences – From a mathematical perspective, relatively small inconsistencies in within-sampler precision can result in large computed percent differences if the magnitudes of the $PM_{2.5}$ concentrations are small. In this case, the resulting percent difference is not relevant from an engineering or human health perspective. From prior studies, EPA has determined that the lowest ambient concentration that can be used for calculating within-sampler precision and network bias relative to the PEP audit sampler is 3 $\mu g/m^3$.[2] Therefore, the following cases were evaluated: (a) each sampler in a pair measured
< 3 $\mu g/m^3$, and (b) either sampler 1 or sampler 2 measured < 3 $\mu g/m^3$.

Notwithstanding the historical data set, it is conceivable that only one sampler may capture a very small amount of particulate, EPA has selected case (a), using the AND operator, for evaluating the relevance of notable differences based on concentrations < 3 $\mu g/m^3$. If concentrations from both samplers in the comparison measure < 3 $\mu g/m^3$, then the normalized percent difference from the pair will not be used to identify the sampler for further investigation. However, if only one of the two measurements is < 3$\mu g/m^3$, then the normalized percent difference will remain in the data set for evaluating the collocated samplers.

Step 4. Sampler-specific relevant notable differences – For any collocation study (consisting of 3 or more sampling days) the number of calculated normalized differences representing within-sampler precision is dependent upon the number of samplers participating in the study, and can be large. For example, ten samplers participating on each of three days results in 45 normalized differences on each day, and 135 differences over a 3-day period. One objective of the collocation exercise is to identify samplers that consistently generate larger differences than are normally expected. If, for example, a sampler is involved in a single notable difference over the course of 3-days, this finding could easily be due to random variation within the expected range of differences. Therefore, to specify individual samplers for further investigation, the following criteria were tested: (a) there must be more than one notable difference computed during the collocation study, and (b) the sampler must be involved with at

[2] See proposal at 71 FR 2728, January 17, 2006 and promulgation at 71 FR 61255, October 17, 2006.

least 50% of the relevant notable differences computed over the entire collocation study. EPA determined this to be a reasonable approach for identifying inconsistently performing samplers.

Results of Simulation

PEP collocation studies should include at least three days of testing, however, data shows that historically the testing period has ranged from 1 to 3 days. During a study, the number of samplers evaluated on any specific day could vary. The largest number of samplers on a specific day was 14. **Table 1** presents a program-level summary of the simulation results.

Table 1. Program-Level Summary of Simulation Results

		Normalized Percent Difference >10%	Normalized Percent Difference >15%	Normalized Percent Difference >20%
Total number of notable differences:		1,017	515	349
Number of notable differences involving concentrations < 3 µg/m^3:	using AND operator	72	44	30
	using OR operator	116	80	60
Minimum number of samplers requiring evaluation:	using AND operator	108	59	46
	using OR operator	108	56	42

Note: The total number of differences from paired sample results in the PEP data set is 11,405.

Examination of the study-level results and the Table 1 program-level summary provides the following findings:

a. Changing the QA criteria for the identification of notable differences from >10% to >15% decreased the number of paired sampler results where further evaluation would be warranted by 49% (this is consistent with the log-normal distribution of differences presented in the histogram). A change from >10% to >20% results in a reduction in differences remaining for evaluation by 65%.

b. The choice of the two logical operators (AND / OR) for identifying differences between samples with concentrations < 3 µg/m^3 is relatively significant, with the number of differences using the OR operator (72) having as much as a 62% increase over those identified using the AND operator (116) for the >10% scenario. However, the overall effect of changing the logical operator on the identification of specific samplers for evaluation is small. For example, the minimum number of samplers identified for the >15% scenario was 59 for the AND operator versus 56 for the OR operator. This evaluation reinforces the decision to use the AND operator in the analysis.

c. The cascading decision framework results in a minimum of 108 PEP sampler evaluations using the >10% criteria. Note that the 108 evaluations are based on samplers within a study that were involved in the greatest number of calculated differences meeting the decision criteria. For some collocation studies, EPA may need to further evaluate more than one sampler with differences exceeding the decision criteria. The overall effect of excluding the differences associated with samplers having concentrations < 3 µg/m^3, prior to selecting samplers for further review, is minimal.

d. Examination of the historical data shows that specific samplers in some Regions have repeatedly exceeded the decision criteria. EPA will take proactive steps to correct or replace those samplers which exhibit repetitive exceedances.

Conclusion

The decision framework outlined above is shown to provide a logical method for identifying individual samplers that display inconsistency in $PM_{2.5}$ measurements relative to other samplers. EPA will continue to evaluate the selected decision criteria as more collocation studies are conducted.

To facilitate efficiency and ensure consistency, the decision framework will be implemented using automated programming methods. Following each collocation study, EPA will review the program output. Any samplers identified as displaying inconsistent measurements will be further investigated. If the overall collocation study results show a high number of notable differences, EPA will investigate not only the samplers, but the filter handling process for all personnel involved in the collocation study.

Figure 1. 2005 Precision Data for FRM Network
(SLT samplers collocated with other SLT samplers)

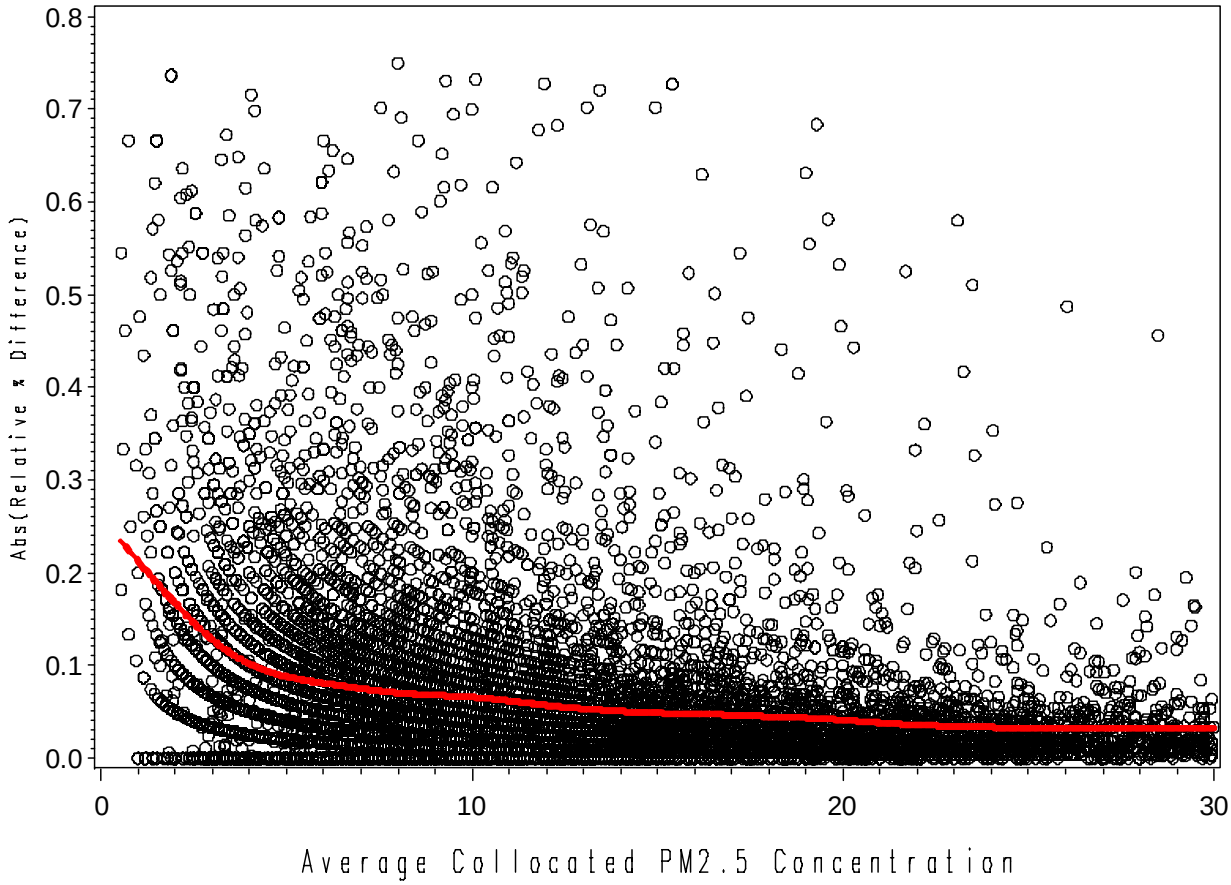


Figure 2. PEP Collocation Studies: Paired Concentration Differences vs. Daily Mean 1999 - 2007

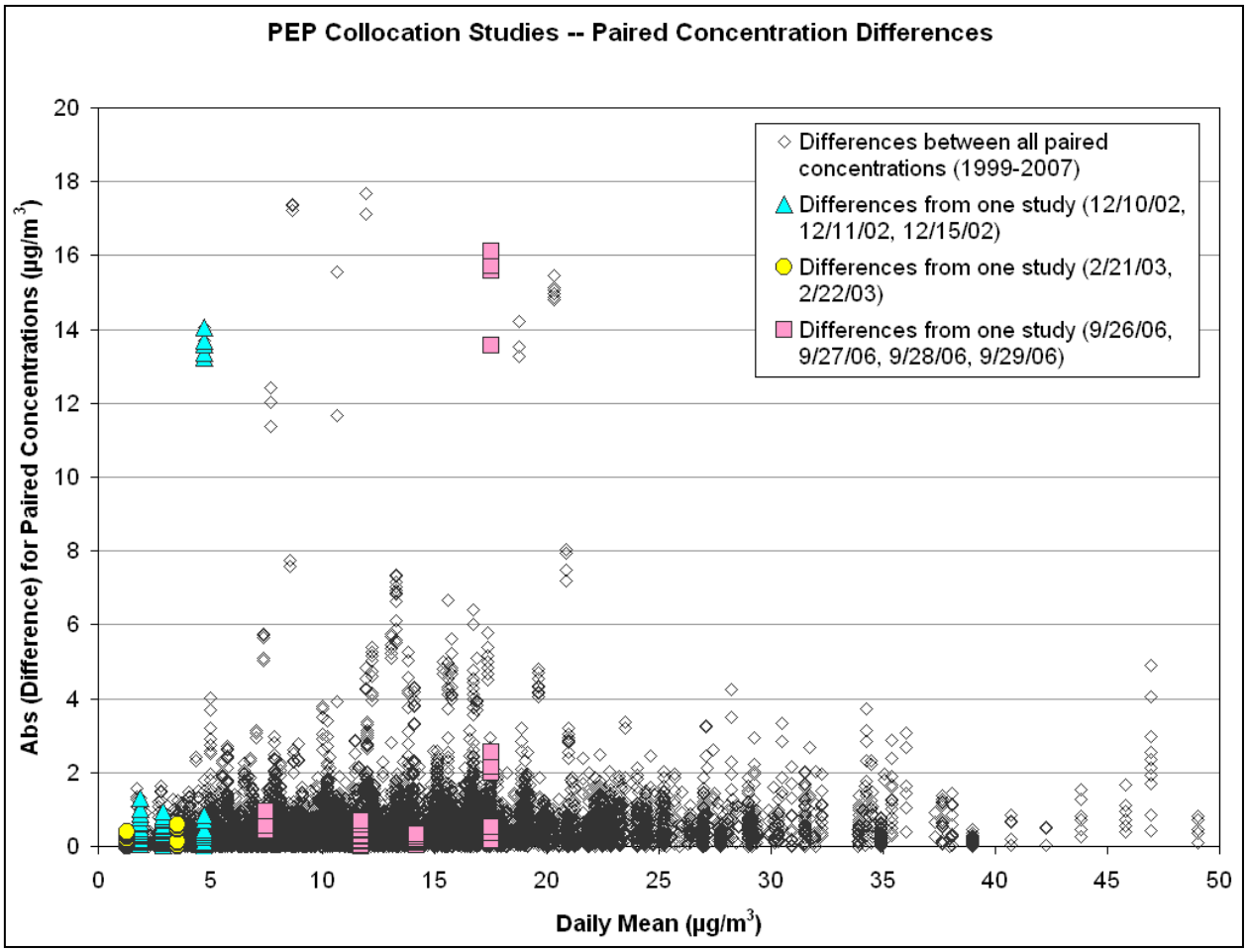


Figure 3. PEP Collocation Studies: "CV" for Paired Concentrations vs. Daily Mean 1999 - 2007

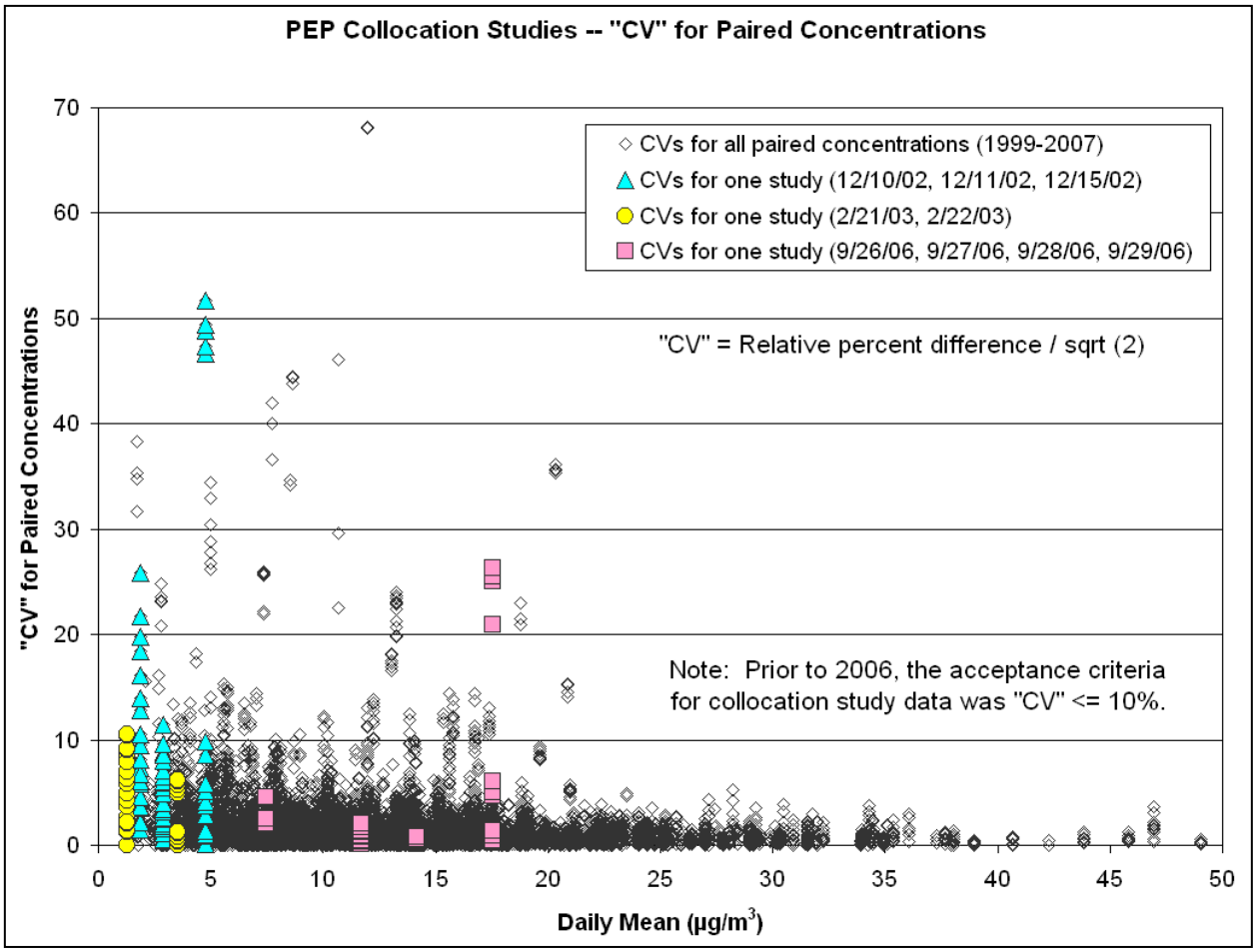


Figure 4. PEP Collocation Studies: Normalized Paired Differences vs. Daily Mean 1999 - 2007

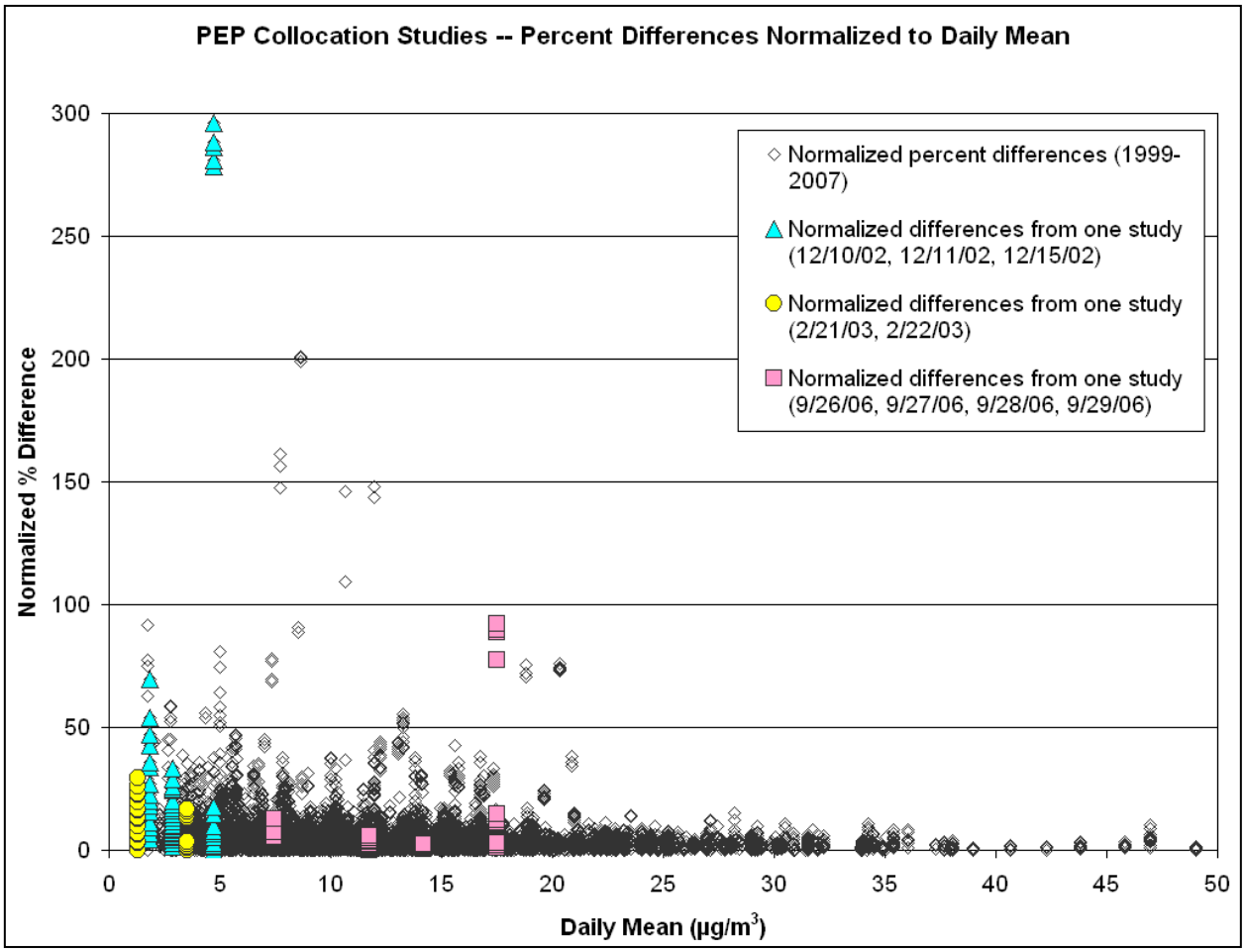


Figure 5. PEP Collocation Studies: Distribution of Paired Differences
1999 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<1% of total observations)

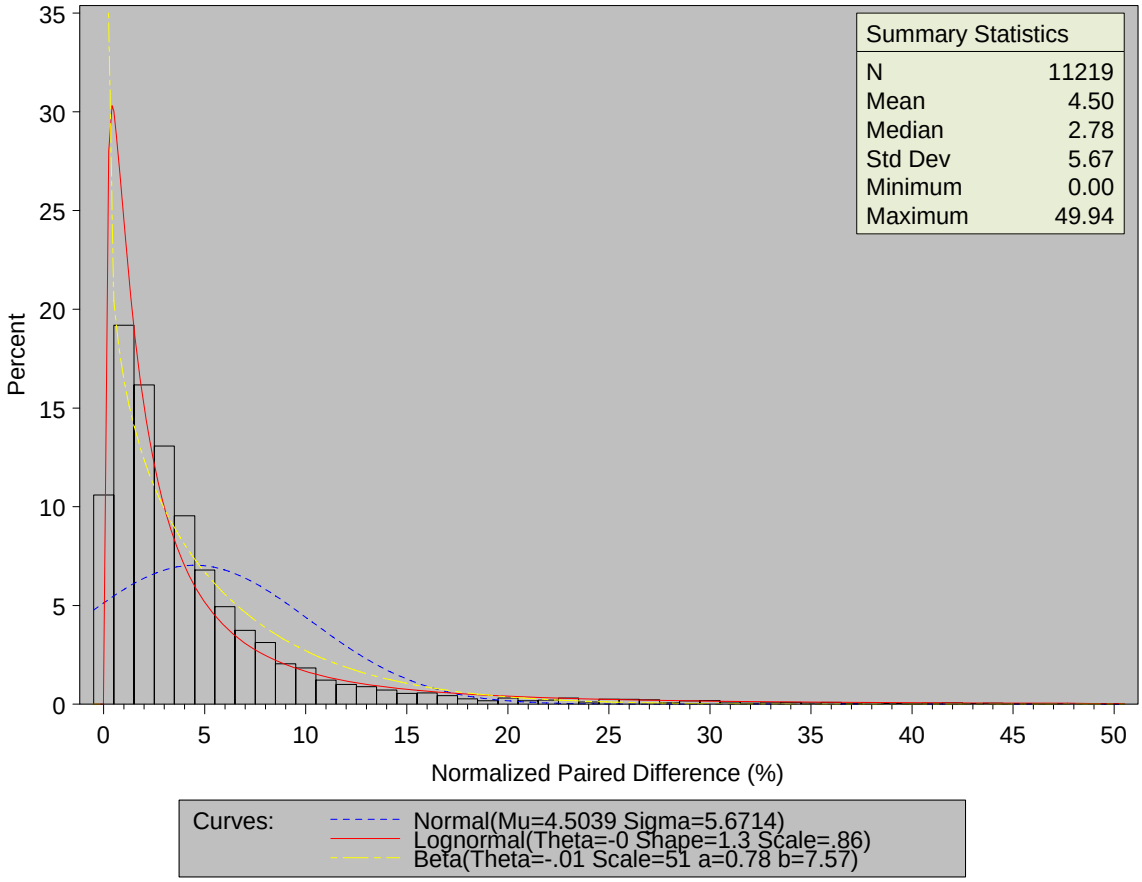


Figure 6. PEP Collocation Studies: Distribution of Paired Differences
2002 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<1% of total observations)

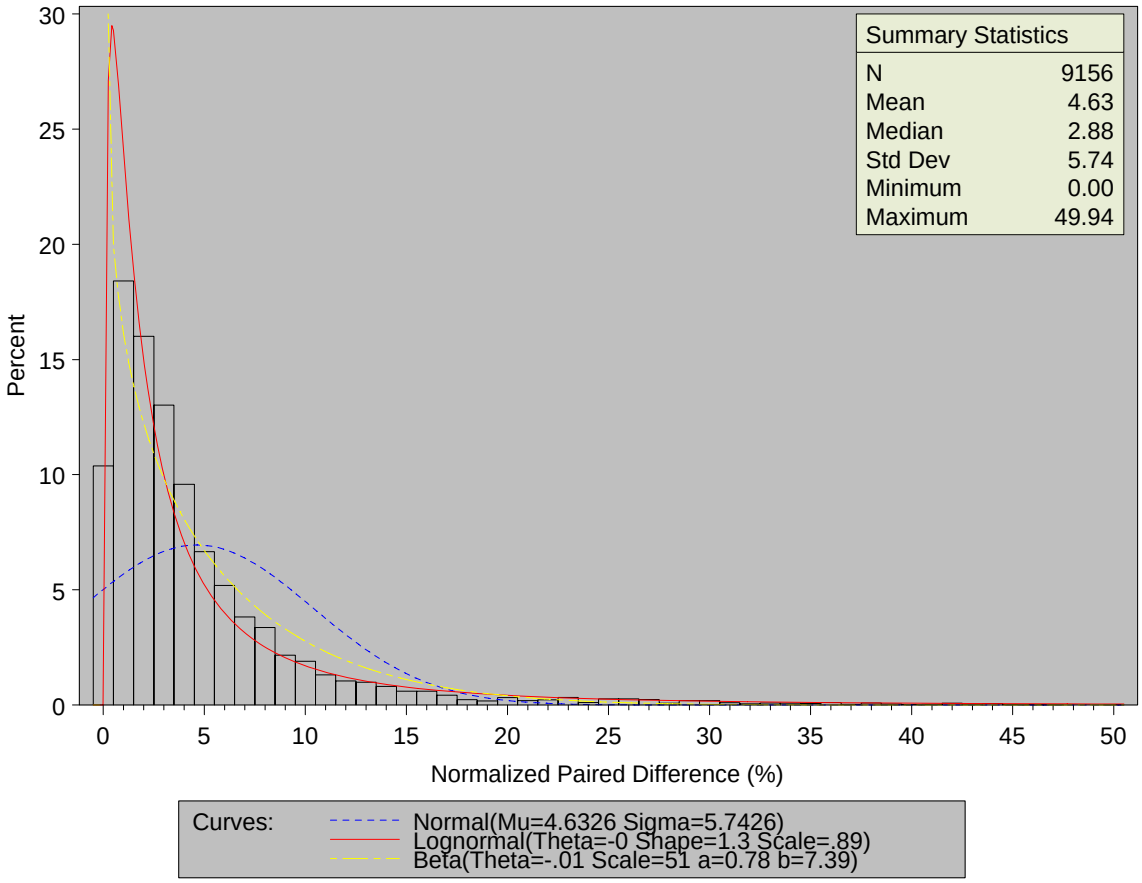


Figure 7. PEP Collocation Studies: Distribution of Paired Differences
Regions 1 – 4: 2002 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<1% of total observations

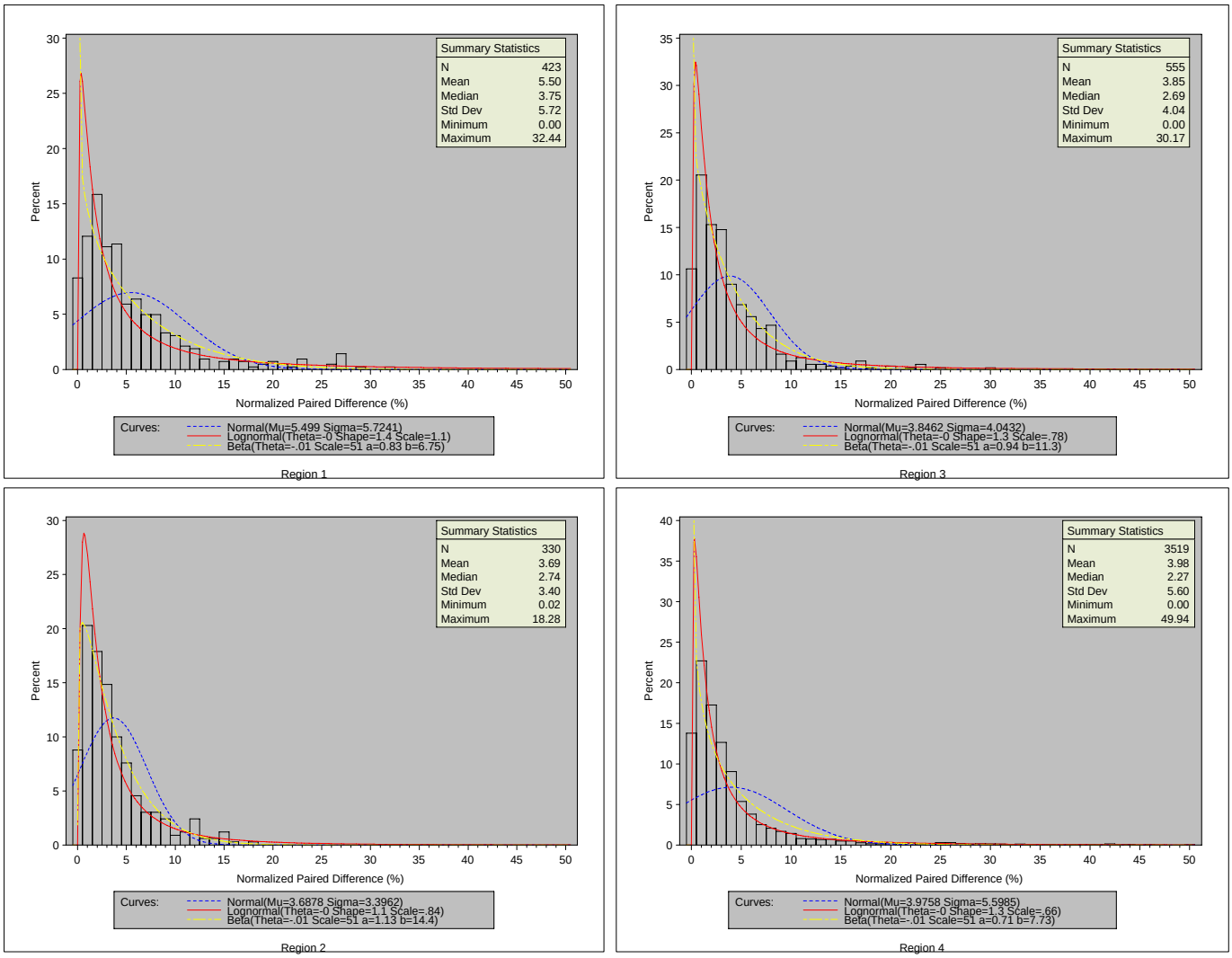


Figure 8. PEP Collocation Studies: Distribution of Paired Differences
Regions 5 – 8: 2002 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<1% of total observations

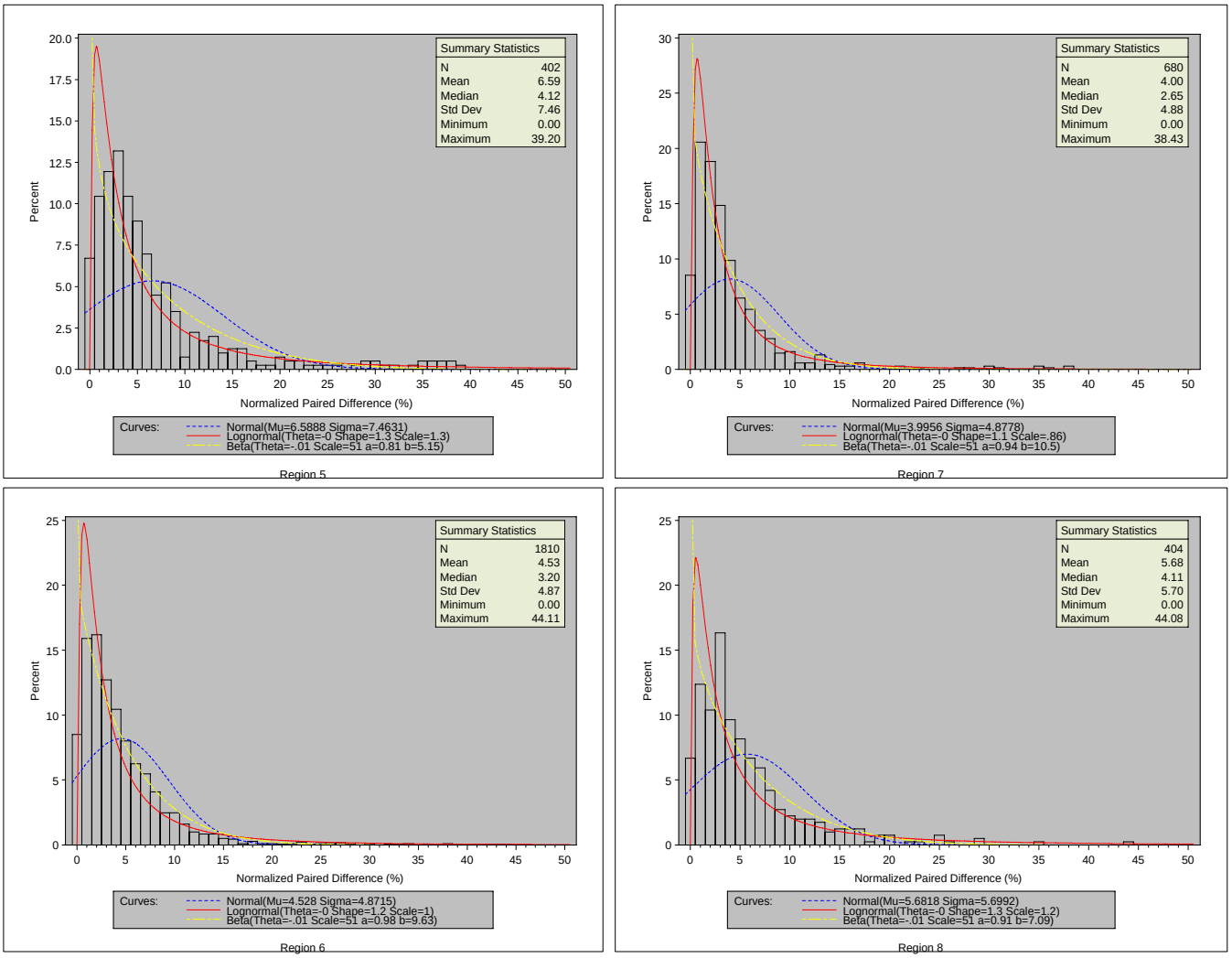
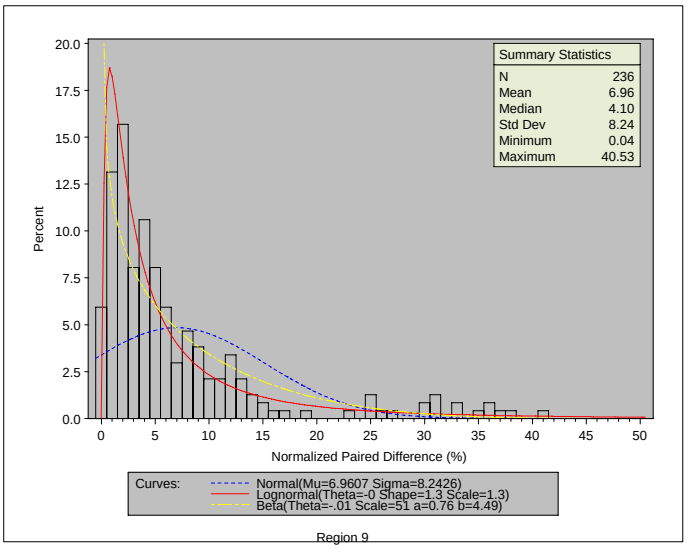


Figure 9. PEP Collocation Studies: Distribution of Paired Differences
Regions 9 – 10: 2002 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<1% of total observations



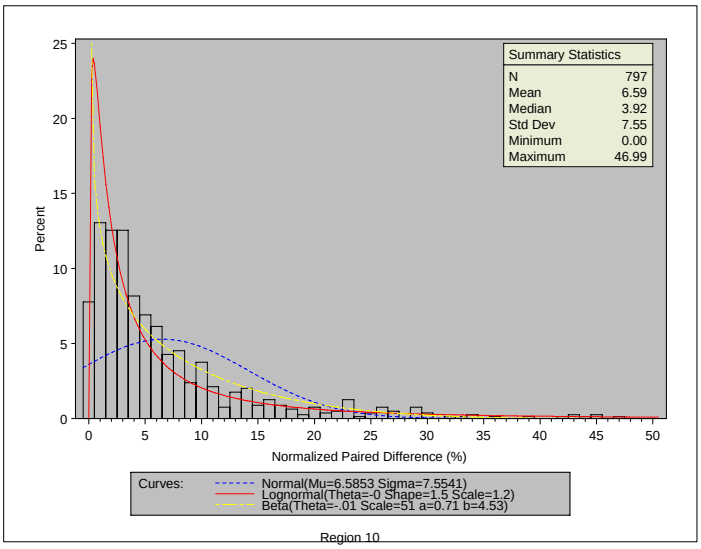


Figure 10. PEP Audits of SLT Samplers: Distribution of Paired Differences
2002 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<3% of total observations)

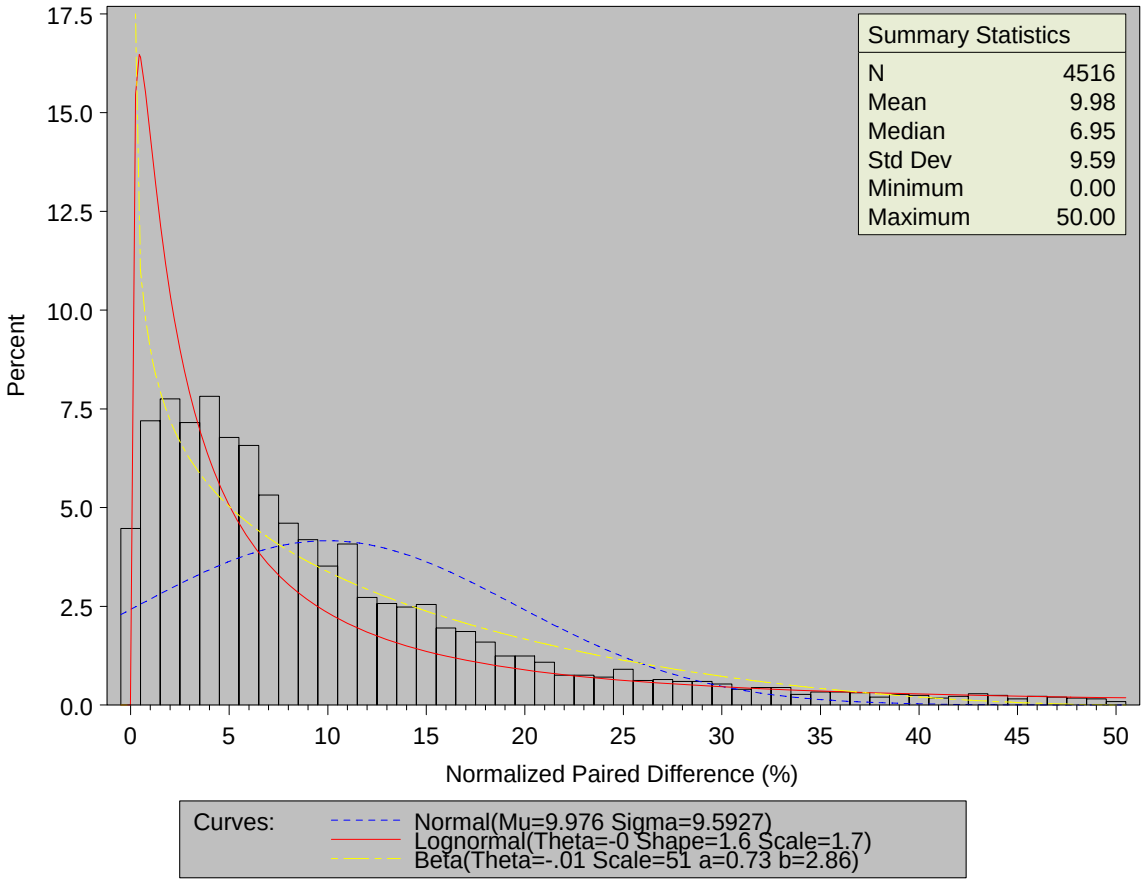


Figure 11. PEP Audits of SLT Samplers: Distribution of All Paired Differences
Regions 1 – 4: 2002 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<3% of total observations)

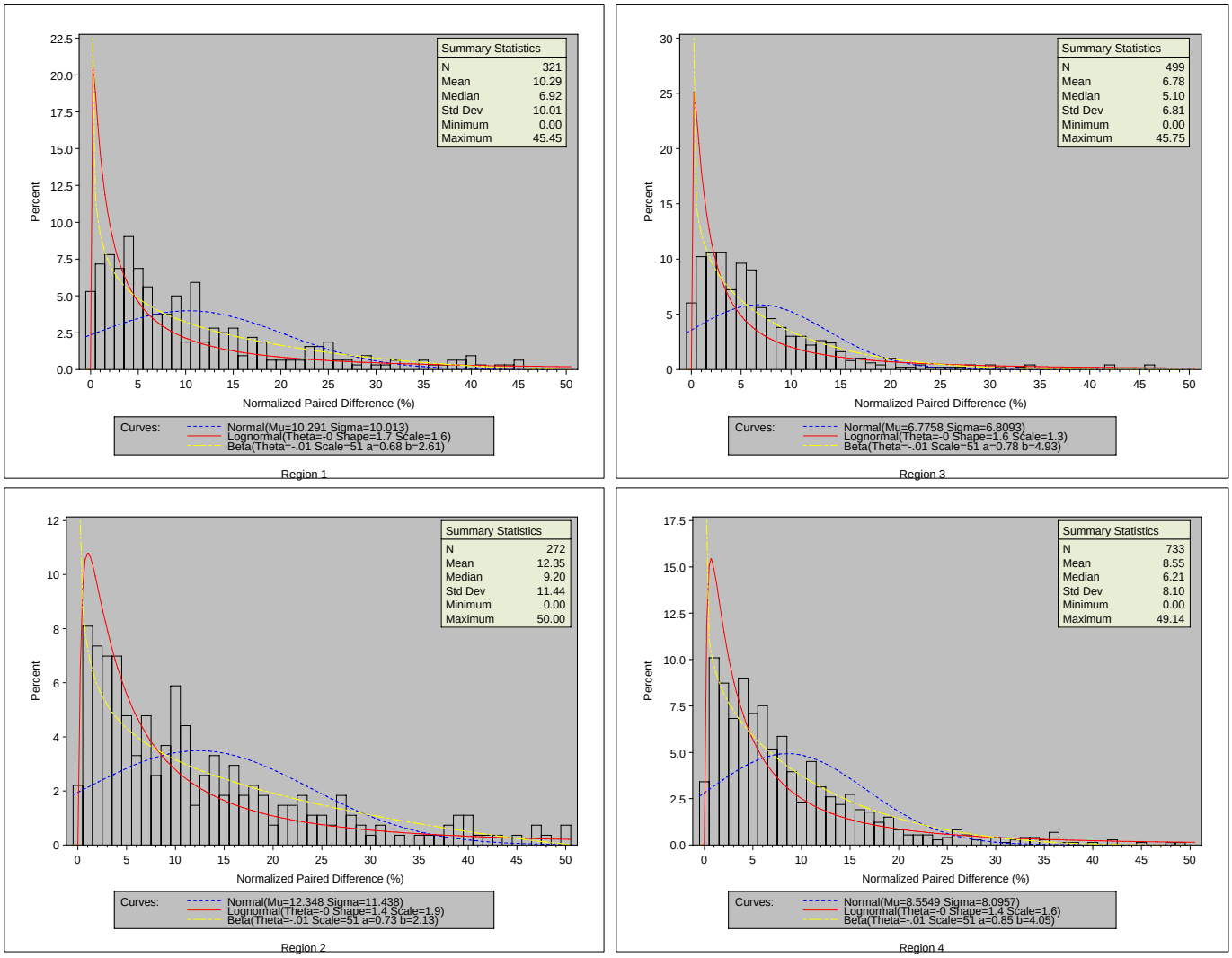
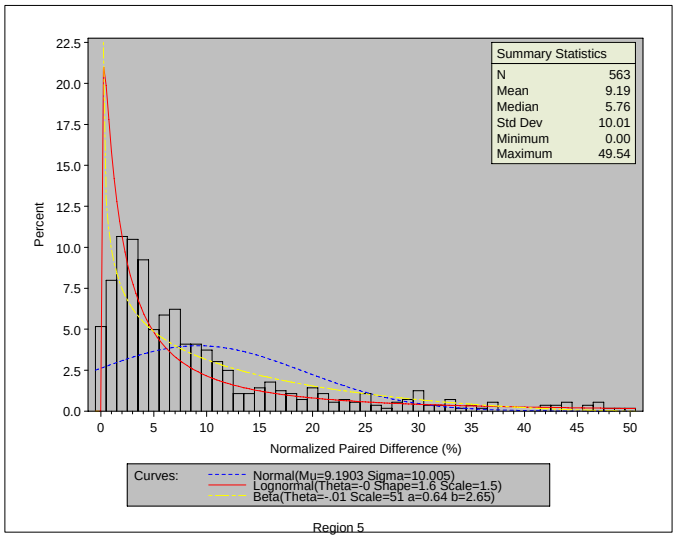
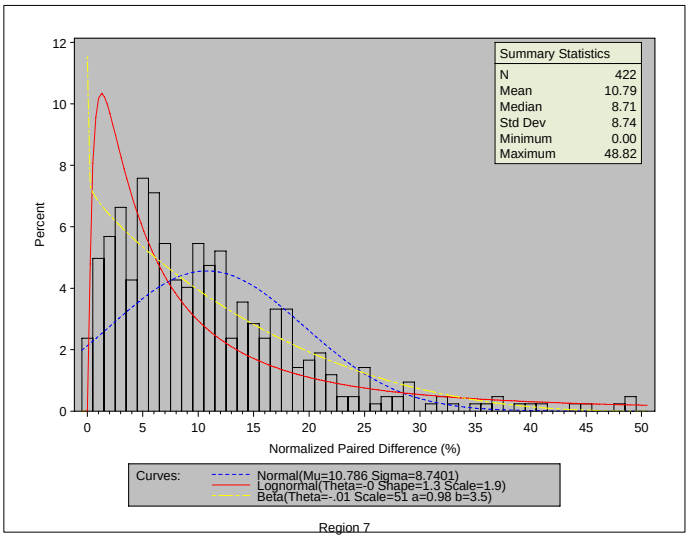
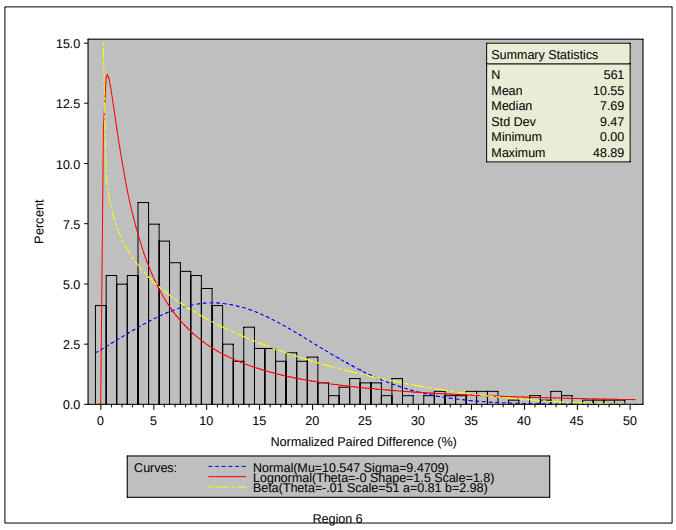


Figure 12. PEP Audits of SLT Samplers: Distribution of All Paired Differences
Regions 5 – 8: 2002 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<3% of total observations)







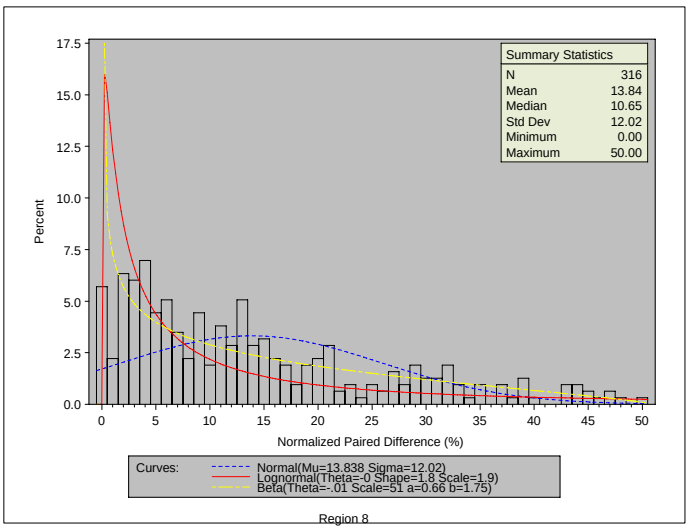
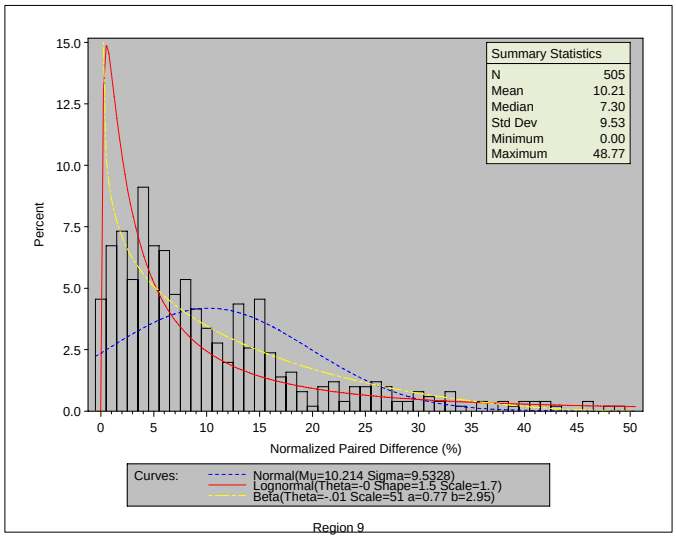
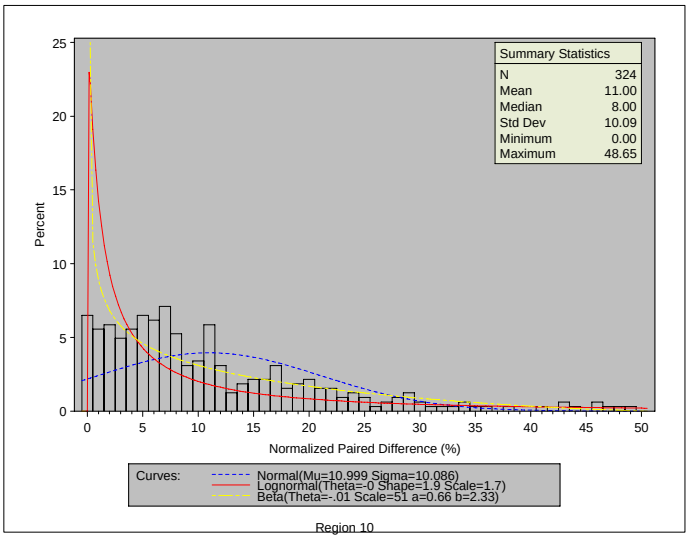


Figure 13. PEP Audits of SLT Samplers: Distribution of All Paired Differences
Regions 9 – 10: 2002 - 2007
Normalized Paired Differences Greater than 50% Not Shown (<3% of total observations)





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Appendix C

Training Certification Evaluation Forms

The following forms will be used by the PEP to certify the $PM_{2.5}$ field and laboratory personnel have performed environmental data operations at a satisfactory level.

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Trainee/Operator's Name _____ Date_____

Field Performance Examination Checklist

STANDARD OPERATING PROCEDURE		
Section 2.1 Equipment Inventory and Storage	**ACCEPT**	**RETEST**
1. Field Scientist has a general understanding of the requirements for inventorying and procuring equipment		
Notes:		
Section 2.2 Communications	**ACCEPT**	**RETEST**
1. Field Scientist demonstrates general knowledge of the communication requirements		
2. Field Scientist understands how to document communications (e.g., e-mails, phone calls)		
3. Field Scientist understands when and how often to talk with the State, local, or Tribal entity		
4. Field Scientist understands requirements for the monthly progress report and the expected information needed for it		
Notes:		
Section 2.3 Preparation for PEP Sampling Events	**ACCEPT**	**RETEST**
1. Field Scientist understands the requirements and uses for the Site Data Sheet		
2. Field Scientist understands the purpose for a site visit		
3. Field Scientist knows the procedure for audit event equipment preparation		
4. Field Scientist understands the notification procedures for scheduling an audit event		
5. Field Scientist knows the appropriate days to sample and when it is possible to sample at a different schedule		
Notes:		
Section 3.1 Cassette Receipt, Storage, and Handling	**ACCEPT**	**RETEST**
1. Field Scientist knows the procedure for receiving filters from the laboratory		
2. Field Scientist understands the critical filter holding time requirements		
3. Field Scientist knows the procedure for storing filters at the field office, during transport to the field, and if samples must come back to the field office		
4. Field Scientist knows the procedure for handling unexposed and exposed filters		
Notes:		

STANDARD OPERATING PROCEDURE			
Section 4.1 Sampler Transport and Placement		**ACCEPT**	**RETEST**
Field Scientist understands the procedure for safe transport of the main sampler unit and travel cases to the sampling location			
Notes:			
Section 5.1 Sampler Assembly, Section 6.4 Sampler Disassembly		**ACCEPT**	**RETEST**
Field Scientist properly assembles the unit (overall)			
	Legs		
	AC power supply		
	Weather shroud (back plate)		
	Gill screen		
	Inlet assembly and downtube		
	WINS impactor assembly or VSCC inspection		
	Removal of transport filter cassette		
Field Scientist properly powers the unit			
Field Scientist properly sets date and time			
Field Scientist properly disassembles the unit by storing components in correct travel cases			
Notes:			
Section 6.5 Sampler Maintenance and Cleaning		**ACCEPT**	**RETEST**
Field Scientist properly identifies and performs maintenance areas to be checked each visit (overall)			
	Water collector		
	Impactor well or VSCC		
	O-rings of impactor assembly or VSCC assembly		
	Downtube		
Field Scientist properly identifies and performs maintenance on the O-rings of the inlet			
Notes:			

STANDARD OPERATING PROCEDURE		
Section 5.2 Leak Check Procedures	**ACCEPT**	**RETEST**
1. Field Scientist properly configures sampler for leak check		
2. Field Scientist navigates to the correct "screen"		
3. Field Scientist slowly releases vacuum		
4. Field Scientist has an awareness of the internal leak check procedure		
5. Field Scientist records data on the Field Data Sheet correctly		
6. Field Scientist has an awareness of troubleshooting procedures		
Notes:		

Section 5.3 Barometric Pressure Verification	**ACCEPT**	**RETEST**
1. Field Scientist installs the barometric pressure transfer standard correctly and allows time for the equipment to equilibrate to ambient conditions		
2. Field Scientist navigates to the correct sampler "screen"		
3. Field Scientist records data on the Field Data Sheet correctly		
4. Field Scientist has an awareness of troubleshooting procedures		
Notes:		

Section 5.4 Temperature Verification	**ACCEPT**	**RETEST**
1. Field Scientist installs the temperature transfer standard correctly and allows time for equipment to equilibrate to ambient conditions		
2. Field Scientist navigates to the correct sampler "screen"		
3. Field Scientist performs the ambient temperature verification properly		
4. Field Scientist performs the filter temperature verification properly		
5. Field Scientist records data on the Field Data Sheet correctly		
6. Field Scientist has an awareness of troubleshooting procedures		
7. Field Scientist has an awareness of the filter overheat ("F") flag.		
Notes:		

STANDARD OPERATING PROCEDURE		
Section 5.5 Flow Rate Verification	**ACCEPT**	**RETEST**
1. Field Scientist correctly installs and zeroes the flow transfer standard		
2. Field Scientist correctly installs the test/transport filter cassette		
3. Field Scientist navigates to the correct sampler "screen"		
4. Field Scientist performs the flow rate verification properly		
5. Field Scientist calculates percent difference for comparison to flow rate acceptance criteria (if flow transfer standard is the primary or back-up flow standard)		
6. Field Scientist compares the flow transfer standard with the sampler flow rate		
7. Field Scientist compares the flow transfer standard with the design flow rate		
8. Field Scientist records data on the Field Data Sheet correctly		
9. Field Scientist returns the sampler to normal operation		
10. Field Scientist has an awareness of troubleshooting procedures		
Notes:		
Section 5.6 Preparing to Sample	**ACCEPT**	**RETEST**
1. Field Scientist attaches the inlet assembly		
2. Field Scientist installs the WINS impactor assembly or VSCC		
3. Field Scientist completes the installation (checks that the sampler is secure and that the inlet is level, puts away installation tools and shipping materials, covers electrical connections)		
Notes:		
Section 6.1 Conducting the Filter Exposure	**ACCEPT**	**RETEST**
1. Field Scientist installs the field blank filter cassette into the sampler (performs additional steps, including inspection, documentation of Cassette ID, and placement into a 3" x 5" bag)		
2. Field Scientist has a awareness of trip blank procedures		
3. Field Scientist installs the Routine PE filter cassette into the sampler		
4. Field Scientist programs the Cassette ID and the AQS Site Code into the sampler		
5. Field Scientist programs the sampler to run for the next day		
6. Field Scientist programs the sampler to run the day after next		
Notes:		

STANDARD OPERATING PROCEDURE		
Section 6.2 Sample Recovery and Data Download	**ACCEPT**	**RETEST**
1. Field Scientist records information on the Field Data Sheet from the sampling run		
2. Field Scientist removes the filter cassette from the sampler (performs additional steps, including inspection, documentation, and placement into a 3" x 5" bag)		
3. Field Scientist performs data download onto a laptop computer and a 3.5" disk (or other portable storage media)		
Notes:		
Section 6.3 Filter Packing and Shipment	**ACCEPT**	**RETEST**
1. Field Scientist performs packing procedure correctly		
2. Field Scientist includes all necessary items in the shipping cooler (filter cassettes, ice packs, min/max thermometer, documentation, data storage media)		
3. Field Scientist demonstrates knowledge of the time requirements for shipment		
Notes:		
Section 7.1 Chain-of-Custody Form and Field Data Sheet	**ACCEPT**	**RETEST**
1. Field Data Sheet(s) have been appropriately and completely filled out		
2. Chain-of-Custody Form(s) have been appropriately and completely filled out		
Notes:		
Section 8.1 Quality Assurance/Quality Control	**ACCEPT**	**RETEST**
1. Field Scientist demonstrates general knowledge of the required QA activities for the PEP		
2. Field Scientist has awareness of how frequently the QA/QC activities should be conducted		
3. Field Scientist knows procedures for scheduling, ordering filters, sampler set-up, and conduct of "parking lot" collocation studies. Field Scientist understands how to interpret results with respect to their Region's samplers.		
Notes:		
Section 8.2 Field Data Verification and Validation	**ACCEPT**	**RETEST**
1. Field Scientist has awareness of field data verification procedures and how frequently they should be performed		
Notes:		

STANDARD OPERATING PROCEDURE		
Section 9.1 Information Retention	**ACCEPT**	**RETEST**
1. Field Scientist demonstrates general knowledge of the information retention requirements		
Notes:		

Instructor's/Auditor's Name _____

Instructor's/Auditor's Name _____

Instructor's/Auditor's Name _____

Instructor's/Auditor's Name _____

Performance Examination Checklist for Weighing Laboratory Training

Trainee: _____ Date: _____

Evaluator: _____ Fully Successful: _____

WEIGHING LABORATORY ACTIVITY	Success (Yes/No)	COMMENTS
Section 6.1 FILTER CONDITIONING *(Pre-Sampling)*		
1. Determine how many filters need to be conditioned for the next shipment		
2. Select filter boxes for conditioning after checking the appropriate form		
3. Determine the filter conditioning period for the lot based on earlier measurements		
4. Check whether temperature and relative humidity (RH) values in the conditioning environment are within the acceptance criteria		
5. Put on gloves and a lab coat		
6. Use forceps to handle filters only by their rings		
7. Inspect filters for defects		
8. Transfer acceptable filters to the Petri dish, place the cover three-quarters of the way across it, put the dish on the tray, put the tray in the rack, and transfer rejected filters to the envelope		
9. Record data on the Filter Inventory Form		
10. Conduct pre-sampling filter conditioning test with three filters from the batch, weigh them periodically until the weights stabilize, and keep filters in the conditioning environment until the conditioning period is complete		
SCORE		**OF 10 POSSIBLE**

WEIGHING LABORATORY ACTIVITY	Success (Yes/No)	COMMENTS
Section 8.1 MANUAL FILTER WEIGHING *(Pre-sampling and Post-sampling)*		
1. Record temperature and RH of the conditioning period and record on appropriate data form; and check whether they meet the acceptance criteria		
2. Put on gloves and a lab coat		
3. Clean the microbalance's weighing chamber with appropriate brush, and then clean the balance table surface and two forceps		
4. Exercise the microbalance draft shield to equilibrate the air in the weighing chamber		
5. Zero (i.e., tare) and calibrate the microbalance		
6. Use appropriate forceps to handle the working standards		
7. Weigh the first working mass reference standard, record the value on the appropriate form, and compare this value against verified value		
8. Weigh the second working mass reference standard, record the value on the appropriate form, and compare this value against the verified value		
9. Close the chamber door and check zero		
10. Select the filter, the Record ID, and indicate the filter type on the appropriate data form		
11. Use the appropriate forceps to handle filters only by their outside ring, and then move filters from the Petri dishes to the antistatic strip and wait for 30 to 60 seconds		
12. Move the filters from the antistatic strip to the center of microbalance weighing pan and close the draft shield		
13. Weigh the filters and return them to the Petri dishes; record weighing data on the appropriate form		
14. At the end of the batch, reweigh one of the filters; decide if more filters need duplicate weighings; record weighing data on the laboratory data form; and then check for agreement with previous values		

WEIGHING LABORATORY ACTIVITY	Success (Yes/No)	COMMENTS
15. At the end of the batch, reweigh the two working standards; record the working standard measurements on the appropriate form; and then check for agreement with verified values		
16. Weigh laboratory blanks; record, check for agreement with previous values, and return them to the Petri dishes that are labeled as laboratory blanks		
17. Save the appropriate filter for reweighing with the next batch (only in post-sampling)		
SCORE		**OF 17 POSSIBLE**
Section 8.1 FILTER WEIGHING and Section 9.1 SHIPPING *(Filter Shipping to Field)*		
1. Put on gloves and a lab coat		
2. Select the weighed filter and a clean cassette; record the Cassette ID on the appropriate form		
3. Use forceps to handle the filters; hold the filter only by the outside ring		
4. Move filters from Petri dishes to the bottom section of filter cassette that has a backing screen and is secure with the cassette top		
5. Record the Cassette ID on a new 3" x 5 " antistatic self-sealing bag		
6. Put caps on the filter/cassette assemblies		
7. Put capped filter/cassette assemblies into a labeled 3" x 5" bag		
8. Add the Cassette ID and pre-sampling weighing date to the appropriate form		
9. Select the filter cassette assemblies that are still contained in the 3" x 5" bag from the appropriate form		
10. Completely fill in the appropriate section of the Chain-of-Custody Form (COC-2)		
11. Place multiple filter cassette assemblies, each still in 3" x 5" bags, with appropriate COC forms in a larger 9" x 12" bag		
12. Wrap in bubble wrap, pack them, fill out FedEx shipping papers, and notify the Regional Office Field Scientist of the shipment		
SCORE		**OF 12 POSSIBLE**

WEIGHING LABORATORY ACTIVITY	Success (Yes/No)	COMMENTS
Section 9.1 FILTER CHAIN OF CUSTODY *(Filter Receipt)*		
1. Open the shipping container; find cassette assemblies, Chain-of-Custody Form (COC-2), Field Data Sheet, and the sampler data diskette; and check these over to ensure that the shipment is complete and that data sheets are appropriately filled out		
2. Store the diskette in folder by Region		
3. Completely fill out Part V of COC-2, record temperature data on the Chain-of-Custody Form, move the sealable bags to the refrigerator or weigh room depending on when post sample weighs will be performed		
4. Describe how long filter cassette assemblies in the 3" x 5" bag should be thermally equilibrated in the weigh room before opening		
SCORE		**OF 4 POSSIBLE**
Section 6.1 FILTER CONDITIONING *(Post-Sampling)* and Section 9.1 FILTER CHAIN OF CUSTODY *(Filter Receipt)*		
1. Match the Cassette ID/Filter Type on the bag with the information listed on COC-2		
2. Remove the filter cassette assembly from the 3" x 5" sealable bags		
3. Remove the caps from filter/cassette assemblies		
4. Put on gloves and remove the filter from the cassette		
5. Use forceps to handle filters; hold the filter only by the rings		
6. Inspect the filters for defects		
7. Move the filters from the cassettes to the Petri dishes, label the Petri slide with the Filter ID and Filter Type, place the cover three-quarters over the dish, put the dish on the tray, and place the tray in the rack		
8. Allow the filter to condition for no less than 24 hours; conduct the post-sampling filter conditioning test with three filters before the remainder of the batch is weighed		
SCORE		**OF 8 POSSIBLE**
Trainee 100% successful:		

Appendix D

Data Qualifiers/Flags

A sample qualifier or a result qualifier consists of three alphanumeric characters which act as an indicator of the fact and the reason that the subject analysis (1) did not produce a numeric result; (2) produced a numeric result, but it is qualified in some respect relating to the type or validity of the result; or (3) produced a numeric result, but for administrative reasons, it is not to be reported outside the laboratory.

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Field Qualifiers

Code	Definition	Description
CON	Contamination	Contamination, including observations of insects or other debris
DAM	Filter damage	Filter appeared damaged
EST [1/]	Elapsed sample time	Elapsed sample time out of specification
EVT	Event	Exceptional event expected to have effected sample (e.g., dust, fire , spraying)
FAC	Field accident	An accident in the field occurred that either destroyed the sample or rendered it not suitable for analysis
FAT	Failed temperature check ambient	Ambient temperature check out of specification
FIT	Failed temperature check internal	Internal temperature check out of specification
FLR [1/]	Flow rate	Flow rate, 5-minute average out of specification
FLT [1/]	Filter temperature	Filter temperature differential, 30-minute interval out of specification
FMC	Failed multipoint calibration verification	Failed the initial multipoint calibration verification
FPC	Failed pressure check	Barometric pressure check out of specification
FSC	Failed single-point calibration verification	Failed the initial single-point calibration verification
FVL	Flow volume	Flow volume suspect
GFI	Good filter integrity	Filter integrity, upon post-sampling field inspection looks good
LEK	Leak suspected	Internal/external leak suspected
SDM	Sampler damaged	Sampler appears to be damaged which may have effected filter

1/- Flag generated by sampling equipment

Laboratory Qualifiers

Code	Definition	Description
ALT	Alternate measurement	Subject parameter determined by using an alternate measurement method; value believed to be accurate but could be suspect
AVG	Average value	Average value (used to report a range of values)
BDL	Below detectable limits	There was not a sufficient concentration of the parameter in the sample to exceed the lower detection limit in force at the time the analysis was performed. Numeric results field, if present is at best, an approximate value.
BLQ	Below limit of quantitation	The sample was considered above the detection limit but there was not a sufficient concentration of the parameter in the sample to exceed the lower quantitation limit in force at the time the analysis was performed
CAN	Canceled	Analysis of this parameter was canceled and not performed
CBC	Cannot be calculated	Calculated analysis result cannot be calculated because an operand value is qualified
EER	Entry error	The recorded value is known to be incorrect but the correct value cannot be determined to enter a correction.
FBK	Found in blank	The subject parameter had a measurable value above the established QC limit when a blank was analyzed using the same equipment and analytical method. Therefore, the reported value may be erroneous.
FCS	Failed collocated sample	Collocated sample exceeded acceptance criteria limits
FFB	Failed field blank	Field blank samples exceeded acceptance criteria limits
FIS	Failed internal standard	Internal standards exceeded acceptance criteria limits
FLB	Failed laboratory blank	Laboratory blank samples exceeded acceptance criteria limits
FLD	Failed laboratory duplicate	Laboratory duplicate samples exceeded acceptance criteria limits
FLH	Failed laboratory humidity	Laboratory humidity exceeded acceptance criteria limits
FLT	Failed laboratory temperature	Laboratory temperature exceeded acceptance criteria limits
FQC	Failed quality control	The analysis result is not reliable because quality control criteria were exceeded when the analysis was conducted; numeric field, if present, is estimated value.
FTB	Failed trip blank	Trip blank sample exceeded acceptance criteria limits
GSI	Good shipping integrity	Integrity of filter upon receipt by shipping/receiving looked good
HTE	Holding time exceeded	Filter holding time exceeded acceptance criteria limits
ISP	Improper sample preservation	Due to improper preservation of the sample, it was rendered not suitable for analysis

Code	Definition	Description
INV	Invalid sample	Due to single or a number or flags or events, the sample was determined to be invalid.
LAC	Laboratory accident	There was an accident in the laboratory that either destroyed the sample or rendered it not suitable for analysis.
LLS	Less than lower standard	The analysis value is less than the lower quality control standard.
LTC	Less than criteria of detection	Value reported is less than the criteria of detection
NAR	No analysis result	There is no analysis result required for this subject parameter
REJ	Rejected	The analysis results have been rejected for an unspecified reason by the laboratory. For any results where a mean is being determined, these data were not used to calculate the mean.
REQ	Re-que for re-analysis	The analysis is not approved and must be re-analyzed using a different method.
RET	Return(ed) for re-analysis	The analysis result is not approved by laboratory management and re-analysis is required by the bench analyst with no change in the method.
RIN	Re-analyzed	The indicated analysis results were generated from a re-analysis
STD	Internal standard	The subject parameter is being used as an internal standard for other subject parameters in the sample. There is no analysis result report, although the theoretical and/or limit value(s) may be present
UND	Analyzed but undetected	Indicates material was analyzed for but not detect

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Appendix E

Technical Systems Audit Forms

(These forms are available from OAQPS in electronic format.)

Document **Page**

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PEP Field Technical Systems Audit Form

Part 1 - Quality System Documentation and Facility Operations

Agency Being Evaluated:

Office or Lab Location:

AQS Site ID:

Assessor Name: Affiliation:

Observer(s) Name: Affiliation:

Assessment Date:

Section 1. Organization and Responsibilities

1. Field Operations Manager

Name: Affiliation:

Phone:

Address:

Phone:

E-mail:

2. PEP Field Operators(s)

Name: Affiliation:

Phone:

Address:

Phone:

E-mail:

Name: Affiliation:

Phone:

Address:

Phone:

E-mail:

PEP Field Technical Systems Audit Form

Section 1. Organization and Responsibilities (Cont'd)

Audit Questions (Block for the correct answer is highlighted yellow. If answer other than correct answer, enter response in Comments Section.)

(O = Other)

		RESPONSE		
		Y	N	O
1	Does the SLT PEP operate under an approved quality assurance project plan (QAPP)?			
	Date of QAPP approval?			
2	Are there significant differences between the Federal PEP QAPP and the SLT PEP QAPP			
	If yes list or briefly describe the differences in the comment section.			
3	If yes, does the approved QAPP contain the field operations SOP(s)?			
4	Is a copy of the approved QAPP and SOP available for review by field operators?			
	If no, briefly describe how and where QA and QC requirements and SOPs are documented			
5	Have all appropriate personnel reviewed the QAPP?			
6	Are there any deviations from the field SOP(s) at your site?			
	If yes, briefly describe why.			
7	Have the PEP Field operators attended PEP training ?			
	When?			
	Lab Technicians if applicable			

Section 1 Comments (Place question number and comment)

PEP Field Technical Systems Audit Form

Section 2. Safety

Audit Questions (Block for the correct answer is highlighted yellow. If answer other than correct answer, enter response in Comments Section.)

		(O = Other) RESPONSE Y	N	O
1	Is the field operator authorized to suspend a PEP audit in the event of a health or safety hazard If not, then who?			
2	Has the operator been trained in the particular hazards of the instrument/materials with which they are operating?			
3	Are personnel outfitted with any required safety equipment? E.g., extreme weather clothing, harnesses, head gear, repellants.			
4	Are personnel trained regarding OSHA Limits for manually lifting and carrying loads?			
5	Are personnel trained regarding other safety issues and procedures?			

Section 2 Comments (Place question number and comment)

Section 3. Sampler Siting

Use 40 CFR Appendix A and E for siting requirements

Audit Questions (Block for the correct answer is highlighted yellow. If answer other than correct answer, enter response in Comments Section.)

		(O = Other) RESPONSE Y	N	O
1	Has the auditor evaluated the site of the FRM sampler and PEP sampler used in this TSA to determine if it conforms to the siting requirements of 40 CFR 58, Appendices A and E?			
2	Has permission been given for not complying with the siting criteria? If yes, please explain.			
3	Are there any noticeable problems at the site that would affect sample integrity?			
4	Are there any visible sources that might influence or impact the monitoring instrument? If present list the influencing sources in the comment section			

Section 3 Comments (Place question number and comment)

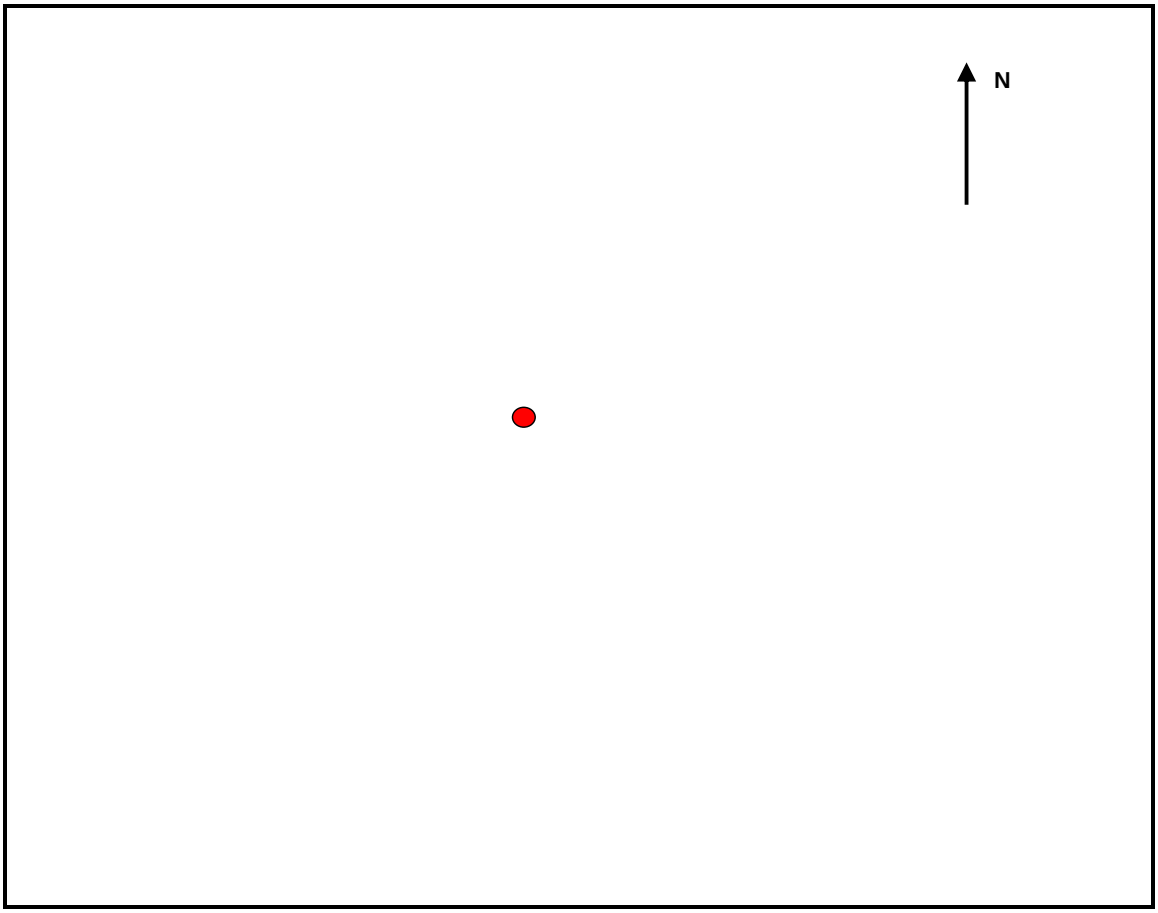
PEP Field Technical Systems Audit Form

Drawing of site SLT is Auditing During TSA

Briefly draw the monitoring location and illustrate all obstructions including distances to the nearest roadways and/or obstructions. Use the table below to indicate objects, distance from object to sampler (m), height of object (m), and orientatation from sampler (degrees).

	Object(s)	Distance from sampler to object, (m)	Height of object, (m)	Orientation from sampler to object, (degrees)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

After your sketch, please photograph the sampler from 8 cardinal directions, and then take photographs looking from the sampler in the 8 directions.



Place the PM sampler in middle of drawing.

PEP Field Technical Systems Audit Form

Basic siting criteria from 40 CFR Appendix A and E

1 The height of the inlet to the sampler should be between 2 and 15 meters above ground surface.

2 For samplers located on roofs or other structures, the minimum separation distance between the inlet and any structure should be greater than 2 meters.

3 The sampler should be located away from obstacles so that the monitor is at a distance least twice the height of the obstacle. For example, a tree is 10 meters tall and is east of the sampler. The sampler would need to be placed at least 20 meters away from a tree.

4 An unrestricted air flow of 270° must exist around the inlet.

5 If the sampler is located on the side of a building, a 180° air flow clearance is required.

6 Sampler inlet should be placed at least 20 meters from the drip line of any tree.

7 Minimum distance to any roadway is 10 meters, but this value is determined by the average daily number of vehicles (refers to 40 CFR Part 58 Appendix E for exact table).

8 The inlet for a co-location sampler and audit sampler should agree vertically within 1 meter.

9 The closest horizontal distance to place a co-location sampler to a Lo-Vol sampler or Hi-Vol sampler is 1 and 2 meters, respectively. The maximum horizontal distance a co-location sampler can be from any sampler is 4 meters.

Comments:

Section 4. Monitoring Site Information & Audit Event Planning

Block for the correct answer is highlighted yellow. If answer other than correct answer, enter response in Comments Section.

		(O = Other) RESPONSE Y	N	O
1	Does SLT auditor have Site Data Sheet for the site being audited			
2	Does SLT maintain a data base to permanently store information			
3	Is the sampling platform or set-up area clean and in good repair?			
4	Is there adequate room to perform the needed operations?			
5	Does the SLT PEP have a tentative audit plan for the current calendar year			
6	Does field operator have a working knowledge of the correct sampling days Explain in comment section the contingency measures if planned audits do not take place			

Section 4 Comments (Place question number and comment)

PEP Field Technical Systems Audit Form

Section 5. Sample Handling

Audit Questions (Block for the correct answer is highlighted yellow. If answer other than correct answer, enter response in Comments Section.)

(O = Other)

		RESPONSE		
		Y	N	O
	Receiving:			
1	Does Field Operator log information on COC and Initiate FDS			
2	Does Field Operations have adequate clean and conditioned temporary storage space			
3	Are all samples handled to avoid contamination and/or loss of material during field operation?			
4	Does the operator know how to perform trip and field blank events?			
	Have operator show steps. Document any discrepancy from SOP.			

Satisfactory=S, Unsatisfactory=U, Need Review =R, Not Assessed=NA

		RESPONSE			
		S	U	R	NA
5	Observe the following handling steps for PEP samples, verifying that the auditor follows the sample handling SOPs correctly:				
a.	Receipt and temporary storage of sampling filters at the auditor's office facility				
b.	Documents receipt of sampling filter on chain of custody form				
c.	Inspection of the sampling filter prior to sampling				
d.	Installation of sampling filter in the sampler				
e.	Retrieval of exposed filter from the sampler after a sampling event				
f.	Completion of chain of custody and field data forms and shipping package included				
g.	Filters transferred to local operator's facility, follows temporary transport procedures				

6 How are sample handling problems communicated and to whom?

Section 5 Comments (Place question number and comment)

PEP Field Technical Systems Audit Form

Section 6. Demonstration of Properly Setting-up and Running a PEP Audit

Satisfactory=S, Unsatisfactory=U, Need Review =R, Not Assessed=NA

	Set-up of the Sampler:	RESPONSE S	U	R	NA
1	Auditor properly sets-up PEP sampler				
2	Auditor properly powers the unit				
3	Field Scientist properly set date/time				
	Field Scientist properly conducts sampler performance verifications in correct order:				
4	Leak Check				
5	Ambient Temperature Measurement				
6	Barometric Pressure Measurement				
7	Flow Rate setting and calibration				
8	Filter Temperature Measurement				
9	Field Scientist properly programs the audit sampler for subsequent sampling event				
10	Field Scientist properly recovers the exposed filter and downloads or records run data				
11	Field scientist properly disassembles unit and stores components in correct transport cases				

Section 6 Comments (Place question number and comment)

Section 7. Shipping

Audit Questions (Block for the correct answer is highlighted yellow. If answer other than correct answer, enter response in Comments Section.)

(O = Other)

		RESPONSE Y	N	O
1	Is there adequate freezer space to for blue ice on site or in the office?			
2	Does site operator have knowledge of filter holding/use/shipping times?			
3	Are there weekend storage procedures in place?			
4	Are the coolers and samples being packed according to the SOPs? Have site operator demonstrate procedure and document any discrepancies.			

Section 7 Comments (Place question number and comment)

PEP Field Technical Systems Audit Form

Part 2 - MQOs for Audit Samplers, Calibrations, and Audit Devices

(The blue highlighted cells below will be filled by values entered on page 1.)

Monitoring Site Location:

AQS Site ID: **Assessment Date:**

The following activities and acceptance criteria are in the PEP QAPP and PEP Field SOP (http://www.epa.gov/ttn/amtic/pmpep.html). They should be consistent with the regulations at 40 CFR Part 50 Appendix L and Part 58 Appendix A.

Checks/Maintenance	Frequency	Requirement	Last Date	Performed Correctly?		
				Y	N	OTHER
Clock check	Every Run	Current date, time ± 5 minute				
Leak check	Every Run	< 80 mL/min				
Flow rate check	Every Run	±4% sampler design FR & Ref Std				
Filter temperature check	Every Run	Current temp ± 2°C*				
External temperature check	Every Run	Current temp ± 2°C*				
Ambient pressure check	Every Run	Current pressure +/- 10 mm Hg*				
Inspect and, if necessary, empty water collector jar	Every Run	Per service manual				
Inspect/clean impactor or cyclone	Every Run	Per service manual				
Inspect visible O-rings in the flow path	Every Run	Per service manual				
Clean sampler's inlet surfaces	Quarterly	Per service manual				
Clean main (first-stage) size-selective inlet (PM-10 head)	Quarterly	Per service manual				
Clean impactor housing and jet surfaces	Quarterly	Per service manual				
Clean cyclones	Every 10 Runs and Quarterly	Per service manual				
Clean interior of sampler unit	Quarterly	Per service manual				
Check condition of sample transport containers	Quarterly	Per service manual				
Clean sampler downtube	Quarterly	Per service manual				
Inspect cooling air intake fan(s) and filter	Quarterly	Per service manual				
Inspect all O-rings and reapply vacuum grease as needed	Quarterly	Per service manual				
Inspect vacuum tubing, tube fittings, and other connections to the pump and electrical components	Quarterly	Per service manual				
Clock check w/independent std	Quarterly	Current date, time ± 5 minute				
Flow rate audit w/independent std	Quarterly	±4% sampler design FR & Ref Std				
Filter temperature check w/independent std	Quarterly	Current temp ± 2° C*				
External temperature audit w/independent std	Quarterly	Current temp ± 2° C*				
Ambient pressure audit w/independent std	Quarterly	Current pressure +/- 10 mm Hg*				
Flow rate calibration device	Annually	Certify as NIST-traceable**				
Temperature calibration device	Annually	Certify as NIST-traceable**				
Pressure calibration device	Annually	Certify as NIST-traceable**				
Flow rate audit device	Annually	Certify as NIST-traceable**				
Temperature audit device	Annually	Certify as NIST-traceable**				
Pressure audit device	Annually	Certify as NIST-traceable**				

* Comparison should be made to NIST-traceable audit device.

** Certifications may be performed by EPA, its contractor, or by the manufacturer.

Are corrective actions in place when Measurement Quality Objectives (MQOs) are **not** met (e.g. out-of-control calibration data)?

Part 2 MQO Comments

PEP Sampler Audit Worksheet

$PM_{2.5}$ Performance Evaluation Program **U.S. Environmental Protection Agency**

Location:

AQS Site ID: **Date:**

Latitude (if known): Longitude (if known):

Audit Information

Auditor(s): Affiliation:

Site Operator: Affiliation:

Phone No.:

Sampler Model Sampler S/N:

Last Calibration Date: Collocated? Yes (X):

No (X):

Reference Std Model: Reference Standard S/N:

Calibration Date:

Significant Findings:

PEP Sampler Audit Worksheet

Location:

AQS Site ID: **Date:**

Clock Test:

If Local Time is under daylight savings, convert Ref Std to Local Standard Time. Daylight Saving Time begins for most of the United States at 2:00 a.m. on the first Sunday of April. Time reverts to standard time at 2:00 a.m. on the last Sunday of October.

	Time (hh:mm)			Difference Minutes	5 minutes or less?	
	Ref Std		PQ200		Pass	Fail
Audit						
Recalibrated						
Date						

Leak Test

	Initial Audit	After Correction		Change < 5 cmH2O for 2-min interval		
				Difference	Pass	Fail
Start cm H_2O			Initial:			
Stop cm H_2O			After Correction:			

Flow Test **Calibration**

For the reference standard, enter "UR" for under range and "OR" for over range flow readings.

	L/min			Less than 4%?	
	Ref Std	PQ200	% Difference	Pass	Fail

Retest after Calibration

	L/min			Less than 4%?	
	Ref Std	PQ200	% Difference	Pass	Fail

PEP Sampler Audit Worksheet

Location:

AQS Site ID: **Date:**

Reference Standard vs Design Flow

	L/min			Less than 4%?	
	Ref Std	PQ200	% Difference	Pass	Fail
Channel 1		16.70			

Retest after Calibration

	L/min			Less than 4%?	
	Ref Std	PQ200	% Difference	Pass	Fail
Channel 1		16.70			

Ambient Temperature Test

	Degrees C			Less than 2 degrees?	
	Ref Std	PQ200	Difference	Pass	Fail

Retest After Recalibration

Filter Temperature Test

	Degrees C			Less than 2 degrees?	
	Ref Std	PQ200	Difference	Pass	Fail

Retest After Recalibration

Pressure Test

	mm Hg			Less than 10 mm?	
	Ref Std	PQ200	Difference	Pass	Fail

Retest after recalibration

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PEP Laboratory Technical Systems Audit Form

Audit Location and Attendees
(include Names, Affiliations, and Addresses)

Date(s) of Audit: _____

Audit Report Date: _____

Laboratory

Summary of Findings

Auditor(s)	**Phone No.**	**E-mail**

Observer(s)	**Phone No.**	**E-mail**

EPA Lab Oversight Personnel	**Phone No.**	**E-mail**

Laboratory Supervisor	**Phone No.**	**E-mail**

Laboratory Analyst(s)	**Phone No.**	**E-mail**

PEP Laboratory Technical Systems Audit Form

Finding Level: 1=exemplary; 2=satisfactory; 3=needs small improvement; 4=unsatisfactory and needs significant attention; 5=critical or catastrophic condition that needs immediate attention

Section-Question No.	Audit Question	Yes	No	N/A	Response or Comment	Finding Level
Section 1	**Laboratory Management and Quality System Requirements**					
1-1.	Does the Laboratory operate under a Quality Management Plan?					
1-2.	Are the EPA organizational structure and responsibilities of oversight personnel well documented and understood?					
1-3.	Does the Laboratory operate under a unique Quality Assurance Project Plan?					
1-4.	When was it last updated?					
1-5.	Does the PEP Laboratory operation follow an up-to-date SOP?					
1-6.	When was it last updated?					
1-7.	How are QA documents controlled?					
1-8.	How often are QA documents reviewed for accuracy?					
1-9.	Are obsolete documents such as the old version of an SOP retained?					
1-10.	How long are technical records maintained before they are disposed?					
1-11.	Who is authorized to halt program activities due to inadequate quality?					
1-12.	What kind of internal audit procedures exist?					
1-12a.	Existence of Class 1 or 0 ASTM-certified weights					
1-12b.	Last certification date(s)					
1-12c.	Existence of NIST-traceable temperature and humidity std and data logger					
1-12d.	Accuracy					
1-12e.	Last certification date(s)					
1-13.	Are reports available from the most recent internal and previous external audits?					
1-14.	Were there any significant findings and if so what were they?					
1-15.	Are reports available for recent preventive or corrective actions associated with last internal and external audits?					
1-16.	Is there a primary and a back-up PM2.5 PEP Laboratory Analyst?					
1-17.	Have PM2.5 PEP Laboratory Analysts been thoroughly trained on the PEP field and laboratory operations and specifically on lab support functions?					
1-18.	Does the EPA Laboratory Manager conduct an annual review or audit of procedures with the analysts and laboratory supervisor?					
1-19.	In the event of a catastrophic failure or suspension of the Laboratory; is there a back-up laboratory and contingency plans for continued support?					

PEP Laboratory Technical Systems Audit Form

Section-Question No.	Audit Question	Yes	No	N/A	Response or Comment	Finding Level
Section 2	**General Facilities**					
2-1.	Are isles and hallways to and from the filter processing and weighing lab free of obstructions?					
2-2.	Is access to the weighing lab limited and controlled?					
2-3.	Is there a place in the log book for recording entry and use of the weighing lab?					
2-4.	Are samples maintained in a secure area at all times after being delivered to the facility?					
2-5.	Does adequate refrigerated storage capacity exist?					
2-6.	Are samples that are stored in the refrigerator logged-in, maintained on an inventory list, and logged-out at disposal? Provide an example page.					
2-7.	Does the operator keep the filter-handling area neat and clean?					
2-8.	Is the weighing lab clear of extraneous papers, trash, and especially dust?					
2-9.	Is there a sticky mat at the entrance of the lab and has the top sheet be removed recently, revealing a sticky surface to collect dirt and dust from shoes?					
2-10.	Is the analytical balance positioned on a weighted table?					
2-11.	Are supplies and instruments such as alcohol wipes and tweezers stored away neatly when not in use?					
2-12.	Is there a climate control system for the weighing lab and is it engaged and working properly?					
2-13.	Is there a monitor or strip-chart recorder that is easily read by the lab attendants and in plain view?					
2-14.	Does the climate control system have an alarm to indicate when conditions inside the weighing lab are not suitable for weighing samples?					
2-15.	Please provide strip charts or graphs of the last two weeks' recordings.					
2-16.	Has the climate control system satisfactorily maintained critical parameters for the last two months? If "no" explain.					
2-17.	Is there a routine maintenance or service contract in place for the climate control system?					
2-18.	Are important routine maintenance procedures for the climate control system conducted? Produce record or data.					

PEP Laboratory Technical Systems Audit Form

Section-Question No.	Audit Question	Yes	No	N/A	Response or Comment	Finding Level
Section 3	**General PM2.5 PEP Laboratory Procedures**					
3-1.	Are logbooks kept up-to-date and properly filled in clearly and completely?					
3-2.	How are records of critical consumables (such as filter lot numbers) maintained?					
3-3.	Do analysts have a supply of disposable laboratory jackets and shoe covers that attract and retain dust particles?					
3-4.	Are filters handled with the necessary care and finesse to avoid contamination and/or loss of material?					
3-5.	Does the analyst thoroughly understand filter conditioning requirements and procedures for pre-exposed and post-exposed filters?					
3-6.	Are new filters placed in the conditioning environment immediately upon arrival and stored there not less than 24 hours prior to weighing?					
3-7.	Is the analytical balance located in the same controlled environment in which the filters are conditioned?					
3-8.	Are filters conditioned at the same environmental conditions before both the pre- and post-sampling weighing?					
3-9.	Do analysts have a thorough understanding of the timing requirements for the life-cycle of a PEP filter?					
Section 4	**Balance Maintenance and Weighing Procedures**					
4-1.	Is the balance serviced under a calibration and maintenance plan? Specify date of last service.					
4-2.	Is there an up-to-date, formal logbook or file for balance maintenance?					
4-3.	Does the analytical balance used to weigh filters have a readability of ±1 µg?					
4-4.	Does a back-up balance exist that has a current calibration certificate?					
4-5.	Does a unique set of Class 0 reference weight standards exist for routine calibration checks of the balance?					
4-6.	Does a certification exist? Last certification date? Certifying laboratory?					
4-7.	Are regular (e.g., daily, when in use) calibration checks made and recorded?					
4-8.	Analyst should demonstrate weighing calibration weights. Please produce results for last 2 weighing sessions.					
4-9.	Does a device exist for removal of static charges from the filter prior to and during the weighing process?					
4-10.	The analyst should demonstrate the use of the antistatic device(s) during a weighing exercise.					

PEP Laboratory Technical Systems Audit Form

Section-Question No.	Audit Question	Yes	No	N/A	Response or Comment	Finding Level
4-11.	Are the filters weighed immediately following the conditioning period without intermediate or transient exposure to other conditions or environments?					
4-12.	Are both the pre- and post sampling weighing performed on the same analytical balance?					
4-13.	Analyst should demonstrate weighing of conditioned filters. Data should be provided for last two sets of filters.					
4-14.	Does analyst understand the function and importance of lab blanks?					
4-15.	Analyst should describe what a lab blank is and how it is incorporated into the weighing routine.					
4-16.	Does analyst understand the function and importance of field and trip blanks?					
4-17.	Are replicate weighing performed by the same analyst? If not are results of round robin weighing between all analysts to determine biases?					
4-18.	Analyst should demonstrate proper loading of filters into cassettes.					
Section 5	**Data handling and data validation**					
5-1.	Does the lab analyst have thorough understanding and high proficiency for entering data into the PEP database (PED)?					
5-2.	Does the analyst record PEP filters in the database according to the PEP protocol, which assigns cassette ID numbers and identifies trip blanks? Lab analyst should demonstrate.					
5-3.	Is there a procedure to QA the data by the lab analyst? Have them describe it and provide an example of result; i.e., graph or statistics, etc.					
5-4.	Is there a procedure for a lab manager or supervisor to QA the data generated by the lab analyst? Have them describe.					
5-5.	Does the analyst understand the significance of the Chain-of-Custody Form?					
5-6.	Does the analyst know how to enter all information on the Field Data Sheet into the PEP database?					
5-7.	Do the analysts and supervisor know the schedule for validating PEP audit data and posting it on the Region 4 website and its importance?					
5-8.	Does documentation exist that shows when, why and by whom any invalid data is overridden and re-validated?					
5-9.	Do the analysts and supervisor know the schedule for validating PEP audit data and posting it in AQS and its importance?					
5-10.	Do the analysts and supervisor know the contact at EPA or within the PEP support contractor's organization, if there is an issue with the PED?					
5-11.	Do the analysts and supervisor know the archiving schedule for filters?					

PEP Laboratory Technical Systems Audit Form

Section-Question No.	Audit Question	Yes	No	N/A	Response or Comment	Finding Level
5-12.	Do the analysts and supervisor know the file storage numbering system for the PEP?					
5-13.	Describe system back-ups.					