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Environmental Protection  
Agency  
Air

Office of Air Quality  
Planning and Standards  
Research Triangle Park, NC 27711

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# Quality Assurance Document

## Quality Assurance Project Plan for the PM<sub>2.5</sub> Performance Evaluation Program



## *Foreword*

EPA policy requires that all projects involving the generation, acquisition, and use of environmental data be planned and documented and have an Agency-approved quality assurance project plan or QAPP prior to the start of data collection. The primary purpose of the QAPP is to provide an overview of the project, describe the need for the measurements, and define QA/QC activities to be applied to the project, all within a single document.

The following document represents the QAPP for the environmental data operations involved in the PM<sub>2.5</sub> Performance Evaluation Program.

This QAPP was generated using the EPA QA regulations and guidance as described in *EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans* and the accompanying document *EPA QA/G-5, Guidance for Quality Assurance Project Plans*. All pertinent elements of the QAPP regulations and guidance are addressed in this QAPP.

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

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

## *Acknowledgments*

This QAPP is the product of the combined efforts of the EPA Office of Air Quality Planning and Standards, the EPA Regional Offices, and the State and local organizations. The development and review of the material found in this document was accomplished through the activities of the PM<sub>2.5</sub> QA Workgroup. The following individuals are acknowledged for their contributions.

### **State and Local Organizations**

George Apgar, State of Vermont, Waterbury, VT  
Randy Dillard, Jefferson County Department of Health, Birmingham AL  
Gordon Pierce and Kevin Goohs, Colorado Department of Public Health & Environment, Denver, CO  
Russell Grace and Tom Pomales, California Air Resources Board, Sacramento, CA  
Jeff Miller, Pennsylvania Department of Environmental Protection, Harrisburg, PA  
Richard Heffern, State of Alaska Department of Environmental Conservation, Juneau, AK  
Dan Harman, North Dakota Department of Health, Bismarck, ND

### **EPA Regions**

#### Region

- 1 Don Porteous, Norman Beloin, Mary Jane Cuzzupe
- 2 Clinton Cusick
- 3 Victor Guide, Theodore Erdman
- 4 Jerry Burger, Herb Barden
- 5 Mary Ann Suero, Gordon Jones, Mike Rizzo, Basim DiHu
- 6 Mary Kemp, Mark Sather, Kuenja Chung, Timothy Dawson, Ruth Tatom
- 7 Leland Grooms, Mike Davis, Shane Munsch
- 8 Ron Heavner, Gordon MacRae, Joe Delwiche
- 9 Manny Aquitania, Bob Pallarino
- 10 Barry Towns, Bill Puckett, Karen Marasigan

### **National Exposure Research Laboratory**

Frank McElroy, David Gemmill

### **Research Triangle Institute**

Jim Flanagan, Cynthia Salmons, Cary Eaton, Bob Wright

### **Office of Air Quality Planning and Standards**

Joe Elkins, Shelly Eberly, Tim Hanley, David Musick, Mark Shanis

## *Acronyms and Abbreviations*

AIRS	Aerometric Information Retrieval System
ANSI	American National Standards Institute
APTI	Air Pollution Training Institute
ASTM	American Society for Testing and Materials
AWMA	Air and Waste Management Association
CAA	Clean Air Act
CFR	Code of Federal Regulations
CMD	Contracts Management Division
CMZ	community monitoring zone
CO	Contracting Officer
COC	chain of custody
DAS	data acquisition system
DCO	Document Control 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
FRM	Federal reference method
GIS	geographical information systems
GLP	good laboratory practice
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
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
PC	personal computer
POC	pollutant occurrence code
PD	percent difference
PE	performance evaluation
PM <sub>2.5</sub>	particulate matter $\leq 2.5$ microns
PTFE	polytetrafluoroethylene
Q <sub>a</sub>	sampler flow rate at ambient (actual) conditions of temperature and pressure.
QA/QC	quality assurance/quality control
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
QMP	quality management plan
SIPS	State Implementation Plans
SLAMS	state and local monitoring stations
SOP	standard operating procedure
SOW	statement or scope of work
SPMS	special purpose monitoring stations
SYSOP	system operator
$T_a$	temperature, ambient or actual
TSA	technical system audit
TSP	total suspended particulate
$V_a$	air volume, at ambient or actual conditions
VOC	volatile organic compound
WAM	Work Assignment Manager

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## 1.0 QA Project Plan Identification and Approval

**Title:** *PM<sub>2.5</sub> Performance Evaluation Program QA Project Plan*

The attached QAPP for the PM<sub>2.5</sub> Performance Evaluation Program (PEP) is hereby recommended for approval and commits the participants of the program to follow the elements described within.

Signature: *Joe Elkins* Date: 2/26/99  
Joe Elkins- QA Manager Office of Air Quality Planning and Standards

Signature: *Mary Joe M. Curry* Date: 2/12/99  
Region 1

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Region 2

Signature: *Charles Jones Jr* Date: 2-9-99  
Region 3 *Regional Q.A. Officer*

Signature: *Sally Bennett* Date: 1-19-99  
Region 4

Signature: *Hendon S. Jones* Date: 1-21-99  
Region 5

Signature: *Kuen-jin C. Chung* Date: 01/15/99  
Region 6

Signature: *Ernest L. Amador* Date: 2/4/99  
Region 7

Signature: *P. Medina* Date: 1-6-98  
Region 8

Signature: *Van B. Tong* Date: 1-15-99  
Region 9

Signature: *W.B. [Signature]* Date: 1/25/99  
Region 10

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### 3.0 Distribution

A hardcopy of this QAPP has been distributed to the individuals in Table 3-1. The Regional Work Assignment Managers (WAMs) will be responsible for distributing the QAPP to each Environmental Services Assistance Team (ESAT) contractor participating in the environmental data operations of the PEP. The Regional WAMS may also want to provide a copy of this QAPP to their Regional QA Managers.

**Table 3-1 Distribution List**

Name	Address	Phone Number	Electronic Mail
<b>ESAT</b>			
Angela Edwards Kathleen Engel Colleen Walling	U.S. EPA 401 M Street, SW. Washington, DC 20460.  Colleen Walling 5203G Kathleen and Angie 3805R	(703) 603-8709 (202) 564-4504 (703) 603-8814	edwards.angela@epa.gov engel.kathleen@epa.gov walling.colleen@epa.gov
<b>OAQPS</b>			
Joe Elkins Michael Papp David Musick Tim Hanley Mark Shanis	USEPA Office of Air Quality, Planning & Standards MQAG (MD-14) RTP, NC 27711	(919) 541-5653 (919) 541-2408 (919) 541-2396 (919) 541-4417 (919) 541-1323	elkins.joe@epa.gov papp.michael@epa.gov musick.david@epa.gov hanley.tim@epa.gov shanis.mark@epa.gov
<b>REGIONS</b>			
<b>Region 1</b> <b>WAM</b> Mary Jane Cuzzupe  <b>PO</b> Tony Palermo	USEPA-Region 1 New England Regional Laboratory 60 Westview Street Lexington, MA 02421	(781) 860-4383   (781) 860-4682	cuzzupe.maryjane@epa.gov   palermo.anthony@epa.gov
<b>Region 2</b> <b>WAM</b> Clinton Cusick <b>PO</b> Dick Coleates	USEPA-Region 2 Raritan Depot / MS103 2890 Woodbridge Ave Edison, NJ 08837-3679	(908) 321-6881   (732) 321-6662	cusick.clinton@epa.gov   coleates.dick@epa.gov
<b>Region 3</b> <b>WAM</b> Theodore Erdman  <b>PO</b> Fred Foreman	USEPA-Region 3 841 Chestnut Building / 3ES11 Philadelphia, PA 19107  US EPA- ESC 701 Maps Road Ft. Meade, MD 20755-5350	(215) 597-1193   (410) 305-2629	erdman.ted@epa.gov   foreman.fred@epa.gov

Name	Address	Phone Number	Electronic Mail
<b>Region 4</b> <b>WAM</b> Herb Barden Steve Hall  <b>PO</b> Mike Birch	US-EPA Reg 4 Science and Ecosystem Support Division 980 College Station Road Athens, Georgia 30605-2720  USEPA-Region 4 APTMD Atlanta Federal Center 61 Forsyth St. SW Atlanta, GA 30303-3104	  (706) 355-8737 (706) 355-8615    (706) 355-8552	  barden.herbert@epa.gov hall.johns@epa.gov    birch.mike@epa.gov
<b>Region 5</b> <b>WAM</b> Gordon Jones  <b>PO</b> Jay Thakkar	USEPA-Region 5 77 West Jackson Blvd. / AR18J Chicago, IL 60604-3507  / SM5J	  (312) 353-3115    (312) 886-1972	  jones.gordon@epa.gov    thakkar.jay@epa.gov
<b>Region 6</b> <b>WAM</b> Kuenja Chung  <b>PO</b> Melvin Ritter	USEPA-Region 6 First Interstate Bank Tower at Fountain Place 1445 Ross Avenue Dallas, TX 75202-2733  USEPA Region 6 Laboratory Houston Branch/ 6MD-HC 10625 Fallstone Road Houston TX 77099	  (214) 665-8345    (281) 983-2146	  chung.kuenja@epa.gov    ritter.melvin@epa.gov
<b>Region 7</b> <b>WAM</b> Mike Davis  <b>PO</b> Harold Brown	USEPA-Region 7 ENSV / EMWC 25 Funston Road Kansas City, KS 66115  USEPA Region 7 726 Minnesota Ave/ENSV/RLAB Kansas City, KS 66101	  (913) 551-5081    (913)-551-5127	  davis.michale@epa.gov    brown.harold@epa.gov
<b>Region 8</b> <b>WAM</b> Joe Delwiche  <b>PO</b> Barbara Daboll	USEPA-Region 8 999 18th Street /8P2-A Suite #500 Denver, CO 80202-2466  /8TMS-L	  (303) 312-6448    (303) 312-7757	  delwiche.joseph@epa.gov    daboll.barbara@epa.gov
<b>Region 9</b> <b>WAM</b> Mathew Plate  <b>PO</b> Rose Fong	USEPA-Region 9 75 Hawthorne St. /PMD-3 San Francisco, CA 94105	  (415) 744-1493    (415) 744-1534	  plate.mathew@epa.gov    fong.rose@epa.gov
<b>Region 10</b> <b>WAM</b> Karen Marasigan  <b>PO</b> Gerald Dodo	USEPA-Region 10 1200 Sixth Ave / ES-095 Seattle, WA 98101  USEPA Region 10 Manchester Laboratory 7411 Beach Drive East Port Orchard, WA 98366	  (206) 553-1792    (206) 553-8728	  marasigan.karen@epa.gov    dodo-gerald@epa.gov

## 4.0 Project/Task Organization

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

The degree of complexity and the number of agencies 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 the involved organizations. The purpose of the following descriptions of roles is to facilitate communications, and to outline very basic responsibilities. Figure 4.1 provides a basic diagram of the organization and lines of communication. Table 3-1, in Section 3.0 provides a listing of primary personnel involved in the PEP.

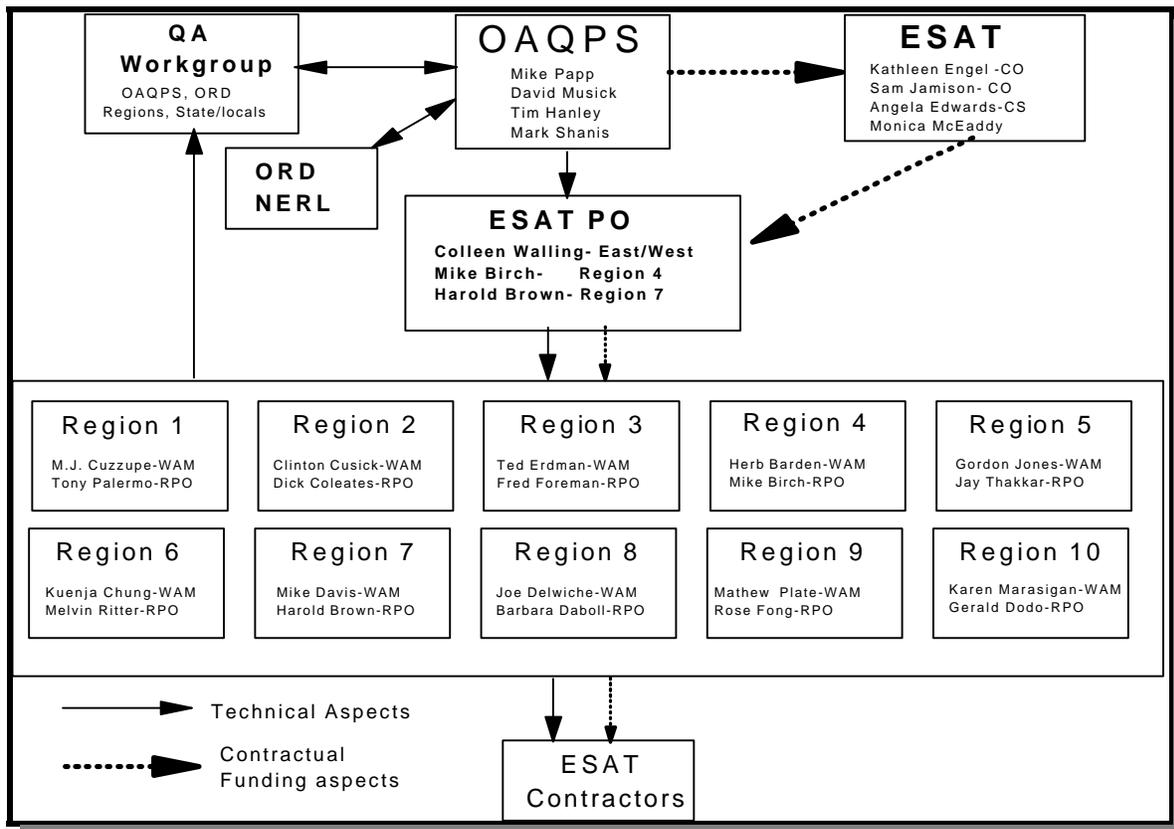


Figure 4.1 Organizational chart of the technical and contractual aspects of the Performance Evaluation Program

## 4.1 PM<sub>2.5</sub> QA Workgroup

The PM<sub>2.5</sub> Quality Assurance (QA) Workgroup was formed to address the QA aspects of the PM<sub>2.5</sub> Program. Members on the group include personnel from Office of Air Quality Planning and Standards (OAQPS), EPA Regions, the Office of Research and Development (ORD) National Exposure Research Laboratory (NERL) and State and local air monitoring organizations. The QA Workgroup meets approximately every month to discuss various QA issues. Many of the Regional participants on this Workgroup will also function as work assignment managers (WAMs) for the ESAT Contract. The Workgroup plays an advisory role and will assist in the development of the Implementation Plan, the field and laboratory SOPs, the PEP QAPP and other guidance related to the PEP.

## 4.2 EPA Office of Air Quality Planning and Standards (OAQPS)

OAQPS has oversight for ensuring the quality of the nation's ambient air data. OAQPS has developed specific regulations for the development of a quality system as found in 40 CFR Part 58, Appendix A. One specific element of this quality system is the development of the PEP. OAQPS has the following responsibilities to ensure the development of this Program including the following activities:

- ▶ coordinating and overseeing the PEP
- ▶ providing a contractual vehicle for the manufacturing and distribution of the FRM portable evaluation sampler
- ▶ developing a Memorandum of Understanding with the ESAT Office
- ▶ working with the EPA Regions to determine which State/local organizations will utilize the federally implemented PEP
- ▶ transferring the necessary funds to the EPA ESAT contracts management division to support the PEP and to the Regional offices for laboratory equipment and consumables
- ▶ procuring the majority of the field capital equipment and consumables
- ▶ distributing filters to the national laboratories
- ▶ developing the PEP Implementation Plan, the ESAT Work Assignment (WA), 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 an information management system
- ▶ assessing the concentration information uploaded to the AIRS data base and assisting in reconciling significant differences
- ▶ initiating and instituting a communications network and acting as a liaison to groups working on the PEP
- ▶ interacting with the Regional, State, and local agency personnel concerning the set-up, operation, and data results of the performance evaluations

- ▶ ensuring the success of the program by performing various oversight activities such as management systems reviews and technical systems audits

Most budgetary and technical planning activities are coordinated through OAQPS. The Monitoring and Quality Assurance Group (MQAG) within the Emissions, Monitoring, and Analysis Division (EMAD) is ultimately responsible for the implementation of the PEP and this QAPP, most technical components (with support from ORD, Regional Offices, and States/locals), 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 Information Transfer and Program Integration Division is responsible for the AIRS data management system.

### 4.3 ESAT Organization

The ESAT contract is in reality four contracts; 2 zone contracts and contracts in Region 4 and 7. The ESAT is organized of contracting officers (COs), contracting specialists (CSs), project officers (POs), and regional project officers (RPOs). Table 2-1 provides information on the four zones and the important contacts within them.

**Table 4-1 ESAT Organization**

Kathleen Engel- Contracting Officer- Eastern, Western, Region 7 zones Sam Jamison- Contracting Officer- Region 4 zone Angela Edwards - Contracting Specialist			
Zone	Regions	Headquarters PO	RPOs
Western	6 8 9 10	Colleen Walling	Melvin Ritter Barbara Daboll Rose Fong Gerald Dodo
Eastern	1 2 3 5	Colleen Walling	Tony Palermo Dick Coleates Fred Foreman Jay Thakkar
Region 4	4	Mike Birch	Mike Birch
Region 7	7	Harold Brown	Harold Brown

Some important aspects of the ESAT contract include:

- ▶ only the WAM, RPO/PO, 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 given in writing

- ▶ the work assignments will be prepared by the WAMs and RPOs and are effective only upon approval by the CO

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

### **Contracting Officers**

- ▶ working with OAQPS on the securing, obligating, committing, and distributing funds for work performed under the ESAT Contract
- ▶ ensuring work assignment activities fall within the ESAT Scope of Work
- ▶ approving work assignments

### **Headquarters Project Officers**

- ▶ acting as a regional liaison between the RPO and the CO
- ▶ providing contract-wide administration
- ▶ developing a memorandum of understanding with OAQPS

### **Regional Project Officers**

- ▶ providing overall management and overseeing performance of respective regional teams
- ▶ reviewing region specific invoices with input from WAMs
- ▶ preparing (with WAM) PEP work assignments
- ▶ assisting in the development of the PEP Implementation Plan and the ESAT Work Assignment
- ▶ ensuring there are qualified contractual personnel available to implement the PEP
- ▶ providing administrative and logistical support for the ESAT contract
- ▶ overseeing the performance of the required activities of the contractor
- ▶ communicating on a regular basis with program participants (OAQPS, Region, etc.)

### **Work Assignment Managers**

The Work Assignment Manager (WAM) will, in most cases, be a technical person from the Regional air monitoring branch/division who will be responsible for assisting in the technical aspects of the program. Some of the WAMs' activities may also include the activities listed in Section 4.4, but the responsibilities, as they relate to the ESAT contract, include the following:

- ▶ preparing (with RPO) PEP work assignments

- ▶ setting up a file system containing all relevant documentation including notes of conversations with the contractor and other items that will provide an audit trail of their actions under the work assignment as well as all technical information related to the PEP
- ▶ reviewing the contractor's workplan and preparing findings on proposed tasks, labor hours skill mix, and materials and quantities
- ▶ monitoring compliance with the work assignments and the QAPP
- ▶ tracking dollars and hours, providing technical direction (in accordance with the terms of the contract) and reviewing monthly technical and financial reports
- ▶ verifying contractor representations of deliverables received and accepted, and/or progress
- ▶ communicating contractor performance and administrative/logistical issues to RPO
- ▶ validating and accepting data (Regions 4 and 10)

#### **4.4 EPA Regional Offices**

The EPA Regional Offices are the major communication link with State/local agencies in terms of both communicating the needs and concerns of States to EPA Headquarters Offices and in communicating the objectives and guidance that often are developed by OAQPS to the State/local agencies. This role is absolutely necessary for the development of effective policies and programs. For the PEP, the Regional offices have the following specific responsibilities:

##### **All Regions–**

- ▶ assisting, through QA workgroup activities, in the development of all pertinent PEP guidance documents
- ▶ reviewing and approving the workplans submitted by the ESAT contractors
- ▶ providing WAMs to oversee the technical aspects of field activities that are performed by the ESAT contractors
- ▶ training and certifying ESAT field personnel (if certified)
- ▶ providing technical oversight of the field activities by performing technical systems audits of these activities
- ▶ working with State and local agencies in developing a yearly schedule of site evaluations
- ▶ providing a yearly schedule of site evaluations for the ESAT contractors
- ▶ informing State and local organizations of an upcoming performance evaluation
- ▶ evaluating the performance evaluation data and informing State/locals of significant differences
- ▶ participating in training and certification activities including multi-State conferences, EPA satellite broadcasts, and other training vehicles
- ▶ attending conference calls and meetings on performance evaluation activities

#### **Regions 4 and 10 (including items listed above)--**

- ▶ providing work assignment managers to oversee the technical aspects of laboratory activities that are performed by the ESAT contractors
- ▶ developing the primary laboratories for this program with respect to logistical, technical, and analytical support, including necessary facilities to store, condition, weigh, distribute and archive filters and the distribution of filters (including coolers, ice packs, etc.) to the Regions
- ▶ training and certifying ESAT laboratory personnel (if certified)
- ▶ providing technical oversight of the laboratory activities by performing technical systems audits of these activities
- ▶ validation of data prior to AIRS upload

#### **4.5 ESAT Contractors**

The ESAT contractor's will perform the specific tasks associated with the PEP. The ESAT contractors responsibilities include:

- ▶ developing a work plan and cost estimates for each work assignment
- ▶ staffing appropriately to meet the requirements of the work assignment
- ▶ successfully implementing the activities described in the work plan and work assignment
- ▶ becoming trained and certified to perform field and laboratory PEP activities
- ▶ understanding government regulations as they relate to contracts and inherent government functions

#### **4.6 State and Local Agencies**

EPA could not effectively plan and execute this program without State/local agency participation. State and local agencies bear a tremendous level of responsibility for developing, implementing, and tracking the entire national PM<sub>2.5</sub> monitoring program. It is imperative that State and local agencies work with the EPA Regional Offices throughout this process to identify problems as early as possible, and to help find solutions. The State and local agencies have the following specific responsibilities:

##### **If not utilizing the federal PEP:**

- ▶ implementing the PEP at the same frequency
- ▶ adhering to the definition of independent assessment (see Figure 1.1)
- ▶ undergoing similar training and certification activities
- ▶ procuring necessary equipment and consumables
- ▶ developing the necessary SOPs and QA procedures into their respective QAPPs
- ▶ transmitting data to AIRS

- ▶ selecting the sites for evaluation

**If utilizing the federal PEP:**

- ▶ operating their PM<sub>2.5</sub> monitoring network according to the established regulations and guidelines; this includes proper siting, operations, and quality assurance procedures
- ▶ creating an accurate list of SLAMS sites with addresses, AIRS ID's, and makes/models of routine sampling equipment
- ▶ assisting, through QA workgroup activities, in the development of pertinent PEP guidance documents
- ▶ on a yearly basis, determining whether to continue utilizing the federal implementation of the PEP
- ▶ identifying the sites within their monitoring network for performance evaluations
- ▶ ensuring an agency representative is on-site when the PEP field scientist arrives and performs the evaluation; this includes communicating with the operator, operating the routine monitor in the normal operating mode, and generally supporting the PEP
- ▶ ensuring the success of the program by performing various oversight activities such as technical systems audits of field and laboratory activities
- ▶ participating in training activities, including multi-State conferences, EPA satellite broadcasts, and other training vehicles
- ▶ reviewing routine and performance evaluation data and working with the EPA Region on corrective actions

## **4.7 Other Affected Entities**

### **EPA Office of Research and Development (ORD)**

The ORD's primary role in the implementation of the PEP will be 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 portable audit sampler must be designated by ORD through their Federal Reference and Equivalency Program (40 CFR 53). This overall responsibility includes:

- ▶ designating PM<sub>2.5</sub> 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 Contracts Management Division (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 EMAD technical staff. The CMD is responsible for all communications with vendors and extramural contract organizations. The CMD's responsibilities include:

- ▶ 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 contracting officers and other contracting support for national procurements

### **National Performance Audit Program**

The National Performance Audit Program (NPAP) is a federally implemented national audit program required for all SLAMS (40 CFR Part 58, Appendix A). Since the PEP affects the PM<sub>2.5</sub> SLAMS monitors, the NPAP may assume responsibility of the evaluations, depending on future logistical and financial constraints of the ESAT program. Since this is uncertain, the NPAP will continue to have the capability to assume this responsibility without incurring any financial or logistical costs.

## 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

Between the years 1900 and 1970, the emission of six principal ambient air pollutants increased significantly. The current principal pollutants, also called criteria pollutants, are: particulate matter (PM<sub>10</sub>, PM<sub>2.5</sub>), sulfur dioxide, carbon monoxide, nitrogen dioxide, ozone, and lead. In 1970 the Clean Air Act (CAA) was signed into law. The CAA and its amendments provides the framework for all pertinent organizations to protect air quality. This framework provides for the monitoring of these criteria pollutants by State and local organizations through the Ambient Air Quality Surveillance as defined in 40 CFR 58.

The criteria pollutant defined as particulate matter 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 part of the Ambient Air Quality Monitoring Program, two particle size fractions will be measured; those less than or equal to 10 micrometers (PM<sub>10</sub>), and those less than or equal to 2.5 micrometers (PM<sub>2.5</sub>). This QAPP focuses on one QA activity, the Performance Evaluation Program that is associated with PM<sub>2.5</sub> monitoring

The background and rationale for the implementation of the PM<sub>2.5</sub> ambient air monitoring network can be found in the Federal Register. In general, some of the findings are listed below.

- The characteristics, sources, and potential health effects of larger or "coarse" particles (from 2.5 to 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 kicked up 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 sulfur dioxide, 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 health effects such as aggravation of asthma. EPA's "staff paper" concludes that fine particles, which

also deposit deeply in the lungs, are more likely than coarse particles to contribute to the health effects (e.g., premature mortality and hospital admissions) found in a number of recently published community epidemiological studies.

- These recent community studies find 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 a year to several years) periods.
- These health effects include 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 cardiopulmonary 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.

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

1. To judge compliance with and/or progress made towards meeting the National Ambient Air Quality Standards (NAAQS).
2. To develop, modify or activate control strategies that prevent or alleviate air pollution episodes.
3. To observe pollution trends throughout the region, including non-urban areas.
4. To provide a data base 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 six basic monitoring objectives listed below:

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

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

The **SLAMS** consist of a network of ~ 3,500 monitoring stations whose size and distribution are largely determined by the needs of State and local air pollution control agencies to meet their respective State implementation plan (SIP) requirements.

The **NAMS** (~1,080 stations) are a subset of the **SLAMS** network with emphasis being given to urban and multi-source areas. In effect, they are key sites under **SLAMS**, with emphasis on areas of maximum concentrations and high population density.

The **PAMS** network is required to measure ozone precursors in each ozone non-attainment area that is designated serious, severe, or extreme. The required networks will have from two to five sites, depending on the population of the area. There is a phase-in period of one site per year starting in 1994. The ultimate **PAMS** network could exceed 90 sites at the end of the 5 year phase-in period.

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

***This QAPP focuses only on the QA activities of the SLAMS and NAMS network and the objectives of this network which include any PM<sub>2.5</sub> sampler used for comparison to the NAAQS.***

Throughout this document, the term *decision maker* will be used. This term represents individuals that 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. Since 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 the determination of attainment of the **NAAQS**.

Since the data for the **NAMS/SLAMS** network is used for **NAAQS** comparisons, the quality of this data is very important. A quality system has been developed to control and evaluate the quality of data in order to make **NAAQS** determinations within an acceptable level of confidence. During the development of the **PM<sub>2.5</sub>** **NAAQS**, the EPA used the data quality objective process to determine the allowable measurement system imprecision and bias that would not significantly effect a decision makers ability to compare pollutant concentrations to the **NAAQS**. The precision requirement (10%CV) and bias requirement ( $\pm 10\%$ ) are based on total measurement uncertainty, which incorporates errors from all phases (field sampling, handling, analysis etc.) of the measurement process. The collocated samples provide adequate estimates of precision. The **FRM** Performance Evaluation, if properly implemented, can provide an evaluation of bias.

The **FRM** Performance Evaluation Program (PEP) is a quality assurance activity which will be used to evaluate measurement system bias of the **PM<sub>2.5</sub>** monitoring network. The pertinent regulations for this performance evaluation are found in 40 CFR Part 58, Appendix A, section 3.5.3. The strategy is to collocate a portable **FRM** **PM<sub>2.5</sub>** air sampling instrument within 1 to 4

meters of a routine NAMS/SLAMS air monitoring instrument, operate both monitors as required in the Federal Reference Method and standard operating procedures (SOPs), and compare the results.

The implementation of the FRM Performance Evaluation is a State/local responsibility. However, due to a number of comments made during the review period for the December 13, 1996 PM<sub>2.5</sub> NAAQS Proposal, the Agency assessed the PEP and consequently made the following revisions:

- ▶ modified the system to include an independent FRM Performance Evaluation;
- ▶ reduced the burden of this program by changing the audit frequency from all sites to 25% of the PM<sub>2.5</sub> sites;
- ▶ reduced the audit frequency from six times a year to four times a year; and
- ▶ made allowances to shift the implementation burden from the State and local agencies to the federal government.

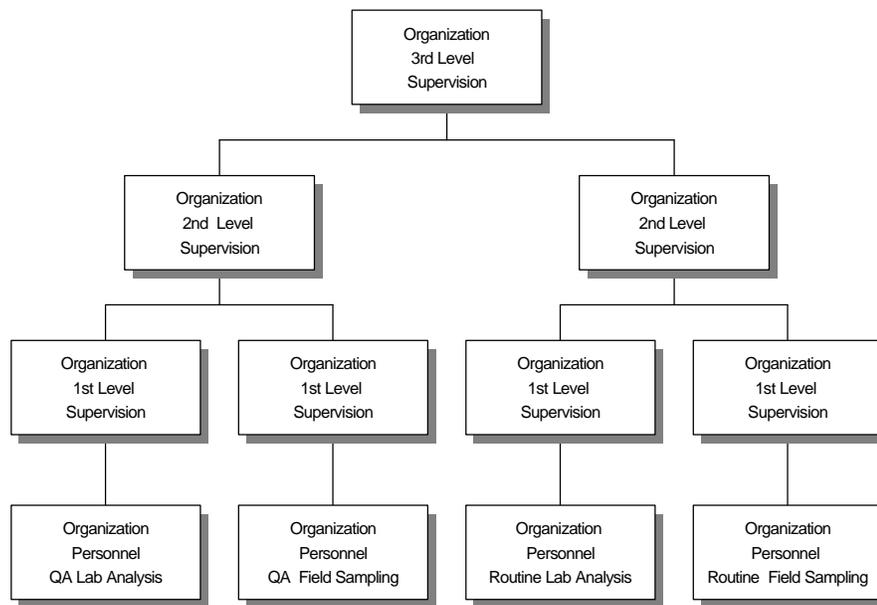
A performance evaluation is defined as a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory. In the case of the PEP, the goal is to evaluate total measurement system bias, which includes measurement uncertainties from the field and the laboratory activities. Independent assessment (Figure 5.1) was defined by the PM<sub>2.5</sub> QA Workgroup (see Element 4) in order to ensure that an appropriate level of independence is maintained during State and local implementation of the PEP.

One goal of the PM<sub>2.5</sub> program is to establish a PM<sub>2.5</sub> monitoring network by December 31, 1999. Sites within this network will include SLAMS/NAMS sites using FRM and federal equivalent method (FEM) samplers, chemical speciation sites, visibility measurement sites, and special purpose monitoring sites. Each year 25% of the SLAMS/NAMS monitors will be identified for performance evaluations at a frequency of 4 times per year.

During the months of August through October 1997, the EPA discussed the possibility of federal implementation with the EPA Regions, SAMWG and various State and local organizations (NESCAUM, MARAMA, WESTAR, individual organizations). The majority of the responses from these organization were towards federal implementation of the PEP.

EPA looked into potential contracting mechanisms to assist in the implementation of this activity and will use the Environmental Services Assistance Team (ESAT) Contract, currently in place in each Region, to provide the necessary field and laboratory activities. Each EPA Region will implement the field component of this activity while Regions 4 and 10 will also operate the laboratory component.

**Independent assessment** - an assessment performed by a qualified individual, group, or organization that is not part of the organization directly performing and accountable for the work being assessed. This auditing organization must not be involved with the generation of the routine ambient air monitoring data. An organization can conduct the FRM Performance Evaluation 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, as illustrated in Figure 1. 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 FRM Performance Audit field and laboratory training and certification requirements. The State and local organizations are also asked to consider participating in the centralized field and laboratory standards certification process.



**Figure 1**

**Figure 5.1 Definition of independent assessment**

## 6.0 Project/Task Description

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

### 6.1 Description of Work to be Performed

In general, the measurement goal of the  $PM_{2.5}$  PEP is to estimate the concentration, in units of micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ), of particulates less than or equal to 2.5 micrometers ( $\mu\text{m}$ ) that have been collected on a 46.2mm polytetrafluoroethylene (PTFE) filter and compare these values against the data from the routine monitor that the PEP monitor was collocated with. 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 network.

The FRM Performance Evaluation can be segregated into a field and a laboratory component. The following information provides a brief description of these activities. Detailed standard operating procedures (SOPs) have been developed for all field and laboratory activities and have

been distributed to all field and lab personnel and all personnel on the distribution list in Element 3. Figure 6.1 provides a basic description of the PEP in five steps:

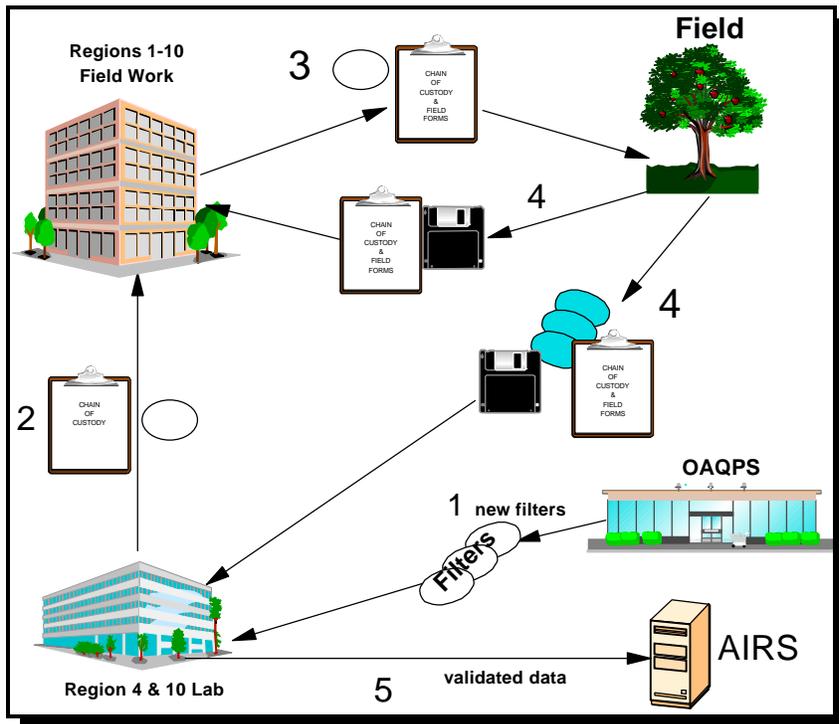


Figure 6.1 Performance Evaluation Program implementation summary

1. EPA will send filters to the Regions 4 and 10 laboratories where they will be inventoried, inspected, equilibrated, weighed and prepared for the field
2. Regions 4 and 10 laboratories will ship or deliver the filters and accompanying chain of custody to all Regions
3. The field scientists will

take the filters, field forms, and chain of custodies to the field and operate the portable FRM monitor

4. The field scientist will send the filter, data (diskette), field forms and chain-of-custody back to the appropriate laboratory (as well as keeping a set of data and records)
5. Regions 4 and 10 laboratories will receive, equilibrate and weigh filters. Data will be validated and uploaded to AIRS

## 6.2 Field Activities

The FRM portable audit samplers will be used in a collocated manner to perform the evaluations. These samplers have been approved by EPA as a Federal Reference Method Sampler 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. The total weight of the sampler shall not exceed 120 pounds. While these samplers have been specifically designed to perform these evaluations, precautions must still be taken to ensure the quality of the data. Specific detailed instructions will be found in this PEP QAPP and the Standard Operating Procedures (SOPs) which have been developed specifically for this program.

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

- ▶ adherence to the vendor's operations manual for the proper operation of the sampler; this includes the proper transport, assembly, calibration, and operation
- ▶ adherence to the guidance outlined in *QA Hand Book Document 2.12 Monitoring PM<sub>2.5</sub> in Ambient Air Using Designated Reference or Class I Equivalent Methods*.
- ▶ adherence to the SOPs for the PEP
- ▶ adherence to the standards, principles, and practices outlined in the PEP QAPP, and specific site plan for the identified sites
- ▶ completion of the required training and certification program
- ▶ special attention must also be given to any activity involving filter handling (loading, transport, removal, etc.) since this data collection phase contains the greatest potential for measurement uncertainty

### 6.2.1 Field activity summary

The following activities are covered in detail in the field SOPs.

1. One fully trained operator will transport a portable PM<sub>2.5</sub> FRM Performance Evaluation sampling device to an established PM<sub>2.5</sub> site located at any of the SLAMS/NAMS sites within each EPA Region.
2. The operator will assemble the instrument, collocate the sampler, perform time, barometric pressure, temperature and flow verifications, install a filter and operate the instrument from midnight to midnight on the same scheduled sampling day as the

- SLAM/NAMS primary sampler.
3. If scheduling permits, the operator will leave this location to set up additional 24-hour performance evaluations at other routine sampling locations. If the schedule does not allow for another set up, the operator may perform additional activities at the site.
  4. The operator shall return to each site after the 24-hour sampling time, review the run data, download the stored electronic monitoring data, remove and properly store the filter for transport, and disassemble the instrument.
  5. The operator shall properly package the filter for shipment to the laboratory.

The performance requirements of the PEP air sampler has been specified in Part 50, Appendix L of the 7/18/97 Federal Register Notice . Table 6-1 summarizes some of the more critical performance requirements.

**Table 6-1 Design/Performance Specifications**

Equipment	Frequency	Acceptance Criteria	Reference
<b>Filter Design Specs.</b>	Vendor Cert.	see reference	40 CFR Pt. 50, App.L Sec 6.0
Size	“	46.2 mm dia $\pm$ 0.25mm	“ Sec 6.1
Medium	“	Polytetrafluoroethylene	“ Sec 6.2
Support ring	“	Polymethylpentene	“ Sec 6.3
	“	0.38mm thick	“
	“	46.2 mm $\pm$ 0.25mm outer dia.	“
	“	3.68 ( $\pm$ 0.00, -0.51mm) width	“
Pore size	“	2 $\mu$ m	“Sec 6.4
Filter thickness	“	30-50 $\mu$ m	“Sec 6.5
Max. pressure drop	“	30 cm H <sub>2</sub> O @ 16.67L/min	“Sec 6.6
Max. Moisture pickup	“	10 $\mu$ g increase in 24 hr.	“Sec 6.7
Collection efficiency	“	99.7%	“Sec 6.8
Filter weight stability	“	<20 $\mu$ g	“Sec 6.9.1 and 6.9.2
Alkalinity	“	< 25.0 microequivalents/gram	“Sec 6.10
<b>Sampler Performance Specs.</b>	All Instruments		
Sample Flow Rate	“	1.000 m <sup>3</sup> /hr.	40 CFR Pt. 50, App.L Sec7.4
Flow Regulation	“	1.000 $\pm$ 5% m <sup>3</sup> /hr.	“
Flow Rate Precision	“	2% CV	“
Flow Rate Accuracy	“	$\pm$ 2%	“
External Leakage	“	Vendor specs	“
Internal Leakage	“	Vendor specs	“
Ambient Temp Sensor	“	-30° - 45° C	Vol-II -MS. 2.12
Filter Temp Sensor	“	1° C res. $\pm$ 1.6°C accuracy -30° - 45° C	40 CFR Pt. 50, App.L Sec7.4
Barometric Pressure	“	0.1° C res. $\pm$ 1.0°C accuracy 600-800 mm Hg	“
Clock/Timer	“	5 mm res. $\pm$ 10mm accuracy Date/time. 1 sec. res. $\pm$ 1 min/month accuracy	“

The air samplers will be purchased, distributed, and certified by the EPA as meeting the

requirements specified in the Federal Register. Therefore, the PEP assumes the sampling instruments to be adequate for the sampling for PM<sub>2.5</sub>. Other than the required federal reference or equivalent air sampler, there are no special personnel or equipment requirements. Section 15 lists all the equipment requirements for the PEP PM<sub>2.5</sub> data collection operations.

## 6.2.2 Critical Field Measurements

Table 6-2 represents the field measurements that must be collected as presented in the Federal Register<sup>1</sup> as Table L-1 of Appendix L. These measurements are made by the air sampler and are stored in the instrument for downloading by the field scientist during routine visits.

**Table 6-2 Field Measurement Requirements**

Information to be provided	Appendix L section reference	Availability				Format	
		Anytime <sup>a</sup>	End of period <sup>b</sup>	Visual display	Data output <sup>d</sup>	Digital reading <sup>e</sup>	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, CV, for the sample period	7.4.5.2	*	✓	*	✓●	XX.X	%
Flow rate, 5-min average out of spec. (FLAG) <sup>f</sup>	7.4.5.2	✓	✓	✓	✓●	On/Off	
Sample volume, total	7.4.5.2	*	✓	✓	✓●	XX.X	m <sup>3</sup>
Temperature, ambient, 30-second interval	7.4.8	✓	—	✓	—	XX.X	°C
Temperature, ambient, min., max., 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, min., max., 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 spec. (FLAG) <sup>f</sup>	7.4.11	*	✓	✓	✓●	On/Off	
Filter temperature, maximum differential from ambient, date, time of occurrence	7.4.11	*	*	*	*	XX, 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
Sample period start time	7.4.12	—	✓	✓	✓●	YYYY/MM/DD HH:mm	Yr/Mo/Day Hr min

Information to be provided	Appendix L section reference	Availability				Format	
		Anytime <sup>a</sup>	End of period <sup>b</sup>	Visual display	Data output <sup>d</sup>	Digital reading <sup>e</sup>	Units
Elapsed sample time	7.4.13	*	✓	✓	✓●	HH:mm	Hr min
Elapsed sample time out of spec. (FLAG) <sup>f</sup>	7.4.13	—	✓	✓	✓●	On/Off	
Power interruptions >1 min, start time of first 10	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.
- \* Provision of this information is optional. If information related to the entire sample period is optionally provided prior to the end of the sample period, 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 AIRS data bank.
- <sup>a</sup> Information is required to be available to the operator at any time the sampler is operating, whether sampling or not.
- <sup>b</sup> Information relates to the entire sampler period and must be provided following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.
- <sup>c</sup> Information shall be available to the operator visually.
- <sup>d</sup> Information is to be available as digital data at the sampler's data output port following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.
- <sup>e</sup> Digital readings, both visual and data output, shall have no less than the number of significant digits and resolution specified.
- <sup>f</sup> 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 off (unset) flag may be indicated by the absence of a flag warning. Sampler users should refer to Section 10.12 of Appendix L regarding 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 Field SOPs and help to identify the samples, ensure proper chain of custody, holding times, and data quality. The values are recorded on the chain of custody form and the field data sheet.

### 6.3 Laboratory Activities

The PEP also requires extensive laboratory activities, including filter handling, inspection, equilibration, weighing, data entry/management and archival. Regions 4 and 10 will develop and implement the laboratories for this program. Detailed Laboratory SOPs have been developed. In addition, good laboratory practices must be followed. The following activities must also be observed concerning the laboratory activity:

- ▶ adherence to the vendor's operations manual for the proper calibration and operation of the microbalances
- ▶ adherence to the SOPs for the program
- ▶ adherence to the standards, principles, and practices outlined in the PEP QAPP
- ▶ completion of the required training and certification program.
- ▶ special attention must also be given to any activity involving filter handling (pre-sampling equilibration, weighing, post-sampling equilibration, transport, etc.) since this data

collection phase contains the greatest potential for measurement uncertainty

The following information represents a summary of the laboratory activities that are detailed in the laboratory SOPs.

**Pre-Sampling weighing--**

1. Filters will be received from EPA and examined for integrity.
2. Filters will be enumerated for data entry.
3. Filters will be equilibrated and weighed.
4. Filters will be prepared for field activities or stored.
5. The laboratory will develop and maintain shipping/receiving requirements which would include containers, cold packs, max/min thermometers, and chain-of-custody requirements/documentation.

**Post-Sampling weighing--**

1. Filters will be received in the laboratory, checked for integrity (damage, temperature, etc.) and logged in.
2. Filters will be archived (cold storage) until ready for weighing.
3. Filters will be brought into the weighing facility and equilibrated for 24-hours.
4. Filters will be weighed and the data entered.
5. Field data will be entered into the data entry system in order to calculate a concentration.
6. Filters will be archived for 3 years.
7. Required data will be transferred to the AIRS database.

The details for these activities are included in various sections of this document as well as 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 or chamber or equivalent. Mean relative humidity between 30 and 40 percent, with a variability of not more than ±5 percent over 24 hours. Mean temperature should be held between 20 and 23 °C, with a variability of not more than ±2 °C over 24 hours.
Mass reference standards	Standards bracket weight of filter, individual standard's tolerance less than 25 µg, handle with smooth, nonmetallic forceps

### **6.3.1 Critical Laboratory Measurements**

In order to generate a concentration, the most critical measurements of the laboratory are the filter pre-weights (unexposed) and post weights (exposed). The difference between these two measurements provide the net weight of particles in micrograms ( $\mu\text{g}$ ) that when combined with the field air volume in cubic meters ( $\text{m}^3$ ) provides a final concentration ( $\mu\text{g}/\text{m}^3$ ). In addition to these critical measurements, supporting lab data will also be collected. These additional parameters are identified in the laboratory SOPs and help to identify the samples, ensure proper chain of custody, holding times, and data quality.

### **6.4 Schedule of Activities**

In order to ensure that the PEP is implemented in calendar year 1999, many aspects of the program must be completed in a timely, efficient fashion.

#### **6.4.1 Planning Time Lines**

Figure 6.2 provides the key planning aspects of the program that must be completed within the specified time frames in order to meet a 1/1/99 implementation date. The dates in Figure 6.2 run from April 1998 through July 1999

ID	Task Name	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	
1	<b>Samplers</b>																		
2	First Article Sampler Delivery		◆																
3	Sampler Evaluation			■															
4	Sampler Designation				■														
5	Sampler Evaluations				■														
6	Order Samplers					■													
7	Delivery of samplers to R's								■										
8	<b>Documents</b>																		
9	FRM Implementation Plan			■															
10	Field SOPs (DRAFT)				■														
11	Lab SOPs (DRAFT)					■													
12	QAPP (DRAFT)						■												
13	Field SOPs (FINAL)							◆											
14	Lab SOPs (FINAL)								◆										
15	QAPP (FINAL)										◆								
16	Data Management Plan											◆							

ID	Task Name	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	
17	<b>Lab Equipment</b>																		
18	Equipment List Complete			◆															
19	Lab Equipment Ordered				■														
20	balance/software selection					◆													
21	All Equipment in							◆											
22	<b>Field Equipment</b>																		
23	Filters available				◆														
24	Equipment list completed					◆													
25	Field equipment ordering					■													
26	Calibration equip eval/selection					■													
27	Filters to Lab -test/training							◆											
28	Select transportation								◆										
29	Equipment in Regions									◆									
30	Filters to lab-Routine										◆								
31	Vehicles in regions											◆							

ID	Task Name	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	
32	<b>ESAT Activities</b>																		
33	Transfer funds to ESAT				◆														
34	ESAT Work Assignment						◆												
35	ESAT Contractor onboard-Lab							■											
36	ESAT Contractor Onboard Field								■										
37	<b>Work Assignments</b>																		
38	Training -field/lab					◆													
39	Information Management					◆													
40	ESAT								◆										
41	<b>Information Management</b>																		
42	Lab System					■													
43	Field System					■													
44	Integration/Airs Upload								■										
45	Data Management Plan											◆							

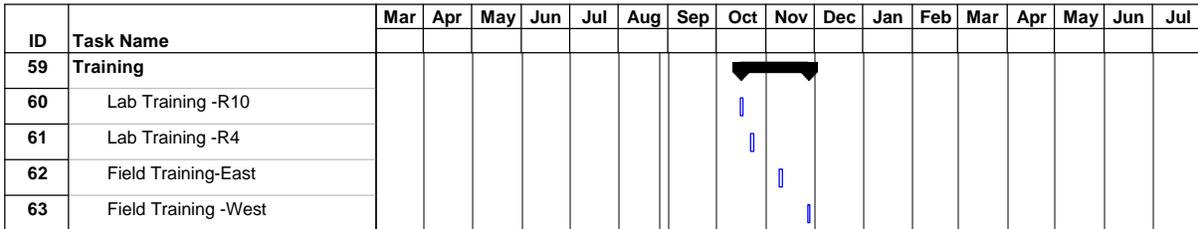
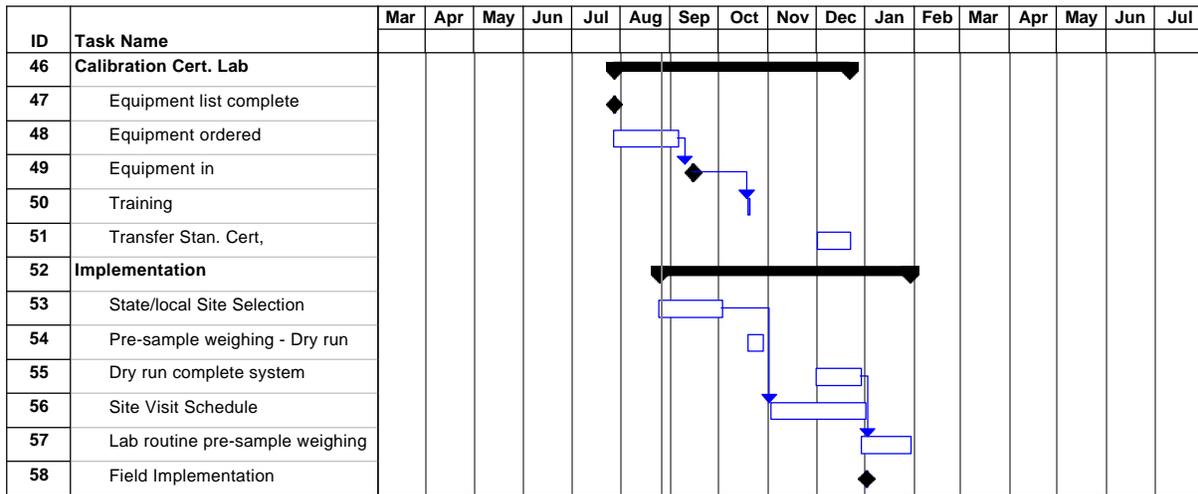


Figure 6.2 Planning Time Line 4/98 - 7/99

### 6.4.2 Implementation Time Lines

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

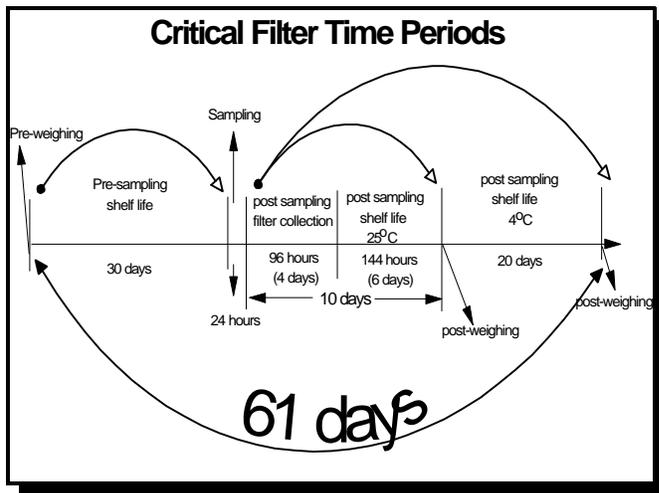


Figure 6.3 Critical filter holding times

#### 6.4.2.1 Laboratory Time Lines

In order for field implementation to begin 1/1/99 the Region 4 and 10 laboratories must be operational in December 1998. The *PEP Implementation Plan* details how this will occur.

An aspect of the implementation process that is time critical is the filter holding time dates. As is illustrated in Figure 6.3 and stipulated in the Code of Federal Regulations, filters must be used within

30 days of pre-sampling weighing or they must be reconditioned and reweighed. Therefore, it is critical that Region 4 and 10 laboratories develop a schedule to provide the field scientists with filters that will be utilized in the appropriate time frame.

Table 6-4 provides an estimate of the number of filters to be prepared for the field each month (filters/month); it includes field blanks and collocated filters but does not include laboratory QC filters. This spread sheet was developed for the Region 4 and 10 laboratories to help provide a more accurate estimate of filter preparation. This estimate is based upon the numbers of SLAMS/NAMS samplers that are expected to be sited in FY 98. However, the actual filter values may be somewhat higher when the exact method designations for each routine monitor within each reporting organization are known.

**Table 6-4 Filter Estimates**

Region	NAM/SLAMS	sites/year	sites/quarter	site/month	filters/month	filters/year
1	67	17	17	6	9	113
2	58	15	15	5	8	99
3	95	24	24	8	13	155
4	181	45	45	15	24	284
5	162	41	41	14	21	255
6	114	29	29	10	15	183
7	66	17	17	6	9	111
8	51	13	13	6	7	89
9	105	26	26	9	14	170
10	48	12	12	4	7	84
<b>Total</b>	<b>947</b>	<b>239</b>	<b>239</b>	<b>59</b>	<b>127</b>	<b>1575</b>

Based upon the estimates in Table 6-4, Table 6-5 provides a summary of the monthly filter preparation requirements for each laboratory. The values in some cases are higher than the estimates in Table 6-4 due to specific regional requests for additional filters for field blanks and spares.

**Table 6-5 Monthly Filter Preparation Estimates.**

Region 4 Laboratory		Region 10 Laboratory	
Region	Monthly Filter Requirement	Region	Monthly Filter Requirement
1	9	5	34
2	8	7	9
3	13	8	20
4	24	9	20
6	30	10	16
<b>Total</b>	<b>84</b>	<b>Total</b>	<b>99</b>

Figure 6.3 also indicates that filters must be weighed within 10 days (if maintained at 25°C) or 30 days (if maintained at 4°C) of the sampling end date. The Region 4 and 10 laboratories will be able to post-sampling weigh within the 10 day window, even though they will maintain filters at 4°C prior to filter conditioning.

#### 6.4.2.2 Data Input/Assessment/Upload

It is anticipated that an automated data entry system will be in place so that minimal data entry will be required. Once a batch of samples has completed post-sampling weighing, the data will be reviewed, verified, and validated by the ESAT contractor. This process will be completed in 10 working days. Upon further data validation and acceptance by the EPA WAM, the data will be uploaded to AIRS by the ESAT contractor. This should be completed within 5 working days from data validation.

#### 6.4.2.3 Field Time Lines

Figure 6.3 indicates that filters must be collected within 96 hours of the end of the sample period. In most instances the field personnel will collect the filters within 8 to 48 hours of the end of the sample period. Samples will be sent the day of removal to the appropriate laboratory via next day delivery. Data will be immediately downloaded from the portable sampler and stored in two mediums (hard drive and two diskettes). One diskette of the data will be shipped with the sample. Data may also be transmitted, via modem, to the appropriate laboratory. In addition, the most critical data values will also be recorded from the sampler's LCD screen onto field data sheets and sent to the laboratory with the samples.

#### 6.4.2.4 Implementation Summary

Table 6-6 provides a summary of the key activities discussed above. Although the filter collection and filter shipment time lines are more stringent than Figure 6.3, the SOPs will allow for excursions from these time lines on occasion, as long as they meet at a minimum the time line in Figure 6.3.

**Table 6-6 Implementation Summary**

<b>Implementation</b>	<b>Activity</b>	<b>Acceptable Time frame</b>
Laboratory	Pre-sampling weighing	30 days
	Post-sample weighing	10 days
	Data input/review/validation	10 working days
	AIRS Upload	5 working days
Field	Filter use	30 days of pre-sample weighing
	Filter collection	8-24 hours from sample end date/time
	Filter/data shipment	within 8 hours of sample removal

**6.4.3 Assessment Time Lines**

6.4.3.1 Data Availability

In order to assess the PE data, the data from the routine sampler must also be available in AIRS. State/local requirements for data upload to AIRS is 90 days after the quarter in which the data is collected. However, the time frame for pre- and post-sampling weighing, as illustrated in Figure 6.3, is also a requirement for the routine samplers. Therefore, data for the routine sampler that was evaluated could be available within 30 days of the sample end date. If possible, submittal of routine sampler data as soon as possible is encouraged if data assessment is to occur in a timely manner.

6.4.3.2 Assessments

Once both routine data and PE data for a site are in AIRS, OAQPS, Regions and State and locals can use the AIRS data evaluation programs, based on data quality assessment techniques, to assess this information. OAQPS will review this information every month and will summarize their comments on the ESAT Workgroup and PM<sub>2.5</sub> QA Workgroup calls.

**6.4.4 OAQPS Reporting Time Lines**

6.4.4.1 QA Reports

As mentioned in Section 3, OAQPS plans on the development of a yearly QA Summary Report and the interpretive QA Report every three years. The yearly report will be based on a calendar year and will be completed six months from the last valid entry of routine data by the State and local agencies. The three year QA Report will be generated 9 months after the last valid entry of routine data by the State and local agencies for the final year.

#### 6.4.4.2 Audit Reports

OAQPS will also perform technical systems audits of the ESAT contractors (anticipated 1/region/year). Audit reports will be completed within 15 working days of the audits.

### 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, performance evaluation (PE), management systems review (MSR), peer review, inspection, or surveillance. Definitions for each of these activities can be found in the glossary (Appendix A). Section 20 will discuss the details of the assessments.

Table 6-7 will provide information on the parties implementing the assessment and there frequency.

**Table 6-7 Assessment Schedule**

Assessment Type	Assessment Agency	Frequency
Technical Systems Audit	EPA Regional Office (WAMS) OAQPS	2 per year 1 every 2 years
Surveillance	EPA Regional Office (WAMS)	as required
Management Systems Review	STAPPA/ALAPCO	1 every 2 years
Data Quality Assessment	OAQPS	every year

### 6.6 Project Records

The field and laboratory programs will establish and maintain procedures for the timely preparation, review, approval, issuance, use, control, revision and maintenance of documents and records. Table 6-8 represents the categories and types of records and documents which are applicable to document control for PM<sub>2.5</sub> information. Information on key documents in each category are explained in more detail in Section 9.

**Table 6-8 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	QA Project Plans Standard operating procedures (SOPs) 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 SLAMS air quality information Data/summary reports Journal articles/papers/presentations
Data Management	Data algorithms Data management plans/flowcharts PM <sub>2.5</sub> Data Data Management Systems
Quality Assurance	Good Laboratory Practice Network reviews Control charts Data quality assessments QA reports System audits Response/Corrective action reports Site Audits

**References**

1. U.S. EPA (1997a) National Ambient Air Quality Standards for Particulate Matter - Final Rule. 40 CFR Part 50. *Federal Register*, **62**(138):38651-38760. July 18,1997.

## 7.0 Quality Objectives and Criteria for Measurement Data

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 employed in generating the data.

### 7.1 Data Quality Objectives (DQOs)

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<sup>1</sup>. By applying the DQO Process to the development of a quality system for PM<sub>2.5</sub>, the EPA guards against committing resources to data collection efforts that do not support a defensible decision. During the months from April to July of 1997 the DQO Process was implemented for the PM<sub>2.5</sub>. Appendix B provides information on this process. 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 ( $\pm 10\%$ ) were identified. These precision and bias values will be used as a goal 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 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. Since there is presently no accurate way of introducing a known concentration of particles into a PM<sub>2.5</sub> FRM sampler, the PEP was developed to serve as closely as possible as a reference standard.

The data collected under the PEP is to be used to determine whether there is bias in the measurement system being used to measure PM<sub>2.5</sub> for comparison to the PM<sub>2.5</sub> NAAQS. The definition of bias being used is the deviation between the measurement system of the reporting agency and the PEP, and as such, it is important to control the repeatability of the measurements from each PEP sampler. It is important to be sure there is sufficient data on which to make a decision about the presence of bias. The more samples used in the decision, the larger the confidence. However, it is important not to waste resources by collecting too many samples. To determine the relationship between the confidence level in the decision and the number of samples, power curves were developed. The assumptions used to development of these power curves are described below.

*Notation: Let  $X$  be an observation from the primary sampler. Let  $Y$  be an observation from the collocated PEP sampler. Let  $R=(X-Y)/Y$ .*

*Hypotheses: Null: Bias is zero (in statistical terms,  $E[R]=0$ ).  
Alternative: Bias is not zero (in statistical terms,  $E[R] \neq 0$ )*

Test Statistic for testing the hypothesis: Average ratio  $R$ , denoted .

$$\bar{R} = \sum_{i=1}^n \frac{(X_i - Y_i)}{Y_i}$$

Distribution of  $\bar{R}$ : By the Central Limit Theorem and the distribution of Student's  $t$ ,

$$\frac{\bar{R}}{s / \sqrt{n}}$$

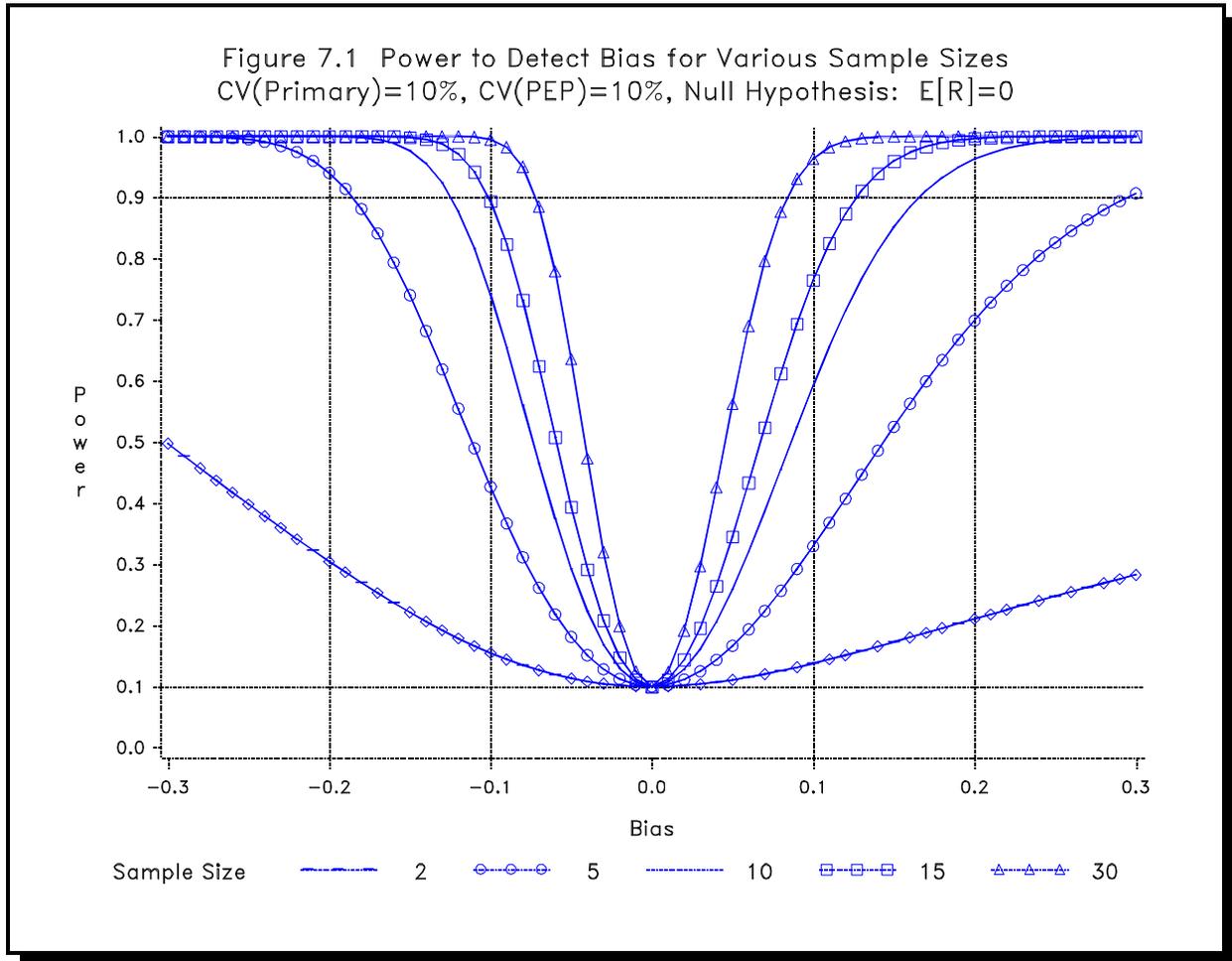
is distributed according to a  $t$  distribution with  $(n-1)$  degrees of freedom, where  $s$  is the standard deviation of  $R$  and  $n$  is the number of collocated pairs of data. Under the null hypothesis, the non-centrality parameter (bias) for the  $t$  distribution is 0 and under the alternative, the non-centrality parameter (bias) is not zero and is denoted  $c$ .

Estimation of  $s$ : A Taylor Series approximation is used to estimate the variance of  $R$ , from which  $s$  can be estimated by taking the square root. The variance can be shown to be a function of the coefficient of variation for  $X$  ( $CV_x$ ), the coefficient of variation for  $Y$  ( $CV_y$ ), and the non-centrality parameter  $c$ . In particular,

$$\text{Var}(R) \cong (CV_x^2 + CV_y^2) \times (1 + c)^2$$

Figure 7-1 presents the power associated with this hypothesis test for various number of collocated pairs. This figure assumes that the coefficient of variation for the primary sampler is 10% and that the coefficient of variation for the PEP sampler is also 10%. This figure shows that if a positive bias of 10% truly exists between the primary and PEP sampler, then it will take approximately 22 collocated samples to declare that there is a bias, with a decision error rate of 10%. If a negative bias of 10% truly exists between the primary and PEP sampler, then it will take only 15 collocated samples to declare that there is a bias, with a decision error rate of 10%. Two general characteristics of the power curves are that more than 15 collocated samples are needed to find biases greater than 10% or less than -10% and that positive biases take more samples to find than negative biases.

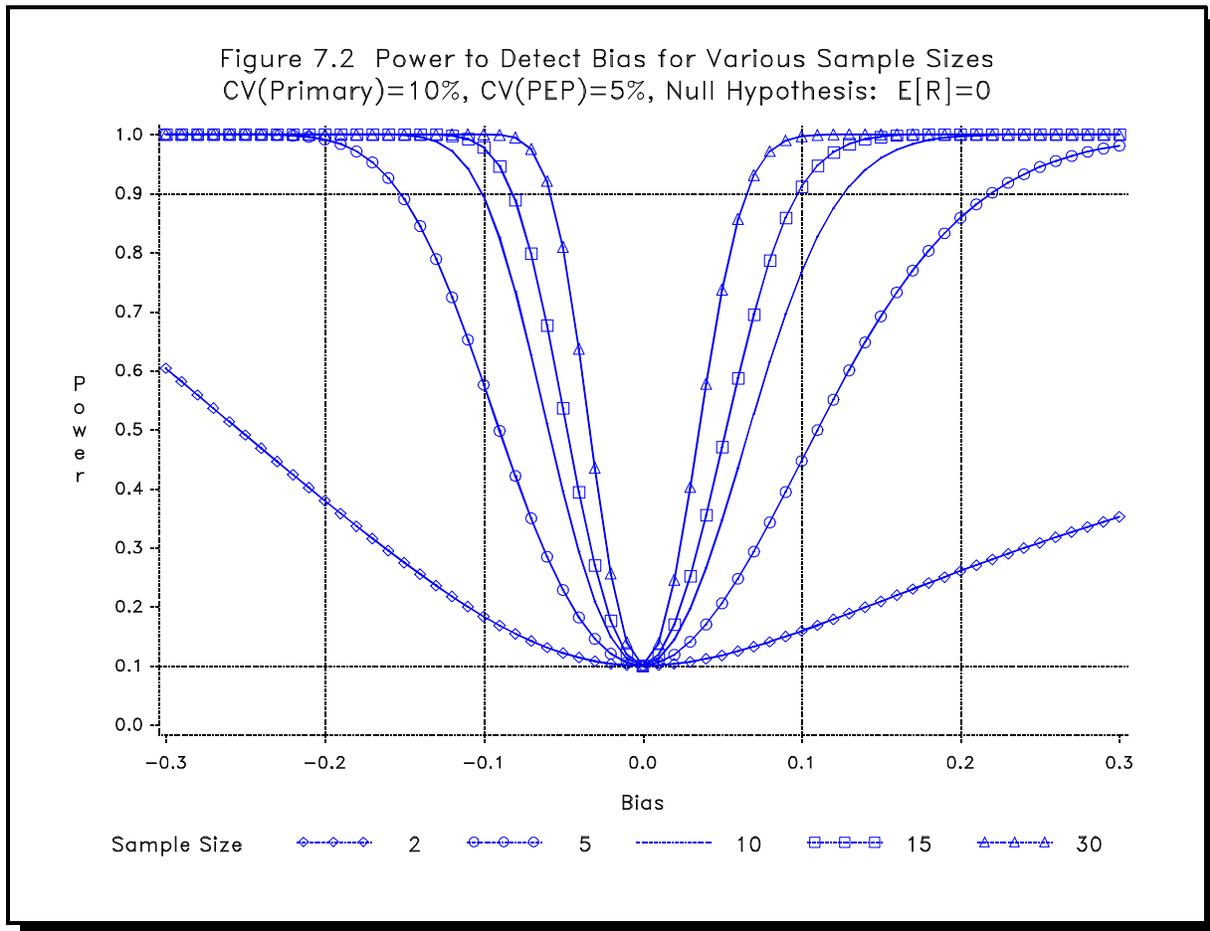
The power of the test is relatively insensitive to the coefficient of variation, assuming that it is less than 10%. Figure 7-2 presents the power for the same test except where the PEP coefficient of variation has been reduced from 10% to 5%. This figure shows that if a positive bias of 10% truly exists between the primary and PEP sampler, then it will take 15 collocated samples to declare that there is a bias, with a decision error rate of 10%. If a negative bias of 10% truly declare that there is a bias, with a decision error rate of 10%. Although these sample sizes are smaller than those for the case where the PEP coefficient of variation is assumed to be



10%, exists between the primary and PEP sampler, then it will take only 10 collocated samples to they are not substantially smaller. This means that the power of this test is not terribly sensitive to the coefficient of variation, for small coefficients of variation.

The coefficient of variation for the primary samplers (non-FRM types) has been demonstrated to be controllable to less than 10%. The initial estimates of the coefficient of variation for the PEP samplers (FRM types) is approximately 5%, although this estimate is based on a small sample size meaning that the true coefficient of variation may be greatly different from this estimate. However, even if the true coefficient of variation is twice this initial estimate, the power curves presented in Figure 7-1 are appropriate.

Since the bias DQO is based upon the NAAQS, which are based upon three years of data from individual monitors, it is important to assess the DQO at the same frequency and level of aggregation. However, since the evaluation frequency of the PEP is 25%, any one monitor would receive an evaluation (four collocated pairs) once every four years. Therefore, the PE data has limited use at determining bias at the monitor level of aggregation. However, the



monitor level of data can be used for quality control. As one moves to the reporting organization and national levels there will be sufficient amount of data to statistically evaluate bias. As shown above, the aggregation needs to incorporate approximately 22 samples to detect true biases greater than 10% or less than -10%, with at least 90% confidence. The reporting organization level of aggregation is the priority since the majority of the QA/QC standards for quality systems developed in CFR are at the reporting organization level. Statistics at the national level of aggregation can be used to evaluate systematic biases seen by method designation or by laboratory across the nation.

Since the PEP will perform the same activities as the routine monitoring network, it will be required to meet or exceed the QA/QC requirements specified for the routine monitoring network. The requirements are listed in Table 7-2. Therefore a CV of 10%, as illustrated in Figure 7.1, is required to detect the bias component of the DQO. The CV will be evaluated and controlled through various collocation methods. As routine and QA/QC PEP data are collected, data quality assessments (DQAs) will be performed which may show that the PEP is capable of achieving a “tighter” CV DQO and the program will be adjusted accordingly. Similarly, if it is found that the CVs used in the development of the power curves are too tight, then the decision

errors will need to be re-evaluated.

## 7.2 Measurement Quality Objectives (MQOs)

Once a DQO is established, the quality of the data must be evaluated and controlled to ensure that it is maintained within the established acceptance criteria. Measurement quality objectives are designed to evaluate and control various phases (sampling, preparation, analysis) of the measurement process to ensure that total measurement uncertainty is within the range prescribed 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 deviation from the true value as a percentage of the true value.

**Representativeness** - a measure of the degree 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 Pt. 50).

**Comparability** - a measure of confidence with which one data set can be compared to another.

Accuracy has been a term frequently used to represent closeness to “truth” and includes a combination of precision and bias error components. This term has been used throughout the CFR and in some of the sections of this document. If possible, the PEP will attempt to distinguish measurement uncertainties into precision and bias components.

For each of these attributes, acceptance criteria have been 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*<sup>2</sup>. In theory, if these MQOs are met, measurement uncertainty should be controlled to the levels required by the DQO. 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 the SOPs.

### References

1. EPA Guidance for Quality Assurance Project Plans EPA QA/G-5, EPA/600/R-98/018, February 1998
2. U.S. EPA Quality Assurance Guidance Document 2.12: Monitoring PM<sub>2.5</sub> in Ambient Air Using Designated Reference or Class I Equivalent Methods. December, 1998

**Table 7-2 Measurement Quality Objectives - Parameter PM2.5**

Requirement	Frequency	Acceptance Criteria	40 CFR Reference	Lab/field SOP Reference
<b>Filter Holding Times</b> Pre-sampling  Post-sampling Weighing	all filters  “	< 30 days before sampling  < 10 days at 25 <sup>o</sup> C from sample end date < 30 days at 4 <sup>o</sup> C from sample end date	Part 50, App.L Sec 8.3  “  “	PEPL-4.01  “  “
<b>Reporting Units</b>	All data	$\mu\text{g}/\text{m}^3$	Part 50.3	
<b>Detection Limit</b> Lower DL Upper Conc. Limit	All data All data	$2 \mu\text{g}/\text{m}^3$ $200 \mu\text{g}/\text{m}^3$	Part 50, App.L Sec 3.1 Part 50, App.L Sec 3.2	
<b>Data Completeness</b>	quarterly	75%	Part 50, App. N, Sec. 2.1	
<b>Filter</b> Visual Defect Check Filter Conditioning Environment Equilibration Temp. Range Temp. Control Humidity Range Humidity Control Exposure Lot Blanks	All Filters  All filters “ “ “ “ 3 filters per exposure lot	See reference  24 hours minimum 20-23 <sup>o</sup> C + 2 <sup>o</sup> C over 24 hr 30% - 40% RH ± 5% RH over 24 hr. less than 15 $\mu\text{g}$ change between weighings	Part 50, App.L Sec 6.0  Part 50, App.L Sec 8.2  “ “ “ “	PEPL-5.01  PEPL-6.01 “ “ “ “ “
<b>Lab QC Checks</b> Field Filter Blank  Lab Filter Blank  Balance Check  Duplicate Filter Weighing	1/week/instrument  10% or 1 per weighing session beginning/end of weighing session  1 per weighing session, 1 carried over to next session	$\pm 30 \mu\text{g}$ change between weighings $\pm 15 \mu\text{g}$ change between weighings $\leq 3 \mu\text{g}$  $\pm 15 \mu\text{g}$ change between weighings	Part 50, App.L Sec 8.2  “  “	PEPF-10.01  PEPL-8.01 PEPL-8.01 PEPL-8.01

Requirement	Frequency	Acceptance Criteria	40 CFR Reference	Lab/field SOP Reference
<b>Calibration/Verification</b> Flow Rate (FR) Calibration FR multi-point verification One point FR verification External Leak Check Internal Leak Check Temperature Calibration Temp Multi-point Verification One- point temp Verification Pressure Calibration Pressure Verification Clock/timer Verification	If multi-point failure 1/yr every sampling event every sampling event upon failure of external If multi-point failure on installation, then 1/yr 1/week 1/yr, or one point failure 1/week 1/week	$\pm 2\%$ of transfer standard $\pm 2\%$ of transfer standard $\pm 4\%$ of transfer standard 80 mL/min 80 mL/min $\pm 2\%$ of standard $\pm 2^\circ\text{C}$ of standard $\pm 4^\circ\text{C}$ of standard $\pm 10$ mm Hg $\pm 10$ mm Hg 1 min/mo	Part 50, App.L, Sec 9.2 Part 50, App.L, Sec 9.2.5 Part 50, App.L, Sec 7.4 " " Part 50, App.L, Sec 9.3 Part 50, App.L, Sec 9.3 " " " " Part 50, App.L, Sec 7.4	PEPF-7.03 PEPF-7.03 PEPF-6.04 PEPF-6.01 PEPF-6.01 PEPF-7.02 PEPF-7.02 PEPF-6.03 PEPF-7.01 PEPF-6.02
<b>Accuracy</b> Flow Rate Audit External Leak Check Internal Leak Check Temperature Audit Pressure Audit Balance Audit	4/yr (manual) 4/yr 4/yr 4/yr 4/yr 1/yr	$\pm 4\%$ of audit standard $< 80$ mL/min $< 80$ mL/min $\pm 2^\circ\text{C}$ $\pm 10$ mm Hg Manufacturers specs	Part 58, App A, Sec 3.5.1 Not described " " " " " " " "	PEPF-10.01 " " " " " " " "
<b>Precision</b> Collocated samples Paired All samplers in Region-	1/month 1/year	$\text{CV} \leq 10\%$ $\text{CV} \leq 10\%$		PEPF-10.01 PEPF-10.01
<b>Calibration &amp; Check Standards</b> Flow Rate Transfer Std. Field Thermometer Field Barometer Working Mass Stds. Primary Mass Stds.	1/yr 1/yr 1/yr 3-6 mo. 1/yr	$\pm 2\%$ of NIST-traceable Std. $\pm 0.1^\circ\text{C}$ resolution $\pm 0.5^\circ\text{C}$ accuracy $\pm 1$ mm Hg resolution $\pm 5$ mm Hg accuracy 0.025 mg 0.025 mg	Part 50, App.L Sec 9.1 and 9.2 not described not described not described not described not described not described	PEPF-10.01 " " " " " " PEPL-7.01 " "



## 8.0 Special Training Requirements/Certification

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

The 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 concerning the PM<sub>2.5</sub> monitoring network, the principles of PM<sub>2.5</sub> monitoring, the operation of a PM<sub>2.5</sub> monitor, and the quality assurance procedures. This phase of training is ongoing and includes:

- ▶ national broadcasts of the specific subject matter
- ▶ air pollution training institute courses
- ▶ national level conferences and workshops
- ▶ training videos
- ▶ development of an air training facility for hands-on experience
- ▶ national and regional level conference calls
- ▶ individual one-on-one sessions upon request

Training information for PM<sub>2.5</sub> is available on the AMTIC Bulletin Board (<http://www.epa.gov/ttn/amtic/pmtrn.html>)

The second phase of training specifically concerns the PEP. This phase includes:

- ▶ specific, extensive hands-on field and laboratory training sessions sponsored and developed by OAQPS, involving the ESAT contractors, Regional personnel, and State/local agency 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 successful certification.

### 8.1 QAQPS Training Facilities

OAQPS has developed an Air Training Facility (ATF), with the objectives to:

- ▶ develop internal expertise in fine particulate monitoring and gravimetric analysis
- ▶ have monitoring equipment readily accessible to EPA staff for questions and concerns
- ▶ perform training of personnel: EPA staff, Regions, State and local agencies and ESAT personnel
- ▶ perform special studies: study monitor performance, evaluate measurement uncertainty
- ▶ perform research studies for future monitoring activities

The ATF presently covers the needs of the PM<sub>2.5</sub> program and includes a field platform for training on monitor operations and a PM<sub>2.5</sub> weighing room facility. Both facilities are operable and will be used extensively in the PEP for both training and research needs.

## 8.2 Training Program

The field and laboratory PEP training program will involve four phases:

1. **Classroom lecture-** will include an overall review of the PM<sub>2.5</sub> program and it's relation to the PEP. Classroom lectures will also be implemented for each training module (see below)
2. **Hands-on activities-** After a class room lecture, personnel will be taken to the training area where the field/lab activities will be demonstrated and then the trainees will perform the same activity under instruction
3. **Certification-Written exam-** a written test to cover the activities of importance in each of the training modules
4. **Certification-Performance evaluation-** this is a review of the actual field implementation activities under evaluation by the trainer/evaluator. Appendix C contains performance evaluation forms for this review.

Trainers will include OAQPS personnel from the MQAG QA Team and contractors who have assisted in the development of the PEP field/lab SOPs.

## 8.3 Field Training

Prior to implementation on 1/1/99, all personnel performing field data collection activities for the PEP will be trained. Personnel include EPA Regional WAMs and ESAT contractors. In addition, State and local agencies are welcome to attend this training.

In FY98, the actual dates of training will be dependent on the designation of the portable instruments as federal reference methods and then the subsequent ordering and delivery of these instruments. Training is initially scheduled for the November 1998 time frame.

Two field training activities will occur; in Research Triangle Park (RTP), NC at the Air Training Facility (ATF), and in Las Vegas, NV. Field personnel supported by the Region 4 (Table 6.5) laboratory will attend the RTP session while those supported by the Region 10 laboratory will attend the Las Vegas session.

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

## Field Training Modules

Field training will be segregated into the following discrete modules:

- ▶ Planning and Preparation
- ▶ Sampler Transport and Placement
- ▶ Verifications/Calibrations
- ▶ Chain of Custody and Field Data Sheet
- ▶ Information Retention
- ▶ Cassette Receipt, Storage, Handling
- ▶ Sampler Assembly and Maintenance
- ▶ Sample Filter Handling
- ▶ Quality Assurance Quality Control

## 8.4 Laboratory Training

Laboratory training will occur for the routine PEP filter preparation/weighing activities at the Regions 4 and 10 laboratories.

### 8.4.1 PEP Weighing Laboratory Training

Tentative scheduling for this activity is October 1998. Lab training is expected to last 2-3 days; the first part to include an overview and hands on training, and the second part for testing and certification. The Region 4 and 10 WAMs and the ESAT lab contractors will be trained in the modules listed below:

- ▶ General Laboratory Preparation
- ▶ Communications
- ▶ Filter Conditioning
- ▶ Filter Weighing
- ▶ Chain of Custody
- ▶ Quality Assurance Quality Control
- ▶ Equipment Inventory and Maintenance
- ▶ Filter Handling
- ▶ Calibrations
- ▶ Filter Shipping
- ▶ Data Entry and Data Transfer
- ▶ Storage and Archiving

## 8.5 Certification

Certification is required and will help to ensure that field and laboratory 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 State and local agencies.

Both the written exam and the performance review are considered part of the certification requirements. The written exam is gauged to a review of the more critical aspects of the PEP and to identify where the individual requires additional training. The written test will be generated by

OAQPS. A 90% is required for acceptance on the written exam. The performance evaluation is focused on ensuring that the individual understands and follows the SOPs. The trainer(s) will evaluate the trainees implementation of the modules identified in the field and lab 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 in order to ensure that the PEP is implemented comparably across the Nation. By testing and evaluating each module, the trainer(s) will be able to identify where individuals will require additional training. If there are many individuals failing a particular module, it may also indicate that the classroom or hands-on training is not appropriate. In any case, failure by individuals of parts of either the written or performance evaluation will indicate that additional training is required. Trainees will be required to attend additional training on these modules. Trainers will be available for an additional day of field/lab training and will ensure personnel are certified by the end of the training session.

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

## **8.6 Out Year PEP Field and Laboratory Training**

It is expected that there will be contractor personnel turnover and therefore the need for additional training. The WAMs will contact OAQPS as soon as possible when training is required. Three options are available for out year training:

- ▶ WAM provided training- Since WAMs will be trained and certified along with ESAT contractors, the WAMs are certified to train additional ESAT personnel
- ▶ Individual training any time at the RTP ATF (1 month notice required).
- ▶ Scheduled training across the country- OAQPS will work with the Regions to schedule additional training at sites across the nation at some scheduled frequency (i.e., two times a year).

OAQPS will work with the ESAT Workgroup to determine the need for training and what method is logistically the most efficient.

## **8.7 Additional Ambient Air Monitoring Training**

Appropriate training is be available to employees supporting 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, a number of courses have been developed for personnel involved with ambient air monitoring and quality assurance aspects. Formal QA/QC training is offered through the following organizations:

- ▶ Air Pollution Training Institute (APTI) <http://www.epa.gov/oar/oaq.apti.html>
- ▶ Air & Waste Management Association (AWMA) <http://awma.org/epr.htm>
- ▶ American Society for Quality Control (ASQC) <http://www.asqc.org/products/educat.html>
- ▶ EPA Institute
- ▶ EPA Quality Assurance Division (QAD) <http://es.inel.gov/ncerqa/qa/>
- ▶ EPA Regional Offices

Table 8-1 presents a sequence of core ambient air monitoring and QA courses for ambient air monitoring staff, and QA managers (marked by 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 (SI = self instructional)	Number	Source
1*	Air Pollution Control Orientation Course (Revised), SI:422	422	APTI
2*	Principles and Practices of Air Pollution Control, 452	452	APTI
3*	Orientation to Quality Assurance Management	QA1	QAD
4*	Introduction to Ambient Air Monitoring (Under Revision), 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*	Data Quality Objectives Workshop	QA2	QAD
8*	Quality Assurance Project Plan	QA3	QAD
9	Atmospheric Sampling (Under Revision), 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
*	Data Quality Assessment	QA4	QAD
*	Management Systems Review	QA5	QAD
*	Beginning Environmental Statistical Techniques (Revised), SI:473A	473	APTI
*	Introduction to Environmental Statistics, SI:473B	473B	APTI
*	Quality Audits for Improved Performance	QA6	AWMA
*	Statistics for Effective Decision Making	STAT1	ASQC
	AIRS Training	AIRS1	OAQPS
*	FRM Performance evaluation Training (field/lab)	QA7	OAQPS
*	PM <sub>2.5</sub> Monitoring Implementation (Video)	PM1	OAQPS

\* Courses recommended for QA Managers

## **9.0 Documentation and Records**

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

For the Ambient Air Monitoring Program, there are number of 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 United States 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. This term will be defined as all the information required to support the concentration data reported to EPA, which includes all data required to be collected as well as data deemed important by the PEP. Table 9-1 identifies these documents and records.

### **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 in a similar manner to the EPA's records management system (EPA-220-B-97-003) and follows the same coding scheme in order to facilitate easy retrieval of information during EPA technical systems audits and reviews. Table 9-1 includes the documents and records that will be filed according to the statute of limitations discussed in Section 9.3. In order to archive the information as a cohesive unit, all the PEP PM<sub>2.5</sub> information will be filed under the major code "PEP", followed by the codes in Table 9-1. Each field and laboratory SOP provides instruction on the proper filing of data collected during the particular procedure.

**Table 9-1 PM<sub>2.5</sub> Reporting Package Information**

Categories	Record/Document Types	File Codes
Management and Organization	Organizational structure Personnel qualifications and training Training Certification Quality management plan EPA Directives Support Contracts	ADMI/106 PERS/123 AIRP/482 AIRP/216 DIRE/007 CONT/003
Site Information	Site characterization file Site maps Site Pictures	AIRP/237 AIRP/237 AUDV/708
Field and Laboratory Environmental Data Operations	QA Project Plans Standard operating procedures (SOPs) Field and laboratory notebooks communications Sample handling/custody records Inspection/Maintenance records	PROG/185 SAMP/223  SAMP/502/COM TRAN/643 AIRP/486
Raw Data	Any original data (routine and QC data) including data entry forms	SAMP/223
Data Reporting	Data/summary/progress reports Journal articles/papers/presentations	AIRP/484 PUBL/250
Data Management	Data algorithms Data management plans/flowcharts PM <sub>2.5</sub> Data Data Management Systems	INFO/304 INFO/304 INFO/160 INFO/304
Quality Assurance	Good Laboratory Practice Control charts Data quality assessments QA reports System audits Response/Corrective action reports Site Audits	COMP/322 SAMP/223 SAMP/223 OVER/203 OVER/255 PROG/082 OVER/203

### 9.1.2 Notebooks

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

**Field/Lab Notebooks** -The PEP will issue notebooks to each field scientist and laboratory. This 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/Lab Binders** - binders will be issued to each field scientist and laboratory analyst. These will be 3-ring binders that will contain the appropriate data forms for routine operations as well as inspection and maintenance forms and SOPs.

**Sample Shipping/ Receipt**- one notebook will be issued to each field and laboratory shipping and receiving facility. This notebook will be uniquely numbered and associated with the PM<sub>2.5</sub> program. It will include standard forms and areas for free form notes.

**Field and Laboratory Communications Notebook**- one communications notebook will be issued to each field scientist and laboratory analyst to record communications. Element 21 provides more information on this activity.

### **9.1.3 Electronic data collection**

All raw data required for the calculation of a PM<sub>2.5</sub> concentrations, including QA/QC data, are collected electronically or on data forms that are included in the field and laboratory SOPs. Data listed in Table 6-2 will be collected electronically, as well as the laboratory pre and post sampling weights. Therefore, both the primary field and laboratory data will be collected electronically and the calculation of the primary data into a final concentration will also be electronically calculated. Further details of this process can be found in Elements 18 and 19.

It is anticipated that other instruments will provide an automated means for collecting information that would otherwise be recorded on data entry forms. Information on these systems are detailed in Sections 18 and 19. In order to reduce the potential for data entry errors, automated systems will be utilized where appropriate and will record the same information that is found on data entry forms. In order to provide a back-up, a hardcopy of automated data collection information will be stored for the appropriate time frame in project files.

### **9.1.4 Hand Entered Data**

There will be a number of data forms that will be entered by hand. These can be found at the end of each field and laboratory SOP. All hardcopy information will be filled out in indelible ink. Corrections will be made by inserting one line through the incorrect entry, initialing 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.

## **9.2 Reports to Management**

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

### **9.2.1 Laboratory Weekly Report**

The LA will provide to the WAM a progress report in writing every Friday or the last day of the scheduled work week. The LA will maintain a complete record of the weekly progress report in a three ring binder and include an updated Filter Tracking Form (see PEPL-4.01). See PEP Lab PEPL-4.01 for the details of this report. This report will be filed under AIRP/484. WAMS may request additional information they feel is necessary to include in weekly reports.

### **9.2.2 Field Monthly Report**

The FS will provide to the WAM a progress report in writing at the end of each month. See PEP Field SOP PEPF-2.02 for the details of this report. This report will be filed under AIRP/484. The monthly progress report Form COM-2 will be used to convey the following information:

- ▶ Reporting Date - beginning and end date that report covers
- ▶ Reporter - person writing reports
- ▶ Progress - progress on field activities
  - Evaluations scheduled within reporting date
  - Evaluations conducted within reporting date
- ▶ Issues -
  - Old issues- issues reported in earlier reports that have not been resolved
  - New issues- arising within 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.

WAMS may request additional information they feel is necessary to include in monthly reports.

## **9.3 Data Reporting Package Archiving and Retrieval**

The information listed in Table 9-1 will be retained by the ESAT contractor for 3 years and is based on a calendar year (i.e., all data from calendar year 1999 will be archived until 12/31/2002). Upon reaching the 3 year archival date, the ESAT contractor will inform OAQPS that the material has met the archive limit and will ask for a decision on further archiving, or disposal.

## 10.0 Sampling Design

The purpose of this Element is to describe all of the relevant components of the PEP monitoring network; the key parameters to be estimated; the number and types of samples to be expected; and how the samples are to be taken.

### 10.1 Scheduled Project Activities, Including Measurement Activities

Section 6.4 details the critical time lines and activities for the PEP.

### 10.2 Rationale for the Design

This QAPP reflects the EDO's for a QA activity, not a routine monitoring activity. The sampling design has been codified in 40 CFR Part 58 Appendix A Section 3.5.3, as described below.

The FRM Performance Evaluation is an independent assessment of the total measurement system bias. The evaluation will be performed under the National Performance Audit Program (Section 2.4) or a comparable program. Twenty-five percent of the SLAMS monitors within each reporting organization will be assessed with an FRM evaluation each year. Additionally, every designated Federal Reference Method (FRM) or Federal equivalent method (FEM) within a reporting organization must:

1. have at least 25 percent of each method designation evaluated, including collocated sites (even those collocated with FRM instruments), (values of .5 and greater round up).
2. have at least 1 monitor evaluated.
3. be evaluated at a frequency of 4 evaluations per year (1/quarter).
4. have all FRM or FEM samplers subject to an FRM performance evaluation at least once every 4 years.

For  $PM_{2.5}$  sites during the initial deployment of the SLAMS network, special emphasis should be placed on those sites in areas likely to be in violation of the NAAQS. Once areas are initially determined to be in violation, the FRM Performance Evaluation Program should be implemented according to the following protocol:

1. Eighty percent of the FRM evaluations should be deployed at sites with concentrations  $\geq$  ninety percent of the mean annual  $PM_{2.5}$  NAAQS (or 24-hour NAAQS if that is affecting the area); one hundred percent if all sites have concentrations above either NAAQS, and each area determined to be in violation should implement an FRM evaluation at a minimum of one monitor within that area.
2. The remaining 20 percent of the FRM evaluations should be implemented at sites with concentrations  $<$  ninety percent of the mean annual  $PM_{2.5}$  NAAQS (or 24-hour NAAQS if that is affecting the area)
3. If an organization has no sites at concentration ranges  $\geq$  ninety percent of the mean annual  $PM_{2.5}$  NAAQS (or 24-hour NAAQS if that is affecting the area), 60 percent of the FRM evaluations should be implemented at those sites with the annual mean  $PM_{2.5}$  concentrations (or 24-hour NAAQS if that is affecting the area) among the highest 25 percent for all  $PM_{2.5}$  sites in the network.

Since the PEP sample design is detailed in regulation, it will be followed. State and local organizations will be asked to select the sites they feel meet the criteria above and provide a list of sites for the evaluations conducted in each calendar year on or before October 1 of the previous year. Table 6-4 reflects the number of evaluations that will be conducted in each Region. The Regional WAMS, with the assistance of the ESAT contractors, will determine the most efficient site visit schedule. This schedule will be based upon:

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

### 10.3 Design Assumptions

The intent of the sampling design is to determine that the total measurement bias is within the DQOs described in section 7. 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 will be aggregated at the following three levels.

1. **Monitor**- monitor/method designation
2. **Reporting Organization**- monitors in a method designation, all monitors
3. **National** - monitors in a method designation, all monitors

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

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

Since the DQO is based upon the NAAQS, which are based upon three years of data from individual monitors, it is important to assess the PE data against the DQO at the same frequency and level of aggregation. However, since the evaluation frequency of the PEP is 25% , any one monitor would receive an evaluation once every four years. Therefore, the PE data has limited use at the monitor level of aggregation, other than the actual assessment of the particular monitor. As one moves to the reporting organization and national levels of aggregation, a sufficient amount of data will be available to evaluate bias. The uncertainty of the PEP data will be controlled and evaluated through the use of various QA/QC samples described in Element 7 and 14. For example, the aggregation of the full collocation (all samplers) and paired collocation (1/month) over the three year period will determine the precision of the program. Use of various blanks, verification checks, and interlaboratory comparison studies can help to determine bias.

## 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 samplers attempt to represent parameter variations at a sampling point by locating within 1- 4 meters of the primary sampler and operating at the same sampling schedule. In addition, the PEP ensures representativeness of sampling within the SLAMS network by sampling all method designations within a reporting organization each year and sampling all monitors in a 4-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 polytetrafluoroethylene (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 quality assurance guidance.

Since all PE monitors must meet the requirements of 40 CFR Part 50 and be designated by EPA as a federal reference method (FRM) it is assumed that they collect a representative sample of suspended particulate matter in the  $PM_{2.5}$  size range; similar to the primary sampler at the site.

## Homogeneity

The PE monitor must be placed within 1-4 meters of the primary routine monitor for which it is being compared. The assumption is that the air within this 1-4 meter area is homogenous and 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 to be correct.

## 10.4 Procedure for Locating and Selecting Environmental Samples

Sections 10.2 and 10.3 adequately explain the:

- ▶ **frequency**- 25% of the monitors with a method designation 4 times a year (1/quarter).
- ▶ **location**- 1-4 meters from monitor to be evaluated. The physical location of the routine monitor is the responsibility of the State and local agencies and does not effect the intent of the PE evaluation. Site locational information is entered by the State into the AIRS database. The critical piece of information is the AIRS Monitor Site ID (State, county, unit, pollution occurrence code) which must be entered into AIRS in order for primary data to be loaded to AIRS. The ESAT field scientist will have access to this information.

For each site, the ESAT contractor will develop a Site Data Sheet that contains information such as:

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

This information listed above can be placed on one sheet and included in a site file (filed by AIRS Site ID). 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 or set-up in conditions that are deemed unsafe. Unsafe conditions include weather as well as monitoring platforms where the field scientists feel that they cannot transport or set up the monitor without jeopardizing their personnel safety. If these situations arise, the field scientist will document this so mechanisms can be instituted to make the platform safely accessible for a performance evaluation. This information will be conveyed to the WAM.

## **10.5 Classification of Measurements as Critical/Noncritical**

Sections 6.2.2 and 6.3.1 classify the critical 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**

Since the PEP is deploying only FRMs and will be operating them according to the established SOPs, there will not be any non-standard measurements. Also, since 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 fine particulate matter having an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ( $PM_{2.5}$ ) 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 detailed set of sampling methods has been developed for the QAPP. This document is entitled *PM<sub>2.5</sub> FRM Performance Evaluation Program Compendium of Standard Operating Procedures for Field Activities*. The following section will provide summaries of some of the more detailed information in the Field SOPs. The summaries do not replace the SOPs.

### 11.1 Sample Collection and Preparation

Portable FRM monitors will be used for the collection of  $PM_{2.5}$  samples for the PEP. There is one model currently available, the BGI™ PQ200A, and two models that are in the process of being designated as an FRM; the Anderson™ RAAS2.5-200, and the Rupprecht and Patashnic™ Partisol. Due to a goal to provide comparable results across the nation, the use of one portable monitor to evaluate all the routine monitors is advantageous because it reduces the chance that bias and imprecision among the different portable instrument models will confound the routine monitor comparisons. Since the BGI was the only portable to be granted FRM designation before 1/1999 it will be used as the primary instrument. Therefore, the field SOPs have been written based on this instrument. The other two instruments will be purchased and used as back-up instruments or due to their design, in areas where they have advantages. Studies of all three portable instruments will be conducted by EPA, prior to use, in order to determine comparability among each FRM.

#### 11.1.1 Preparation

Prior to an evaluation excursion for the week, and based upon the number of sites to be visited, the sampling equipment and consumables will be inspected to ensure proper operation and adequate supplies are on hand. At least one spare portable monitor and calibration equipment will be available. Filters will be selected and stored appropriately (per SOPs) for transport to the sites. Filter chain of custody sheets will be started and the filters checked to ensure they have not gone past their 30 day pre-sampling time period. Site data sheets and field data sheets should be available for each site. For the initial visits, some of the information on the Site Data Sheets may be blank and must be completed during the first visit. The field personnel will review the site schedule to be sure that they understand which tasks will be implemented at the sites they are visiting that week.

Shipment of the filters back to the laboratories will require the use of ice substitutes. These must be kept frozen until use. During transport to/from the sites, the ice substitutes will be placed in an electric transport cooler to maintain their frozen state.

### **11.1.2 Field Sample Collection**

Field scientists will travel to the sites and meet the person (typically the site operator) that will allow them access to the monitoring site. The portable FRM monitors will be transported to within 1-4 meters of the routine monitor, set-up and calibrated per the SOPs. Filters will be installed and the monitor set to run on a midnight-to-midnight schedule. The field scientist will then either perform additional tasks as required at this site or proceed to another site for sampling. If there are any delays in the sampling schedule, the ESAT field scientist will contact the affected State and local organizations and also notify the Regional WAM.

Upon completion of sampling, the field scientist will return to the site(s), remove the sampling filter, visually inspect the filter, store it appropriately for transport to the laboratory and download the data per SOPs. Each field scientist will have a portable laptop as well as data loggers provided by the portable sampler manufacturers. Laptops should be used as a first option to acquire the data from the samples; data loggers should be used when safety or precipitation prevents use of a laptop. A diskette of this information is required to 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 National laboratories as soon as possible. Filters will be shipped the same day that they are removed from the monitors via Federal Express<sup>®</sup> next day. Filters, ice packs, max/min thermometers, copies of the chain of custody forms, field data sheets and a field data diskette of the monitor information will be included in the shipment. The field scientist will keep a copy of the field data sheet and the chain of custody form which will include the number of containers shipped and the air bill number. The day of shipping, the field scientist will contact the laboratory to make them aware of the shipment and provide the laboratory with the number of containers shipped and the air bill number.

### **11.1.4. Return to Station**

Upon completion of a sampling excursion, the field scientist will return to the Regional Office. The field scientist will ensure all equipment and consumables are properly stored and determine if resupply or equipment maintenance is required. A second diskette of the weeks field information will be downloaded to diskette and given to the WAM. Vehicles will be serviced as required. The field scientist will debrief the WAM on the field excursion including whether the site visits remain on schedule.

### **11.1.5 Field Maintenance**

A maintenance list will be developed for all sensitive capital equipment. The list will contain the item, the maintenance schedule and date columns that will be filled in when scheduled or unscheduled maintenance is performed. See element 15 for this information.

## **11.2 Support Facilities for Sampling Methods**

The analytical support facilities will be the Region 4 and 10 laboratories. The laboratories have been developed to meet the measurement quality objectives described in Table 7-4.

## **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 in writing who will convey the issue to the PM<sub>2.5</sub> ESAT Workgroup. The Workgroup will review the change, and attempt to classify the change according to the effect 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 found to be acceptable by the ESAT 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 filled out that will describe the change and will distributed to all WAMS and ESAT personnel.

Class 2 - the change provides for an alternate that does not affect the quality of the data but may provide for efficiencies in some circumstances or be cost effective. If found to be acceptable by the ESAT Workgroup the original SOP will not be altered but an addendum to the procedure will be initiated which will describe the modification and provide for the use of the 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 will be modified during a class 1 change (where appropriate) or be corrected during the development of a full revision to the document.

Upon agreement by the ESAT Workgroup to institute a change, hard copies of class 1 and 2 changes will be distributed using the Quality Bulletin illustrated in Figure 11.1.

### Quality Bulletin

Subject:

Number \_\_\_\_\_  
Date \_\_\_\_\_  
Page \_\_\_\_\_ of \_\_\_\_\_  
Supersedes No. \_\_\_\_\_  
Dated \_\_\_\_\_

**Replace and Discard Original**

**Add Material to Document**

**Notes:**

\_\_\_\_\_  
PM<sub>2.5</sub> 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 PM<sub>2.5</sub> Air Quality Monitoring Network will be taken to ensure the data quality objectives are attained. There is the potential for many types of sampling and measurement system corrective actions. Table 11-1 is an attempt to detail the expected problems and corrective actions needed for a well-run PM<sub>2.5</sub> network.

**Table 11-1 Field Corrective Action**

Item	Problem	Action	Notification
Filter Inspection (Pre-sample)	Pinhole(s) or torn	1.) If additional filters have been brought, use one of them. Void filter with pinhole or tear. 2.) Use new field blank filter as sample filter. 3.) Obtain a new filter from lab.	1.) Document on field data sheet. 2.) Document on field data sheet. 3.) Notify WAM
Filter Inspection (Post-sample)	Torn or otherwise suspect particulate by-passing 46.2 mm filter.	1.) Inspect area downstream of where filter rests in sampler and determine if particulate has been by-passing filter. 2.) Inspect in-line filter before sample pump and determine if excessive loading has occurred. Replace as necessary.	1.) Document on field data sheet. 2.) Document in log book.
WINS Impactor	Heavily loaded with coarse particulate. Will be obvious due to a "cone" shape on the Impactor well.	Clean downtube and WINS Impactor. Load new Impactor oil in WINS Impactor well	Document in log book
Sample Flow Rate Verification	Out of Specification ( $\pm$ 4% of transfer standard)	1.) Completely remove flow rate measurement adapter, re-connect and re-perform flow rate check. 2.) Perform leak test. 3.) Check flow rate at 3 points (15.0 LPM, 16.7 LPM, and 18.3 LPM) to determine if flow rate problem is with zero bias or slope. 4.) Re-calibrate flow rate	1.) Document on data sheet. 2.) Document on data sheet. 3.) Document on data sheet. Notify WAM 4.) Document on data sheet. Notify WAM.
Leak Test	Leak outside acceptable tolerance (80 mL/min)	1.) Completely remove flow rate measurement adapter, re-connect and re-perform leak test. 2.) Inspect all seals and O-rings, replace as necessary and re-perform leak test. 3.) Check sampler with different leak test device.	1.) Document in log book. 2.) Document in log book, notify WAM, and flag data since last successful leak test. 3.) Document in log book and notify WAM.

Item	Problem	Action	Notification
Sample Flow Rate	Consistently low flows documented during sample run	1.) Check programming of sampler flowrate. 2.) Check flow with a flow rate verification filter and determine if actual flow is low. 3.) Inspect in-line filter downstream of 46.2 mm filter location, replace as necessary.	1.) Document in log book. 2.) Document in log book. 3.) Document in log book.
Ambient Temperature Verification, and Filter Temperature Verification.	Out of Specification ( $\pm 4^{\circ}\text{C}$ of standard)	1.) Make certain thermocouples are immersed in same liquid at same point without touching sides or bottom of container. 2.) Use ice bath or warm water bath to check a different temperature. If acceptable, re-perform ambient temperature verification. 3.) Connect new thermocouple. 4.) Check ambient temperature with another NIST traceable thermometer.	1.) Document on data sheet. 2.) Document on data sheet. 3.) Document on data sheet. Notify WAM. 4.) Document on data sheet. Notify WAM.
Ambient Pressure Verification	Out of Specification ( $\pm 10$ mm Hg)	1.) Make certain pressure sensors are each exposed to the ambient air and are not in direct sunlight. 2.) Call local Airport or other source of ambient pressure data and compare that pressure to pressure data from monitors sensor. Pressure correction may be required 3.) Connect new pressure sensor	1.) Document on data sheet. 2.) Document on data sheet. 3.) Document on data sheet. Notify WAM
Elapsed Sample Time	Out of Specification ( 1 min/mo)	Check Programming, Verify Power Outages	Notify WAM
Elapsed Sample Time	Sample did not run	1.) Check Programming 2.) Try programming sample run to start while operator is at site. Ensure the transport filter is in the unit.	1.) Document on data sheet. Notify WAM 2.) Document in log book. Notify WAM.
Power	Power Interruptions	Check Line Voltage	Notify WAM
Power	LCD panel on, but sample not working.	Check circuit breaker, some samplers have battery back-up for data but will not work without AC power.	Document in log book
Data Downloading	Data will not transfer to laptop computer	Document key information on sample data sheet. Make certain problem is resolved before data is written over in sampler microprocessor.	Notify WAM.

## **11.4 Sampling Equipment, Preservation, and Holding Time Requirements**

This sections 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, Section 15 provides information on monitor maintenance in order 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 PM<sub>2.5</sub> network has rigid requirements for preventing sample contamination. Powder free antistatic gloves are worn while handling filter cassettes in the laboratory. Once the filter cassette is taken outside of the weigh room it must never be opened as damage may result to the 46.2 mm Teflon filter. Filter cassettes will be stored in protective containers. Once samples have been preweighed, they are to be stored with the particulate collection side up, capped with metal caps, and individually stored in static resistant zip lock bags.

### **11.4.2 Sample Volume**

The volume of air to be sampled is specified in 40 CFR Part 50. Sample flow rate of air is 16.67 L/min. The total sample of air collected will be 24 cubic meters based upon a 24 hour sample. Samples are expected to be 24 hours; however, in some cases a shorter sample period may be necessary, not to be less than 23 hours. Since capture of the fine particulate is predicated upon a design flowrate of 16.67 L/min, deviations of greater than 10% from the design flowrate will enable a shut-off mechanism for the sampler. If a sample period is less than 23 hours or greater than 25 hours, the sample will be flagged and the WAM notified.

### **11.4.3 Temperature Preservation Requirements**

The temperature requirements of the PM<sub>2.5</sub> network are explicitly detailed in 40 CFR Part 50, Appendix L<sup>1</sup>. During transport from the laboratory the sample 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 a closed-up car during summer). During sampling (24 hour period), the filters will be subject 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 PEPF-8.03). 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 start of conditioning.	Protected from exposure to temperatures over 25° C.	40 CFR Part 50, Appendix L, Section 10.13
Post sample transport so that final weight may be determined up to 30 days after end of sample period.	4° C or less	40 CFR Part 50, Appendix L, Section 8.3.6

#### 11.4.4 Permissible Holding Times

The permissible holding times for the PM<sub>2.5</sub> sample are clearly detailed in both 40 CFR Part 50, Appendix L, and Quality Assurance Guidance Document 2.12. These holding times are provided in Table 11-3. The PEP will require a more restrictive holding time requirement than is required in regulation. The PEP holding time requirements are represented in bold/italics in Table 11-3.

**Table 11-3 Holding Times**

Item	Holding Time	From:	To:	Reference
Pre-weighed Filter	≤30 days	Date of Pre-weigh	Date of Sample	40 CFR Part 50, Appendix L, Section 8.3.5
Recovery of Filter	≤96 hours <b>≤48 hours</b>	Completion of sample period	Time of sample recovery	40 CFR Part 50, Appendix L, Section 10.10
Transport of Filter	<24 Hours (ideally) <b>≤8 hours</b>	Time of recovery	Time placed in conditioning room	40 CFR Part 50, Appendix L, Section 10.13
Post Sample Filter stored at <4° C.	≤30 days <b>≤10 days</b>	Sample end date/time	Date of Post Weigh	40 CFR Part 50, Appendix L, Section 8.3.6
Post Sample Filter continuously stored at <25° C.	≤10 days	Sample end date/time	Date of Post Weigh	40 CFR Part 50, Appendix L, Section 8.3.6

## **12.0 Sampling Handling and Custody**

Due to the potential use of the PM<sub>2.5</sub> data for comparison to the NAAQS and the requirement for extreme care in handling the sample collection filters, sample custody procedures will be followed. The laboratory SOPs (PEPL-5.01 and 10.01) and the field SOPs (PEPF- 3.01 and 11.01) provide detailed instruction on filter handling and the chain of custody procedures which will not be included in this section. As illustrated in Figure 6.1 the 3-part carbon less chain of custody form starts at the Region 4 and 10 laboratories, proceeds through field activities, and are sent back to the laboratories.

## 13.0 Analytical Methods Requirements

The methods 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 (presampling) from the final weight (postsampling). Once calculated, the net weight gain can be used with the total flow volume passed through a filter (derived from the field data) to calculate the concentration for comparison to the routine primary monitor.

All analytical methods are included in the document entitled *Quality Assurance Guidance Document Method Compendium PM<sub>2.5</sub> Mass Weighing Laboratory Standard Operating Procedure for the Performance Evaluation Program*. The PEP laboratories in Regions 4 and 10 will be responsible for implementing these analytical SOPs. The following sections provides a brief summary of the more detailed information in the Lab SOPs. The summaries do not replace the SOPs.

### 13.1 Preparation of Sample Filters

Upon delivery of 46.2 mm Teflon filters to the laboratory, the receipt is documented and the filters 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, opened one at a time and 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 slides.

### 13.2 Analysis Method

#### 13.2.1 Analytical Equipment and Method

A complete listing of the analytical equipment is found in the laboratory SOPs and Element 17.

The analytical instrument used for gravimetric analysis in the FRM or equivalent PM<sub>2.5</sub> sampler method (gravimetric analysis) is the microbalance. The PEP laboratories will use the Sartorius<sup>®</sup> MC-5, which has a readability of 1  $\mu\text{g}$  and a repeatability of 1  $\mu\text{g}$ . The microbalance is calibrated yearly by a technician under a service agreement between the Regional laboratories and the microbalance vendor.

As Figure 13.1 indicates, the method of analysis consists of a presampling and a postsampling

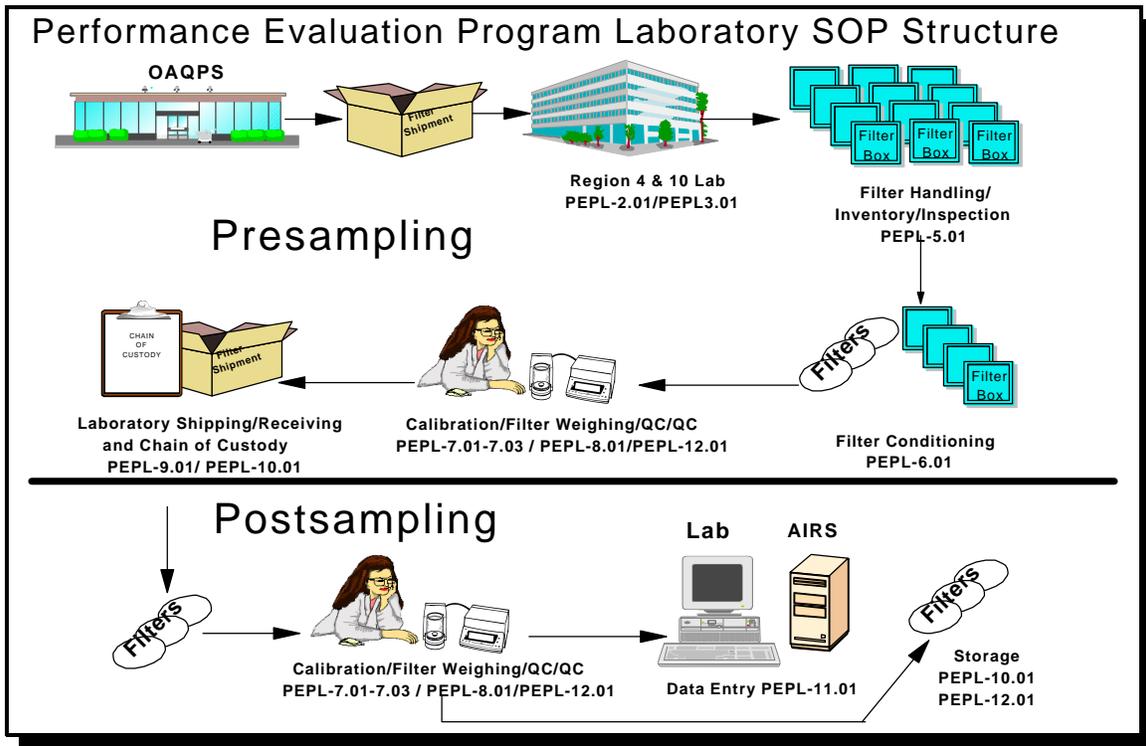


Figure 13.1 Laboratory activities

stages. Figure 13.1 also indicates the SOP number where detailed procedures can be found in the laboratory SOPs.

**Presampling stage:**

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

**Post-Sampling stage**

- ▶ filters will be received in the laboratory, checked for integrity (damage, temperature, etc.) and logged in
- ▶ filters will be archived (cold storage) until ready for weighing
- ▶ filters will be brought into the weighing facility and equilibrated for 24-hours
- ▶ filters will be weighed and the data entered
- ▶ field data will be entered into the data entry system in order to calculate a concentration
- ▶ data is verified and validated
- ▶ filters will be archived for 3 years.
- ▶ required data will be transferred to the AIRS database.

### **13.2.2 Conditioning and Weighing Room**

The primary support facility for the PM<sub>2.5</sub> analysis is the filter conditioning and weighing room/laboratory. Additional facility space is dedicated for long term archiving of the filter. This weigh room laboratory is used for both presampling weighing and postsampling weighing of each PM<sub>2.5</sub> filter sample. The facilities (Region 4 and 10 labs) have been constructed to minimize contamination from dust (hepa-filters and sticky mats, etc. ) or other potential contaminants and will have restricted access to laboratory analysts who will wear appropriate lab attire at all times.

Specific requirements for environmental control of the conditioning/weighing room laboratory are detailed in 40 CFR Part 50 Appendix L. Temperature is controlled at a minimum from 20 - 23° C. Humidity is controlled from 30 - 40% relative humidity. 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 both the pre- and post-sampling weighings. 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 SOPs**

The ESAT contractors are responsible for implementing this QAPP and the laboratory 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 SOPs or QAPP, the ESAT contractor will notify the Regional WAM in writing who will convey the issue to the PM<sub>2.5</sub> ESAT Workgroup. The Workgroup will review the change, and attempt to classify the change according to the effect the change would have on the data. The required procedure is discussed in Element 11.4.1 for the field SOPs.

### **13.3.2 Data Operations**

A QC notebook or database (with disk backups) will be maintained which 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. QC control charts will be maintained for each microbalance and included in this notebook. These charts may allow the discovery of excess drift that could signal an instrument malfunction.

Each weighing session will include a number of QC checks that will assist the laboratory analysts in controlling and evaluating the quality of data during a weighing session. These QC checks include:

- ▶ mass working standards weighed at the beginning and end of each sample batch

- ▶ blanks, both field and laboratory that will be used in determining contamination
- ▶ duplicate routine weights to determine repeatability of the instrument within the weighing session as well as filter stability

The acceptance requirements for these QC checks can be found in Table 7-4, are explained in the SOPs, and in more detail in Section 14.

Corrective action measures in the PM<sub>2.5</sub> FRM system 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	Humidity	Out of Spec.	Check HVAC system	Lab WAM
Weigh Room	Temperature	Out of Spec.	Check HVAC system	Lab WAM
Balance	Internal Calibration	Unstable	Redo and check working standards	Lab WAM
Balance	zero	Unstable	Redo and check for drafts, sealed draft guard	Lab WAM
Balance	Working Standards	Out of Spec.	1.Check T & RH and redo 2 Recalibrate and check WS 3 Check w/ primary standards	Document, Lab WAM
Balance	Filter Weighing	Unstable	Check lab blank filters	Document in 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/year establish IDL	Resolution of 1 µg, repeatability of 1 µg	Obtain proper microbalance
Control of bal. environment	5min values temp 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 laboratory primary standards	Standards bracket weight of filter, individual standard's tolerance less than 25 µg, handle with smooth, nonmetallic forceps	Obtain new standards or forceps
Filter handling	Observe handling procedure	Use powder-free gloves and smooth forceps. Replace <sup>210</sup> Po antistatic strips every 6 months	Discard mishandled filter or old antistatic strip
Filter integrity check	Visually inspect each filter	No pinholes, separation, chaff, loose material, discoloration, or filter non-uniformity	Discard defective filter

Activity	Method and frequency	Requirements	Action if the requirements are not met
Filter identification	Write filter number on COC, cassette number on protective container, and both numbers on laboratory data form in permanent ink	Make sure the numbers are written legibly	Replace label or correct form
Pre-sampling filter equilibration	Determine the correct equilibration conditions and period (at least 24 hours) for each new lot of filters. Observe and record the equilibration chamber relative humidity and temperature; enter to lab data form.	Check for stability of lot exposure blank filter weights. Weight changes must be <15 µg on successive weighings of lot exposure blanks. Mean relative humidity between 30 and 40 percent, with a variability of not more than ±5 percent over 24 hours. Mean temperature will be held between 20 and 23 °C, with a variability of not more than ±2 °C over 24 hours.	Revise equilibration conditions and period. Repeat equilibration
Initial filter weighing	Observe all weighing procedures. Perform all QC checks	Neutralize electrostatic charge on filters. Wait until balance indicates a stable reading	Repeat weighing
Internal QC	<p>1) After approximately every 15th filter, reweigh the two working standards.</p> <p>2) Weigh laboratory filter blanks.</p> <p>3) reweigh the first filter as the last routine weight with each sample batch (duplicate weighing).</p>	<p>1)The working standard measurements must agree to within 3 µg of the certified values.</p> <p>2)The blank measurements must agree to within 15 µg.</p> <p>3) first/last filter reweigh measurements must agree to within 15 µg.</p>	<p>1)Stop weighing and trouble shoot .</p> <p>2)Flag values for validation activities</p> <p>3) Flag. Reweigh 2<sup>nd</sup> and 3<sup>rd</sup> and if failure recondition all sample in run and reweigh.</p>
Post-sampling inspection, documentation, and verification	Examine the filter and field data sheet for correct and complete entries. If sample was shipped in a cooled container, verify that low temperature was maintained.	No damage to filter. Field data sheet complete. Sampler worked OK.	Notify Lab WAM. Flag filters.
Post-sampling filter equilibration	Equilibrate filters for at least 24 hours. Observe and record the equilibration chamber relative humidity and temperature; enter to lab data sheet. Must be within ± 5% RH of pre-sampling weighing conditions.	Mean relative humidity between 30 and 40 percent, with a variability of not more than ±5 percent over 24 hours. Mean temperature will be held between 20 and 23 °C, with a variability of not more than ±2 °C over 24 hours.	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 filter sample from contamination, temperature preservation requirements, and the permissible holding times to ensure against degradation of sample integrity.

### **13.4.1 Sample Contamination Prevention**

The analytical support component of the PM<sub>2.5</sub> network has rigid requirements for preventing sample contamination. Filters are equilibrated/conditioned and stored in the same room where they are weighed and will be protected in petri slides. This conditioning/weighing room has been developed for climate and contamination control (see Section 13.2.2). Powder free gloves are worn while handling filters and filters are only contacted with the use of smooth nonserrated forceps. Upon determination of its pre-sampling weight, the filter is placed in its cassette, filter caps are placed on the cassette and then placed in a plastic shipping bag; only to be opened when being installed in a monitor. Once the filter is taken outside of the weigh room it will never be removed from the cassette until it is back in the weigh room (postsampling).

### **13.4.2 Temperature Preservation Requirements**

The temperature requirements of the PM<sub>2.5</sub> network are explicitly detailed in 40 CFR Part 50. In the weigh room laboratory, the filters must be conditioned for a minimum of 24 hours prior to pre-weighing; although, a longer period of conditioning may be required. The weigh room laboratory temperature must be maintained between 20 and 23° C, with no more than a +/- 2° C change over the 24 hour period prior to weighing the filters. During transport from the weigh room to the sample location, there are no specific requirements for temperature control; however, the filters will be located in their protective container and excessive heat 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<sup>1</sup>. These requirements pertain to both sample media before collection and both the sample media and sample after a sample has been collected. Additionally, during the sample collection there are requirements for temperature control. The temperature requirements are detailed in Table 13-3.

**Table 13-3 Temperature Requirements**

Item	Temperature Requirement	Reference
Weigh Room	20 - 23° C	40 CFR Part 50, Appendix L, Section 8.3.1
Pre-weighed Filter	+/- 2° C for 24 hours prior to weighing	40 CFR Part 50, Appendix L, Section 8.3.2
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 so that final weight may be determined up to 30 days after end of sample period	4° C or less	40 CFR Part 50, Appendix L, Section 8.3.6

### 13.4.3 Permissible Holding Times

The permissible holding times for the PM<sub>2.5</sub> sample are clearly detailed in both 40 CFR Part 50<sup>1</sup> and Section 2.12 of the U.S. EPA QA Handbook<sup>2</sup>. A summary of these holding times are provided in Table 11-3 in subsection 11.5.4.

### References

The following documents were utilized in the development of this section:

1. U.S. EPA (1997a) National Ambient Air Quality Standards for Particulate Matter - Final Rule. 40 CFR Part 50. *Federal Register*, **62**(138):38651-38760. July 18,1997.
2. U.S. EPA Quality Assurance Guidance Document 2.12: Monitoring PM<sub>2.5</sub> in Ambient Air Using Designated Reference or Class I Equivalent Methods. March, 1998

## 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 quality assurance activities, such as establishing policies and procedures, developing data quality objectives, assigning roles and responsibilities, conducting oversight and reviews, and implementing corrective actions. The other function is the control of the measurement process through the implementation of specific quality control procedures, such as audits, calibrations, checks, replicates, routine self-assessments, etc. In general, the greater the control of a given monitoring system, the better will be the resulting quality of the monitoring data.

Quality control (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 they meet the stated requirements established by the customer. In the case of the Ambient Air Quality Monitoring Network, QC activities are used to ensure that measurement uncertainty, as discussed in Section 7, is maintained within acceptance criteria for the attainment of the DQO. Figure 14.1 represents a number of QC activities that help to evaluate and control data quality for the PM<sub>2.5</sub> Program. The activities in this figure are implemented by the PEP and are discussed in the appropriate sections of this QAPP.

### 14.1 QC Procedures

Day-to-day quality control is implemented through the use of various check samples or instruments that are used for comparison. The measurement quality objectives table (Table 7-1) in Section 7 contains a complete listing of these QC samples as well as other requirements for the PM<sub>2.5</sub> Program. The procedures for implementing the QC samples are included in the 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 contains a summary 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.

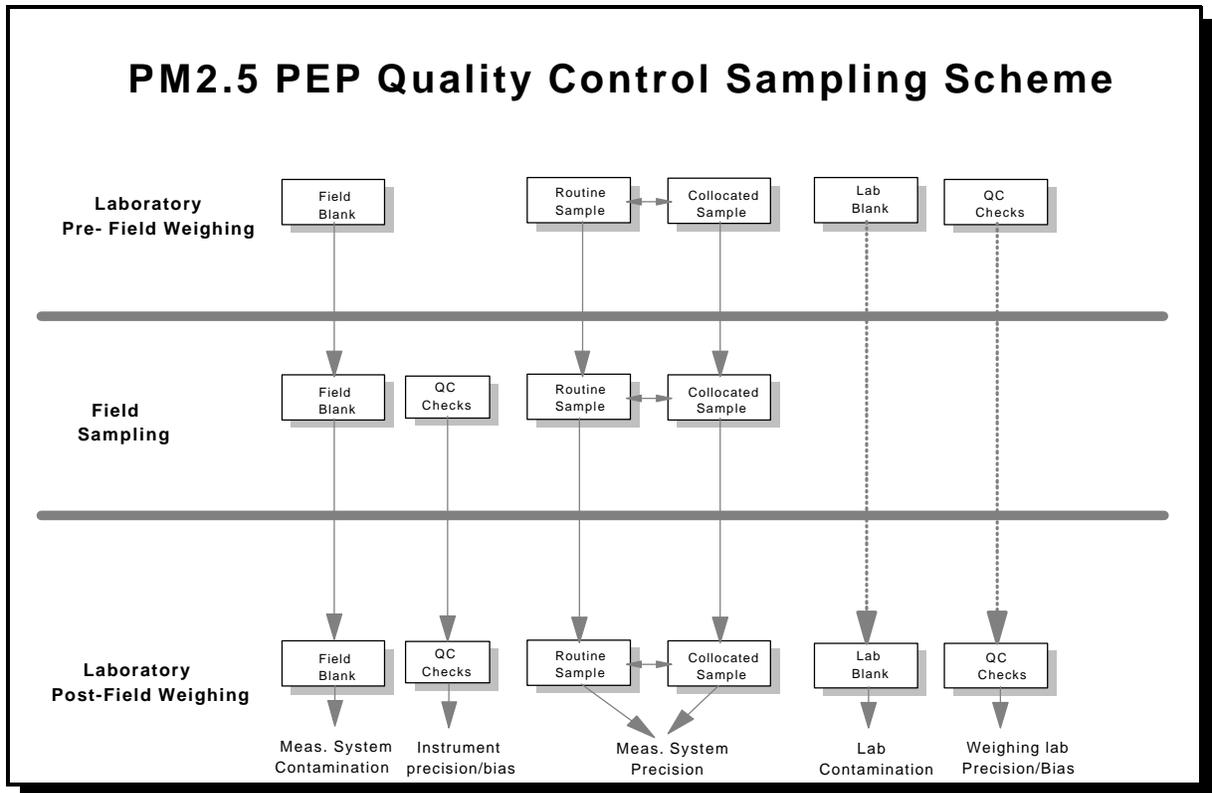
**Table 14-1 Field QC Checks**

Requirement	Frequency	Acceptance Criteria	CFR Reference	Field SOP Reference	Information Provided
<b>Calibration Standards</b> Flow Rate Transfer Std. Field Thermometer  Field Barometer	1/yr 1/yr  1/yr	$\pm 2\%$ of NIST-traceable Std. $\pm 0.1^\circ\text{C}$ resolution $\pm 0.5^\circ\text{C}$ accuracy $\pm 1$ mm Hg resolution $\pm 5$ mm Hg accuracy	Part 50, App.L Sec 9.1, 9.2 not described not described not described not described	PEPF-10.01	Certification of Traceability Certification of Traceability  Certification of Traceability
<b>Calibration/Verification</b> Flow Rate (FR) Calibration FR multi-point verification One point FR verification External Leak Check Internal Leak Check Temperature Calibration Temp multi-point verification One- point temp Verification Pressure Calibration Pressure Verification Clock/timer Verification	If multi-point failure 1/yr every sampling event every sampling event if external LC failure 80 mL/min 80 mL/min If multi-point failure on installation, then 1/yr every sampling event every sampling event on installation, then 1/yr every sampling event every sampling event	$\pm 2\%$ of transfer standard $\pm 2\%$ of transfer standard $\pm 4\%$ of transfer standard 80 mL/min 80 mL/min $\pm 2\%$ of standard $\pm 2^\circ\text{C}$ of standard $\pm 4^\circ\text{C}$ of standard $\pm 10$ mm Hg $\pm 10$ mm Hg 1 min/mo	Part 50, App.L, Sec 9.2 Part 50, App.L, Sec 9.2.5  Part 50, App.L, Sec 7.4 " " Part 50, App.L, Sec 9.3 Part 50, App.L, Sec 9.3 " " " Part 50, App.L, Sec 7.4	PEPF-7.03 PEPF-7.03 PEPF-6.04 PEPF-6.01 PEPF-6.01 PEPF-7.02 PEPF-7.02 PEPF-6.03 PEPF-7.01 PEPF-6.02 PEPF-6.02	Calibration drift and memory effects Calibration drift and memory effects Calibration drift and memory effects Sampler function Sampler function Calibration drift and memory effects Calibration drift and memory effects Calibration drift and memory effects Calibration drift and memory effects Calibration drift and memory effects Verification of to assure proper function
<b>Blanks</b> Field Blanks	1/week/sampler	$\pm 30 \mu\text{g}$	Part 50, App.L Sec 8.2	PEPF-10.01	Measurement system contamination
<b>Precision Checks</b> Collocated samples Full monitor collocation	every month 1/year	$\text{CV} \leq 10\%$ $\text{CV} \leq 10\%$	Part 58, App.A, Sec 3.5, 5.5 Not described	PEPF-10.01 PEPF-10.01	Measurement system precision Measurement system precision
<b>Accuracy</b> Flow rate audit External Leak Check Internal Leak Check Temperature Check Pressure Check	1/3mo (manual) 4/yr 4/yr 4/yr 4/yr	$\pm 4\%$ of transfer standard $< 80$ mL/min $< 80$ mL/min $\pm 2^\circ\text{C}$ $\pm 10$ mm Hg	Part 58, App A, Sec 3.5.1 not described not described not described	PEPF-10.01 " " " "	Instrument bias/accuracy Sampler function Sampler function Calibration drift and memory effects Calibration drift and memory effects
<b>Audits (external assessments)</b> FRM Performance evaluation <b>Flow rate audit</b> External Leak Check Internal Leak Check Temperature Audit Pressure Audit	25% of sites 4/yr 1/yr 1/yr 1/yr 1/yr 1/yr	$\pm 10\%$ $\pm 4\%$ of audit standard $< 80$ mL/min $< 80$ mL/min $\pm 2^\circ\text{C}$ $\pm 10$ mm Hg	Part 58, App A, Sec 3.5.3 not described not described not described not described not described		Measurement system bias External verification bias/accuracy Sampler function Sampler function Calibration drift and memory effects Calibration drift and memory effects

**Table 14-2 Laboratory QC**

Requirement	Frequency	Acceptance Criteria	Lab SOP Reference	Information Provided
<b>Blanks</b> Lot Lot Exposure Lab	9/lot 3/box 10% or 1/weighing session	$\pm 15 \mu\text{g}$ difference $\pm 15 \mu\text{g}$ difference $\pm 15 \mu\text{g}$ difference	PEPL-6.01 PEPL-6.01 PEPL-8.01	Filter stabilization/equilibrium Filter stabilization/equilibrium Laboratory contamination
<b>Calibration/Verification</b> Balance Calibration Lab Temp. verification Lab Humidity verification	1/yr 3 mo 3 mo	Manufacturers spec. $\pm 2^\circ\text{C}$ $\pm 2\%$	PEPL-7.02 PEPL-7.03 "	Verification of equipment operation Verification of equipment operation Verification of equipment operation
<b>Accuracy</b>  Balance Audit  Balance Check	  1/year  beginning, end of batch	  $\pm 15 \mu\text{g}$ for unexposed filters  $\leq 3 \mu\text{g}$	  2.12 Sec 10.2  PEPL-8.01	  Laboratory technician operation  Balance accuracy/stability
<b>Calibration standards</b> Working Mass Stds. Primary Mass Stds.	3- mo. 1/yr	25 $\mu\text{g}$ 25 $\mu\text{g}$	PEPL-7.01 "	Standards verification Primary standards verification
<b>Precision</b> Duplicate filter weighings Interlaboratory comparisons	1 per weighing session 4 mo	$\pm 15 \mu\text{g}$ difference ???	PEPL-8.01 PEPL-12.01	Weighing repeatability/filter stability Between laboratory repeatability

**14.1.1 Calibrations**



**Figure 14.1 PEP Quality control scheme**

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<sup>1</sup>. The purpose of calibration is to minimize bias.

For PM<sub>2.5</sub>, calibration activities follow a two step process:

1. Certifying the calibration standard and/or transfer standard against an authoritative standard, and
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 the calibration section (Section 16) and in the field and laboratory SOPs

### **Calibration Evaluation–**

Calibration data will be compared against actual standards acceptance.

**Accuracy of a verification/calibration checks - Single Check (Quarterly) Basis ( $d_i$ ).** The percentage difference ( $d_i$ ) for a single calibration check  $i$  is calculated using Equation 13, where  $X_i$  represents the standard value (known) and  $Y_i$  represents the indicated (measured) value.

$$d_i = \frac{Y_i - X_i}{X_i} \times 100 \quad \text{Equation 13}$$

**Corrective Action-** The 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. Usually troubleshooting and corrective action will take place and the verification/calibration will be redone. If the instrument cannot be calibrated, a spare will be used. If a field situation arises where a spare sampler cannot be used, the sample may be taken but will be flagged appropriately.

### **14.1.2 Blanks**

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

**Lot blanks** - a shipment of 46.2mm filters will be sent from EPA to the Region 4 and 10 laboratories. The shipment may contain a number of 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 it takes the lot to stabilize. 3 filter boxes will be randomly selected from the lot and 3 filter lot blanks will be randomly chosen from each box (9 filters total) and be subjected to the conditioning/pre-sampling weighing procedures. The blanks will be measured every 24 hours for a minimum of one week to determine the length of time it takes to condition filters (see PEPL-6.01).

**Lot exposure blanks** - Similar to lot blanks, lot exposure blanks are used to determine whether a specific set of filters to be conditioned at one time period are stable for pre-weighing (see PEPL-6.01).

**Field blanks** - provide an estimate of total measurement system contamination. By comparing information from laboratory blanks against the field blanks, one can assess contamination from field activities. Details of the use of the field blanks can be found in field SOP PEPF-10.01

**Lab blanks** -provide an estimate of contamination occurring at the weighing facility. Details of the use of the lab blanks can be found in lab SOP PEPL-8.01.

#### **Blank Evaluation --**

The PEP will include at a minimum 1 field and 1 lab blank into each weighing session sample batch. 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 Equation 1, where  $X$  represents the concentration produced from the original weight (presampling) and  $Y$  represents the concentration reported for the duplicate weight (postsampling)

$$d = |Y-X| \quad \text{Equation 1}$$

**Percent Difference for a Single Check ( $d_i$ )**. The percentage difference,  $d_i$ , for each check is calculated using Equation 2 where  $X_i$  represents the original weight and  $Y_i$  represents the concentration reported for the duplicate weight.

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

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**Mean difference for batch ( $d_z$ )** - The mean difference  $d_z$  for both field and lab blanks within a weighing session batch, is calculated using equation 3 where  $d_1$  through  $d_n$  represent individual differences (calculated from equation 1) and  $n$  represents the number of blanks in the batch.

$$d_z = \frac{d_1 + d_2 + d_3 \dots d_n}{n} \quad \text{Equation 3}$$

**Corrective action-** The acceptance criteria for field blanks is 30  $\mu\text{g}$  difference, while lot and lab blanks are 15  $\mu\text{g}$  difference and is determined by equation 1. However the mean difference based upon the number of blanks in each batch will be used for comparison against the acceptance criteria. If the mean difference of either the field or laboratory blanks is greater than 30  $\mu\text{g}$  or 15  $\mu\text{g}$  respectively, all the samples in the weighing session will be re-weighed. Prior to re-weighing, the laboratory balance will be checked for proper operation. If the blank means of either the field or lab blanks are still out of the acceptance criteria, all samples within the weighing session will be flagged with the appropriate flag (FFK or FLB), and efforts will be made to determine the source of contamination. In theory, field blanks should contain more contamination than laboratory blanks. Therefore, if the field blanks are outside of the criteria while the lab blanks are acceptable, weighing can continue on the next batch of samples while field contamination sources are investigated. If the mean difference of the laboratory blanks is greater than 20  $\mu\text{g}$  and 2 or more of the blanks were greater than 15  $\mu\text{g}$ , the laboratory weighing will stop until the issue is satisfactorily resolved. The laboratory technician will alert the WAM of the problem. The problem and solution will be reported and appropriately filed under response and corrective action reports (PROG/082 OVER/658, see Section 9)

Lab and field blanks will be control charted (see Section 14.3). The percent difference calculation (equation 2) is used for control charting purposes and can be used to determine equilibrium status.

### 14.1.3 Precision Checks

Precision is the measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. In order to meet the data quality objectives for precision, the PEP must ensure the entire measurement process is within statistical control. Two types of precision measurements will be made in the  $\text{PM}_{2.5}$  Program.

- ▶ Collocated monitoring
- ▶ Filter duplicates

### Collocated Monitoring - -

In order to evaluate total measurement precision, collocated monitoring will be implemented. Collocated monitoring will be implemented either at a PE site or at the Regional office at a

frequency of 1 every month.

**Evaluation of Collocated Data-** Collocated measurement pairs are selected for use in the precision calculations only when both measurements are above  $6 \mu\text{g}/\text{m}^3$ .

The following algorithms will be used to evaluate collocated data. These algorithms are included in *40 CFR Part 58 Appendix A*. The equation numbers in 40 CFR will also be utilized in this QAPP.

**Percent Difference for a Single Check ( $d_i$ ).** The percentage difference,  $d_i$ , for each check is calculated by using Equation 19, where  $X_i$  represents the concentration produced from the primary sampler and  $Y_i$  represents the concentration reported for the duplicate sampler.

$$d_i = \frac{Y_i - X_i}{(Y_i + X_i)/2} \times 100 \quad \text{Equation 19}$$

**Coefficient of Variation (CV) for a Single Check ( $CV_i$ ).** The coefficient of variation,  $CV_i$ , for each check is calculated by dividing the absolute value of the percentage difference,  $d_i$ , by the square root of two as shown in Equation 20.

$$CV_i = \frac{|d_i|}{\sqrt{2}} \quad \text{Equation 20}$$

**Precision of a Single Sampler - Quarterly Basis ( $CV_{j,q}$ ).** For particulate sampler  $j$ , the individual coefficients of variation ( $CV_{j,q}$ ) during the quarter are pooled using Equation 21, where  $n_{j,q}$  is the number of pairs of measurements from collocated samplers during the quarter.

$$CV_{j,q} = \sqrt{\frac{\sum_{i=1}^{n_j} CV_i^2}{n_{j,q}}} \quad \text{Equation 21}$$

**The 90 percent confidence limits for the single sampler's CV** are calculated using Equations 22 and 23, where  $\chi^2_{0.05,df}$  and  $\chi^2_{0.95,df}$  are the 0.05 and 0.95 quantiles of the chi-square ( $\chi^2$ ) distribution with  $n_{j,q}$  degrees of freedom.

$$\text{Lower Confidence Limit} = CV_{j,q} \sqrt{\frac{n_{j,q}}{\chi_{0.95, n_{j,q}}^2}} \quad \text{Equation 22}$$

$$\text{Upper Confidence Limit} = CV_{j,q} \sqrt{\frac{n_{j,q}}{\chi_{0.05, n_{j,q}}^2}} \quad \text{Equation 23}$$

**Precision of a Single Sampler - Annual Basis.** For particulate sampler  $j$ , the individual coefficients of variation,  $CV_i$ , produced during the calendar year are pooled using Equation 21, where  $n_j$  is the number of checks made during the calendar year. The 90 percent confidence limits for the single sampler's CV are calculated using Equations 22 and 23, where  $\chi_{0.05,df}^2$  and  $\chi_{0.95,df}^2$  are the 0.05 and 0.95 quantiles of the chi-square ( $\chi^2$ ) distribution with  $n_j$  degrees of freedom.

**Corrective Action: Single Monitor -** Single collocated pairs with values >10% will be flagged FCS and reweighed. If the value remains between 10-20% the field technician will be alerted to the problem. If the CV is greater than 20% CV for both the initial and reweigh, all the primary sampler data will be flagged FCS from the last precision check and corrective action will be initiated. Paired CVs and percent differences will be control charted to determine trends (section 14.2). The laboratory technician will alert the WAM of the problem. The problem and solution will be reported and appropriately filed under response and corrective action reports (PROG/082 OVER/658, see Section 9).

### **Duplicate Laboratory Measurements --**

During laboratory preweighing and post weighing sessions, the first routine sample filter will be weighed a second time at the end of the weighing session (see PEPL-8.01). Equations 1 and 2 will be generated for this information. The difference in the weights of the filter must be  $\leq 15\mu\text{g}$ . Failure may be due to transcription errors, microbalance malfunction, or that the routine samples have not reached equilibrium. Other QC checks (balance standards and lab blanks) will eliminate microbalance malfunction. If the duplicate does not meet the criteria, the second and third routine sample will be selected and reweighed as a second and third duplicate check. 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.

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#### 14.1.4 Accuracy or Bias Checks

Accuracy is defined as the degree of agreement between an observed value and an accepted reference value and includes a combination of random error (precision) and systematic error (bias). Three accuracy checks are implemented in the PM<sub>2.5</sub> program:

- ▶ Collocated monitors
- ▶ Flow rate audits
- ▶ Balance checks

##### Collocated Monitors --

Although the collocated monitors are primarily used for evaluating and controlling precision, they can be used to determine accuracy or bias. By using equation 19 to determine percent difference, one can track trends or bias between the two instruments without knowing which instrument is producing the “true” value.

**Corrective Action** - The percent difference of the paired values will be control charted to determine trends. If it appears that there is a statistically significant bias (> 10% at the 90% confidence level) between the pairs, corrective action will be initiated. The process will include eliminating uncertainties that may be occurring at filter handling, transport and laboratory stages, in order to determine that the bias is truly at the instrument. Corrective actions at the instrument will include multi-point temperature, pressure, and flow rate checks as well as complete maintenance activities. Additional corrective action could include a request for vendor servicing.

##### Flow Rate --

The PEP will implement a flow rate verification with each setup. Details of the implementation aspects of the audit are included in Field SOP PEPF-6.04. The verification is implemented by measuring the analyzer's normal operating flow rate using a certified flow rate transfer standard. The audit (actual) flow rate and the corresponding flow rate indicated or assumed by the sampler are reported. The procedures used to calculate measurement uncertainty are described below.

**Accuracy of a Single Sampler - Single Check (Quarterly) Basis ( $d_i$ ).** The percentage difference ( $d_i$ ) for a single flow rate audit  $i$  is calculated using Equation 13, where  $X_i$  represents the audit standard flow rate (known) and  $Y_i$  represents the indicated flow rate.

$$d_i = \frac{Y_i - X_i}{X_i} \times 100 \quad \text{Equation 13}$$

**Bias of a Single Sampler - Annual Basis ( $D_j$ ).** For an individual particulate sampler  $j$ , the average ( $D_j$ ) of the individual percentage differences ( $d_i$ ) during the calendar year is calculated using Equation 14, where  $n_j$  is the number of individual percentage differences produced for sampler  $j$  during the calendar year.

$$D_j = \frac{1}{n_j} \times \sum_{i=1}^{n_j} d_i \quad \text{Equation 14}$$

**Corrective Action** - The single sampler accuracy requirement is  $\pm 4\%$  . If the verification violates the acceptance criteria, the sampling instrument will be checked for internal and external leaks, ensure that temperature and pressure are within acceptable ranges, and the audit run a second time. If the audit is still unacceptable, a multi-point calibration followed by a one-point verification is required. The back-up portable monitor will be used, assuming it meets the acceptance criteria while the affected instrument is being evaluated/repaired.

#### **Balance Checks -**

Balance checks are frequent checks of the balance working standards (100 and 200 mg standards) against the balance to ensure that the balance is within acceptance criteria throughout the pre- and post-sampling weighing sessions. The PEP will use ASTM class 1 weights for its primary and secondary (working) standards. Both working standards will be measured at the beginning, and end of a batch of filters ( a batch is  $\sim 15$  routine filters). Balance check samples will be controlled charted (see Table 14-4).

**Balance Check Evaluation-** 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 Equation 3, where  $X$  represents the certified mass weight and  $Y$  represents the reported weight .

$$d_y = Y - X \quad \text{Equation 3}$$

**Corrective Action** - The difference among the reported weight and the certified weight must be  $\leq 3\mu\text{g}$ . Since this is the first check before any pre-or post-sampling weighings, if the acceptance criteria is not met, corrective action will be initiated. Corrective action may be as simple as allowing the balance to perform internal calibrations or to sufficiently warm-up, which may require checking the balance weights a number of times. If the acceptance criteria is still not met, the laboratory technician will be required to verify the working standards to 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 trouble shooting techniques fail, the Sartorius® service technician (see Section 15) will be called to perform corrective action.

If the balance check fails acceptance criteria during a run, the QC check samples will be reweighed. If the balance check continues to fail, trouble shooting, as discussed above, will be initiated. The samples values of the sample batch will be recorded and flagged FIS, but will be remain with the unweighed samples 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

In order to ensure that the PEP includes all types of QC samples within a weighing session, the PEP will use the concept of sample batches. A batch of samples will consist of the samples indicated in Table 14-3 which is the PEP pre- and postsampling filter weighing data entry form

### Sample Distribution --

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

## 14.3 Control Charts

Control charts will be used extensively in the PEP. They provide a graphical means of determining whether various phases of the measurement process are in statistical control. The PEP will utilize property charts which graph single measurements of a standard or a mean of several measurements. Table 14-4 indicates which QC samples will be control charted. The control charts will be utilized as an “early warning system” to evaluate trends in precision and bias. They will be discussed in the *QA Annual QA Report* (Section 21). They will be appropriately filed (SAMP/223) and archived.

**Table 14-4 Control Charts**

QC Check	Plotting technique
Flow rate calibration verification check	single values plotted
Lab/Field Blanks	difference of from pre-weighed value
Flow rate audit	single values plotted
Balance check	mean value of each batch
Collocated monitoring pairs	Percent difference each pair charted by site coefficient of variation each pair coefficient of variation of all sites per quarter.
Duplicate filter weighings	Percent difference each pair by batch

**Table 14-3 PEP Pre- and Postsampling Filter Weighing Data Entry Form**

<b>PEP Filter Weighing Data Entry Form</b>						
Batch Type: <u>PRE</u> <u>POST</u> Batch No. _____						
Date _____ Analyst Initials _____						
Mean Temp for Past 24 hours: _____SD:_____						
Mean RH for 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						

## References

1. Taylor, J.K. 1987 Quality Assurance of Chemical Measurements. Lewis Publishers, Chelsea, Michigan. 328pp.
2. U.S. EPA (1997b) Revised Requirements for Designation of Reference and Equivalent Methods for PM<sub>2.5</sub> and Ambient Air Quality Surveillance for Particulate Matter-Final Rule. 40 CFR Parts 53 and 58. *Federal Register*, **62**(138):38763-38854. July 18,1997.

## **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 AIRP/486. See Element 9 for document and record details.

### **15.1 Testing**

All PM<sub>2.5</sub> samplers used in the PEP will be designated federal reference methods (FRM) that have been certified as such by EPA. Therefore, they 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<sup>1</sup>. Prior to field implementation, the field scientists within each region will assemble and run all the samplers at the regional site (full collocation). The field scientists will perform external and internal leak checks and temperature, time, pressure and flow rate multi-point verification checks. If any of these checks are out of specification (see Table 14-1), the field scientist or WAM will contact the vendor for initial corrective action. If the sampling instrument meets the acceptance criteria, it will be assumed to be operating properly. These tests will be properly documented and filed (AIRP/486).

### **15.2 Inspection**

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

#### **15.2.1 Inspection in Weigh Room Laboratory**

There are several items that need routine inspection in the weigh room laboratory. Table 15-1 details the items to inspect and 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
Weigh room Temperature	Daily	20 - 23° C	1.) Check HVAC System 2.) Call service provider that holds maintenance agreement	1.) Document in weigh room log book 2.) Notify Lab WAMr
Weigh Room Humidity	Daily	30 - 40° RH	1.) Check HVAC System 2.) Call service provider that holds maintenance agreement	1.) Document in weigh room log book 2.) Notify Lab WAM
Dust in Weigh Room	Monthly	Use glove and visually inspect	Clean Weigh Room	Document in Weigh Room Log Book

### 15.2.2 Inspection of Field Items

There are several items to inspect in the field before and after a PM<sub>2.5</sub> sample has been taken. Table 15-2 details the inspections performed in the field before and after samples are taken.

**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 log book
WINS Impactor well	Every site visit	“Cone” shape of particulate on Impactor well	Replace Impactor well (including new Impactor oil)	Document in log book
Rain collector	Every site visit	>1/3 full	Empty	Document in log book
O-rings	Every site visit	Any damage	Replace	Document in logbook
Filter Cassettes	After each sample run	Visible particulate	Check downtube and WINS Impactor	Document in log book
Cassette Seals	Each sample	Clean and smooth	Clean with a clean dry cloth, or replace as needed	Document when replaced
In-line filter	Every 6 months	Loaded particulate	Replace	Document in log book
Battery	Every 6 months	Decrease in voltage	Replace	Document in 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 weigh room items or field items.

### 15.3.1 Weigh Room Maintenance Items

The successful execution of a preventive maintenance program for the weigh room laboratory will go a long way towards the success of the PEP. Weigh room laboratory preventive maintenance is handled through the use of service agreements. The two EPA Regional laboratories have both entered into maintenance agreements with the vendors who developed their heating, ventilation, and air conditioning system (HVAC). Preventive maintenance for the micro-balance is performed by the Sartorius<sup>®</sup> service technician. Preventive maintenance for the micro-balance is scheduled to occur at initial set-up and every 6-months thereafter. In the event that there is a problem with the micro-balance that cannot be resolved within the laboratory, the Sartorius<sup>®</sup> service technician can be paged. Each laboratory also has a spare micro-balance in case of failure of the balance in use.

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

The following table details the weigh room maintenance items, how frequently they will be replaced, and who will be responsible for performing the maintenance.

**Table 15-3 Preventive Maintenance in Weigh Room Laboratories**

Item	Responsibility	Service Agreement # (if appropriate)	Frequency
General lab maintenance Cleaning Table cleaning Overall lab Cassette ethanol wiping/washing Adhesive-coated floor mats  HEPA filter change Polonium strip change Polonium strip cleaning	LA LA LA LA  LA LA LA		Every day Once a month After each use Weekly or when soiled to a point of non-performance Once a month Every 6 months Monthly or as shown by blank data
Microbalance Cleaning Service cleaning/calibration Calibration verification	LA Service provider LA		6 months Twice a year Every sample weighing

Temperature/humidity readers Calibration Verification	LA		Once every 3 months
Computer Back-up	LA		Weekly
Computer Virus Check	LA		Weekly
Computer system preventive maintenance (clean out old files, compress harddrive, inspect)	PC support personnel		Yearly

### 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<sub>2.5</sub> samplers and their frequency. Field SOP PEPF-5.02 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	<ol style="list-style-type: none"> <li>1. Inspect and empty water collector bottle.</li> <li>2. Clean or change-out Impactor well.</li> <li>3. Inspect O-rings of Impactor assembly.</li> </ol>
Every 10 sampling events or as needed.	<ol style="list-style-type: none"> <li>1. Clean sampler inlet surfaces.</li> <li>2. Clean Impactor housing and Impactor jet surfaces. Examine O-rings.</li> <li>3. Clean interior of sampler case.</li> <li>4. Check condition of sample transport containers.</li> <li>5. Clean Impactor downtube.</li> <li>6. Inspect and service cooling air intake filter and fans.</li> </ol>
Quarterly (every 3 months)	<ol style="list-style-type: none"> <li>1. Inspect O-rings of inlet. Apply light coat of vacuum grease if required.</li> <li>2. Clean sampler downtube.</li> <li>3. Inspect and service O-ring and water seal gasket where downtube enters sampler case.</li> <li>4. Inspect and service O-rings of Impactor assembly.</li> <li>5. Inspect and service vacuum tubing, tube fittings, and other connections to pump and electrical components.</li> </ol>

### References

The following documents were utilized in the development of this section:

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

## 16.0 Instrument Calibration and Frequency

This element of the QAPP concerns the calibration procedures that will be used for instruments involved in the environmental measurements. Table 16-1 indicates the instruments requiring verification and calibration, the frequencies, the acceptance criteria and the SOPs describing the procedures. All calibration activities are described in detail in the field and laboratory SOPs identified in Table 16-1.

Calibrations that involve instrument adjustments should only be accomplished when it is obvious that calibration is required. Therefore, the PEP uses a three phased approach to calibration which involves:

- ▶ one-point verification - ensuring that calibration is within acceptance limits by performing frequent one-point verifications that does not include instrument adjustments.
- ▶ multi-point verification - Similar to one-point verifications, these occur at established frequencies as well as when there is a failure of a one-point verification. This multi-point verification does not include instrument adjustment.
- ▶ multi-point calibration- occurs when there is a failure of a multi-point verification. Instrument adjustment occurs at this point and are followed by a one-point verification.

**Table 16-1 Instrument Calibrations**

Type	Frequency	Acceptance Criteria	SOP
<i>Lab Calibration/Verification</i> Mass Standards verification Micro-balance calibration Temperature Relative Humidity	3 months 1/year 3 months 3months	$\pm 2$ ug manufacturers specs $\pm 2^{\circ}\text{C}$ of standard $\pm 2\%$ of standard	PEPL-7.01 PEPL-12.01 PEPL-7.03 PEPL-7.03
<i>Field Calibration/Verification</i> Flow Rate (FR) Calibration FR multi-point verification One point FR verification Temperature Calibration Temp Multi-point Verification One- point temp Verification Pressure Verification/Calibration One point Pressure verification Clock/timer Verification	If multi-point failure 1/yr every sampling event If multi-point failure 1/yr every sampling event 1/yr every sampling event 1/yr every sampling event 1/yr	$\pm 2\%$ of transfer standard $\pm 2\%$ of transfer standard $\pm 4\%$ of transfer standard $\pm 2\%$ of standard $\pm 2^{\circ}\text{C}$ of standard $\pm 4^{\circ}\text{C}$ of standard $\pm 10$ mm Hg $\pm 10$ mm Hg 1 min/mo	PEPF-7.03 PEPF-7.03 PEPF-6.04 PEPF-7.02 PEPF-7.02 PEPF-6.03 PEPF-7.01 PEPF-6.02 PEPF-6.02
<i>Standards Recertifications</i> Flow Rate Transfer Std. Field Thermometer Field Barometer Working Mass Stds. Primary Mass Stds.	1/yr 1/yr 1/yr 3 mo. 1/yr	$\pm 2\%$ of NIST-traceable Std. $\pm 0.1^{\circ}\text{C}$ resolution $\pm 0.5^{\circ}\text{C}$ accuracy $\pm 1$ mm Hg resolution $\pm 5$ mm Hg accuracy 0.025 mg 0.025 mg	PEPF-10.01 " " " " PEPL7.01 NA

## **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<sup>®</sup> MC-5 microbalance. As indicated in Section 13, the balance is calibrated (and mass standard check weights recertified) once a year under a service agreement. 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 WAM, which after review, is appropriately filed (see Section 9).

#### **16.1.1.2 Laboratory Temperature and Relative Humidity Recorders**

The laboratory reference, instant model Fisherbrand<sup>™</sup> Certified Traceable Digital Hygrometer/Thermometer (DH/T), is placed inside the conditioning environment, which is allowed to vary, during a 24 hour period, up to a  $\pm 2$  °C control limit within an allowed 20 to 23°C operating range and up to  $\pm 5\%$  RH control limit within an allowed 30 to 40% RH operating range. The responses of the reference instrument's combination probe are then compared with the responses of the conditioning environment control system's recording thermometer and recording hygrometer. 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 deviations are converted to the appropriate T or RH units and compared to the control limits and must be within them.

### **16.1.2 Field Equipment - The PM<sub>2.5</sub> Portable Sampler**

Upon receipt of a new portable sampler, multi-point verifications/calibrations will be performed as indicated in Table 16-1. The following calibrations are performed in the field:

- ▶ verification/calibration of sampler's temperature probes and against the working temperature pressure standard
- ▶ verification/calibration of the sampler barometric pressure against the working pressure standard
- ▶ verification/calibration of volumetric flow rate meter in FRM samplers against the working standard
- ▶ verification of the sampler's internal clock against a timepiece.

#### 16.1.2.1 Temperature Probes

The portable sampler has an ambient and internal temperature probe. The field scientists will perform one-point field verifications of both sensors every sampling event using a digital NIST-traceable temperature probe. A multi-point temperature verification/calibration will take place yearly, or after a one-point verification failure.

#### 16.1.2.2 Barometric Pressure

A NIST-Traceable digital handheld pressure device (DPI 705) will be used in the field for one-point verifications of the portable sampler's pressure sensor during each sampling event. A NIST-traceable digital manometer will be used in the field office as a primary standard to perform multi-point pressure verification/calibrations once a year or after a one-point verification failure.

#### 16.1.2.3 Time Sensor

Time will be checked using the atomic clock which can be found on the Internet (<http://www.checkthenet.com/atomic.htm>) or through a phone number. Times can be checked each day prior to heading to the field.

#### 16.1.2.4 Flow Rate

Prior to every sampling event, after leak checks, temperature and pressure verifications are performed a one-point flow rate verification will be performed using a NIST-traceable orifice device (Chinook<sup>®</sup> FTS). A NIST-traceable primary standard (Anderson<sup>®</sup>) of a dry gas meter type will be used in the field office as a primary standard to perform multi-point pressure verification/calibrations once a year or after a one-point verification failure.

### **16.2 Calibration Method That Will Be Used for Each Instrument**

The Calibration methods are described in detail in each field and Lab SOPs as indicated in Table 16-1

### **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<sub>2.5</sub> data required in 40 CFR parts 50, Appendix L, and part 58. Table 16-1 presents the acceptance requirements of each of the standards used in the program; Table 16-2 presents the accuracy and resolution of each standard. All 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<sub>2.5</sub> Calibration**

Parameter	Stand. -S App-A	Description		Mfr. Name	Model #
Mass Primary Working Std.	S S	Class 1 weights Class 1 weights	Weight tolerance 0.010 mg 0.010 mg	Daigger Daigger	AX7097R AX7097R
Temperature Primary-Field Working-Field	A A	Digital Thermometer Digital Thermometer	Accuracy $\pm 0.2^{\circ}\text{C}$ Res. 0.1 $^{\circ}\text{C}$ Same as above	VWR VWR	61220-601 61220-601
Pressure -Field Primary Working	A A	digital manometer/calibrator digital pressure indicator	Accuracy $\pm 0.1\%$ Res. 0.01 psig Accuracy $\pm 0.1\%$ Res. 0.01 psig	Cole-Parmer Druck	E-86860-10 DPI705
Flow Rate -Field Primary Working	A A	Gas Meter Orifice	Accuracy $\pm 2\%$ Res 20 ml/min Accuracy $\pm 2\%$ Res 20 ml/min	Anderson Chinook	Streamline FTS Dwyer Mark III
Lab Temperature/ Relative Humidity	A	Hygrometer/Thermometer	Temp Accuracy $\pm 0.2^{\circ}\text{C}$ Res. 0.01 $^{\circ}\text{C}$ RH Accuracy $\pm 1.5\%$ Res. 0.01%	Fisher	11-661-7B

## 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 required in Appendix L of 40 CFR Part 50, the manufacturer's operating instruction manual and any others indicated in the field and laboratory SOPs. The records will normally be controlled by the ESAT field scientists or laboratory analysts and located in the labs or field offices when in use. Eventually all calibration records will be appropriately filed (see Section 9)

## 16.5 Standards Recertifications

All primary and transfer 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 in order 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 PM<sub>2.5</sub> monitoring network 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 section details the supplies/consumables, their acceptance criteria, and the required documentation for tracking this process.

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

- ▶ Field and laboratory inventory form (INV-01) Figure 17.1
- ▶ Field/laboratory procurement log (PRO-01) Figure 17.2
- ▶ Field/laboratory equipment/consumable receiving report (REC-01) Figure 17.3

### **17.2 Critical Supplies and Consumables**

This section attempts to describe the needed supplies for the PEP PM<sub>2.5</sub> monitoring network and includes items for the weigh room laboratory and the field. Generally, critical field and laboratory equipment has been selected by the PEP organizers based upon the required performance specifications of resolution, accuracy and ease of use.

#### **17.2 1 Laboratory Supplies**

During the development of the PEP, OAQPS, with the assistance of the Region 4 and 10 laboratory WAMs, developed a list of the critical laboratory equipment. These items are listed in Table 17-1. Equipment that was not deemed critical (affecting data quality) was left to the individual laboratory manager to select. In order to maintain consistency in the program, all consumables/equipment in Table 17-1 that have a model number will be purchased using the same model number when supplies run low. The laboratory analyst is required to keep and inventory of all equipment using Form INV-01, illustrated in Figure 17.1.

**Table 17-1 Weighing Laboratory Equipment.**

Quant.	units	Item	Vendor	Model Number
2	each	Microbalance	Sartorius	MC-5
2	set	ASTM Class 1 weight set	Rice Lake Weighing Systems	11909
2	each	Balance Table	Fisher Scientific	HM019945
1	each	Computer	Dell	
1	each	GLIMS Software		
1	each	Bar Code Reader		
1	each	Bar Code Printing Software	Cole-Parmer	E-21190-10
1	each	Humidity/Temp Monitor		
1	each	NIST Traceable Thermometer	Fisher-Scientific	15-041A
1	each	Tacky Mat plastic frame	Fisher-Scientific	06-528A
1	each	Uninterruptable Power Supply	Cole-Parmer	E-05158-60
1	each	Refrigerator		
1	each	Freezer		
1	each	Dish Washer		
2	each	Antifatigue Floor Mat,	Richmond	19-61-763
2	each	Acrylic Desiccator with sliding tray's	Cole-Parmer	E-08933-10
1	each	Laser Jet Printer		
1	each	De-humidifier		
1	each	Light Table		
1	each	Microsoft Access 97 Win 32		077-00370
		Sarto-Wedge@software for	Sartorius	YSW01
		Bar Code printing Software	Cole-Palmer	E-21190-10
		Software for temp and RH data logger	Power and Systems Innovations (Orlando, FL)	TrendReader® for Windows
24	each	HVAC Filters		
1	Case of 1000	Powder-Free Antistatic Gloves	Fisher-Scientific	11-393-85A
12	each	Polonium Strips	Sartorius	
7	Pack of 100	Petri-dishes	Gelman	7231
1	Case of 12 bottles	Staticide	Cole-Parmer	E-33672-00
1	case of 15 packs	Low-lint wipes	Kimwipes	34155
1	each	HVAC Service Contract	Local	
1	each	Microbalance Service Contract (2 scheduled visits per year)	Sartorius	
6	sets	Chart Paper & Pens		
1		Cleaning Supplies	Local	
2	each	Worklon Antistatic Lab Coats	Fisher-Scientific	01-352-69B
2	each	Forceps (SS w/plastic tips)	VWR	25672-100
1	case	Anti-Static Reclosable Bags 3"x5" (for cassettes)	Consolidated Plastics	90202KH
1	box	Bar-code stickers		

Quant.	units	Item	Vendor	Model Number
1	Case of 1000	Alcohol swipes	Fisher-Scientific	14-819-2
20	each	6-Pack Coolers		
4	Case of 24	Re-usable U-Tek Refrigerant Packs (-1C)	Fisher-Scientific	03-528B
1	case	Anti-Static Reclosable Bags 9X12" (for data sheet and second bagging of cassettes)	Consolidated Plastics	90210KH
4	each	Log Books		
20	each	min/max thermometers (various digital ones available)	VWR	
3	120 sheets	Hard surface Tacky Mat (moderate tack)	Fisher-Scientific	06-527-2

As consumables run low or 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 was initially procured unless the WAM suggests a different item due to improved quality, reduction in contamination, ease of use, or lower cost (without sacrificing quality). The following procedures will be required.

1. The LA will develop procurement requests as per EPA requirements.
2. Upon order, add items to the Laboratory Procurement Log PRO-01.
3. Once a month provide a copy of the PRO-01 to the WAM.
4. File PRO-01 in file AIRP/486.

### 17.2.2 Field Equipment and Supplies

In order to ensure consistency and meet the data quality objectives, OAQPS has purchased all equipment and consumables for the field activities. Table 17-2 lists this equipment. The field scientist is required to keep an inventory of all equipment which include the warranty period.

**Table 17-2 Field Equipment and Supplies**

Quant/ FTE	PEP Field Equipment and Supplies	Vendor/Catalog #	Make/Model #
	<b><u>Monitoring Equipment and Supplies</u></b>		
1	Transport cases for loose equipment/consumables	Forestry Suppliers/31113	Collapsible crate
1	Back pack frame for carrying samplers	Forestry Suppliers/35913	Camp Trails Freighter Frame
5	Portable FRM PM <sub>2.5</sub> sampler(s) with carrying case		
NA	Pre-weighed 46.2-mm diameter filters in the proper cassette.		
NA	Chain of Custody form for <u>each</u> filter		
1	Impactor oil and dropper		
NA	Impactor filters (37 mm diameter glass fiber)		

Quant/ FTE	PEP Field Equipment and Supplies	Vendor/Catalog #	Make/Model #
4	Sample shipping containers (coolers)		
5	min/max thermometer	Daigger / AX24081B	Sentry
1 box	cold packs (ice substitutes) 36/box		Utek- 1°C/ 429
1	Electric transport cooler with 12 volt to ac transformer	Globe Mart/ 5615-807	Coleman 16 qt
5	Filter Transport Coolers (6 quart)	Forestry Suppliers /31179	Rubbermaid 6 pack
5	Bubble Wrap		
1	FRM Operations manual		
2	Field notebook(s)		
1	Clipboard (8 x 14")	Forestry Suppliers /53283	Cruiser mate
1	Grip Binders	Office Depot/501-627	Presstex
3 box's	Data Diskettes		BASF 2HD
1	Silicone grease for O-rings (Vacuum Grease)	Daigger/ AX23061A	
1	PEP Field SOPs (this document)		
1 set	Documentation forms or data sheets, preprinted		
1	Laptop computer with PQ200A job control software)		
1/FS 1/Reg	Datatrans to download data	BGI /DC201	
1	Cables for connecting the data download device to the Portable FRM sampler		
1	Magnetic compass or other means of determining site orientation (optional)	Forestry Suppliers/ 37177	Suunto Partner II
1	Tape Measure (metric)	Forestry Suppliers/ 39651	Lufkin/ W 9210ME
1	Cellular phone		
1 box	Mechanical Pencils	Skilcraft	9mm
1 box	Markers (indelible)	Sharpees	Ultrafine
	<b><u>Mounting Equipment and Tools</u></b>		
140'	Rope for hoisting equipment		
1	Bubble level for checking the portable FRM sampler	Mayes (torpedo)	10198
NA	Wooden shims or other means for leveling the Portable FRM sampler		
1	Tool box with basic tools		
1	Flashlight with spare batteries		

Quant/ FTE	PEP Field Equipment and Supplies	Vendor/Catalog #	Make/Model #
1	Heavy-duty, grounded, weatherproof electrical extension cord with multiple outlets (25 ft. length)	Unicor	Style3 Class2 Series2
1	Heavy-duty, grounded, weatherproof electrical extension cord with multiple outlets (12 ft. length)	Unicor	Style3 Class2 Series2
NA	Tie-down cables, anchors, plywood sheet, bungee cords etc., to anchor and stabilize the portable FRM sampler and to dampen vibration. (optional)		
3 rolls 3 rolls 3 rolls	Masking tape Packaging tape Strapping tape	GSA-7510-00-283-0612 GSA-7510-00-079-7906 GSA-7510-00-159-4450	
<b><u>Calibration/Verification Standards and Related Equipment</u></b>			
1	Downtube flow rate adapter		
1 FTE 1Rg	Flow-check device (NIST-traceable)	Chinook Streamline FTS  Dwyer Series Mark III	  475-D
1	Flow multipoint verification/calibration device (NIST-traceable)	Andersonl	Dry gas meter
1	Portable barometric pressure verification device (NIST-traceable)	DPI Absolute	
1	Barometric pressure multipoint verification/calibration device (NIST-traceable)	Meri-cal	LP200
1FTE 1Rg.	Temperature verification/calibration standard (NIST-traceable) with probe	VWR	61220-601
1	Thermos container for temperature calibrations		
NA	Flow-check filter in transport cassette		
1	Impermeable "filter" disk for internal leak checks		
1	Accurately set timepiece		
1	Hand calculator (scientific)	Office Depot/397-554	Casio
<b><u>Spare Parts and Optional Equipment</u></b>			
NA	Spare O-rings for the portable FRM sampler		
NA	Spare Batteries (for all battery-powered equipment)		
NA	Fuses, as required by all equipment used		
NA	Spare in-line filters (if required by the portable FRM sampler)		
1	Voltmeter/ammeter for troubleshooting		
NA	Spare impactor(s)		
<b><u>Cleaning Supplies and Equipment</u></b>			

Quant/ FTE	PEP Field Equipment and Supplies	Vendor/Catalog #	Make/Model #
1 box	Low-lint laboratory wipes for cleaning WINS and other sampling equipment	Daigger/AX5661	Kay-Pees Disposable paper towels
1 box	Large locking plastic bag for cleanup of debris, wipes, etc		
1	Soft brush,		
NA	Supply of deionized water for cleaning and rinsing equipment		
NA	Isopropyl alcohol to aid in removal of grease and dirt		
1 box	Alcohol wipes (hand cleaning)		
NA	Lint-free pipe cleaners		
1	Safety pin/dental pick		
1 box	Lint-free cotton-tipped swabs		
1	wooden dowel, and cloth wads to clean downtube		

As consumables run low or 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 was initially procured unless the WAM suggests a different item due improved quality, reduction in contamination, ease of use, or lower cost (without sacrificing quality). The following procedures will be required.

1. The FS will develop procurement requests as per EPA requirements.
2. Upon order, add items to the Field Procurement Log PRO-01.
3. Once a month provide a copy of the PRO-01 to the WAM.
4. File PRO-01 in file AIRP/486.

### 17.3 Acceptance Criteria

For the major pieces of capital equipment, namely:

**Laboratory**

micro balance  
 mass weights  
 temperature recorder  
 humidity recorder  
 calibration equipment (see Element 16)

**Field**

portable sampler  
 calibration equipment (see Element 16)

the equipment and consumables have been selected based upon their advertized specifications on

accuracy and resolution and the portable sampler has been built to federal reference method performance specifications and has been accepted as such. Upon receipt of equipment, they will be inspected and tested using calibration standards (see element 16) to ensure they operate within the performance parameters. All equipment is warranted and the equipment listed above will undergo yearly calibration and certification as discussed in Element 16.

Both field and laboratory personnel will utilize procurement logs (Fig 17.2) for purchases of new equipment and consumables. These logs also indicate whether the items are accepted or rejected. In addition, the laboratory and field personnel are required to keep an equipment inventory form (Fig. 17.1) which lists each equipment item and their warranty dates.

#### **17.4 Tracking and Quality Verification of Supplies and Consumables**

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

1. Receiving personnel will perform a rudimentary inspection of the packages as they are received from the courier or shipping company. 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 receiving report 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 in AIRP/486.
5. If the quantity, items, or condition are not acceptable, complete REC-01 with remarks and send a copy of the form to the WAM.
6. Call the vendor to report the problem with the package/contents
7. Add receipt information to the Procurement Log PRO-01 and to the Inventory Form INV-01.

In addition, any conversations field or lab 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 #	Quantity	Purchase Date	Warranty

Figure 17.1. Field/laboratory inventory form

Procurement Log									
Item	Model #	Qty	PO#	Vendor	Date		Cost	Initials	Accept /Reject
					Ordered	Received			

Figure 17.2 Field/laboratory procurement log



## **18.0 Data Acquisition Requirements**

This section addresses data not obtained by direct measurement from the PEP. The majority of data used in the PEP will be direct measurements acquired by the field scientists and laboratory analysts 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 section lists this data and addresses quality issues related to the PM<sub>25</sub> Ambient Air Quality Monitoring Program.

#### **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 that 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 of the Region's Air Division QA Officer. The following sources may be used in the PEP without prior approval:

- National Institute of Standards and Technology (NIST)
- ISO, IUPAC, ANSI, and other widely-recognized national and international standards organizations
- U.S. EPA
- The current edition of certain standard handbooks may be used without prior approval of the PEP Air Division QA Officer. Two that are relevant to the fine particulate monitoring program are CRC Press' *Handbook of Chemistry and Physics*, and *Lange's Handbook*.

#### **Sampler Operation and Manufacturers' Literature**

Another important source of information needed for sampler operation is manufacturers' literature. Operations manuals and users' manuals frequently provide numerical information and equations pertaining to specific equipment. PEP personnel are cautioned that such information are sometimes in error, and appropriate cross-checks will be made to verify the reasonableness of information contained in manuals. Whenever possible, the field scientists will compare physical and chemical constants in the operator's manuals to those given in the sources listed above. If discrepancies are found, the WAM should be contacted who will bring these issues up on PEP conference calls. 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

### **Site Information**

In order to determine the site and the monitor that the PE will be compared against, the field scientist must rely on the site information provided to him/her by the State or local monitoring agency that will be included in the site file and on each field data sheet. This will include the following parameters:

- ▶ AIRS Site ID
- ▶ Monitor Type
- ▶ Method designation (routine instrument)
- ▶ Reporting Organization

These values should be available in the AIRS data base and can be double checked for their accuracy before proceeding to a site.

### **External Monitoring Data Bases**

It is the policy of the PEP that no data obtained from the Internet, computer bulletin boards, or data bases from outside organizations shall be used in creating reportable data or published reports without approval of the EPA Region's Air Division QA Officer. This policy is intended to ensure the use of high quality data in PEP publications.

Data from the EPA AIRS data base may be used in published reports with appropriate caution. Care must be taken in reviewing/using any data that contain flags or data qualifiers. If data are flagged, such data shall not be utilized unless it is clear that the data still meets critical QA/QC requirements. It is impossible to assure that a data base such as AIRS is completely free from errors including outliers and biases, so caution and skepticism is called for in comparing routine data from other reporting agencies as reported in AIRS. 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 section describes the data management operations pertaining to PM<sub>2.5</sub> measurements for the PEP. This includes an overview of the mathematical operations and analyses performed on raw (“as-collected”) PM<sub>2.5</sub> data. These operations include data recording, transformation, transmittal, reduction, validation, analysis, management, storage, and retrieval.

Data processing for PEP PM<sub>2.5</sub> data are summarized in Figure 19-1. At the writing of this QAPP, the data management system has been developed to collect the critical information that must be uploaded to AIRS and is required to calculate a PM<sub>2.5</sub> concentrations. As time allows, system features will be added to automate and electronically store other important information. The current system is set up so that as a default, all information can be manually recorded. The critical data values will be entered into the PC data management system and processed using a set of programs written in Microsoft® Access. The PEP PM<sub>2.5</sub> data base will reside on PC's running in the Region 4 and 10 laboratories. This machine ( or an individual laboratory) is shown in the upper left of Figure 19-1.

In essence, data for the PEP can be seen as accumulating at three stages:

1. **Pre-sampling filter weighing** - At this stage the filters are given a unique filter ID/cassette ID combination and are given a pre-sampling weight value.
2. **Field** - The filter is installed and the sampler is operated providing a number of values that are automatically downloaded from the sampler to a data logger, laptop, and diskette. In particular, the critical measurement value collected in the field is the air volume sampled during the filter exposure.
3. **Post-sampling filter weighing** - At this stage the exposed filter is sent back to the laboratory where the filter is equilibrated and weighed again. The difference between the initial pre-sampling weight and the post-sampling weight is the particulate load on the filter which is a critical value.

During these stages, additional data is collected that ensures the quality of the critical values. This includes chain of custody data, calibration data, and laboratory atmospheric data (temperature/relative humidity) that will be recorded in hardcopy and/or electronic form, and appropriately stored.

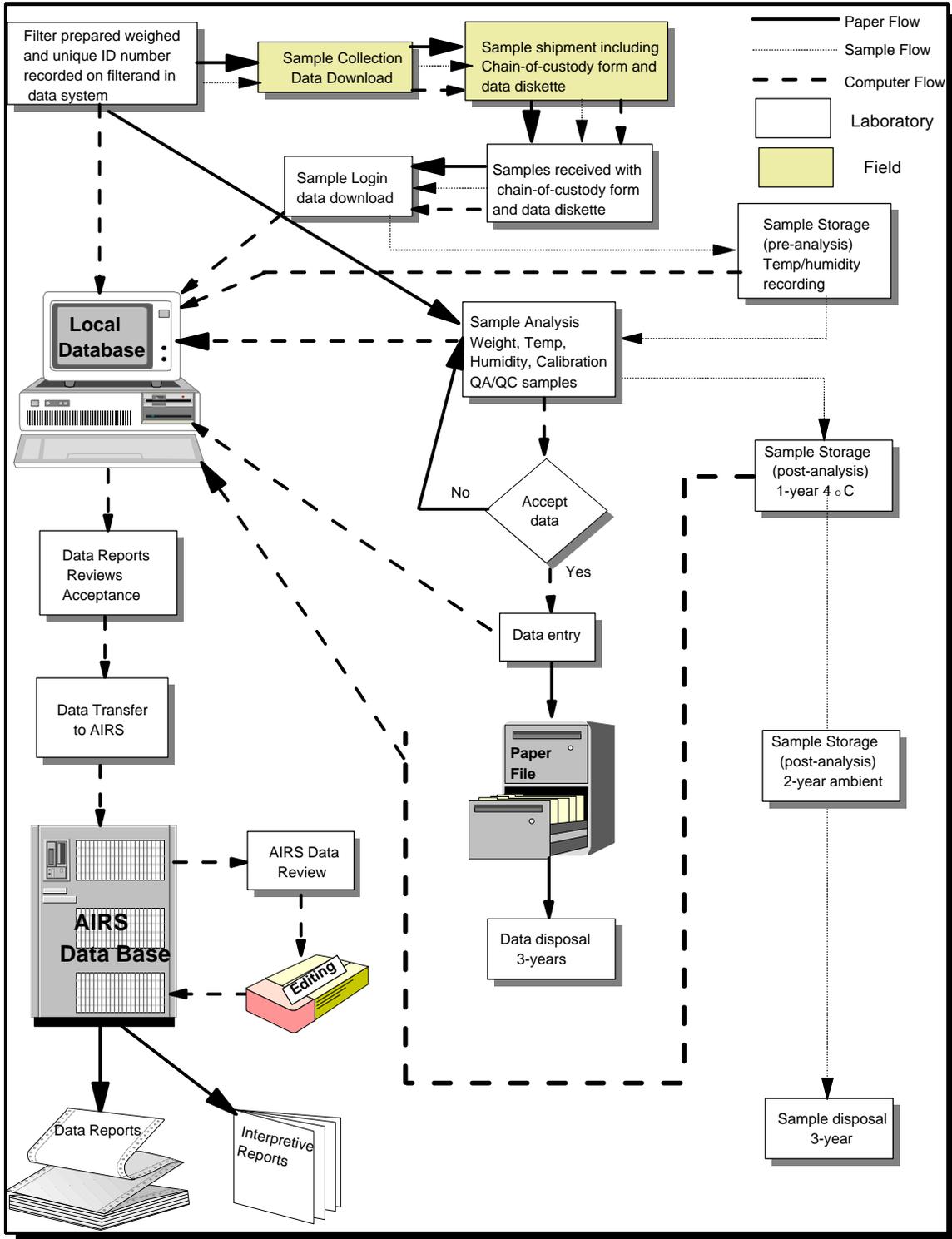


Figure 19.1 PEP Information management flow

## **Information Management Security**

All users must be authorized by the WAM and receive a password necessary to log on to the DAS. Different privileges are given each authorized user depending on that person's need. The following privilege levels are defined:

- ▶ Data Entry Privilege - The individual may see and modify only data within PEP DAS that he or she has personally entered. After a data set has been "committed" to the system by the data entry operator, all further changes will generate entries in the system audit trail. The laboratory analyst(s) and the WAM will have this privilege
- ▶ Reporting Privilege - This privilege permits generation of data summary reports available under the PEP DAS. No data changes are allowed without additional privileges. Since the reporting privilege will not effect the integrity of the data, the WAM can indicate who receives these privileges.
- ▶ Data Administration Privilege - Data Administrators for the PEP DAS are allowed to change data as a result of QA screening and related reasons. All operations resulting in changes to data values are logged to the audit trail. The Data Administrator is responsible for performing the following tasks on a regular basis
  - merging/correcting the duplicate data entry files
  - running verification and validation routines and correcting data as necessary
  - generating summary data reports for management
  - uploading verified/validated data to EPA AIRSThe laboratory analyst(s) and the WAM will have this privilege

## **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 field or lab SOP that the data collection is performed, as summarized in Table 19-1.

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

SOP Number	Title	Description (data related)
PEPL-8.01	<i>Filter Weighing</i>	Describes the procedure for pre-sample weighing and post-sample weighing of the filter and recording data
PEPL-10.01	<i>Filter Chain of Custody</i>	Describes the laboratory procedure for starting a chain of custody form as well as receiving the same form from the field.
PEPF-8.01	<i>Filter Exposure</i>	Describes how to program the sampler to start collection information.
PEPF-8.02	<i>Filter Sample Collection</i>	Describes the acquisition of data from the portable sampler.
PEPF-9.01	<i>Filter Chain of Custody</i>	Describes the field procedure for completing the field portions of the chain of custody form.
AIR-IS-FP2	<i>Data processing procedures for the PM<sub>2.5</sub> monitoring program</i>	Describes the procedures for data entry, processing, merging, validation, reporting, and reduction.
AIR-IS-FP3	<i>AIRS data transmittal procedures system for the PEP monitoring program</i>	Describes the procedures used to format and transmit PM <sub>2.5</sub> data to AIRS. (Will be used in conjunction with SOP AIR-IS-SLAMS7, which describes transmittal of other ambient monitoring data to AIRS.)

### 19.3 Data Validation

Data validation is a combination of checking that data processing operations have been carried out correctly and of monitoring the quality of the field and laboratory operations. Data validation can identify problems in either of these areas. Once problems are identified, the data can be corrected or invalidated, and corrective actions can be taken for field or laboratory operations. Numerical data stored in the PEP DAS are never internally overwritten by condition flags. Flags denoting error conditions or QA status are saved as separate fields in the data base, so that it is possible to recover the original data.

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

- ▶ **100 % data review** - the following data are subjected to 100% data review by the lab analyst and random reviews once a month: filter weight reports, field data sheets, chain of custody sheets.
- ▶ **Range Checks** - almost all monitored parameters have simple range checks programmed in. For example, valid times must be between 00:00 and 23:59, summer temperatures must be between 10 and 50 degrees Celsius, etc. The data entry operator is notified immediately when an entry is out of range. The operator has the option of correcting the entry or overriding the range limit. The specific values used for range checks may vary depending on

season and other factors. The currently used range values for data entry acceptance are provided in SOP AIR-IS-FP2. Since these range limits for data input are not regulatory requirements, the Air Division QA Officer 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 filter must have a start time, an end time, an average flow rate, dates weighed, and operator and technician names. At a minimum field data sheets, chain of custody forms and pre/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 PM<sub>2.5</sub> DAS. For example, the end time of a filter must be greater than the start time. Computed filter volume (integrated flow) must be approximately equal to the exposure time multiplied by the nominal flow. Additional consistency and other checks will be implemented as the result of problems encountered during data screening. See the most recent version of SOP AIR-IS-FP2 for the currently implemented consistency checks.
- ▶ **Data Retention** - Raw data sheets are retained on file in the laboratory files for a minimum of 3 years, and are readily available for audits and data verification activities. After 3 years, hardcopy records and computer backup media are cataloged and boxed for storage at the OAQPS. The laboratory analyst will request instructions from OAQPS on the disposition of archived sample filters.
- ▶ **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 run on a monthly schedule and prior to any data submission to AIRS. Data validation is the process by which raw data are screened and assessed before it can be included in the main data base (i.e., the PM<sub>2.5</sub> DAS).
- ▶ **Sample Batch Data Validation**- which is discussed in Section 23, associates flags, that are generated by QC values outside of acceptance criteria, with a sample batch. Batches containing too many flags would be rerun and or invalidated.

Table 19-2 summarizes the validation checks applicable to the PM<sub>2.5</sub> 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<sub>2.5</sub> sampling are bias and precision. As defined in 40CFR Part 58, Appendix A, these are based on differences between collocated sampler results and FRM performance evaluations. The WAMs will inspect the results of collocated sampling during each batch validation activity. This 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<sub>2.5</sub> monitoring equipment. Initially, the results of collocated operations will be control charted (see Section 14). From these charts, control limits will be established to flag potential problems. Multiple collocation results must be accumulated to assess data quality with confidence. However, even limited data can be used for system maintenance and corrective action.

## 19.4 Data Transformation

Calculations for transforming raw data from measured units to final concentrations are relatively straightforward, and many are carried out in the sampler data processing unit before being recorded. The following relations in Table 19-3 pertain to PM<sub>2.5</sub> monitoring:

**Table 19-3 Raw Data Calculations**

Parameter	Units	Type of Conversion	Equation
Filter Volume ( $V_a$ ) *	$m^3$	Calculated from average Flow Rate ( $Q_{ave}$ ) in L/min, and total elapsed time (t) in min. multiplied by the unit conversion ( $m^3/L$ )	$V_a = Q_{ave} \times t \times 10^{-3}$
Mass on Filter ( $M_{2.5}$ )	$\mu g$	Calculated from filter post-weight ( $M_f$ ) in mg and filter pre-weight ( $M_i$ ) in mg, multiplied by the unit conversion ( $\mu g/mg$ )	$M_{2.5} = (M_f - M_i) \times 10^3$
PM <sub>2.5</sub> Concentration ( $C_{PM2.5}$ )	$\mu g/m^3$	Calculated from laboratory data and sampler volume	$PM_{2.5} = \frac{M_{2.5}}{V_a}$

\* - 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 copying raw data from a notebook onto a data entry form for keying into a computer file and electronic transfer of data over a telephone or computer network. Table 19-4 summarizes data transfer operations.

**Table 19-4 Data Transfer Operations**

Description of Data Transfer	Originator	Recipient	QA Measures Applied
Keying weighing data into The PM <sub>2.5</sub> DAS	Laboratory Analyst (hand-written data form)	Laboratory Analyst	100% review, random checks by WAM
Electronic data transfer	(between computers or over network)	--	Parity Checking; transmission protocols
Filter Receiving and Chain-of-Custody	Field scientist	Laboratory Analyst	Filter numbers are verified automatically; reports indicate missing filters and/or incorrect data entries
Verification/Calibration and Audit Data	Auditor or field supervisor	Laboratory Analyst	Entries are checked by laboratory analyst and WAM
AIRS data summaries	Laboratory analyst	AIRS (U.S. EPA)	Entries are checked by Air Quality Supervisor and OAQPS QA Officer

The PEP will report all PM<sub>2.5</sub> ambient air quality data and information specified by the AIRS Users Guide (Volume II, Air Quality Data Coding, and Volume III, Air Quality Data Storage),

coded in the AIRS-AQS format. Such air quality data and information will be fully screened and validated and will be submitted directly to the AIRS-AQS via electronic transmission, in the format of the AIRS-AQS, and in accordance with the quarterly schedule. The specific quarterly reporting periods and due dates are shown in the Table 19-5. However, it is anticipated that the PEP data will be uploaded within one month from sample receipt at the laboratory.

**Table 19-5 Data Reporting Schedule**

<b>Reporting Period</b>	<b>Due Date</b>
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

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 U.S. EPA. Examples of data summaries include:

- ▶ average  $PM_{2.5}$  concentration
- ▶ accuracy, bias, and precision statistics based on accumulated FRM/FEM data
- ▶ data completeness reports based on numbers of valid samples collected during a specified period

The Audit Trail is another important concept associated with data transformations and reductions. An audit trail is a data structure that provides documentation for changes made to a data set during processing. Typical reasons for data changes that would be recorded include the following:

- ▶ corrections of data input due to human error
- ▶ application of revised calibration factors
- ▶ addition of new or supplementary data
- ▶ flagging of data as invalid or suspect
- ▶ logging of the date and times when automated data validation programs are run

The  $PM_{2.5}$  DAS audit trail is implemented as a separate table in the Microsoft Access<sup>®</sup> data base. Audit trail records will include the following fields:

- ▶ operator's identity (ID code)

- ▶ date and time of the change
- ▶ table and field names for the changed data item
- ▶ reason for the change
- ▶ full identifying information for the item changed (date, time, parameter, etc.)
- ▶ value of the item before and after the change

When routine data screening programs are run, the following additional data are recorded in the audit trail:

- ▶ version number of the screening program
- ▶ values of screening limits (e.g., upper and lower acceptance limits for each parameter)
- ▶ numerical value of each data item flagged and the flag applied

The audit trail is produced automatically and can only document changes; there is no "undo" capability for reversing changes after they have been made. Available reports based on the audit trail include:

- ▶ log of routine data validation, screening, and reporting program runs
- ▶ report of data changes by station for a specified time period
- ▶ report of data changes for a specified purpose
- ▶ report of data changes made by a specified person

Because of storage requirements, the System Administrator must periodically move old audit trail records to backup media. Audit trail information will not be moved to backup media until after the data are reported to AIRS. All backups will be retained so that any audit trail information can be retrieved for at least three years.

## 19.7 Data Analysis

The PEP is currently implementing the data summary and analysis requirements contained in 40CFR Part 58, Appendix A. It is anticipated that as the PM<sub>2.5</sub> Monitoring Program develops, additional data analysis procedures will be developed. The following specific summary statistics will be tracked and reported for the PM<sub>2.5</sub> network:

- Single sampler bias or accuracy (based on collocated FRM data, flow rate performance audits)
- Single sampler precision (based on collocated data)
- Network-wide bias and precision (based on collocated FRM data, flow rate performance audits)
- Data completeness

Equations used for these reports are given in the Table 19-6.

**Table 19-6 Report Equations**

Criterion	Equation	Reference
Accuracy of Single Sampler Flow - Single Check (d <sub>i</sub> ) X <sub>i</sub> is reference flow; Y <sub>i</sub> is measured flow	$d_i = \frac{Y_i - X_i}{X_i} \times 100$	40 CFR 58 Appendix A, Section 5.5.1.1
Bias of a Single Sampler - Annual Basis (D <sub>j</sub> )- average of individual percent differences between sampler and reference value; n <sub>j</sub> is the number of measurements over the period	$D_j = \frac{1}{n_j} \times \sum_{i=1}^{n_j} d_i$	5.5.1.2
Percent Difference for a Single Check (d <sub>i</sub> ) - X <sub>i</sub> and Y <sub>i</sub> are concentrations from the primary and duplicate samplers, respectively.	$d_i = \frac{Y_i - X_i}{(Y_i + X_i)/2} \times 100$	5.5.2.1
Coefficient of Variation (CV <sub>i</sub> ) for a single Check	$CV_i = \frac{ d_i }{\sqrt{2}}$	5.5.2.2
Pooled Coefficient of Variation, Quarterly Basis (CV <sub>j,q</sub> ). The CV <sub>i</sub> will only be used when the two measurements are both greater than 6 µg/m <sup>3</sup> .	$CV_{j,q} = \sqrt{\sum_{i=1}^{n_j} \frac{CV_i^2}{n_{j,q}}}$	5.5.2.3 (a)
Completeness	$\text{Completeness} = \frac{N_{\text{valid}}}{N_{\text{theoretical}}} * 100$	--

## 19.8 Data Flagging -Sample Qualifiers

A sample qualifier or a result qualifier consists of 3 alphanumeric characters which act as an indicator of the fact and the reason that the data value (a) did not produce a numeric result, (b) produced a numeric result but it is qualified in some respect relating to the type or validity of the result or © produced a numeric result but for administrative reasons is not to be reported outside the laboratory. Qualifiers will be used both in the field and in 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 for the field and laboratory activities. Qualifiers will be placed on field and bench sheets with additional explanations in free form notes areas. When sample batch information is entered into DAS and the validation process run (see Section 23) flags will be generated. During the sample validation process, the flags will be used to decide on validating or invalidating individual samples or batches of data. Section 23 discusses this process.

## 19.9 Data Tracking

The PM<sub>2.5</sub> DAS contains the necessary 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 locations are used to track filter location and status:

- ▶ Laboratory
  - Filter receipt (by lot)
  - Filter pre-sampling weighing (individual filter number first enters the system)
  - Filter packaged for the laboratory (filter numbers in each package are recorded)
- ▶ Shipping (package numbers are entered for both sending and receiving)
- ▶ Laboratory
  - Package receipt (package is opened and filter numbers are logged in)
  - Filter post-sampling weighing
  - Filter archival

In most cases, the tracking data base and the monitoring data base are updated simultaneously. For example, when the filter is pre-weighed, the weight is entered into the monitoring data base and the filter number and status are entered into the tracking data base.

Tracking reports may be generated by any personnel with report privileges on the DAS. The following tracking reports are available:

- ▶ Location of any filter (by filter number)
- ▶ 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 initial weighing date
- ▶ 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 can also be generated using Microsoft Access<sup>®</sup> queries

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

## 19.10 Data Storage and Retrieval

Data archival policies for the PM<sub>2.5</sub> data are shown in Table 19-7.

**Table 19-7 Data Archive Policies**

Data Type	Medium	Location	Retention Time	Final Disposition
Weighing records; chain of custody forms	Hardcopy	Laboratory	3 years	Discarded
Laboratory Notebooks	Hardcopy	Laboratory	3 years	N/A
Field Notebooks	Hardcopy	Air Quality Division	3 years	Discarded
PM <sub>2.5</sub> MP Data Base (excluding Audit Trail records)	Electronic (on-line)	Air Quality Division	indefinite (may be moved to backup media after 5 years)	Backup tapes retained indefinitely
PM <sub>2.5</sub> MP Audit Trail records	Electronic (backup tapes)	Air Quality Division	3 years	Discarded
Filters	Filters	Laboratory	1 year 4°C and 2 years ambient- 3 years total	Discarded

The PM<sub>2.5</sub> data reside on an IBM-PC compatible computer in the Region 4 and 10 laboratories. The security of data in the PM<sub>2.5</sub> data base is ensured by the following controls:

- ▶ Password protection on the data base that defines three levels of access to the data
- ▶ Regular password changes (quarterly for continuing personnel; passwords for personnel leaving the Air Division will be canceled immediately)
- ▶ 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 backup tapes in locked, restricted access areas

## **20.0 Assessments and Response Actions**

An assessment, for this QAPP, 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 quality control efforts are adequate or need to be improved. Documentation of all quality assurance and quality control 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 Section 21). 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 SLAMS data quality are required to be reported to EPA. On the other hand, the selection and extent of the QA and QC activities used by a monitoring agency depend on a number of local factors such as the field and laboratory conditions, the objectives for monitoring, the level of the data quality needed, the expertise of assigned personnel, the cost of control procedures, pollutant concentration levels, etc.

In order to ensure the adequate performance of the quality system, the PEP will perform the following assessments:

- ▶ Management Systems Reviews
- ▶ Technical Systems Audits
- ▶ Surveillance
- ▶ Audits of Data Quality
- ▶ Data Quality Assessments
- ▶ Peer Review

### **20.1 Assessment Activities and Project Planning**

#### **20.1.1 Management Systems Review**

A management systems review (MSR) is a qualitative assessment of a data collection operation or organization to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. This would allow OAQPS to assess consistency of operation among the Regions and improve the quality system. The MQAG QA Team proposes implementing ~3 management systems reviews each year of the EPA Regions on their implementation of the Ambient Air Monitoring Program and will include a review of PEP activities. There is a potential that OAQPS will team up with the EPA QA Division during their management systems reviews of the Regions. Implementation of MSRs are anticipated in FY99.

## 20.1.2 Technical Systems Audits

A technical systems audit (TSA) is an on-site review and inspection of a State or local agency's ambient air monitoring program to assess its compliance with established regulations governing the collection, analysis, validation, and reporting of ambient air quality data. Both OAQPS and the EPA Regions will perform technical systems audits of the field and laboratory activities. The frequency of the audits will be determined through the PM<sub>2.5</sub> QA Workgroup. Key personnel to be interviewed during the audit are those individuals with responsibilities for: planning, field

operations, laboratory operations, QA/QC, data management, and reporting.

TSA's of the PEP network will be accomplished by OAQPS once a year and by the Regional WAMS every six months. It is possible that OAQPS would team with the Region during the annual TSA. The TSA can be accomplished either by a team or by an individual auditor. The TSA will review basically three activities:

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

The audit activities are illustrated in Figure 20.1.

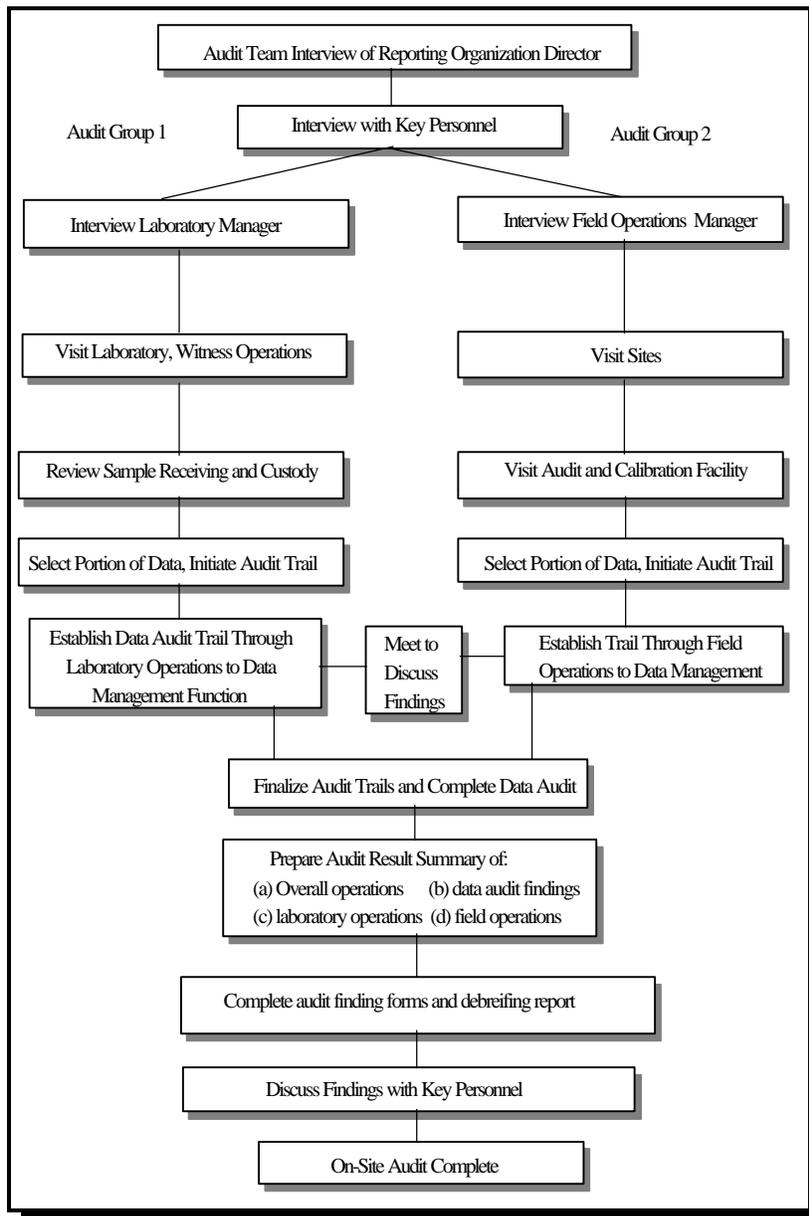


Figure 20.1 Audit Activities

To increase uniformity of the TSA, an audit checklist will be developed and used. As a start, OAQPS will utilize and modify the TSA form found in the *QA Handbook for Air Pollution Measurement Systems Volume II Part 1 Appendix 15*.

The audit team will prepare a brief written summary of findings organized into the following areas: planning, field operations, laboratory operations, quality assurance/quality control, data management, and reporting. Problems with specific areas will be discussed and an attempt made to rank them in order of their potential impact on data quality. For the more serious of these problems, audit findings will be drafted (Fig. 20.2).

<b>Audit Finding</b>	
<b>Audit Title:</b> _____	<b>Audit #:</b> _____ <b>Finding #:</b> _____
<b>Finding:</b>	
<b>Discussion:</b>	
<b>QA Lead Signature:</b>	<b>Date:</b>
<b>Audited Agencies Signature:</b>	<b>Date:</b>

Figure 20.2. Audit Finding Form

The audit finding form has been designed such that one is filled out for each major deficiency that requires formal corrective action. The finding should include items like: finding impact, estimated time period of deficiency, site(s) affected, and reason for action. The finding form will inform the laboratory or field office about serious problems that may compromise the quality of the data and therefore require specific corrective actions. They are initiated by the audit team, and discussed at the debriefing. During the debriefing, if the audited group is in agreement with the finding, the form is signed by the ESAT organization. If a disagreement occurs, the audit team will record the opinions of the group audited and set a time at some later date to address the finding at issue.

**Post-Audit Activities-** The major post-audit activity is the preparation of the systems audit report. The report will include:

- ▶ audit title and number and any other identifying information
- ▶ audit team leaders, audit team participants and audited 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 audit 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 thirty (30) calendar days of the completion of the audit, the audit report will be prepared and submitted. The systems audit report will be submitted to the appropriate ESAT personnel and appropriately filed (Element 9)

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

**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 (Fig 20.3) will be generated by the audited organization for each finding form submitted by the audit team. In addition, ESAT will include corrective action in either their weekly (laboratories) or monthly (field) progress reports. The audit finding response form is signed by the audited organization and sent to the ESAT WAM who reviews and accepts the corrective action. The audit response form will be completed by the audited organization within 30 days of acceptance of the audit report.

### **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 however it serves as a more frequent review of certain important phases of the measurement system (i.e., calibrations and run set-up) rather than a review of the entire implementation process. ESAT WAMs intend to utilize frequent surveillance in the early stages of the PEP to ensure SOPs are followed. WAMs will document surveillance on a surveillance report form (see Figure 20.4)

<b>Audit Finding Response Form</b>	
Audited Division:	_____
Audit Title: _____	Audit #: _____ Finding #: _____
Finding:	
Cause of the problem:	
Actions taken or planned for correction:	
Responsibilities and timetable for the above actions:	
Prepared by: _____	Date: _____
Signed by: _____	Date: _____
QA Division	
Reviewed by: _____	Date: _____
Remarks:	
Is this audit finding closed? _____ When? _____	
File with official audit records. Send copy to auditee	

Figure 20.3. Audit Response Form

### 20.1.4 Audit of Data Quality (ADQ)

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 every year by OAQPS as part of the TSA. Thus, sufficient time and effort will be devoted to this activity so that the auditor or team has a clear understanding and complete documentation of data flow. Pertinent ADQ questions will appear on the TSA check sheets to ensure that the data collected at each stage maintains its integrity. The ADQ will serve as an effective framework for organizing the extensive amount of information

gathered during the audit of laboratory, field monitoring, and support functions within the agency. The ADQ will have the same reporting/corrective action requirements as the TSA.

<b>Surveillance Report</b>		
Reviewer _____ Date of Review: _____		
Personnel Reviewed: _____		
Activity Monitored	Acceptable Performance	
	YES	NO
Notes		
Signature: _____ Date: _____		

**Figure 20.4 Surveillance Report Form**

### **.20.1.5 Data Quality Assessments**

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

1. *Review the data quality objectives (DQOs) and sampling design of the program:* review the DQOs. Define statistical hypothesis, tolerance limits, and/or confidence intervals
2. *Conduct preliminary data review.* Review precision & accuracy (P&A) and other

available QA reports, calculate summary statistics, plots and graphs. Look for patterns, relationships, or anomalies

3. *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
4. *Verify test assumptions:* decide whether the underlying assumptions made by the selected test hold true for the data and the consequences.
5. *Perform the statistical test:* perform test and document inferences. Evaluate the performance for future use

A data quality assessment will be included in the *QA Annual Report*. Details of these reports are discussed in Section 21.

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

**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. The 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, laboratories and aggregated to all monitors.

#### **20.1.6 Peer Review**

Peer review is a documented critical review of work products conducted by qualified individuals who are independent of those performing the work but are collectively equivalent in technical expertise. The OAQPS plans on using the peer review process to assess its products and guidance. Any guidance documents or reports developed during implementation of this program will be reviewed by the PM<sub>2.5</sub> QA Workgroup which will serve as peer review. In addition, guidance documents and published reports will be provided to OAQPS Air Quality Strategies and Standards Division, a separate division from the Monitoring and Quality Assurance Group, who are responsible for the development of the majority of the documents. OAQPS has developed a form for receiving comments that will be used to document the comments, their use, or reasons

for not using a comment.

## 20.2 Documentation of Assessments

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

**Table 20-1 Assessment Summary**

<b>Assessment Activity</b>	<b>Frequency</b>	<b>Personnel Responsible</b>	<b>Schedule</b>	<b>Report Completion</b>	<b>Reporting/Resolution</b>
Management Systems Reviews	1/3 years	OAQPS	1/1/99	30 days after activity	OAQPS to Regional Air Division
Technical Systems Audits	1/ year 1/ 6 months	OAQPS Regional Office	1/1/99 1/1/99	30 days after activity 30 days after activity	OAQPS to ESAT WAM & ESAT Regional EPA to ESAT
Audits of Data Quality	1/ year	OAQPS	1/1/99	30 days after activity	QA Division to Air Monitoring Division
Data Quality Assessment	1/year	OAQPS Monitoring Divisions	1/1/99	120 days after end of calendar year	EPA Regions, State and local organization office/ EPA Region

## 21.0 Reports to Management

This section 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

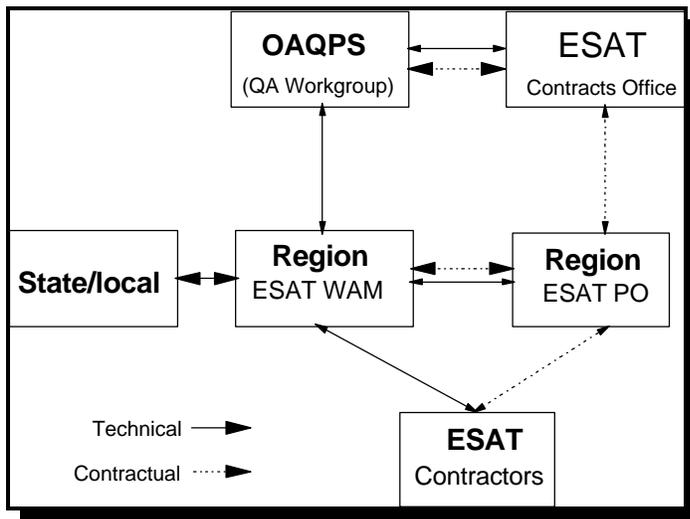


Figure 21.1 Line of communication

## 21.1 Communication

An organized communications framework facilitates the flow of information among the participating organizations as well as other users of the information produced by the PM<sub>2.5</sub> network. Figure 21.1 represents the principal communication pathways. In general, ESAT contractors will be responsible for informing Regional WAMs and Project Officers (POs) on technical progress, issues, and contractual obligations. On the technical side, EPA Regional WAMs will be responsible for communicating with

State and local agencies and informing OAQPS about issues that require technical attention. Contractual issues will be conveyed from the ESAT contractor through POs to the ESAT Contracts Office and, if necessary, to OAQPS. Table 21.1 lists important EPA ESAT contacts.

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

Communications among various participants in the PEP will be critical to the success of the program. The field and laboratory SOPs contain procedures (PEPF-2.02 and PEPL-4.01) for required communication and the documentation of this information.

**Table 21-1 Communications Summary**

Person	Communicates to	Communication Function
Lab WAM	OAQPS LA	Bulk filter shipments Additional resources needs Review of deliverables Review of data Corrective action Schedule changes
LA	WAM FS OAQPS	Lab progress Problems/issues/schedule changes Outgoing filter/equipment shipment Filter shipment receipt from field AIRS uploads
FS	LA	Filter shipment from field Electronic mailing of field data Filter/equipment requests
OAQPS	LA	Data transferred to AIRS

### 21.1.1 Field Communication

Field communications can take place either by phone or e-mail. Phone messages or conversations will be recorded in the field communications notebook to record the highlights of the conversation. All communications related to the PEP 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, these actions will be included in the monthly progress reports (see Section 5.2). 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 WAM may be required. Cellular phones have been provided to each FS for calls related to PEP activities. WAMS should also identify alternates to receive field communications when the WAM is not in the office.

#### 21.1.1.1 Filter Shipment Receipt

Every 2 weeks, filters will be shipped to the field offices by the LA. On the day of receipt, the FS will contact the LA and provide the following information:

1. date of receipt
2. number of filters in shipment
3. number of boxes in shipment
4. air bill number

#### 21.1.1.2 Equipment Shipment Receipt

At appropriate intervals, the laboratory will ship coolers, max/min thermometers, and gel packs back to the field offices. On the day of receipt, the FS will contact the LA and provide the following information:

1. date of shipment
2. number of boxes in shipment
3. tracking number

#### 21.1.1.3 ESAT Conference Calls

The FS may be asked to participate in ESAT Workgroup conference calls to discuss progress or resolution of issues. The WAM will inform the FS of information that needs to be prepared for the call at least 3 days prior to the call. During the 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 done in advance so that both the FS and the site operator have ample advance notice and time to prepare for the on-site visit. The procedure for such communications follows:

1. The WAM (FS in attendance) will contact each site operator (by telephone) no less than 1 month prior to the site visit.
2. About one week prior to the actual evaluation, the WAM (FS in attendance) 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 utilize the phone communications form in the same manner as the field scientist, as described in section 21.1.1 above.

#### **21.1.2.1 Filter Shipment**

Every 2 weeks, filters will be shipped to the field offices by Federal Express . On the day of shipment, the LA will communicate with the field scientist and provide the following information:

- ▶ date of shipment
- ▶ number of filters in shipment
- ▶ number of boxes in shipment
- ▶ air bill number

The LA will also send the field scientist an e-mail containing the same information and will carbon copy both their ESAT laboratory WAM and the EPA Regional Field WAM.

#### **21.1.2.2 Equipment Shipment**

The laboratory will ship coolers, max/min thermometers, and ice substitutes back to the regional offices by FedEx. On the day of shipment, the LA will communicate with the field contact (see the field contact list) and provide the following information:

- ▶ date of shipment
- ▶ number of boxes in shipment
- ▶ tracking number

The LA will also send the field contact an e-mail containing the same information and will carbon copy both their ESAT laboratory WAM and the EPA Regional Field WAM.

## **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 to the WAM a progress report in writing at the end of each month (PEPF-2.02). The monthly progress report Form COM-2 will be used to convey the following

information:

- ▶ Reporting Date - beginning and end date that report covers
- ▶ Reporter - person writing reports
- ▶ Progress - progress on field activities
  - Evaluations scheduled within reporting date
  - Evaluations conducted within reporting date
- ▶ Issues -
  - Old issues- issues reported in earlier reports that have not been resolved
  - New issues- arising within 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.

### **Laboratory Progress Report**

The LA will provide the WAM a progress report in writing every Friday or on the last day of the scheduled work week. Weekly Progress Report Form COM-2 will be used to convey the following information:

- ▶ Reporting date - beginning and ending date that report covers
- ▶ Reporter - person writing reports
- ▶ Progress - progress on laboratory activities
  - Presampling processing- filters prepared within reporting date
  - Postsampling processing- filters weighed within reporting date and data submitted to AIRS
  - Shipments- shipments made to each Region within reporting date
  - Receipt - filters received within reporting date (totals)
- ▶ Issues -
  - Old issues- issues reported in earlier reports that have not been resolved
  - New issues- issues arising within 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.

### **21.1.2 QA Reports**

Various QA Reports will be developed to document the quality of data for the PEP.

**Data quality assessment (DQA)** -is a scientific and statistical evaluation 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. The statistics to be used to evaluate the data in relation to the DQOs are discussed in Section 24. DQAs will primarily be the responsibility of the EPA Regions (Regional assessments) and OAQPS (National assessments). A DQA will be performed once a year.

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

**Assessment Reports** - Technical systems audits will be on file at the EPA Regional Office and OAQPS. AIRS will include an audit tracking area that will allow for the placement of dates when an audit was implemented. Management systems reviews will be on file in MQAG with tracking information on AIRS.

**QA Reports** - A QA report provides an evaluation of QA/QC data for a given time period to determine whether the data quality objectives were met. This report will be more evaluative in nature than the P&A reports in that it will combine the various assessments and the QA data to report on the overall quality system. OAQPS will generate a national QA report on the PEP and its resultant data quality.

The QA Report will include:

- ▶ program overview and update
- ▶ quality objectives for measurement data
- ▶ systems audits
- ▶ data quality assessment
  - completeness
  - precision
  - accuracy and bias
- ▶ summary

### **21.1.3 Response/Corrective Action Reports**

During TSAs the response/corrective action reporting procedure will be followed whenever there is an audit finding. The Response/Corrective Action Report 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 Response/Corrective Action Report 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 Response/Corrective Action Report 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 field or laboratory branch manager, and the QA Division Director will be included in both distributions.

#### **21.1.4 Control Charts with Summary**

Control charts for field and laboratory instruments are updated after every new calibration or standardization as defined in the relevant field and analytical SOPs. Field scientists and laboratory analysts 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 ESAT WAMs. Control charts are also subject to inspection during audits, and laboratory personnel are responsible for maintaining a readily-accessible file of control charts for each instrument.

#### **21.1.5 Data Reporting**

The data reporting requirements of 40 CFR Part 58.35 apply to those stations designated SLAMS or NAMS. 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 AIRS within ~ 25 days of filter receipt from the field. The required reporting periods and due dates are listed in Table 21-2.

**Table 21-2 Quarterly Reporting Schedule**

<b>Reporting period</b>	<b>Due on or before</b>
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)

In accord with the Federal Register Notice of July 18, 1997, all QA/QC data collected will be reported and will be flagged appropriately. This data includes: "results from invalid tests, from tests carried out during a time period for which ambient data immediately prior or subsequent to the tests were invalidated for appropriate reasons, and from tests of methods or analyzers not approved for use in SLAMS monitoring networks . . ." (40 CFR Part 58 Appendix A, Section 4, revised July 18, 1997).

Air quality data submitted for each reporting period will be edited, validated, and entered into the AIRS-AQS using the procedures described in the *AIRS Users Guide, Volume II, Air Quality Data Coding* or the new procedures available once AIRS has been converted to a relational data base.

The PEP will be responsible for preparing the data reports, which will be reviewed by the QAO and Air Branch Manager before they are transmitted to EPA.

**Table 21-3 Report Summary**

<b>Report Type</b>	<b>Frequency</b>	<b>Reporting Organization</b>	<b>Distribution</b>
Field Progress Laboratory Progress	Monthly Weekly	ESAT Contractor ESAT Contractor	EPA WAM and RPO EPA WAM and RPO
Data Quality Assessment	1 per year	OAQPS and EPA Regions	ESAT contractor, EPA Region, AMTIC
P & A	quarterly and yearly	OAQPS/AIRS	AIRS
Systems Audit Region OAQPS	2 per year 1 per year	Region OAQPS	ESAT Contractor, OAQPS ESAT contractor, EPA Region
Response/Corrective Action	1 per finding	ESAT Contractor	ESAT contractor, EPA Region, OAQPS

## 22.0 Data Review, Validation and Verification Requirements

This section will describe 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 for the PEP is to provide data of adequate quality to use in comparison to routine data. This section will describe the verification and validation activities that occur at a number 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 data quality objectives 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. In order to verify and validate the phases of the data collection operation, the PEP will use various qualitative assessments (e.g., technical systems audits, network reviews) to verify that the QAPP is being followed, and will rely on the various quality control samples, inserted at various phases of the data collection operation, to validate that the data will meet the DQOs described in Section 7.

### 22.1 Sampling Design

Section 10 describes the sampling design for the network established by PEP. It covers the number of PE required for each reporting organization and method designation and the frequency of data collection. These requirements have been described in the Code of Federal Regulations. However, it is the responsibility of PEP to ensure that the intent of the regulations are properly administered and carried out.

#### 22.1.1 Sampling Design Verification

Verification of the sampling design will occur through three processes:

**Review of the Implementation Plans** - State and local 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 October 1, of the previous year. This schedule should be based upon the following:

- ▶ the criteria in CFR as discussed in Section 10
- ▶ meeting the same monitoring schedule as the routine sampler being evaluated
- ▶ the sites that are closest in proximity to each other

The implementation plan can then be reviewed and compared to the AIRS data of active SLAMS 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 TSA's.

## **22.2 Sample Collection Procedures**

### **22.2.1 Sample Collection Verification**

Sample collection procedures are described in Section 11 and in detail in the Field SOPs to ensure proper sampling and to maintain sample integrity. The following processes will be used to verify the sampling collection activities:

**Technical Systems Audits** - will be required by OAQPS once a year and by the EPA Regions twice a year, as described in Section 20

**Surveillance** - will be conducted as required by the EPA Regions as required and will be used for frequent monitoring of specific data collection phases.

Both types of audits will be used to verify that the sample collection activities are being performed as described in this QAPP and the SOPs. Deviations from the sample collection activity will be noted in audit finding forms and corrected using the procedures described in Section 20.

### **22.2.2 Sample Collection Validation**

The sample collection activity is just one phase of the measurement process. The use of QC samples that have been placed throughout the measurement process can help validate the activities occurring at each phase. The review of QC data such as the collocated sampling data, field/lab blanks, and sampling/laboratory equipment verification checks that are described in section 14 and 16 can be used to validate the data collection activities. Any data that indicates unacceptable levels of bias or precision or a tendency (trend on a control chart) will be flagged and investigated. This investigation could lead to a discovery of inappropriate sampling activities.

## **22.3 Sample Handling**

Sections 11 and 12 detail the requirements for sampling handling. However, greater detail for both field and laboratory sample handling occur in the Field and Laboratory SOPs (PEPF-3.01 and PEPL-5.01 respectively), 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 mentioned in the above section, technical systems audits and surveillance will be performed to ensure the specifications mentioned in the QAPP and SOPs are being followed. The audits would

include checks on the identity of the sample (e.g., proper labeling and chain-of-custody records), packaging in the field, and proper storage conditions (e.g., chain-of-custody 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 collocated sampling and field, laboratory and lot blanks, that are described in section 14 and 16, and the use of control charts can be used to validate the sample handling activities. Acceptable precision and bias in these samples would lead one to believe that the sample handling activities are adequate. Any data that indicates unacceptable levels of bias or precision or a tendency (trend on a control chart) will be flagged and investigated. This investigation could lead to a discovery of inappropriate sampling handling activities that require corrective action.

## **22.4 Analytical Procedures**

Section 13 details the requirements for the analytical methods, which include the pre-sampling weighing activities that give each sample a unique identification, an initial weight, and prepares the sample for the field; and the post-sampling weighing activity, which provides the mass net weight and the final concentration calculations. The laboratory SOPs, specifically PEPL-8.01, provides the actual procedures. The methods include acceptance criteria (Sections 13 and 14) 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 mentioned in the above sections, both technical systems audits and surveillance will be performed to ensure the analytical method specifications mentioned in the QAPP and SOPs are being followed. The audits will include checks on the identity of the sample. Deviations from the analytical procedures will be noted in audit finding forms and corrected using the procedures described in Section 20.

### **22.4.2 Validation of Analytical Procedures**

Similar to the validation of sampling activities, the review of data from lab blanks, calibration checks, laboratory duplicates, laboratory records for temperature and humidity devices, the filter inventory and tracking form and other laboratory QC that are described in sections 14 and 16 and the laboratory SOPs can be used to validate the analytical procedures. Acceptable precision and bias in these samples or control of the labs temperature and humidity conditions would lead one to believe that the analytical procedures are adequate. Any data that indicates unacceptable levels of bias or precision or a tendency (trend on a control chart) will be flagged and investigated as

described in Section 14. This investigation could lead to a discovery of inappropriate analytical procedures, requiring corrective action.

## **22.5 Quality Control**

Sections 14 and 16 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 replicates, which provide indications of the quality of data being produced by specified components of the measurement process. For each specified QC check, the procedure, acceptance criteria, and corrective action are specified in field and laboratory SOPs.

### **22.5.1 Verification of Quality Control Procedures**

As mentioned in the above sections, both technical systems audits and surveillance will be performed to ensure the quality control 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 quality control 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 the potential effect of the corrective actions on the validity of the routine data. Section 14 describes the techniques used to document QC review/corrective action activities

## **22.6 Calibration**

Section 16, as well as the field (Section 11) and the analytical sections (Section 13) detail the calibration activities and requirements for the critical pieces of equipment for the PM<sub>2.5</sub> network. The Field SOPs (Sections 6 and 7) and the laboratory SOPs (Section 7) provides detailed calibration techniques.

### **22.6.1 Verification of Calibration Procedures**

As mentioned in the above sections, both technical systems audits and surveillance will be performed to ensure the calibration specifications and corrective actions mentioned in the QAPP are being followed. Deviations from the calibration procedures will be noted in audit finding forms and corrected using the procedures described in Section 20.

## **22.6.2 Validation of Calibration Procedures**

Similar to the validation of sampling activities, the review of calibration data that are described in section 14 and 16, 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 indicates unacceptable levels of bias or precision or a tendency (trend on a control chart) will be flagged and investigated as described in Section 14 or 16. This investigation could lead to a discovery of inappropriate calibration procedures, or equipment problems requiring corrective action as detailed in the section. Validation would include the review of the documentation to ensure corrective action was taken as prescribed in the QAPP.

## **22.7 Data Reduction and Processing**

### **22.7.1 Verification of Data Reduction and Processing Procedures**

As mentioned in the above sections, both technical systems audits and surveillance will be performed to ensure 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 audits of data quality, discussed in section 20, a number of sample IDs, chosen at random will be identified. All raw data files, including the following will be selected:

- ▶ Pre-sampling weighing activity
- ▶ Pre-sampling
- ▶ Sampling (sampler download information)
- ▶ Calibration -the calibration information represented from that sampling period
- ▶ Sample handling/custody
- ▶ Post-sampling weighing
- ▶ Corrective action
- ▶ Data reduction

This raw data will be reviewed and final concentrations will be calculated by hand to determine if the final values submitted to AIRS compare to the hand calculations. The data will also be reviewed to ensure that associated flags or any other data qualifiers have been appropriately associated with the data 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 Section 22. If these processes, as written in the QAPP, are followed one would expect to achieve the quality of data required to perform data comparisons with the routine primary samplers. However, exceptional field events may occur, and field and laboratory activities may negatively effect the integrity of samples. In addition, it is expected that some of the QC checks will fail to meet the acceptance criteria. Information on problems that effect the integrity of data are identified in the form of flags (Appendix D). It is important to determine how these failures effect the routine data. The review of this routine data and their associated QC data will be verified and validated on a sample basis, on groups of samples, and on a sample batch basis. Section 14.2 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 the data will be conducted for completeness and data entry accuracy. All raw data that is hand entered on data sheets will be entered into the DAS and a 100% review implemented. Once the data is entered into the DAS, 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 “reverified” that the values are entered correctly. Details of these activities are discussed in Section 19. The data qualifiers or flags can be found in Appendix D.

#### **23.1.2 Validation**

Validation of measurement data can occur at different levels; at the single sample level, on a group of samples that are related (either to a single instrument, operator, or pre or postweighing session), or at the sample batch level. Validation at these three levels will be discussed below. At least one flag will be associated with an invalid sample, that being the “INV” flag signifying invalid, or the “NAR” flag when no analysis result is reported. Additional flags will usually be associated with the NAR or INV flags that help describe the reason for these flags, as well as free form notes from the field scientist or laboratory technician.

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

### 23.1.2.1 Validation of Single Samples or Groups of Samples

Validation criteria, based upon CFR and the judgement of the Validation Template Workgroup, a workgroup made up of EPA and State and local ambient air scientists, have been developed that 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 laboratory for further examination. When the laboratory technician reviews the field data sheet and chain of custody forms he/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 of the ESAT WAM these samples will be invalidated. The flag "NAR" for no analysis result will be placed in the flag area associated with this sample, along with the other associated flags.

A single sample may be invalidated based on a number of criteria such as known or suspected field or laboratory contamination, field or laboratory accidents, or criteria in CFR. Tables 23-1 and 23-3 list the cases where single samples or groups of samples may be invalidated based upon failure of any one acceptance criteria.

Other flags listed in Appendix D may be used in combination to invalidate samples. Table 23-4 identifies the criteria that can be used in combination to invalidate single samples or groups of samples. Since the possible flag combinations are overwhelming and can not 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 resulted in invalidation. These combinations will be listed and will be used by both the Region 4 and 10 laboratories to ensure that the PEP evaluates and invalidates data consistently. It is anticipated that these combinations can be programmed into the DAS system in order to assist the laboratory in evaluating data. As mentioned above, all data invalidation will be documented.

**Table 23-1 Single Flag Invalidation Criteria for Single Samples**

Requirement	Flag	Comment
Contamination	CON	Concurrence with lab technician and branch manager
Filter Damage	DAM	Concurrence with lab technician and branch manager
Event	EVT	Exceptional , known field event expected to have effected sample . Concurrence with lab technician and branch manager
Laboratory Accident	LAC	Concurrence with lab technician and branch manager
Field Accident	FAC	Concurrence with lab technician and branch manager

### 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 that are described in Section 14.2. Based on the types of QC samples that are included in the batch and the field and laboratory conditions that are reported along with the batch (field/lab 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 need to be instituted. Table 23-2 represents the sample batch validation template.

**Table 23-2 Sample Batch Validation Template**

Requirement	# per batch	Acceptance Criteria	Major <sup>1</sup>	Minor <sup>2</sup>	Flag
<b>Blanks</b>					
Field Blanks	1	$\leq \pm 30 \mu\text{g}$	blank $> \pm 40 \mu\text{g}$	one blank $> \pm 30 \mu\text{g}$	FFB
	>1	mean $\leq \pm 30 \mu\text{g}$	mean $\geq \pm 30 \mu\text{g}$		FFB
Lab Blanks	1	$\leq +15 \mu\text{g}$	blank $> \pm 17 \mu\text{g}$	blank $> \pm 15 \mu\text{g}$	FLB
	>1	mean $\leq +15 \mu\text{g}$	mean $\geq \pm 15 \mu\text{g}$		FLB
<b>Precision Checks</b>					
Collocated pairs	1	CV $\leq 10\%$	CV $> 20\%$	CV $> 15\%$	FCS
Filter duplicates	1	$\leq +15 \mu\text{g}$	duplicate $> \pm 17 \mu\text{g}$	duplicate $> \pm 15 \mu\text{g}$	FLD
<b>Accuracy</b>					
Balance Checks	4	$\leq \pm 3 \mu\text{g}$	4 checks $> \pm 3 \mu\text{g}$	2 checks $> \pm 3 \mu\text{g}$	FIS

1-if 2 majors occur data invalidated

2-if 4 minors occur data invalidated. 2 minors equal 1 major

Based upon the number of major and minor flags associated with the batch, the batch may be invalidated. Either the DAS system or the laboratory analysts will evaluate the batch and generate a report based upon the results described in the validation template. If the report describes invalidating the batch of data, the batch will be reanalyzed. Prior to reanalysis, all efforts will be made to take corrective actions, depending on the type of QC checks that were outside of acceptance criteria, to correct the problem. If the batch remains outside the criteria, 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 reanalyzed.

The Region 4 and 10 WAMs will be responsible for determining data validation prior to submittal of data to AIRS. Each week a summary report of all data that was invalidated will be submitted to laboratory WAM along with explanations for batch failures.

All invalidated samples, with the exceptions of samples invalidated for obvious damage and were not analyzed, will be flagged and uploaded to the AIRS data base. There is always the possibility that the QC data used to represent the routine data quality was not representative, and the PE value, when compared to the primary sampler value, shows good correlation.

**Table 23-3 Validation Template Where Failure of Any One Criteria Would Invalidate a Sample or Group of Samples**

<b>CRITERIA DEFINED IN CFR - SAMPLES OR GROUPS OF SAMPLES INVALIDATED FOR ANY FAILED CRITERIA</b>				
<b>S- Single Filter, G- Group of filters (i.e. batch), G1-Group of filters from 1 instrument</b>				
<b>Requirement</b>	<b>Frequency</b>	<b>Acceptance Criteria</b>	<b>40 CFR Reference</b>	<b>Flag Value</b>
<b>Filter Holding Times</b>				
Sample Recovery <b>S</b>	all filters	≤4 days from sample end date	Part 50, App.L Sec 8.3	HTE
Post-sampling Weighing <b>S</b>	“	≤ 10 days at 25° C from sample end date		HTE
<b>S</b>		≤ 30 days at 4°C from sample end date		HTE
<b>Sampling Period</b> <b>S</b>	All data	1380-1500 minutes	Part 50, App.L Sec 3.3	EST
<b>Sampling Instrument</b>				
Flow Rate <b>S</b>	every 24 hours of op	≤ 5% of 16.67	Part 50, App.L Sec 7.4	FLR
<b>S</b>	“	≤ 2% CV	Part 50, App.L Sec 7.4.3.2	FLR
<b>S</b>	“	No flow rate excursions > ±5% for > 5 min.	Part 50, App.L Sec 7.4.3.1	FVL
<b>Filter</b>				
Visual Defect Check <b>S</b>	All Filters	See reference	Part 50, App.L Sec 6.0	DAM
Filter Conditioning Environment				
Equilibration <b>G</b>	All filters	24 hours minimum	Part 50, App.L Sec 8.2	ISP
Temp. Range <b>G</b>	“	24-hr mean 20-23° C	“	ISP
Temp. Control <b>G</b>	“	±2° C SD* over 24 hr	“	ISP
Humidity Range <b>G</b>	“	24-hr mean 30% - 40% RH	“	ISP
Humidity Control <b>G</b>	“	± 5% SD* over 24 hr.	“	ISP
Pre/post sampling RH <b>S/G</b>	“	± 5% RH		ISP
<b>Calibration/Verification</b>				
Flow Rate (FR) Calibration <b>G1</b>	If multi-point failure	± 2% of transfer standard	Part 50, App.L, Sec 9.2	FMC
FR multi-point verification <b>G1</b>	1/yr	± 2% of transfer standard	Part 50, App.L, Sec 9.2	FMC
Design flow rate adjustment <b>G1</b>	at one-point or multi-point	± 2% of design flow rate	Part 50, App.L, Sec 9.2.6	FMC

\*= Variability estimate not defined in CFR

Table 23-4 Validation Template Where Certain Combinations of Failure May Be Used to Invalidate a Sample or Group of Samples

<b>OPERATIONAL EVALUATIONS</b>					
<b><u>1/</u> Identified in CFR, <u>2/</u> Identified as a DQO, <u>3/</u> value must be flagged, S- Single Filter, G- Group of filters (i.e. batch), G1-Group of filters from 1 instrument</b>					
Requirement		Frequency	Acceptance Criteria	40 CFR Reference	Flag Value
<b>Filter Checks</b>					
Lot Blanks	<b>G</b>	3 filters per lot	less than 15 $\mu\text{g}$ change between weighings less than 15 $\mu\text{g}$ change between weighings, no visual defects	not described not described Part 50, App.L Sec 10.2	
Exposure Lot Blanks	<b>G</b>	3 filters per lot			
Filter Integrity (exposed)	<b>S</b>	each filter			
<b>Filter Holding Times</b>					
Pre-sampling	<b>S</b>	all filters	< 30 days before sampling <sup>1/</sup>	Part 50, App.L Sec 8.3	
<b>Detection Limit</b>					
Lower DL	<b>G/G1</b>	All data	$\leq 2 \mu\text{g}/\text{m}^3$ $\geq 200 \mu\text{g}/\text{m}^3$	Part 50, App.L Sec 3.1	
Upper Conc. Limit	<b>G/G1</b>	All data		Part 50, App.L Sec 3.2	
<b>Lab QC Checks</b>					
Field Filter Blank <sup>1/</sup>	<b>G/G1</b>	10% or 1 per weighing session	$\pm 30 \mu\text{g}$ change between weighings	Part 50, App.L Sec 8.3	
Lab Filter Blank <sup>1/</sup>	<b>G</b>	10% or 1 per weighing session	$\pm 15 \mu\text{g}$ change between weighings	Part 50, App.L Sec 8.3	
Balance Check	<b>G</b>	beginning, every 10th sample, end	$\leq 3 \mu\text{g}$	not described	
Duplicate Filter Weighing	<b>G</b>	1 per weighing session	$\pm 15 \mu\text{g}$ change between weighings	not described	
<b>Sampling Instrument</b>					
Filter Temp Sensor	<b>S</b>	every 24 hours of op	no excursions of > 5° C lasting longer than 30min	Part 50, App.L Sec 7.4	
<b>Accuracy</b>					
External Leak Check <sup>1/</sup>	<b>G1</b>	4/yr	< 80 mL/min	not described	
Internal Leak Check <sup>1/</sup>	<b>G1</b>	4/yr	< 80 mL/min	not described	
Temperature Audit <sup>1/</sup>	<b>G1</b>	4/yr	$\pm 2^\circ\text{C}$	not described	
Pressure Audit <sup>1/</sup>	<b>G1</b>	4/yr (?)	$\pm 10 \text{ mm Hg}$	not described	
Balance Audit	<b>G</b>	1/yr	$\pm 0.050 \text{ mg}$ or manufacturers specs, whichever is tighter	not described	
Flow Rate Audit <sup>1/</sup>	<b>G1</b>	4/yr (manual)	$\pm 4\%$ of audit standard $\pm 5\%$ of design flow rate	Part 58, App A, Sec 3.5	

<b>OPERATIONAL EVALUATIONS</b>				
<b><u>1/</u> Identified in CFR, <u>2/</u> Identified as a DQO, <u>3/</u> value must be flagged, S- Single Filter, G- Group of filters (i.e. batch), G1-Group of filters from 1 instrument</b>				
Requirement	Frequency	Acceptance Criteria	40 CFR Reference	Flag Value
<b>Precision</b> Collocated samples <b>G</b>	1/month	CV ≤ 10%	Part 58, App.A, Sec 3.5 and 5.5	
<b>Calibration/Verification</b> One point FR Check <b>G1</b> External Leak Check <b>G1</b> Internal Leak Check <b>G1</b> Temperature Calibration <sup>1/</sup> <b>G1</b> Temp M-point Verification <sup>1/</sup> <b>G1</b> One-point temp Check <sup>1/</sup> <b>G1</b> Pressure Calibration <sup>1/</sup> <b>G1</b> Pressure Verification <sup>1/</sup> <b>G1</b> Clock/timer Verification <b>G1</b> Monitor Calibrations <b>G</b> Lab temperature <b>G</b> Lab humidity	1/4 weeks every 5 sampling events* every 5 sampling events If multi-point failure on installation, then 1/yr 1/4 weeks on installation, then 1/yr 1/4 weeks 1/4 weeks 1/4 weeks Per manufacturers SOP 1/6 months? 1/6months?	± 4% of transfer standard <sup>1/</sup> < 80 mL/min <sup>1/</sup> < 80 mL/min <sup>1/</sup> ± 2°C of standard ± 2°C of standard ± 4°C of standard ±10 mm Hg ±10 mm Hg 1 min/mo ± 2°C ± 2%	Part 50, App.L, Sec 9.2.5 Part 50, App.L, Sec 7.4 " Part 50, App.L, Sec 9.3 Part 50, App.L, Sec 9.3 " " Part 50, App.L, Sec 7.4	
<b>Calibration &amp; Check Standards</b> Field Thermometer  Field Barometer  Working Mass Stds. Primary Mass Stds.	1/yr  1/yr  3 mo. 1/yr	± 0.1° C resolution ± 0.5° C accuracy ± 1 mm Hg resolution ± 5 mm Hg accuracy 0.025 mg 0.025 mg	not described  not described  not described not described	
<b>Monitor Maintenance</b> Impactor <b>G1</b> Inlet/downtube cleaning <b>G1</b> Filter chamber cleaning <b>G1</b> Leak check *	every 5 sampling events every 15 sampling event Monthly See calibration/verification	Cleaned/changed cleaned cleaned	not describe	

1/ Identified in CFR, 2/ Identified as a DQO, 3/ value must be flagged, S- Single Filter, G- Group of filters (i.e. batch), G1-Group of filters from 1 instrument  
 \* Scheduled at the same time as monitor maintenance

## **24.0 Reconciliation with Data Quality Objectives**

The DQOs for the PM<sub>2.5</sub> ambient air monitoring network and the PEP are described in Section 7. This section of the QAPP outlines the procedures that PEP will follow to determine whether the monitors and laboratory analyses are producing data that are sufficiently consistent to evaluate the bias of the routine network. In order for the data from the PEP to be used for estimating the bias associated with the routine PM<sub>2.5</sub> network, the data must be internally consistent, meaning that the data should be precise and unbiased. The following outline is conceptual and will be updated with formal statistical procedures once they have been completely developed. For example, the amount of imprecision and bias that is tolerable in the PEP while maintaining confidence in the estimates of bias for the routine network remains to be determined. An assessment of the quality of the data will be made at the method designation level (if there is more than one method designation being used in the PEP) for various spatial (Reporting Organization, Laboratory, Regional, National) and temporal (annual, 3-year) aggregations. Both the Regional Offices and the OAQPS have responsibilities in the data quality assessment.

### **24.1 Preliminary Review of Available Data**

Section 7 of this QAPP contains the details for the development of the DQOs. Section 10 of this QAPP contains the details for the sampling design, including the rationale for the design, the design assumptions, and the sampling locations and frequency. If changes in the DQOs or sampling design occur, the potential effect should be considered throughout the entire DQA.

A preliminary data review should be performed to uncover potential limitations to using the data, to reveal outliers, and generally to explore the basic structure of the data. The first step is to review the quality assurance 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 Evaluation of Data Collected while All PEP Samplers Collocated - Regional Level.**

The primary objectives for collocating all the samplers is to determine whether one of the samplers is biased relative to the average of all the samplers and to estimate the repeatability of the instruments. An analysis of variance (ANOVA) will be used to evaluate the first objective. Additionally, an output of the ANOVA is an estimate of the repeatability. The conclusions from the ANOVA will allow each Region to determine whether there is a PEP sampler that produces results sufficiently different from the average that the instrument should not be employed in the PEP program. The estimate of the repeatability can be used to evaluate the certainty with which the bias of the routine program within the Region can be estimated.

### **24.3 Evaluation of Data Collected while All PEP Samplers Collocated - National Level.**

The primary objective for a 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. To test for equal variances across all Regions or both laboratories, OAQPS will use both the Bartlett test (an all-purpose statistical test that can be used for equal and unequal sample sizes) and the Hartley test (a statistical test that requires equal sample sizes but is designed to find differences between the largest and smallest variances)<sup>1</sup>. The conclusions from these tests will allow OAQPS to determine whether corrective action needs to be taken to reduce the variability for any of the Regions or for one of the 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.

### **24.4 Evaluation of Data Collected while PEP Samplers Collocated with Routine Network - Regional Level.**

Once a month, collocated PEP samplers are to collect samples during the performance evaluation of a routine sampling site. These monthly pairs between the collocated PEP samplers will be used as an additional estimate of the repeatability of the instruments. The variability of the instruments estimated using the data from the annual collocation of all of the PEP samplers might not be representative of the true variability because of the controlled nature of the experiment. The monthly collocation will provide data to assess the variability of the samplers as they operate in the field. A Regional summary of the variability of the various pairs of PEP samplers should be prepared and compared to the variability observed during the full collocation. If there are disparities between the two estimates of variability, these should be investigated since a good estimate of the variability is essential to finding PEP samplers that generate data that have an apparent bias. Also, as in Section 24.2, this estimate of the repeatability can be used to evaluate the certainty with which the bias of the routine program within the Region can be estimated.

### **24.5 Evaluation of Data Collected while PEP Samplers Collocated with Routine Network - National Level.**

OAQPS will also review the paired data collected by the collocated PEP samplers during the performance evaluation of a routine sampling site. The goals and procedure for a National review is identical to that described in Section 24.3.

#### **References**

1. Neter, J.; W. Wasserman; and M. H. Kutner. *Applied Linear Statistical Models*. 2d ed. Homewood, Illinois: Richard D. Irwin, Inc, 1985.

## *Appendices*

## *Appendix A*

### *Glossary*

The following glossary is taken from the document *EPA Guidance For Quality Assurance Project Plans EPA QA/G-5*

## GLOSSARY OF QUALITY ASSURANCE AND RELATED TERMS

**Acceptance criteria** — Specified limits placed on characteristics of an item, process, or service defined in requirements documents. (ASQC Definitions)

**Accuracy** — 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 EPA recommends using the terms “*precision*” and “*bias*”, rather than “accuracy,” to convey the information usually associated with accuracy. Refer to *Appendix D, Data Quality Indicators* for a more detailed definition.

**Activity** — An all-inclusive term describing 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.

**Assessment** — The 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, performance evaluation (PE), 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). Refer to *Appendix D, Data Quality Indicators*, for a more detailed definition.

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

**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.

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

**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 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. Refer to *Appendix D, Data Quality Indicators*, for a more detailed definition.

**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 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.

**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, they will include the unknown population parameter with the same specified probability.

**Confidentiality procedure** — A procedure 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.

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

**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, 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, and when such 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 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, accuracy (bias is preferred), comparability, completeness, representativeness.

**Data Quality Objectives (DQOs)** — The qualitative and quantitative statements derived from the DQO Process that clarify 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 Quality Objectives (DQO) Process** — A systematic strategic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. The key elements of the DQO process include:

- ! state the problem,
- ! identify the decision,
- ! identify the inputs to the decision,
- ! define the boundaries of the study,
- ! develop a decision rule,
- ! specify tolerable limits on decision errors, and
- ! optimize the design for obtaining data.

DQOs are the qualitative and quantitative outputs from the DQO Process.

**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** — The specifications, drawings, design criteria, and performance requirements. Also, the result of deliberate planning, analysis, mathematical manipulations, and design processes.

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

**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** — 1) The appointment of an environmental contaminant at a point over time, over an area, or within a volume; 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** — Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

**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.

**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 sample*.

**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** — 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 ecology, including results from laboratory analyses or from experimental systems representing such processes and conditions.

**Environmental data operations** — Any work performed to obtain, use, or report information pertaining to environmental 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 pertaining to any work or activities involving the environment, including but not limited to: 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 rededication technologies and their components that may be utilized 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.

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

**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 split samples** — Two or more representative portions taken from the same sample and submitted for analysis to different laboratories to estimate Interlaboratory precision.

**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.

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

**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*.)

**Guidance** — A suggested practice that is not mandatory, intended as 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.”

**Holding time** — The period of time a sample may be stored prior to its required analysis. While 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.

**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 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 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 split samples** — Two or more representative portions taken from the same sample and analyzed by different laboratories to estimate the Interlaboratory 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.

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

**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.

**Matrix spike** — A sample 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, a term denoting 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 in order 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** — 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.

**Method blank** — A blank prepared to represent the sample matrix as closely as possible and analyzed exactly like the calibration standards, samples, and quality control (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.

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

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

**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.

**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.

**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. Refer to *Appendix D, Data Quality Indicators*, for a more detailed definition.

**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** — 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.

**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 describing in comprehensive detail the necessary quality assurance (QA), quality control (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 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 QA/R-5 and QA/G-5.

**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 control (QC) sample** — An uncontaminated sample matrix spiked with known amounts of analytes from a source independent of the calibration standards. 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 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** — 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 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 system** — A structured and documented management system describing 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 quality assurance (QA) and quality control (QC).

**Radioactive waste** — Waste material containing, or contaminated by, radionuclides, subject to the requirements of the Atomic Energy Act.

**Readiness review** — A systematic, documented review of the readiness for the start-up 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.

**Recovery** — The act of determining whether or not the methodology measures all of the analyte contained in a sample. Refer to *Appendix D, Data Quality Indicators*, for a more detailed definition.

**Rededication** — 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** — 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. See also *Appendix D, Data Quality Indicators*.

**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 Interlaboratory 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. Refer to *Appendix D, Data Quality Indicators*, for a more detailed definition.

**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 denoting a requirement that 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 denoting 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 stating requirements and referring to or including 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; used to assess measurement accuracy (spike recovery). 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 quality control (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 has 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, record keeping, data validation, data management, and reporting aspects of a system.

**Traceability** — 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.

**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 concerns the process of examining a product or result to determine conformance to user needs. See also *Appendix G, Data Management*.

**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 concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

*Appendix B*  
*Data Quality Objective Process*

## Developing a Quality System for PM<sub>2.5</sub>

An important concern in any organization that is collecting and evaluating environmental data must be the quality of the results. A quality system<sup>1</sup> must be developed and documented to ensure that the PM<sub>2.5</sub> monitoring results:

- ▶ meet a well-defined need, use, or purpose;
- ▶ satisfy customers expectations;
- ▶ comply with applicable standards and specifications;
- ▶ comply with statutory (and other) requirements of society, and
- ▶ reflect consideration of cost and economics.

The development of a quality system for PM<sub>2.5</sub> requires a coordinated effort between EPA and the State and local monitoring community and tribal organizations. Elements of the quality system include planning, implementation and assessment. As part of the planning effort, EPA is responsible for developing National Ambient Air Quality Standards (NAAQS), defining the quality of the data necessary to make comparisons to the NAAQS, and identifying a minimum set of QC samples from which to judge data quality. The State and local organizations are responsible for taking this information and developing and implementing a quality system that will meet the data quality requirements. Then, it is the responsibility of both EPA and the State and local organizations to assess the quality of the data and take corrective action when appropriate. This document describes the approach used in developing a quality system for the PM<sub>2.5</sub> monitoring program. Following the planning, implementation and assessment theme, the discussion includes the:

6. development of data quality objectives (DQOs),
7. identification of the types and frequencies of QC samples, based upon the DQOs, to evaluate and control measurement uncertainty,
8. data quality assessment (DQA) process used to compare measurement uncertainty to the DQO, and
9. consequences of failing to meet the DQOs.

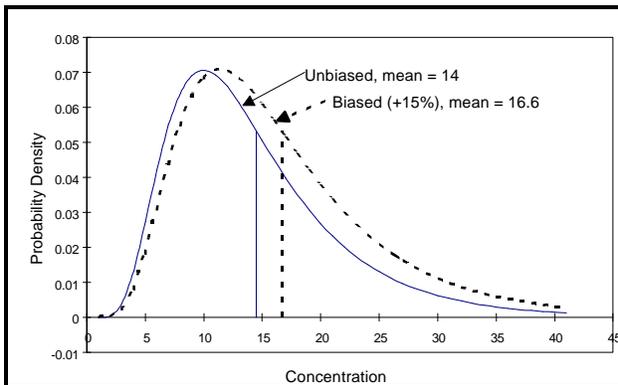
### ***Data Quality Objectives***

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<sup>2</sup>. By applying the DQO Process to the development of a quality system for PM<sub>2.5</sub>, the EPA guards against committing resources to data collection efforts that do not support a defensible decision. The DQO Process that follows illustrates the steps taken to assess the quality of data needed for making decisions resulting from comparisons to the PM<sub>2.5</sub> NAAQS. The focus of this document is the annual NAAQS which is based on the 3-year annual arithmetic mean concentration. Throughout this document, the term *decision maker* will be used. This term represents individuals that are the ultimate users of ambient air data and therefore may be responsible for: setting the NAAQS, developing a quality system, evaluating the data, or making comparisons to the NAAQS to determine if the standard is or is not violated. The DQOs will be based on the data requirements of the decision maker(s).

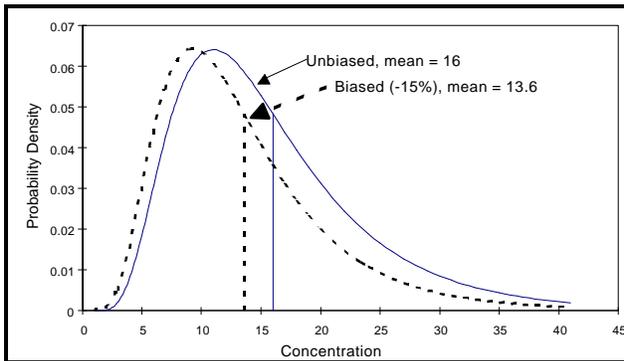
In order to understand the DQO Process, a discussion on data uncertainty will follow, which will lead into the discussion of the PM<sub>2.5</sub> DQO.

## Data Uncertainty

Decision makers need to feel confident that the data used to make environmental decisions are of adequate quality. The data used in these decisions are never error free and always contain some level of uncertainty. Because of these uncertainties or errors, there is a possibility that decision makers may declare an area



**Figure 1. Effect of positive bias on the annual average estimate, resulting in a false positive decision error**



**Figure 2. Effect of negative bias on the annual average estimate resulting in a false negative decision error**

population uncertainty would be an estimate of the uncertainty over the 3-year averaging period. During the development of the NAAQS, population uncertainty, due to temporal variability, was incorporated into the standard by stating that 3 complete years of data (every day sampling) determines a violation of the NAAQS, even though the expected value may be different. Therefore population variability was considered to be zero, as long as every day sampling was implemented. However, 1-in-6 day sampling and 1-in-3 day sampling, or any deviation from every day sampling, have a population variance that must be understood, and if possible, quantified.

**Total Measurement Uncertainty** is the total error associated with the environmental data operation. The environmental data operation for  $PM_{2.5}$  represents various data collection activities or phases including: the initial weighing of the filters (and the conditions in which they are weighed), the transportation of the filters, the calibration of the instrument and its maintenance, the handling and placement of the filters, the proper operation of the instrument (sample collection), the removal, handling and transportation of the filter, the storage and weighing of the sampled filter, and finally, the data reduction and reporting of the

“nonattainment” when the area is actually in “attainment” (false positive error as illustrated in Figure 1) or “attainment” when actually the area is in “nonattainment” (false negative error as illustrated in Figure 2). There are serious political, economic, and health consequences of making such decision errors. Therefore, decision makers need to understand and set limits on the probabilities of making incorrect decisions with these data.

The DQO defines the acceptable level of data uncertainty. The term "uncertainty" is used as a generic term to describe the sum of all sources of error associated with a given portion of the measurement system. The estimate of the overall uncertainty that the decision makers are willing to accept leads to the DQO. Overall data uncertainty is the sum of **total population uncertainty** and **total measurement uncertainty**.

**Total Population Uncertainty** is defined as the natural spatial and temporal variability in the population of the data being evaluated. Confidence in estimates of population uncertainty can be controlled through the use of statistical sampling design techniques, the proper placement of ambient air quality monitors, and spatial averaging (as allowed by the  $PM_{2.5}$  NAAQS). Since the population of concern for the  $PM_{2.5}$  NAAQS violation decision is a single instrument (each instrument can effect the attainment/nonattainment decision), the

value. At each phase of this process, errors can occur, that in most cases, are additive. The goal of a QA program is to control total measurement uncertainty to an acceptable level through the use of various quality control and evaluation techniques. In a resource constrained environment, it is most important to be able to calculate/evaluate the total measurement uncertainty and compare this to the DQO. Various phases (field, laboratory) of the measurement system can be evaluated, subject to the availability of resources.

Two data quality indicators are most important in determining total measurement uncertainty:

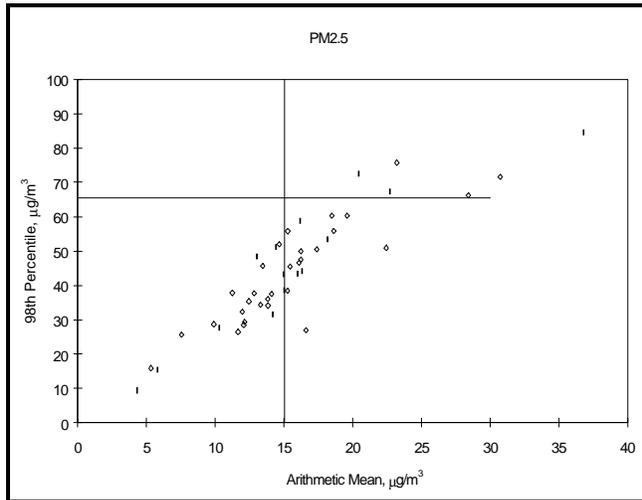
- ▶ **Precision** - a measure of mutual agreement among individual measurements of the same property usually under prescribed similar conditions. This is the random component of error. Precision is estimated by various statistical techniques using some derivation of the standard deviation. For the  $PM_{2.5}$  DQO, the coefficient of variation (CV) is used, which is the standard deviation divided by the mean, multiplied by 100.
- ▶ **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 deviation from the true value as a percentage of the true value.

Accuracy has been a term frequently used to represent closeness to “truth” and includes a combination of precision and bias error components. For  $PM_{2.5}$ , the term accuracy will be used when measurement uncertainty cannot be separately associated with precision or bias.

Three quality control (QC) procedures, at the national level, will be used to evaluate and control measurement uncertainty for the  $PM_{2.5}$  network:

1. **Flow rate checks**- Since flow rate is checked against standards of known value, this check provides estimates of accuracy and/or bias at the instrument level.
2. **Collocated checks**- Since the true concentrations sampled from collocated samples are unknown, these checks provide an estimate of precision of the measurement system. However, the implementation of this check, as described later in this document, has been refined to provide estimates of precision and bias.
3. **Federal Reference Method (FRM) Evaluation** - This evaluation is performed by comparing a monitoring instrument against an instrument that is considered “truth” and can provide an estimate of measurement system bias. Details of this check are described later in this document

If the total measurement uncertainty is within acceptable limits, then one could feel comfortable in using the results; if not, one would need additional QC samples or audits to determine at what measurement phase (field/lab) the errors were occurring. Additional types of QC samples will be implemented during the environmental data operation that will help identify errors occurring at other measurement phases. These samples will not be discussed in this document but will be a part of the overall quality system and will be included in the methods manuals and individual QA project plans.



**Figure 3. Annual arithmetic mean and 24-hour 98th percentiles associated with selected data sets**

## The PM<sub>2.5</sub> DQO

Regarding the quality of the PM<sub>2.5</sub> measurement system, the objective is to control precision and bias in order to reduce the probability of decision errors. Assumptions necessary for the development of the DQO include:

*1. The DQO is based on the annual arithmetic mean NAAQS.*

The PM<sub>2.5</sub> standards are a 15 µg/m<sup>3</sup> annual average and a 65 µg/m<sup>3</sup> 24-hour average. The annual standard is met when the 3-year average of annual arithmetic means is less than or equal to 15 µg/m<sup>3</sup>. Due to rounding, the 3-year average does not meet the NAAQS if it equals or exceeds 15.05 prior to rounding. The 24-hour average standard is met when the 3-year average 98th percentile of daily PM<sub>2.5</sub> concentrations is

less than or equal to 65 µg/m<sup>3</sup>.

AIRS PM<sub>2.5</sub> data were reviewed for two purposes: (a) to determine the relative “importance” of the two standards; and (b) to suggest “reasonable” hypothetical cases for which decision makers would wish to declare attainment and nonattainment with high probability. Twenty-four locations were found to have at least one year of PM<sub>2.5</sub> data in AIRS. Some locations had collocated samples and some produced data for two years (1995 and 1996), yielding a total of 47 single-year estimates of the annual average and the 24-hour 98th percentile. Goodness-of-fit tests identified the lognormal model as a good representation of the distribution of daily PM<sub>2.5</sub> concentrations. Parameters of the lognormal model (geometric mean and standard deviation) were estimated for the 47 data sets. Figure 3 displays the annual averages and 98th percentiles that are associated with lognormal distributions for the 47 data sets. Figure 3 does not display estimates derived according to the standard, as the data sets covered one rather than three years, but it does indicate the relative importance of the two standards. Points to the right of the vertical line may be viewed as exceeding the annual average standard. About half the data sets fall in this category. Points above the horizontal line may be viewed as exceeding the 24-hour average standard. All of those points are also to the right of the vertical line, indicating that the annual standard is the more stringent standard for these locations. For this reason, the DQOs discussed in the remainder of this document focus on attainment with the annual average standard. Estimates of the 47 geometric means and standard deviations were combined to produce a pooled geometric mean (or median) of 12.3 µg/m<sup>3</sup> and a coefficient of variation of 67%.

### *2. Normal distribution for measurement error.*

Error in environmental measurements is often assumed to be normal or lognormal. Figures 4 and 5 attempt to illustrate what happens to the normal and lognormal distribution functions for the same median concentration at two values for measurement error (CV's of 10 and 50%). In the case of PM<sub>2.5</sub>, the measurement error is expected to be in the range of 5 to 10 % of the mean, as shown in Figure 4, where normal or lognormal errors produce close to identical results. Therefore, due to these comparable results and its simplicity in modeling, the normal distribution of error was selected.

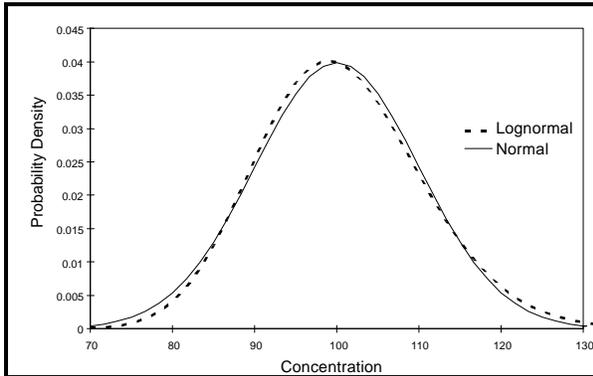


Figure 4. Comparison of normal and lognormal density functions at low measurement error (10% CV)

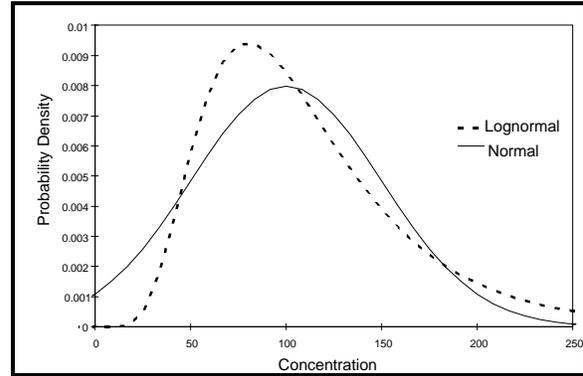


Figure 5. Comparison of normal and lognormal density functions at higher measurement errors (50% CV)

3. Decision errors can occur when the estimated 3-year average differs from the actual, or true, 3-year average.

Errors in the estimate are due to population uncertainty (sampling less frequently than every day) and measurement uncertainty (bias and imprecision). The false positive decision error occurs whenever the estimated 3-year average exceeds the standard and the actual 3-year average is less than the standard (Fig.1). The false negative decision error occurs whenever the estimated 3-year average is less than the standard and the actual 3-year average is greater than the standard (Fig. 2).

4. The limits on precision and bias are based on the smallest number of sample values in a 3-year period.

Since the requirements allow 1 in 6 day sampling and a 75% data completeness requirement, the minimum number of values in a 3-year period is 137. It can be demonstrated that obtaining more data, either through more frequent sampling or the use of spatial averaging, will lower the risk of attainment/non-attainment decision errors at the same precision and bias acceptance levels.

5. The decision error limits were set at 5%.

For the two cases that follow, the decision maker will make the correct decision 95% of the time if precision and bias are maintained at the acceptable levels. For cases that are less “challenging” (i.e., have annual average values that are farther from the standard), the decision maker will make the correct decision more often. This limit was based on the minimum number of samples from assumption 4 above (137) and the present uncertainty in the measurement technology. However, if precision and bias prove to be lower than the DQO, the decision maker can expect to make the correct decision more than 95% of the time.

6. Measurement imprecision was established at 10% coefficient of variation (CV).

By reviewing available AIRS data and other PM<sub>2.5</sub> studies, it was determined that it was reasonable to allow measurement imprecision at 10% CV. While measurement imprecision has relatively little impact on the ability to avoid false positive and false negative decision errors, it is an important factor in estimating bias. CV's greater than 10% make it difficult to detect and correct bias problems.

### Modeling the PM<sub>2.5</sub> Distribution for Development of the DQO

PM<sub>10</sub> data on AIRS were reviewed to find a reasonable statistical model for PM<sub>2.5</sub> that would:

- ▶ include a temporal trend and day-to-day variability of reasonable magnitude for data resulting from sampling less frequently than every day.
- ▶ represent cases where the correct decision (based on the 3-year average without measurement error) is always “attainment” or always “nonattainment.”

PM<sub>10</sub> data, rather than PM<sub>2.5</sub> data, were used because no PM<sub>2.5</sub> data set contained more frequent sampling than 1-in-6 days over a year. Daily results were desired to provide a clearer picture of a temporal trend and the residual variance about the trend. Two PM<sub>10</sub> data sets are displayed in Figures 6 and 7. Figure 6 displays two high-concentration episodes lasting one- to two-months while Figure 7 displays a gradually increasing concentration. A simple mathematical model was identified for the increasing function of Figure 7:

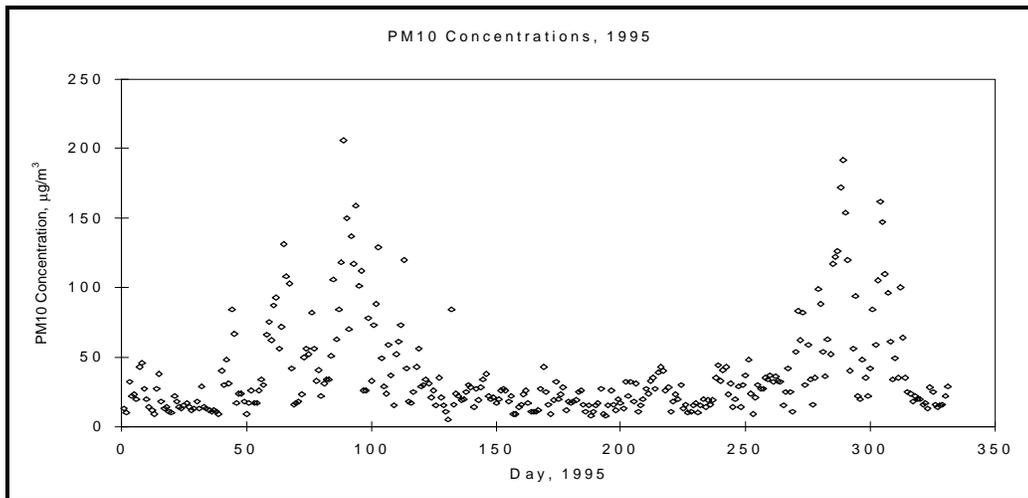


Figure 6. PM<sub>10</sub> distribution containing episodes

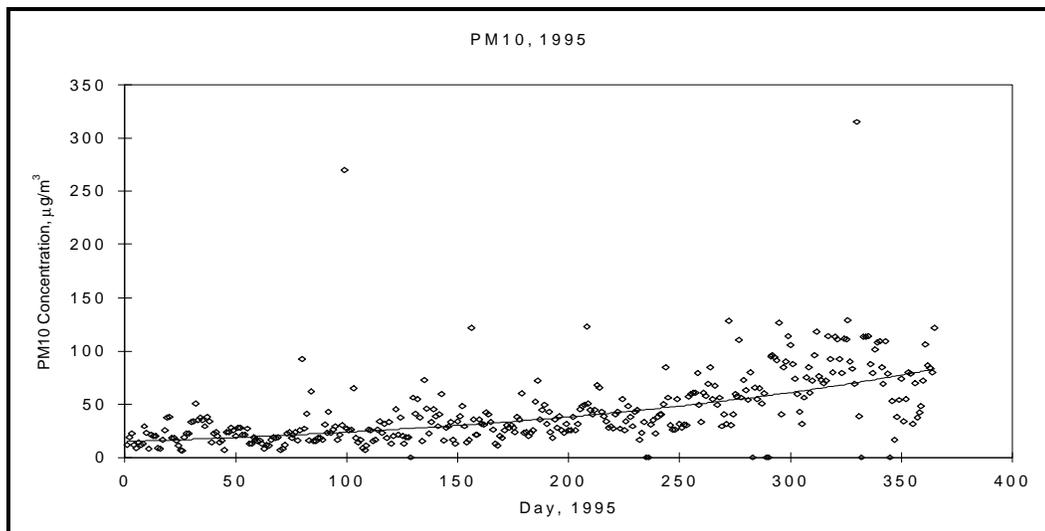


Figure 7. PM<sub>10</sub> distribution with gradually increasing concentration

$$\ln(\text{concentration on Day } D) = a + bD + \epsilon,$$

$$D = 1, 2, \dots, 365$$

where  $\epsilon$  is an error term, normally distributed with mean zero. The estimated CV for Figure 7's data set is 67%, the same as the pooled estimate for the 47  $PM_{2.5}$  data sets used to generate Figure 3. The model explains a significant portion of the total variability, as the error's ( $\epsilon$ 's) variance is 0.47, equivalent to a CV of about 50%.

Sinusoidal models were also considered as starting points for developing DQOs. The following function has the same ratio of maximum to minimum as the function of Figure 7:

$$C_D = \text{concentration on Day } D = 12.75 + 8.90 \sin(2 \pi D / 365) + \delta_D,$$

$$D = 1, 2, \dots$$

where  $\delta_D$  is an error term, normally distributed with mean zero and standard deviation equal to 50% of the expected concentration of day  $D$ . Figure 8 illustrates this function together with simulated daily  $PM_{2.5}$  levels for one year. The long-term average concentration is  $12.75 \mu\text{g}/\text{m}^3$ . A station having  $PM_{2.5}$  levels following this model would virtually always be in a true state of attainment, based on the average of three years' data with no measurement system error.

A second sinusoidal model was constructed to virtually always be in a true state of nonattainment. The

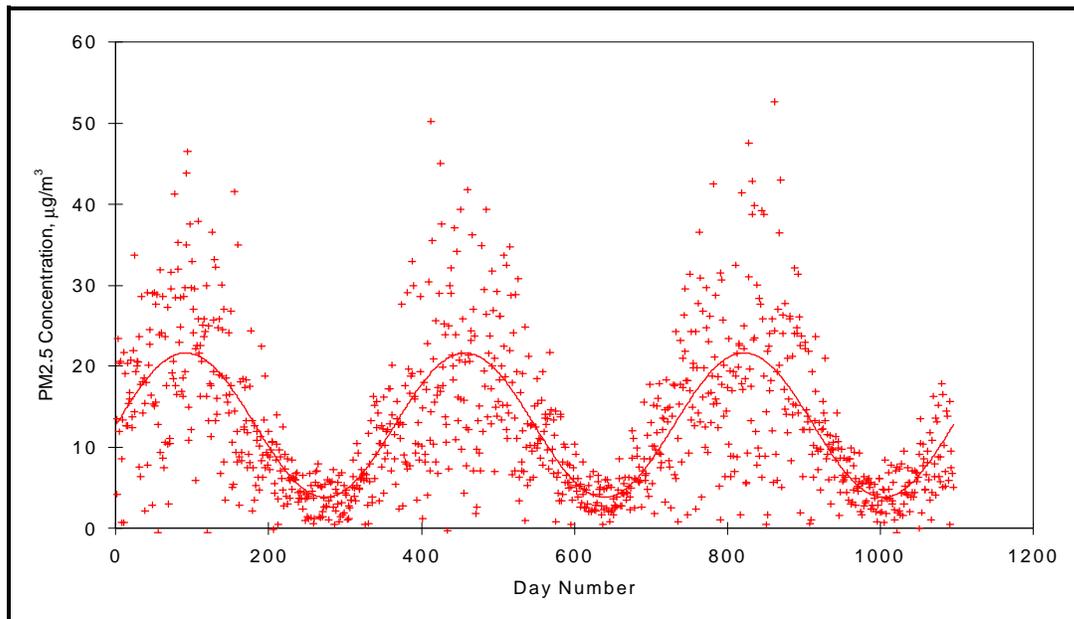


Figure 8. Simulated  $PM_{2.5}$  daily data

model equation for this second case (case 2, Figure 9) is:

$$C_D = \text{concentration on Day } D = 18.4 + 12.85 \sin(2 \pi D / 365) + \delta_D,$$

$$D = 1, 2, \dots$$

and again,  $\delta_D$  is an error term, normally distributed with mean zero and has a standard deviation equal to 50% of the expected concentration of day  $D$ . The ratio of the function's maximum to minimum is the same as for the previous function. The long-term average concentration is  $18.4 \mu\text{g}/\text{m}^3$ .

Figure 9 displays the two sine functions. The area between the distributions of Case 1 and 2 in Figure 9 is where decision makers would be concerned about decision errors. With perfect measurements, the probability of decision error is zero. As stated in the assumptions, the probability of decision error was established at 5% for each case, as shown in Table 1

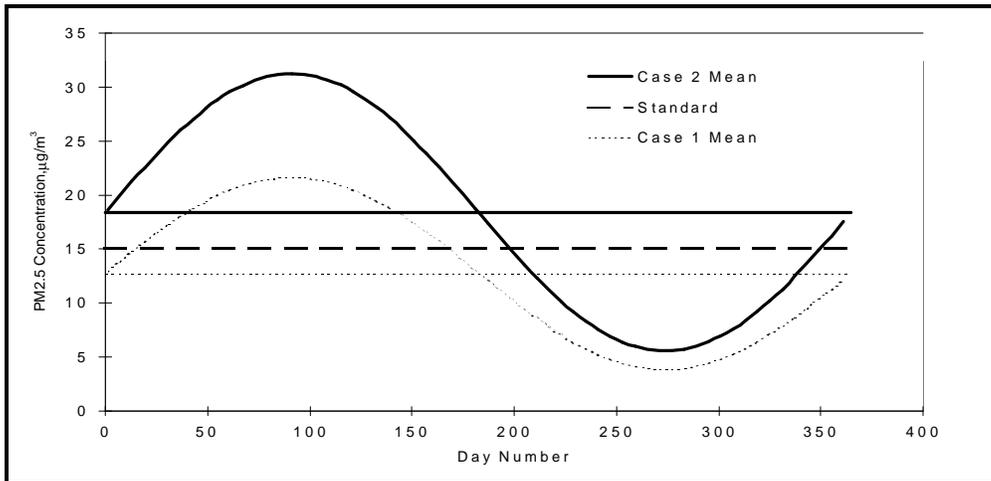


Figure 9. Case 1 and 2 distributions

Table 1. Summary of Case 1 and 2 parameters

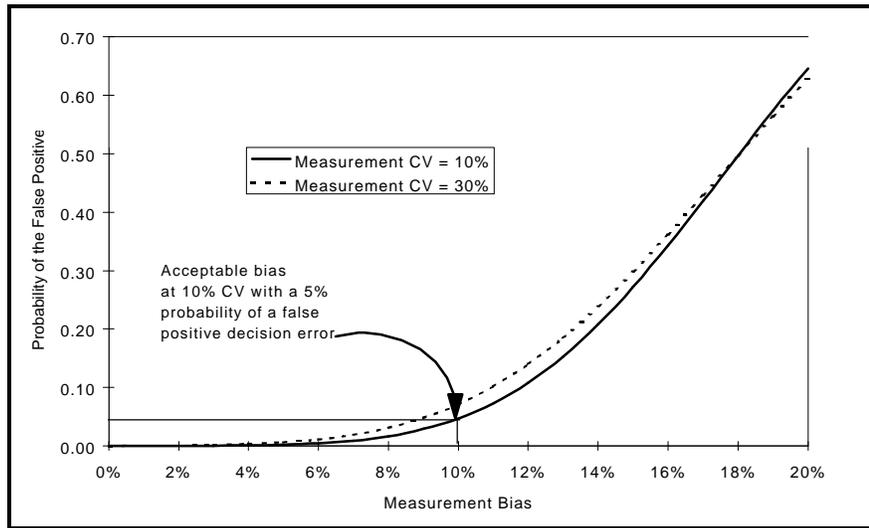
	Model Equation	Mean	Correct Decision	Incorrect Decision	Tolerable Error Rate
Case 1	$C_D=12.75+8.90 \sin(2\pi D/365)+\delta_D$	12.75	Attainment	F(+) = nonattainment	5%
Case 2	$C_D=18.4+12.85 \sin(2\pi D/365)+\delta_D$	18.4	Nonattainment	F(-) = attainment	5%

Table 2. Measurement System Decision

Precision CV (%)	Bias (%)	Decision Error Probability False Positive (%)
0	+5	0.18
0	+10	4.4
0	+15	26.8 (not acceptable)
80	0	1.3
100	0	3.0
10	+10	4.7
15	+10	5.1

**Case 1:** With this model (case 1), the 3-year average is  $12.75 \mu\text{g}/\text{m}^3$ . The correct decision is “attainment.” A false positive error is made when the estimated average exceeds the standard. The probability of the false positive error for sampling every sixth day depends on the measurement system bias and precision, as shown in Table 2. As stated in assumption 6 above, the data in Table 2 show that precision alone has little impact on decision error, but is an important factor for bias, which is an important factor in decision error. Figure 10 also illustrates very little difference between a CV’s of 10 and 30%.

Since the decision error probability limits were set at 5% (assumption 5), acceptable precision (CV) and bias are combinations yielding errors around 5%. Figure 10 displays the probability of the false positive as a function of bias when the CV is 10% and 30%.

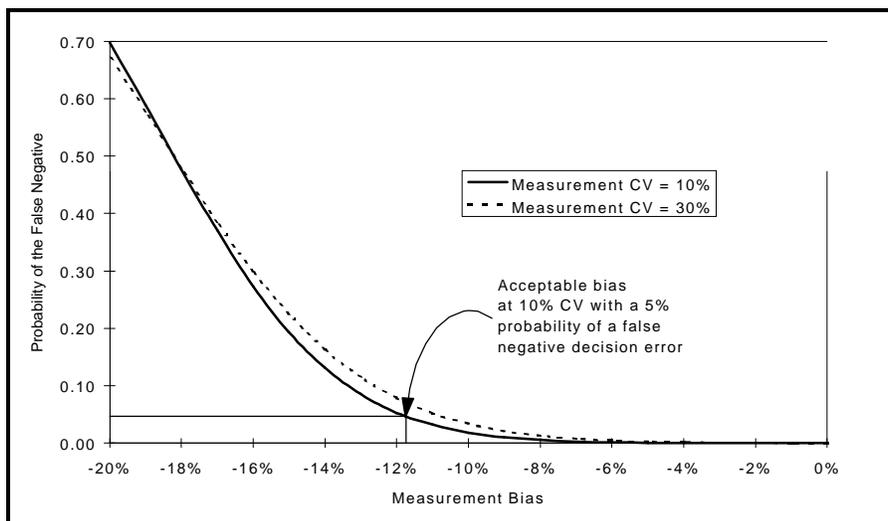


**Figure 10. Probability of a false positive decision error with measurement precisions at 10 and 30% CV**

**Table 3. Measurement System Decision**

Precision CV(%)	Bias(%)	Decision Error Probability False Negative (%)
0	-5	<0.1
0	-10	1.6
0	-15	18.9 (not acceptable)
80	0	1.2
100	0	2.8
10	-10	1.8
15	-10	2.1

**Case 2:** With this model (case 2), the 3-year average is  $18.4 \mu\text{g}/\text{m}^3$ . The correct decision is “nonattainment.” A false negative error is made when the estimated average is less than the standard. The probability of the false negative error for sampling every sixth day depends on the measurement system bias and precision, as shown in the Table 3. Figure 11 displays the probability of the false negative error as a function of bias. Similar to case 1, combinations of precision and bias that yield decision error probabilities around 5% were considered acceptable.



**Figure 11. Probability of a false negative error with measurement precisions at 10 and 30% CV.**

After reviewing cases 1 and 2, based upon the acceptable decision error of 5%, the DQO for acceptable precision (10% CV) and bias ( $\pm 10\%$ ) were identified.

### Acceptance Criteria Based on Precision and Bias

Previous quality control checks for the Ambient Air Quality Monitoring Network (40 CFR Part 58 Appendix A) are based on the use of probability limits. A limit of 15% was selected to protect against unacceptable systematic error (bias) and random error (precision)<sup>4</sup>. The statistic that is compared with 15% is:

$$\text{Limit} = D + 1.96 S_a / \sqrt{2} \qquad \text{Limit} = D - 1.96 S_a / \sqrt{2}$$

where D = is the average of averages of the pooled quality control checks, and  $S_a$  is the pooled standard deviation. Measurement systems operating with bias equal to 15% minus two times the measurement system CV have a 50-50 chance of passing the test. Measurement systems having greater bias or CV will fail most of the time while systems having less bias and lower CV'S will pass most of the time. By combining bias and precision in one test statistic, this test does not perform well when either bias or precision is unacceptable. For  $PM_{2.5}$ , acceptable bias needs to be within  $\pm 10\%$ . A measurement system operating with an unacceptable 15% bias, but with excellent precision (0% CV) would have an equal chance (nearly 50-50) of passing the probability limit test. In order to exercise better control of precision and bias, separate tests (see equations 22, 23, 29, and 30 in Appendix A) were developed for these two quality indicators.

Another advantage of having two tests is that they can be adjusted individually, in the event that the DQOs change over time. For example, if it becomes important to control bias to no more than  $\pm 5\%$  (rather than 10%), the form of the test remains the same, but the test hypothesis changes. The QC test for precision could remain the same.

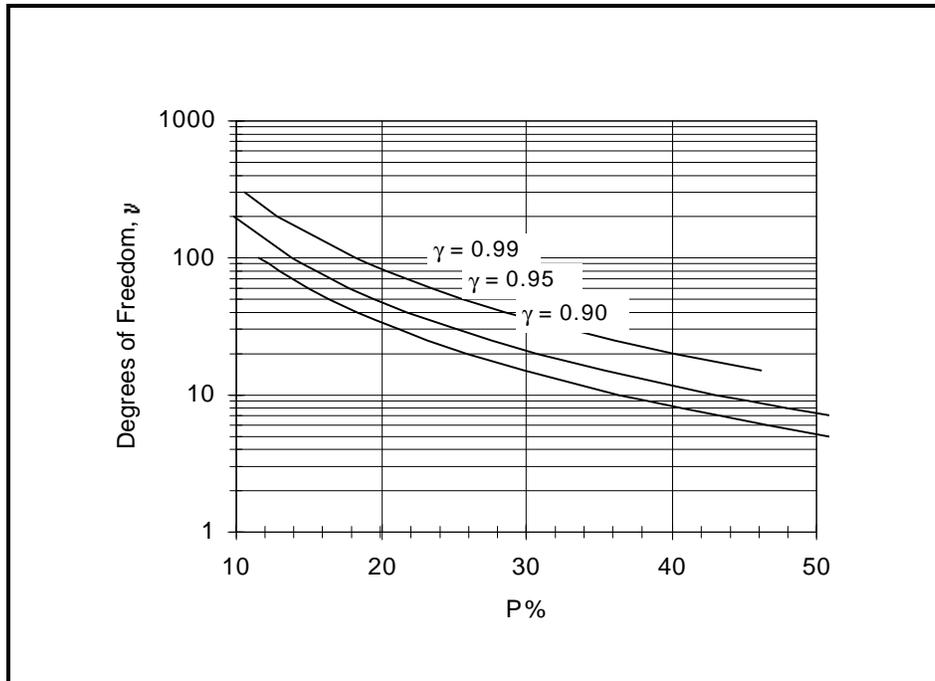
A final advantage of the test is its ability to detect and correct for biases that may be statistically significant, but practically insignificant. For example, if a measurement system consistently shows a positive, but small bias (e.g., -4%), together with excellent precision (e.g., 2% CV), a positive t-test (of the zero bias hypothesis) would alert the operators to a potential quality problem without identifying the monitor as being "out of acceptable criteria." Because the bias is small, the system's data are still useable for attainment decision making and there is no cause for alarm. Still, the problem should be investigated as an opportunity for quality improvement. If the cause of the small bias is corrected, the monitor will produce better measurement data.

### Sampling frequencies for QA/QC Samples

Since QA/QC samples are used to represent the precision and bias in the routine samples, it is important to have enough data to make data quality decisions. The performances of the chi-square test (for precision) and the t-test (for bias) were assessed for various QA/QC sampling frequencies in order to determine the number of collocated samplers and FRM performance evaluation needed to control and evaluate data at the monitor, reporting organization and national level.

**Precision**

Figure 12 represents a chi-square test used to understand the sample size required to estimate the standard deviation with certain precision. The figure shows that about 60 collocated sample pairs (1 year's collocated samples at a site) are required to ensure (at the 90% confidence level) that the CV estimate is within 15% of its true value. For example, if the true CV is 10%, the estimate should fall within 15%, or between 8.5% and 11.5% CV. This table can be used to determine the confidence in precision estimates at various reporting frequencies.



**Figure 12. Number of degrees of freedom required to estimate the standard deviation within P% of its true value with confidence coefficient .**

**Table 4 Power of detecting a bias at varying sampling size**

CV	Bias	Power	Number of QC Samples
0.1	0.15	0.9	36
0.1	0.2	0.9	10
0.1	0.25	0.94	6
0.1	0.25	0.89	5
0.1	0.3	0.9	4
0.1	0.25	0.79	4
0.1	0.3	0.95	4

**Bias**

A t-test was used to test the hypothesis that the absolute value of bias is less than or equal to the acceptance criteria of 10%. Table 4 displays the test's power to detect various unacceptable biases. Based upon the decision error limit of 5%, the chart shows that a bias of 20% can be detected nearly 90% of the time when the measurement CV is 10% with 10 QC samples (shaded example in Table 4).

## *Quality System*

In order to develop the quality system the following are key assumptions:

- ▶ **The DQO Process drives the quality system-** The DQO Process established the acceptable risk (decision error) for attainment/nonattainment decisions. The acceptance requirement for total precision is 10% CV and for total bias is  $\pm 10\%$ .
- ▶ **A quality system is required to evaluate and control measurement system bias and precision-** The measurement system represents all data collection activities, from initial preparation of the filters, through field and laboratory activities, to the data reduction and reporting. At each phase of this process, errors can enter the system. It is important to be able to calculate/evaluate the total measurement system uncertainty and compare this to the DQO; then if possible, to evaluate various phases of the measurement system.
- ▶ **Independent assessments and internal quality control are important-** Development of a quality system requires both components. An independent assessment provides an objective review of the measurement system. The FRM performance evaluations, NPAP, and other technical system audits would be considered independent assessments. Internal quality control includes types of samples that allow personnel implementing the measurement system real-time information to evaluate and control measurement error in order to meet the DQOs (i.e., collocated samples and flow rate checks).
- ▶ **QA data represents routine data precision and bias-** The intent of a good quality system is to provide enough information to represent the measurement uncertainty of routine data with a specified degree of confidence. Usually, when a new measurement system is being implemented, more QA/QC information is initially required; once the measurement system has been determined to be in statistical control, the quality system requirements may be reduced. Therefore, the quality system needs to be developed so that each method designation has adequate representation within a time frame that corrections can be made without a significant loss of routine data.
- ▶ **Collocation with FRM allows for estimates of precision and bias-** The FRM instrument represents “truth” and has more evaluative power to provide estimates of precision and bias. Comparing data from two collocated equivalent methods would allow for estimates only of precision. Also, intra-precision (comparing similarly designated methods) and inter-precision (comparing non-FRM designated methods with FRMs) can both be evaluated with the following quality system.
- ▶ **Incentive for acceptable performance-** Once the measurement system for a monitoring organization (reporting organization) proves to be in statistical control, based upon demonstrated performance, the quality system can be reduced to a level that provides adequate information that acceptable data quality is being maintained.

Three areas of the quality system will be discussed.

- ▶ The focus of QA resources on those sites likely to be close to or in violation of the NAAQS.
- ▶ Collocated Sites.
- ▶ FRM performance evaluations.

### **Focusing QA Resources**

Although all data are important to EPA, sites producing data close to the NAAQS would be the sites to focus limited QA resources. Therefore, the frequency of QA/QC (precision and bias) samples should be prioritized to sites in areas likely to be designated nonattainment, or at least to sites with higher concentrations. EPA recommends focusing 80% of the QA resources on sites with concentrations  $\geq 90\%$

of the annual mean NAAQS ( or 24-hour NAAQS if that is affecting the area), and each area determined to be in violation should be represented by at least one collocated monitor. The remaining 20% of the resources should be focused at sites with concentrations < 90% of the mean annual NAAQS. If an organization has no sites at concentration ranges  $\geq 90\%$  of the mean annual NAAQS, 60% of the resources should be implemented at those sites with the annual mean concentrations among the highest 25% for all PM<sub>2.5</sub> sites in the network. Obviously, for a new network, the selection will be somewhat subjective and based upon the experience of State and local organizations.

### Collocated Monitors

Collocated monitors can provide an estimate of precision when both the routine and collocated monitor are the exact same method designation. However, they can also provide an estimate of a portion of the total measurement bias when the routine monitor is collocated with an FRM monitor. The selection process for collocated monitors follow.

Every method designation *must*:

- a. have 25% of the monitors collocated (values of .5 and greater round up) .
- b. have at least 1 collocated monitor (if total number less than 4). The first collocated monitor must be the FRM.
- c. have 50% of the collocated monitors be FRM monitors and 50% must be the same method designation. If there is an odd number of collocated monitors required, bias in favor of the FRM.

Tables 5 helps to explain the collocated monitor selection procedure mentioned above.

**Table 5. Agency with 43 total monitors with differing numbers of method designation types.**

Method Designation	Total # of Monitors	Total # Collocated	Number of collocated FRMs	Number of collocated method designation monitors
FRM	25	6	6	na
Type A	10	3	2	1
Type C	2	1	1	0
Type D	6	2	1	1
<b>Total</b>	<b>43</b>	<b>12</b>	<b>10</b>	<b>2</b>

### FRM Performance Evaluations

Since the intent of the FRM performance evaluation is to provide an estimate of total measurement system bias, the method that would produce the most reliable results would be an evaluation conducted by an independent organization. Therefore, during the evaluation, the site operator will be in charge of routine sample collection and the filter will be handled, transported and weighed as normal. The independent FRM field scientist will be in charge of the operation of the FRM instrument and the handling of the filter which will be sent to an independent laboratory for analysis. This will allow for a complete estimate of measurement uncertainties. Any deviations from this process could provide estimates of various phases of the measurement system. Allocation of FRM performance evaluations follow. Every method designation *must*:

- ▶ Allocate 25% of sites, including collocated sites (even those collocated with FRM instruments), to FRM performance evaluations (values of .5 and greater round up) each year. All sites would

- ▶ be evaluated within 4 years.
- ▶ have at least 1 monitor evaluated.
- ▶ be evaluated at a frequency of 4 per year.

Table 6 helps to explain the FRM performance evaluation allocation procedure mentioned above.

**Table 6. FRM performance evaluation allocation**

Method Designation	Total # of Monitors	Total # FRM performance evaluations
FRM	25	6
Type A	10	3
Type C	2	1
Type D	6	2

### 3. Data Quality Assessments

A data quality assessment (DQA) is the scientific and statistical evaluation of data to determine if data from environmental data operations are of the right type, quality, and quantity to support their intended use. Since DQOs have been developed for the PM<sub>2.5</sub> attainment/nonattainment objective, the QA/QC data can be statistically assessed at various levels of aggregation to determine whether the DQOs have been attained. Data quality assessments of precision and bias will be aggregated at the following three levels.

1. **Monitor**- monitor/method designation
2. **Reporting Organization**- monitors in a method designation, all monitors
3. **National** - monitors in a method designation, all monitors

The statistical calculations for these assessments are found in Appendix A. It is anticipated that these calculations will be performed on the data in the Aerometric Information Retrieval System (AIRS) which will allow for the generation of reports at the levels specified above. A discussion on the implementation of the DQA activities will be included in the *QA Handbook for Air Pollution Measurement Systems- Volume II Ambient Air Specific Methods*.

### 4. Consequences of Failing Measurement Quality Objectives

Consequences for failure to meet acceptance criteria can be developed at three levels.

1. **Monitor** - Flagging data and development of corrective action.
2. **Reporting Organization** - Additional QA/QC procedures and corrective action
3. **National** - Potential for decertification of method designation, additional field/lab study of instrument.

The actual details of these activities would be included in the *QA Handbook for Air Pollution Measurement Systems- Volume II Ambient Air Specific Methods*

### References

1. American National Standard, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, ANSI/ASQC E4-1994, American Society for Quality Control, 1994

2. Guidance for the Data Quality Objectives Process, U.S. Environmental Protection Agency, Quality Assurance Management Staff, EPA QA/G-4, March 14, 1994.
3. Guidance for the Data Quality Assessment Process EPA QA/G-9 U.S. Environmental Protection Agency, QAD EPA/600/R-96/084, July 1996.
4. Rhodes, R.C. "Guideline on the Meaning and Use of Precision and Accuracy Data Required by 40 CFR Part 58, Appendices A and B." EPA600/14-83-023. U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. June 1983.

## *Appendix A*

### *Data Quality Assessment Calculations*

These calculations can be found in 40 CFR Appendix A. The equation numbers in the second column refer to the equation numbers in 40 CFR.

<b>Data Quality Assessment</b>	<b>Algorithm</b>
<b>Flow Rate</b>	
<p><b>Single sampler accuracy - single check: quarterly basis (<math>d_i</math>).</b> The percentage difference (<math>d_i</math>) for a single flow rate audit <math>I</math> is calculated using Equation 13, where <math>X_i</math> represents the audit standard flow rate (known) and <math>Y_i</math> represents the indicated flow rate</p>	$d_i = \frac{Y_i - X_i}{X_i} \times 100\%$ <p style="text-align: right;">13</p>
<p><b>Bias of a Single Sampler - Annual Basis (<math>D_j</math>).</b> For an individual particulate sampler <math>j</math>, the average (<math>D_j</math>) of the individual percentage differences (<math>d_i</math>) during the calendar year is calculated using Equation 14, where <math>n_j</math> is the number of individual percentage differences produced for sampler <math>j</math> during the calendar year.</p>	$D_j = \frac{1}{n_j} \sum_{i=1}^{n_j} d_i$ <p style="text-align: right;">14</p>
<p><b>Bias of reporting organization- quarterly estimate by individual method designation (<math>D_{k,q}</math>).</b> For method designation <math>k</math> used by the reporting organization, quarter <math>q</math>'s single sampler percentage differences (<math>d_i</math>) are averaged using Equation 15, where <math>n_{k,q}</math> is the number of individual percentage differences produced for method designation <math>k</math> in quarter <math>q</math>.</p>	$D_{k,q} = \frac{1}{n_{k,q}} \times \sum_{i=1}^{n_{k,q}} d_i$ <p style="text-align: right;">15</p>
<p><b>Bias for Each Reporting Organization - Quarterly Basis (<math>D_q</math>).</b> For each reporting organization, quarter <math>q</math>'s single sampler percentage differences (<math>d_i</math>) are averaged using Equation 16, to produce a single average for each reporting organization, where <math>n_q</math> is the total number of single sampler percentage differences for all federal reference or equivalent methods of samplers in quarter <math>q</math>.</p>	$D_q = \frac{1}{n_q} \times \sum_{i=1}^{n_q} d_i$ <p style="text-align: right;">16</p>
<p><b>Bias for Each EPA Federal Reference and Equivalent Method Designation Employed by Each Reporting Organization - Annual Basis (<math>D_k</math>).</b> For method designation <math>k</math> used by the reporting organization, the annual average percentage difference, <math>D_k</math>, is derived using Equation 17, where <math>D_{k,q}</math> is the average reported for method designation <math>k</math> during the <math>q</math>th quarter, and <math>n_{k,q}</math> is the number of the method designation <math>k</math>'s monitors that were deployed during the <math>q</math>th quarter.</p>	$D_k = \frac{\sum_{q=1}^4 n_{k,q} D_{k,q}}{\sum_{q=1}^4 n_{k,q}}$ <p style="text-align: right;">17</p>
<p><b>Bias for Each Reporting Organization - Annual Basis (<math>D</math>).</b> For each reporting organization, the annual average percentage difference, <math>D</math>, is derived using Equation 18, where <math>D_q</math> is the average reported for the reporting organization during the <math>q</math>th quarter, and <math>n_q</math> is the total number monitors that were deployed during the <math>q</math>th quarter. A single annual average is produced for each reporting organization.</p>	$D = \frac{\sum_{q=1}^4 n_q D_q}{\sum_{q=1}^4 n_q}$ <p style="text-align: right;">18</p>

<i>Data Quality Assessment</i>	<i>Algorithm</i>
<b>Collocated Samplers, where the duplicate sampler IS NOT an FRM device</b>	
<p><b>Percent Difference for a Single Check (<math>d_i</math>).</b> The percentage difference, <math>d_i</math>, for each check is calculated by EPA using Equation 19, where <math>X_i</math> represents the concentration produced from the primary sampler and <math>Y_i</math> represents concentration reported for the duplicate sampler</p>	$d_i = \frac{Y_i - X_i}{(Y_i + X_i)/2} \times 100$ <p style="text-align: right;">19</p>
<p><b>Coefficient of Variation (CV) for a Single Check (<math>CV_i</math>).</b> The coefficient of variation, <math>CV_i</math>, for each check is calculated by EPA by dividing the absolute value of the percentage difference, <math>d_i</math>, by the square root of two as shown in Equation 20.</p>	$CV_i = \frac{ d_i }{\sqrt{2}}$ <p style="text-align: right;">20</p>
<p><b>Precision of a Single Sampler - Quarterly Basis (<math>CV_{j,q}</math>).</b> For particulate sampler <math>j</math>, the individual coefficients of variation (<math>CV_{j,q}</math>) during the quarter are pooled using Equation 21, where <math>n_{j,q}</math> is the number of pairs of measurements from collocated samplers during the quarter</p>	$CV_{j,q} = \sqrt{\frac{\sum_{i=1}^{n_{j,q}} CV_i^2}{n_{j,q}}}$ <p style="text-align: right;">21</p>
<p><b>The 90 percent confidence limits for the single sampler's CV</b> are calculated by EPA using Equations 22 and 23, where <math>\chi^2_{0.05,df}</math> and <math>\chi^2_{0.95,df}</math> are the 0.05 and 0.95 quantiles of the chi-square (<math>\chi^2</math>) distribution with <math>n_{j,q}</math> degrees of freedom.</p>	$\text{Lower CL} = CV_{j,q} \sqrt{\frac{n_{j,q}}{\chi^2_{0.95, n_{j,q}}}}$ <p style="text-align: right;">22</p>
	$\text{Upper CL} = CV_{j,q} \sqrt{\frac{n_{j,q}}{\chi^2_{0.05, n_{j,q}}}}$ <p style="text-align: right;">23</p>
<p><b>Precision for Each EPA Federal Reference Method and Equivalent Method Designation Employed by Each Reporting Organization - Quarterly Basis (<math>CV_{k,q}</math>).</b> For each method designation <math>k</math> used by the reporting organization, the quarter's single sampler coefficients of variation, <math>CV_{j,q}</math>s, obtained from Equation 21, are pooled using Equation 24, where <math>n_{k,q}</math> is the number of collocated primary monitors for the designated method (but not collocated with FRM samplers) and <math>n_{j,q}</math> is the number of degrees of freedom associated with <math>CV_{j,q}</math>.</p>	$CV_{k,q} = \sqrt{\frac{\sum_{j=1}^{n_{k,q}} (CV_{j,q}^2 n_{j,q})}{\sum_{j=1}^{n_{k,q}} n_{j,q}}}$ <p style="text-align: right;">24</p>

<b>Data Quality Assessment</b>	<b>Algorithm</b>
<p>Precision for Each Method Designation Employed by Each Reporting Organization- Annual Basis (<math>CV_k</math>). For each method designation <math>k</math> used by the reporting organization, the quarterly estimated coefficients of variation, <math>CV_{k,q}</math>, are pooled using Equation 25, where <math>n_{k,q}</math> is the number of collocated primary monitors for the designated method during the <math>q</math>th quarter and also the number of degrees of freedom associated with the quarter's precision estimate for the method designation, <math>CV_{k,q}</math>.</p>	$CV_k = \sqrt{\frac{\sum_{q=1}^4 (CV_{k,q}^2 n_{k,q})}{\sum_{q=1}^4 n_{k,q}}} \quad 25$
<b>Collocated Samplers, where the duplicate sampler IS an FRM device</b>	
<p>Accuracy for a Single Check (<math>d'_i</math>). The percentage difference, <math>d'_i</math> for each check is calculated by EPA using Equation 26, where <math>X_i</math> represents the concentration produced from the FRM sampler taken as the true value and <math>Y_i</math> represents concentration reported for the primary sampler</p>	$d'_i = \frac{Y_i - X_i}{X_i} \times 100\% \quad 26$
<p><b>Bias of a Single Sampler - Quarterly Basis (<math>D'_{j,q}</math>)</b>. For particulate sampler <math>j</math>, the average of the individual percentage differences during the quarter <math>q</math> is calculated by EPA using Equation 27, where <math>n_{j,q}</math> is the number of checks made for sampler <math>j</math> during the calendar quarter.</p> <p>The standard error, <math>s'_{j,q}</math> of sampler <math>j</math>'s percentage differences for quarter <math>q</math> is calculated using Equation 28.</p> <p>The 95 percent confidence limits for the single sampler's bias are calculated using Equations 29 and 30 where <math>t_{0.975,df}</math> is the 0.975 quantile of Student's <math>t</math> distribution with <math>df = n_{j,q} - 1</math> degrees of freedom</p>	$D'_{j,q} = \frac{1}{n_{j,q}} \times \sum_{i=1}^{n_{j,q}} d'_i \quad 27$ $s'_{j,q} = \sqrt{\frac{1}{(n_{j,q} - 1) \times n_{j,q}} \times \left[ \sum_{i=1}^{n_{j,q}} d_i'^2 \right] - n_{j,q} D_{j,q}'^2} \quad \begin{matrix} 2 \\ 8 \end{matrix}$ $Lower\ CL = D'_{j,q} - t_{0.975,df} \times s'_{j,q} \quad 29$ $Upper\ CL = D'_{j,q} + t_{0.975,df} \times s'_{j,q} \quad 30$

<b>Data Quality Assessment</b>	<b>Algorithm</b>
<p><b>Bias of a Single Sampler - Annual Basis (<math>D'_j</math>).</b> For particulate sampler <math>j</math>, the mean bias for the year is derived from the quarterly bias estimates, <math>D'_{j,q}</math>, using Equation 31, where the variables are as defined for Equations 27 and 28.</p> <p>The standard error of the above estimate, <math>se'_j</math> is calculated using Equation 32.</p> <p>The 95 percent confidence limits for the single sampler's bias are calculated using Equations 33 and 34, where <math>t_{0.975,df}</math> is the 0.975 quantile of Student's <math>t</math> distribution with <math>df=(n_{j,1}+n_{j,2}+n_{j,3}+n_{j,4}-4)</math> degrees of freedom.</p>	$D'_j = \frac{\sum_{q=1}^4 (n_{j,q} D'_{j,q})}{\sum_{q=1}^4 n_{j,q}} \quad 31$ $se'_j = \sqrt{\frac{\sum_{q=1}^4 [s_{j,q}^2 \times (n_{j,q} - 1)]}{\sum_{q=1}^4 (n_{j,q} - 1) \sum_{q=1}^4 n_{j,q}}} \quad 32$ $Lower\ CL = D'_j - t_{0.975,df} \times se'_j \quad 33$ $Upper\ CL = D'_j + t_{0.975,df} \times se'_j \quad 34$
<p><b>Bias for a single reporting organization (<math>D'</math>) - Annual Basis.</b> The reporting organizations mean bias is calculated using Equation 35, where variables are as defined in equations 31 and 32.</p>	$D' = \frac{1}{n_j} \times \sum_{i=1}^{n_j} D'_j \quad 35$
<b>FRM Audits</b>	
<p><b>Accuracy for a Single Sampler, Quarterly Basis (<math>d_j</math>).</b> The percentage difference, <math>d_j</math>, for each check is calculated using Equation 26, where <math>X_i</math> represents the concentration produced from the FRM sampler and <math>Y_i</math> represents the concentration reported for the primary sampler. For quarter <math>q</math>, the bias estimate for sampler <math>j</math> is denoted <math>D'_{j,q}</math>.</p>	Equation 26
<p><b>Bias of a Single Sampler - Annual Basis (<math>D'_j</math>).</b> For particulate sampler <math>j</math>, the mean bias for the year is derived from the quarterly bias estimates, <math>D'_{j,q}</math>, using Equation 31, where <math>n_{j,q}</math> equals 1 because one FRM audit is performed per quarter.</p>	Equation 31
<p><b>Bias for a single reporting organization - Annual Basis (<math>D'</math>).</b> The reporting organizations mean bias is calculated using Equation 35, where variables are as defined in Equations 31 and 32.</p>	Equation 35

*Appendix C*  
*Training Certification Evaluation Forms*

The following forms will be used by the PEP to certify the PM<sub>2.5</sub> field and laboratory personnel have performed environmental data operations at a satisfactory level.

**Trainee's Name** \_\_\_\_\_ **Date** \_\_\_\_\_

**Field Performance Examination Checklist**

<b>STANDARD OPERATING PROCEDURE</b>	<b>ACCEPT</b>	<b>RETEST</b>
<b>PEPF 02.01 Equipment Inventory</b>		
1. General knowledge of the requirement for inventorying and procuring equipment		
Notes:		
<b>PEPF 02.02 Communications</b>		
1. General knowledge of the communication requirements		
2. Knowledge of the use of the phone communication form		
3. Knowledge of when, and how often to talk with the Reporting Organizations		
4. Knowledge of the monthly progress report and the expected information		
Notes:		
<b>PEPF 02.03 Site Visit Preparation</b>		
1. Understanding of the requirements for the Site Data Sheet		
2. Knowledge of the appropriate days to sample and when it is possible to sample at a different schedule		
3. Procedure for site visit equipment preparation		
4. Knowledge of critical filter holding time requirements		
Notes		

STANDARD OPERATING PROCEDURE		ACCEPT	RETEST
<b>PEPF 03.01 Cassette Receipt, Storage and Handling</b>			
1. Understands process required in receiving filters from the laboratory			
2. Knowledge of procedure for storing filters at the field office during transport to the field and if samples must come back to the field office			
3. Good knowledge of procedure for handling pre-exposed and exposed filters			
Notes:			
<b>PEPF 04.01 Sampler Transport and Placement</b>			
Field Scientist safely transports the main unit and transport boxes to the sampling location			
Notes:			
<b>PEPF 05.01 Sampler Assembly/Disassembly</b>			
Field Scientist properly assembles the unit [Overall]			
	Legs		
	AC Power supply		
	Weather shroud (back plate)		
	Gill screen		
	Inlet Assembly and downtube		
	Install WINS impactor assembly		
	Filter transport removal		
Field Scientist properly powers the unit			
Field Scientist properly set date/time			
Field scientist properly disassembled unit by storing components in correct transport cases			
Notes:			

<b>STANDARD OPERATING PROCEDURE</b>		<b>ACCEPT</b>	<b>RETEST</b>
<b>PEPF 05.02 Sampler Maintenance and Cleaning</b>			
Field scientist properly identifies and performs maintenance areas to be checked each visit [Overall]			
	Water collector		
	Impactor well		
	O-rings of impactor assembly		
	Field Scientist properly identifies and performs maintenance on the downtube		
Field Scientist properly identifies and performs maintenance on the O-rings of the inlet			
Notes:			
<b>PEPF 06.01 Leak Check Procedures</b>			
1. Sampler set up properly.			
2. Correct "screen."			
3. Vacuum released slowly.			
4. Awareness of internal leak procedure.			
5. Data entry to form.			
6. Troubleshooting explanation.			
Notes:			
<b>PEPF 06.02 Barometric Pressure Verification Check</b>			
1. BP transfer standard correctly set and stable.			
2. Correct sampler "screen."			
3. Data entry to form.			
4. Troubleshooting explanation.			
Notes:			

<b>PEPF 06.03 Temperature Verification</b>		
1. Temp. transfer standard correctly set and stable.		
2. Correct sampler "screen."		
3. Ambient T check done properly.		
4. Filter T check done properly.		
5. Data entry to form.		
6. Troubleshooting explanation.		
7. Awareness of filter T overheat flag.		
Notes:		
<b>PEPF 06.04 Flow Rate Verification</b>		
1. Flow transfer standard correctly installed and zeroed.		
2. Flow rate filter installed.		
3. Correct sampler "screen."		
4. Data entry to form.		
5. Calculations with FTS equation.		
6. Comparison of FTS with sampler flow rate.		
7. Comparison of FTS with design flow rate.		
8. Return to normal operation.		
9. Troubleshooting explanation.		
Notes:		
<b>PEPF 08.01 Conducting the Filter Exposure</b>		
1. Install Cassette in sampler. Include inspection, documentation of cassette ID and placement of 3"x5" bag.		
2. Program in cassette ID and AIRS code to sampler.		
3. Program to run sampler for the next day		
4. Program sampler to run day after next		
Notes		

<b>PEPF 08.02 Filter Sample and data Retrieval</b>		
1. Record Information on Field Data Sheet from Run		
2. Remove filter cassette from sampler and recover. Include inspection, any needed documentation, and placement in 3"x5" bag.		
3. Download data to laptop computer and 3.5" disk.		
Notes		
<b>PEPF 08.03 Filter Packing and Shipment</b>		
1. Packing procedure performed properly		
2. All items in cooler		
3. Time requirements for shipment known		
4. Appropriate documentation/data shipped		
Notes:		
<b>PEPF 09.01 Chain of Custody and Field Data Sheet</b>		
1. Data sheet appropriately and completely filled out		
2. Chain of custody appropriately filled out		
Notes		
<b>PEPF 10.01 Quality Assurance/Quality Control</b>		
1. General knowledge of the required QA activities for program		
2. Is aware of the frequencies of the QA/QC activities		
Notes		

PEPF 11.01 Information Retention		
1. General knowledge of the information retention requirements		

Instructor's Name \_\_\_\_\_

Instructor's Name \_\_\_\_\_

Instructor's Name \_\_\_\_\_

Instructor's Name \_\_\_\_\_

## Performance Examination Checklist for Weighing Laboratory Training

Trainee: \_\_\_\_\_

Date: \_\_\_\_\_

Evaluator: \_\_\_\_\_

Fully Successful: \_\_\_\_\_

WEIGHING LABORATORY ACTIVITY	Success (Yes/No)	COMMENTS
<b>PEPL-6.01 FILTER CONDITIONING (<i>Pre-Sampling</i>)</b>		
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 lab coat.		
6. Use forceps to handle filters only by their rings.		
7. Inspect filters for defects.		
8. Transfer acceptable filters to Petri dish. Place cover 3/4 across, put dish on tray and tray in rack. Transfer reject filters to envelope.		
9. Record data on filter inventory form.		
10. Conduct presampling filter conditioning test with three filters from the batch and weigh periodically until weights stabilize. Keep filters in conditioning environment until conditioning period is complete.		
<b>SCORE</b>		<b>OF 10 POSSIBLE</b>

WEIGHING LABORATORY ACTIVITY	Success (Yes/No)	COMMENTS
<b>PEPL-8.01 FILTER WEIGHING (<i>Presampling and Post-Sampling</i>)</b>		
1. Record temperature and RH of the conditioning period and record on appropriate data form. Check whether they meet the acceptance criteria.		
2. Put on gloves and lab coat.		
3. Clean the microbalance's weighing chamber with appropriate brush. 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 first working mass reference standard. Record value on the appropriate form. Compare this value against verified value.		
8. Weigh second working mass reference standard. Record value on the appropriate form. Compare this value against verified value.		
9. Close chamber door and check zero.		
10. Select filter, record ID, and indicate filter type on appropriate data form.		
11. Use appropriate forceps to handle filters only by their outside ring. Move filters from Petri dishes to antistatic strip and wait for 30 to 60 seconds.		
12. Move filters from antistatic strip to center of microbalance weighing pan and close draft shield.		
13. Weigh the filters and return them to Petri dishes. Record weighing data on 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. Check for agreement with previous values.		
15. At the end of the batch, reweigh the two working standards. Record the working standard measurements on the appropriate form. Check for agreement with verified values.		

WEIGHING LABORATORY ACTIVITY	Success (Yes/No)	COMMENTS
16. Weigh laboratory blanks; record, check for agreement with previous values, and return them to Petri dishes that are labeled as laboratory blanks.		
17. Save appropriate filter for reweighing with the next batch (only in postsampling).		
<b>SCORE</b>		<b>OF 17 POSSIBLE</b>
<b>PEPL-8.01 FILTER WEIGHING and PEPL-9.01 SHIPPING</b> ( <i>Filter Shipping to Field</i> ) <b>Instructor: Tim Hanley</b>		
1. Put on gloves and lab coat.		
2. Select weighed filter and clean cassette, record cassette ID on appropriate form.		
3. Use forceps to handle filters. Hold the filter only by the outside ring.		
4. Move filters from Petri dishes to bottom section of filter cassette that has a backing screen and secure with cassette top.		
5. Record cassette ID on new 3"x5" antistatic self sealing bag.		
6. Put caps on the filter/cassette assemblies.		
7. Put capped filter/cassette assemblies into labeled 3"x5" bag.		
8. Add the cassette ID and presampling weighing date to appropriate form.		
9. Select filter cassette assemblies still contained in 3"x5" bag from appropriate form.		
10. Completely fill in appropriate section of COC-2.		
11. Place multiple filter cassette assemblies each still in 3"x5" bags with appropriate COC's in larger 9"x12" bag.		
12. Wrap in bubble wrap, pack, fill out FedEx shipping papers, and notify Regional Office Field Scientist of the shipment.		
<b>SCORE</b>		<b>OF 12 POSSIBLE</b>

WEIGHING LABORATORY ACTIVITY	Success (Yes/No)	COMMENTS
<b>PEPL-10.01 FILTER CHAIN OF CUSTODY (<i>Filter Receipt Procedure</i>)</b>		
1. Open shipping container. Find cassette assemblies, chain of custody form COC-2, field data sheet, and sampler data diskette. Check over to ensure shipment is complete and data sheets are appropriately filled out.		
2. Store diskette in folder by Region.		
3. Completely fill out Part V of COC-2. Record temperature data on chain-of-custody form. Move sealable bags to refrigerator or weigh room depending on when post sample weighs are to be performed.		
4. Describe how long filter cassette assemblies in the 3"x5" bag should be thermally equilibrated in the weigh room before opening.		
<b>SCORE</b>		<b>OF 4 POSSIBLE</b>
<b>PEPL-6.01 FILTER CONDITIONING (<i>Post-Sampling</i>) and PEPL-10.01 FILTER CHAIN OF CUSTODY (<i>Filter Receipt Procedures</i>)</b>		
1. Match cassette ID/filter type on bag with COC-2		
2. Remove filter cassette assembly from 3"x5" sealable bags.		
3. Remove caps from filter/cassette assemblies.		
4. Put on gloves and remove filter from cassette.		
5. Use forceps to handle filters. Hold the filter only by the rings.		
6. Inspect filters for defects.		
7. Move filters from cassettes to Petri dishes. Label Petri slide with filter ID and filter type. Put cover 3/4 over dish. Put dish on tray and tray in rack.		
8. Allow the filter to condition for not less than 24 hours. Conduct postsampling filter conditioning test with three filters before the remainder of the batch is weighed.		
<b>SCORE</b>		<b>OF 8 POSSIBLE</b>
<b>Trainee 100% successful:</b>		

## *Appendix D*

### *Data Qualifiers/ Flags*

A sample qualifier or a result qualifier consists of 3 alphanumeric characters which act as an indicator of the fact and the reason that the subject analysis (a) did not produce a numeric result, (b) produced a numeric result but it is qualified in some respect relating to the type or validity of the result or © produced a numeric result but for administrative reasons is not to be reported outside the laboratory.

**Field Qualifiers**

Code	Definition	Description
CON	Contamination	Contamination including observations of insects or other debris
DAM	Filter Damage	Filter appeared damaged
EST <sup>1/</sup>	Elapsed Sample Time	Elapsed sample time out of specification
EVT	Event	exceptional event expected to have effected sample (dust, fire , spraying etc)
FAC	field accident	There was an accident in the field 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 <sup>1/</sup>	Flow Rate	Flow rate 5 min avg out of specification
FLT <sup>1/</sup>	Filter Temperature	Filter temperature differential, 30 minute interval out of specification
FMC	Failed Multi point Calibration Verification	Failed the initial Multi point 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

<sup>1/</sup>- Flag generated by sampling equipment

**Laboratory Qualifiers**

Code	Definition	Description
ALT	alternate measurement	The subject parameter was determined using an alternate measurement method. Value is 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

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	The analysis of this parameter was canceled and not preformed.
CBC	cannot be calculated	The 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.
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.
INV	invalid sample	due to single or a number of 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, this data was not utilized in the calculation of the mean.

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REQ	reque 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 reanalysis 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 utilized 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