

Panel Discussion

The PM2.5 Quality System

Are there attributes of the quality system that added little additional value?

Are there some positive attributes in the quality system and what are they?

Are there redundancies in the quality system and what are they?

Are the QA roles and responsibilities at the Federal and State/locals levels appropriate?

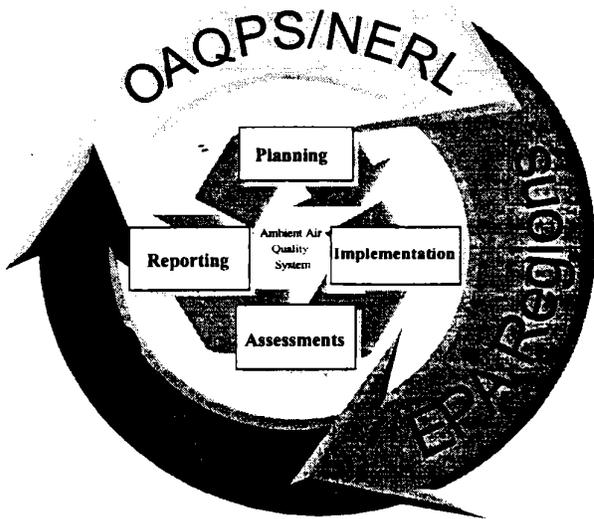
Is there an appropriate level of independence at the Federal and State/locals levels to provide objective assessments of data quality?

How would you improve the quality system?

Panel members:

- | | |
|-----------------|---|
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PM2.5 Quality System Review



This intent of this review is to describe how the major phases of the PM_{2.5} quality system have been implemented, not to describe the detailed technical aspects or rationale for the quality system; this is discussed in a number of guidance documents. This review also focuses mainly on the quality system activities at EPA with recognition that the majority of the quality control and assessment activities occur at the State and local level where quality systems have been developed unique to their situations. OAQPS, in developing this review, could not capture this type of detail.

The review will be categorized into the following sections:

- ▶ Communication
- ▶ Planning
- ▶ Implementation
- ▶ Assessments
- ▶ Reporting

The two major entities involved in the PM_{2.5} implementation include the Federal organizations (OAQPS, NERL and EPA Regions) and the State and local organizations. Following the theme of planning, implementation, assessment and reporting, Table 1 provides a list of the QA roles and responsibilities of these organizations.

As described in the *American National Standard Specifications and Guideline for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E4-1994)*, a quality system is defined as “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 and services. The quality system provides a framework for planning, implementing and assessing work performed by the organization and for carrying out QA and QC”.

The PM_{2.5} quality system was developed and documented to ensure that the PM_{2.5} monitoring results:

- ▶ met OAR’s regulatory and scientific data needs;
- ▶ satisfied customers expectations;
- ▶ complied with applicable standards and specifications;
- ▶ complied with statutory (and other) requirements, and
- ▶ reflected consideration of cost and economics.

Table 1 QA Responsibilities

PM, QA Activities	
Activity/Organization	Responsibilities
Planning OAQPS NERL EPA Regions State/ Locals	QA Regs, DQOs, QA/QC samples, acceptance criteria, guidance documentation, training SOPs PEP, national meetings, AMTIC QA Guidance Document 2.12 DQOs, PEP, systems audit Quality system development, QAPP development, collocation sites, systems audits
Implementation OAQPS NERL EPA Regions State/ Locals	Field/laboratory training, management system reviews, QA Workgroup, PEP, AMTIC Forum. Technical arbiter, reference and equivalent method program Field/laboratory training, answering technical questions. ESAT WAM, QAPP approval, technical systems audits, network reviews, data reviews Quality control, verification, validation, data flagging, corrective action, network reviews, local training
Assessments OAQPS NERL EPA Regions State/ Locals	Network reviews, management systems reviews, P&A assessments, data quality assessments, critical review reports Reference and equivalent methods Network reviews and reports, technical systems audits and reports Performance audits, data quality assessments
Reporting OAQPS NERL EPA Regions State/locals	P&A reports, QA reports, Data quality assessments, MSR reports Special studies Network reviews, Technical system audit reports Data quality assessments, Technical system audit reports

While developing the quality system, the following key assumptions or ideas were kept in mind:

- ▶ **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 occur. Development of a quality system is necessary in order to understand where errors are occurring, determine their magnitude, and to improve data quality.
- ▶ **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 $\pm 10\%$
- ▶ **Independent assessments and internal quality control are important-** Development of a quality system requires both components. Independent assessments provide an objective review of the measurement system. The Performance Evaluation Program, 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 collect enough precision and bias information to adequately 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 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.
- ▶ **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.

Communication

The development of a quality system for PM_{2.5} required a coordinated effort between EPA Headquarters and Regions, and the State and local monitoring community. Figure 1 represents the communication network for QA activities. This communication network was used to develop and implement the PM_{2.5} quality system and resolve QA issues. The various groups in this figure have the following responsibilities:

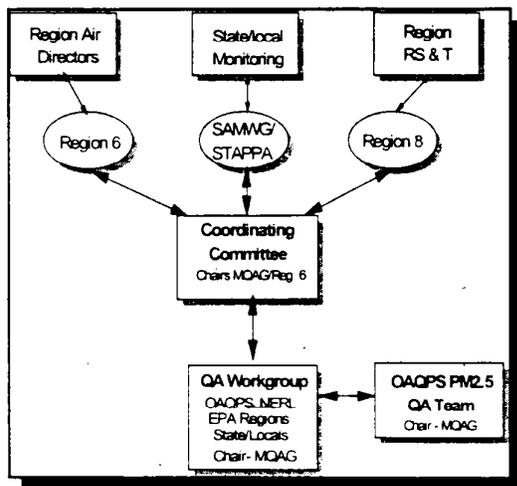


Figure 1

SAMWG/STAPPA/ALAPCO - These organizations represent the State and local perspective of the monitoring program and participated on many of the QA conference calls. STAPPA/ALAPCO also initiated a conference call with OAQPS and the Regions. The QA Workgroup chair attends this conference call.

Region 6- Region 6 is responsible for the coordination of monitoring activities. The Region is responsible for assisting in the dissemination of information from OAQPS to the Regional Air Directors and coordinating the responses and issues from the Regions.

Region 8 - Similar to Region 6's responsibilities, Region 8 is responsible for acting as a liaison between OAQPS and the Regional Science and Technology (RS&T) Divisions. These Divisions play an important role in the mass activity by assisting in the FRM Performance Evaluation Program (PEP) and establishing two national weighing laboratories.

Coordinating Committee - This committee, co-chaired by Region 6 and OAQPS/MQAG was established to address issues related to the implementation of the monitoring program. The co-chairs of the QA workgroup sit on this committee and report on QA issues needing resolution or

clarification. This committee meets every two weeks.

PM_{2.5} QA Workgroup- This group is made up of OAQPS, NERL, EPA Regions, and State and local participants and it is used as an advisory group to assist the OAQPS PM_{2.5} QA Team develop an appropriate and "implementable" quality system. The workgroup is chaired by Region 1 and OAQPS/MQAG. It is used to help develop consensus QA approaches, resolve specific QA issues, and is also used as a communication device to ensure the Regional Air Directors, Regional Science and Technology (RS&T) Directors, and State and local monitoring communities have input into the development of the quality system. Initially the group met about every two weeks, and was reduced to monthly calls in the summer of 99. Presently, calls are less frequent.

In addition, during the implementation year of 1999 another workgroup was formed specifically for the development of validation activities which resulted in the Data Validation Template.

OAQPS QA Team- The QA Team is made up of QA personnel in the OAQPS Monitoring and Quality Assurance Group (MQAG) and meets weekly to address implementation of the PM_{2.5} quality system, develop budget allocations, develop/revise regulations, guidance and training, address specific technical issues and ensure proper communications among Headquarters, Regions, ORD, and State and local monitoring community. This group is ultimately responsible for the development of the quality system and its related guidance and training.

Ambient Monitoring Technology Information Center (AMTIC)

Another important avenue of communication on QA activities is AMTIC. AMTIC presently has an area devoted to PM_{2.5} monitoring. Included in this area is a topic on QA. Important information and guidance documents continue to be posted in this area. During the 99 implementation year, the EPA Regions, NERL and OAQPS were hit with many implementation questions. In many cases the same questions were being asked multiple times. In order to provide more informative and consistent responses, MQAG developed a question/answer forum. State and locals could ask questions on this forum as well as weigh in on responses, and in a way, help each other.

Planning

Table 2 provides a summary of the major QA planning products produced for the Mass PM_{2.5} Monitoring Program. This section will provide brief discussions on the data quality objects (DQOs), implementation plans, methods development, training and guidance.

Table 2 Planning Products

Product	Date
PM _{2.5} data quality objective (DQOs)	5-7/97
Development/revision of QA/QC in CFR Parts 50 and 58	5-7/97
PM _{2.5} Implementation Plans	3/98
Method 2.12	5/98, 11/98

PM2.5 Model QAPP	4/98 *
Revision of QA Handbook Vol II including PM2.5	8/98
Training Broadcasts -Distant Learning Network Regional Haze/ PM2.5 Monitoring Network Design-	10/97 3/98
Balance Room/Monitor Operations Quality Assurance/Quality Control	6/98 10/98
Performance Evaluation Program Implementation Plan Field - Lab SOPs PEP QAPP	8/98 11/98 - 10/98 2/99

PM2.5 Data Quality Objectives

Data collected for the Ambient Air Quality Monitoring Program are used to make very specific decisions that can have an economic impact on the area represented by the data. Data quality objectives (DQOs) are a full set of performance constraints needed to design a monitoring network, including a specification of the level of uncertainty that a decision maker (data user) is willing to accept in the data to which the decision will apply. 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 "nonattainment" when the area is actually in "attainment" (false positive error) or "attainment" when actually the area is in "nonattainment" (false negative error). By applying the DQO Process to the development of a quality system for PM_{2.5} the EPA attempted to guard against committing resources to data collection efforts that did not support a defensible decision.

During the spring and summer of 1997 OAQPS implemented the DQO process in order to identify the bias and precision required to make attainment/nonattainment decisions within a known level of confidence. In summary, precision should be controlled to 10% coefficient of variation and bias to $\pm 10 \mu\text{g}/\text{m}^3$ in order to make attainment decisions with a 95% probability of making the correct decision. The DQO process was used by the OAQPS QA team to develop the implementation requirements for collocated sampling, the PEP and the acceptance criteria for various quality control samples implemented at the various measurement phases of the data collection effort.

Implementation Plans

Two implementation plans were developed for the Mass PM_{2.5} program. The first, the *Implementation Plan PM2.5 Monitoring Program* was developed in 3/98 with the intent of describing the rationale underlying the network and its components, establishing and affirming major products (e.g., training programs, procurements) and time lines required to implement the network, defining roles and responsibilities of organizational groups and individuals and generating consensus among those responsible for network deployment.

The second implementation plan *PM2.5 Performance Evaluation Program Implementation Plan* was developed to describe, similarly to the plan mentioned above, the implementation aspects of the PEP program

Methods

In order to ensure consistent implementation of PM_{2.5} environmental data operations, the following methods were developed:

QA Guidance Document 2.12 - The National Exposure Research Laboratory was responsible for the initial development of this guidance document. The *QA Guidance Document 2.12* includes field and laboratory guidance for the routine operation of designated reference or class 1 equivalent methods. It was placed on AMTIC for State/local review and comment in 5/98 and completed 11/98. The final method will be incorporated into the *Quality Assurance Hand Book for Air Pollution Measurement Systems- Volume II Ambient Air Specific Methods*. This document will be referred to as the *QA Hand Book* for the remainder of this section.

FRM Performance Evaluation Program (PEP) Standard Operating Procedures (SOPs) - Detailed SOPs were developed for the field and laboratory aspects of the PEP. The Field SOPs were completed 11/98 and the lab SOPs were completed 10/98.

Training

A number of training activities which were either devoted to QA or included QA were developed. Table 2 includes the Distant Learning Broadcasts that were conducted for Mass PM_{2.5}. Tapes of these broadcasts are available.

The Air Pollution Training Institute (APTI) has also presented the following three classroom courses revised to contain PM_{2.5} monitoring and quality assurance information:

APTI:470 QA for Air Pollution Measurement Systems - March 22-25, 1999 Sacramento, CA

APTI:435 Atmospheric Sampling - May 10-14, 1999 New Brunswick, NJ
- August 16-20, 1999 San Juis Obispo, CA

Training activities were posted on the PM_{2.5} area of the AMTIC bulletin and were frequently updated by the system operator.

In addition, various monitoring organizations (WESTAR, LADCO, NESCAUM, MARAMA etc.) put on training courses in 97-99.

Field and laboratory personnel implementing the PEP also received detailed training which involved four phases:

1. **Classroom lecture**- an overall review of the PM_{2.5} program and its 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 were taken to the training area where the field/lab activities were demonstrated and then the trainees performed under instruction
3. **Certification-Written exam**- a written test (open book) to cover the activities of importance in each of the training modules (must get a 90%)

4. Certification-Performance evaluation- this is a review of the actual field implementation activities under evaluation by the trainer/evaluator. 100% for passing

Two field training courses and two laboratory training courses were conducted in late 1998 prior to PEP implementation. The training courses were also attend by at least one representative for each EPA Regional office as well as a number of State and local personnel.

Guidance

Guidance served to provide additional details and explanations of the Federal Regulation for PM_{2.5}. The following guidance documents were developed for this program:

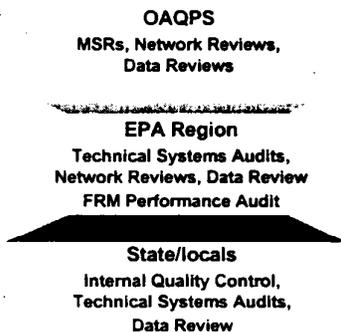
QA Handbook -The intent of the Handbook was twofold. First, the document was written for technical personnel at State and local monitoring agencies to assist them in developing and implementing a *quality system* for the Ambient Air Quality Surveillance Program. Second, the Handbook provided additional information and guidance on the material covered in the Code of Federal Regulations (CFR) pertaining to the Ambient Air Quality Surveillance Program. Where appropriate, each section of this document included information for PM_{2.5} for the mass measurement. The Handbook was revised 8/98.

Model QAPP - Due to the accelerated time frame for implementation of the program, OAQPS, in cooperation with the EPA Regions and State and Local organizations, developed a model QAPP to serve as an example of the type of information and detail necessary for the QAPPs submitted by State and local organizations to EPA Regions. At the completion of the final revision, the Model QAPP was submitted to the Regional QA Managers for review and approval. This was done to ensure that if States developed QAPPs at this level of detail they would be considered "approvable". Signatures were received by 9 Regional QA managers and 1 delegate. The Model QAPP was completed 4/98

Technical Systems Audit (TSA) - Both EPA Regions and State/locals are required to perform technical systems audits at required frequencies. The TSA guidance currently available for the Ambient Air Monitoring Network included in the *QA Hand Book* was revised for PM_{2.5}

Implementation

Table 1 presents a listing of the implementation responsibilities of the organizations participating in the PM_{2.5} monitoring activity. Implementation in the PM_{2.5} quality system is defined as those quality assurance activities whose intent it is to control and/or evaluate either the entire measurement system or a phase of the system. Due to the fact that many of the QA activities have been successfully implemented for other criteria pollutants in the Ambient Air Monitoring Network, their implementation does not need to be discussed here. This section will focus on some of the more major QA/QC activities



QA Implementation Structure

The quality system for PM_{2.5} has been developed at three levels of oversight. Since EPA policy states that data collected using the public resources must have a quality system in place and it also states that quality assurance is an inherently governmental function, OAQPS and the EPA Regions have developed a quality system that will allow for independent assessments of the quality assurance program, at each level, to ensure that the DQOs are met.

Quality Control

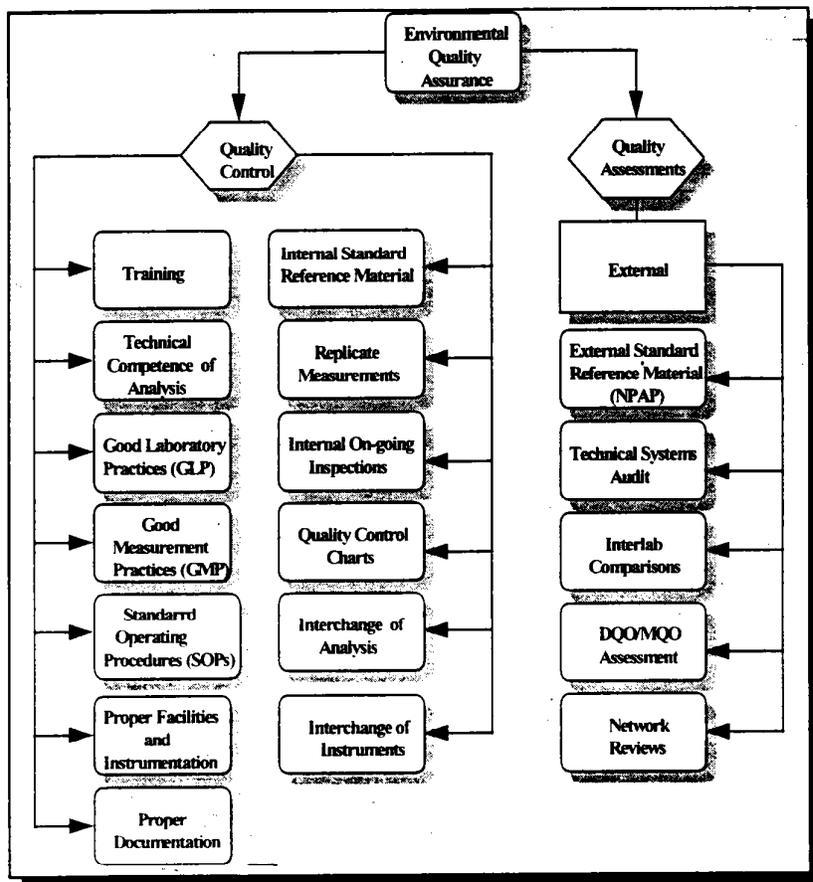


Figure 2 Types of Quality Control and Quality Assessment Activities

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; that are used to fulfill requirements for quality. Figure 2 illustrates a number of QC tools. In the case of the Ambient Air Quality Monitoring Network, QC activities are used to ensure that measurement uncertainty, is maintained within established acceptance criteria for the attainment of the DQOs discussed above.

Federal regulation provides for the implementation of a number of qualitative and quantitative checks to

ensure that the data will meet the DQOs. Each of the checks attempts to evaluate phases of measurement uncertainty. All of the required QA/QC activities are included in *QA Guidance Document 2.12* and the *QA Handbook*. Figure 3 represents a few of the checks that are used in the PM_{2.5} quality system. However, the DQOs are based upon two quality control activities; the collocated sample pairs and the FRM Performance Evaluation Program, since they provide the greatest level of aggregation of errors across the measurement system.

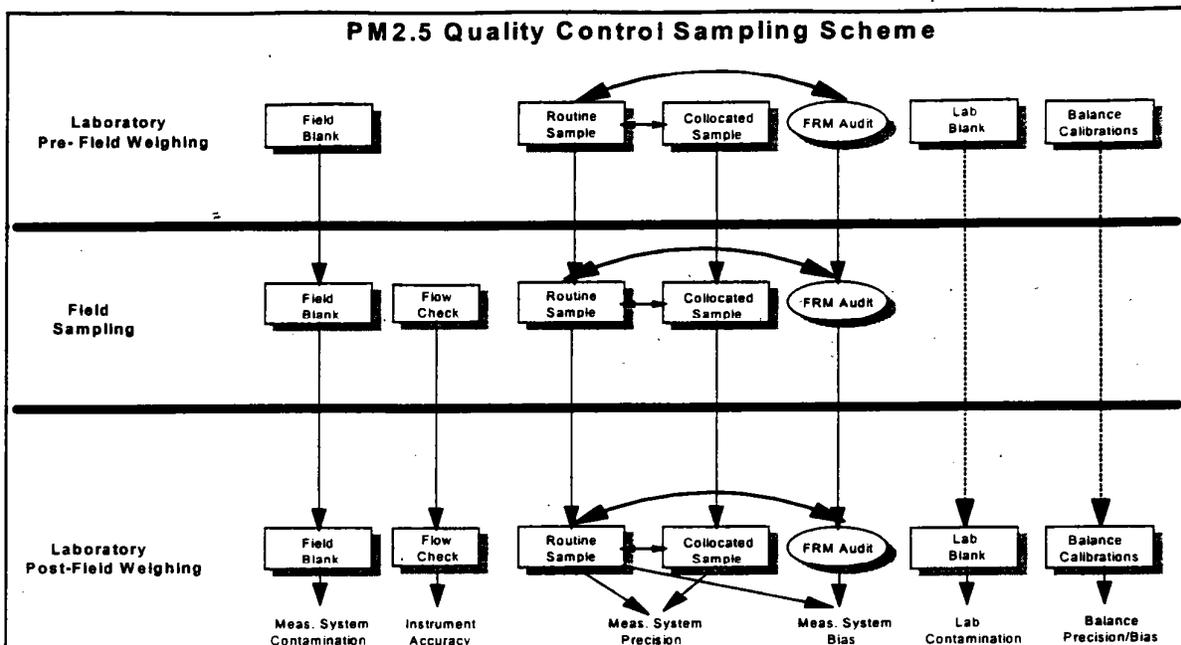


Figure 3 Flow of quantitative quality control samples

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 was prioritized to sites in areas likely to be designated nonattainment, or at least to sites with higher concentrations. EPA recommended 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_{2.5} sites in the network. Obviously, for the new PM_{2.5} network, the selection had to be somewhat subjective and based upon the experience of State and local organizations.

Collocated Monitoring- The implementation of the collocated monitors for PM_{2.5} is very similar to the collocated monitoring scheme for PM₁₀. 40 CFR Part 58 Appendix A and the *QA Handbook* discuss the implementation aspects of this QC activity. State/locals organizations are responsible for the implementation of this activity which will be discussed in their QAPPs

FRM Performance Evaluation Program-The intent of the FRM Performance Evaluation Program (PEP) is to provide an estimate of total measurement system bias, for evaluation against the bias DQO. It was felt that the PEP would produce the most reliable results if it is conducted by an organization **independent** of the organization routinely collecting samples, which would allow for a complete estimate of measurement system bias. A definition of independence was needed. A definition, modified from the *American National Standard - Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* was developed through QA Workgroup discussions. State and locals

could implement the FRM performance audit if they can meet the definition of independence.

Due to a number of reasons, both technical and logistical, OAQPS proposed that the State/locals utilize a federally implemented program. This approach was accepted. OAQPS developed a Memorandum of Understanding with the Environmental Protection Agency's (EPA's) Office of Emergency and Remedial Response (OERR) Contract Management Center (CMC) to "buy-in" to the Superfund Environmental Service and Assistance Team (ESAT) contract. The ESAT contract already had technical personnel stationed in each EPA Region who were available to perform the field activities for the PEP. For laboratory activities, two EPA Regions, (Regions 4 and 10) volunteered to serve as national weighing laboratories and utilized ESAT contractors to perform the required technical activities.

As mentioned earlier, an implementation plan, a QAPP, and field and laboratory SOPs were developed for this activity as well as the training and certification process.

Data Validation-In June 1998, a workgroup was formed to develop a procedure that could be used by State and locals that would provide for a consistent validation of PM_{2.5} mass concentrations across the US. The workgroup included State and locals, EPA Regional Offices, and OAQPS personnel who are involved with assuring the quality of PM_{2.5} mass and was headed by a State and local representative. The workgroup developed three tables of criteria where each table has a different degree of implication about the quality of the data. The criteria included on the tables are from 40 CFR Part 50, 40 CFR Part 50 Appendices L and N, 40 CFR Part 58 Appendix A, Method 2.12, and a few criteria that are neither in CFR nor Method 2.12.

Assessments

An assessment is an evaluation process used to measure the performance or effectiveness of the system and its elements. For the PM_{2.5} network, assessments will include: network reviews technical systems audits, and management systems reviews and data quality assessments. Table 1 indicates the organizations responsible for the various assessments.

Network Reviews - Conformance with network requirements of the Ambient Air Monitoring Network set forth in 40 CFR Part 58 Appendices D and E are determined through annual network reviews of the ambient air quality monitoring system. The network review is used to determine how well a particular air monitoring network is achieving its required air monitoring objective, and how it should be modified to continue to meet its objective. The network reviews are accomplished by the EPA Regional Office. In order to maintain consistency in implementing and collecting information from a network review, EPA developed *SLAMS/NAMS/PAMS Network Review Guidance*. This document was completed in 6/98 by OAQPS with cooperation from the EPA Regions.

Technical Systems Audits - A systems audit 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. A systems audit of each state or autonomous agency within an EPA Region is performed annually by a member of the Regional Quality Assurance (QA) staff. As part of the NAAQS revision, the technical systems audit was revised from every year to once every 3 years for a State and local

organization. Detailed guidance of the audits performed by the EPA and the State and local organizations is found in the *QA Handbook*. Tracking of the audits will occur on the new reengineered AIRS system. In addition, State and locals also perform these audits as an independent assessment of data collection activities. State and locals will include information on the details and the frequencies of the audits in their respective QAPPs. In addition, State and locals were invited to audit the PEP activities which include audits of the field and national laboratories.

Management Systems Reviews (MSR) - This is a qualitative assessment of a data collection operation or organization to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. This would allow OAQPS to assess consistency of operation among the Regions and improve the quality system. The MQAG implemented 3 management systems reviews in 1999.

Data quality assessment (DQA) - is the scientific and statistical evaluation to determine if data are of the right type, quality, and quantity to support their intended use. Since DQOs have been developed for the PM_{2.5} attainment/nonattainment objective, the QA/QC data can be statistically assessed at various levels of aggregation to determine whether the DQOs have been attained. The statistics to be used to evaluate precision and bias were included in *40 CFR Part 58 Appendix A*. The data quality assessments of precision and bias will be aggregated at the following three levels.

- ▶ **Monitor** - monitor/method designation
- ▶ **Reporting Organization** - monitors in a method designation, all monitors
- ▶ **National** - monitors in a method designation, all monitors

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 next revision of the *QA Hand Book*.

Presently, OAQPS/MQAG is performing these assessments on the data available in AIRS. OAQPS anticipates developing a DQA report each year in the August-September time frame.

Reporting

PM_{2.5} data will require data assessments to evaluate the attainment of the DQOs and reports of these assessment reviews. The following types of reports are anticipated

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*.

Assessment Reports - Technical systems audits and network reviews will be on file at the EPA Regional office with tracking information on AIRS (reengineered AIRS). Management systems audits will be on file in MQAG.

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. The first report is expect to be out in August-September 2000.