

United States  
Environmental Protection  
Agency  
Research Triangle Park, NC 27711

EPA 454/R-01-011  
Office of Air Quality  
Planning and Standard  
Office of Air and Radiation

---



# Quality Management Plan For the PM Supersites Program



## ***Foreword***

The following document is a Quality Management Plan (QMP) for the environmental data operations of the PM Supersites Research Monitoring Program. The Office of Air Quality Planning and Standards (OAQPS) staff developed this QMP to outline the roles of organizations involved in the Supersites Particle Monitoring Program.

This QMP was generated using the EPA Quality Assurance (QA) regulations and guidance as described in *EPA QA/R-2*, *EPA Requirements for Quality Management Plans* and the accompanying document, *EPA QA/G-2, Guidance for Developing, Reviewing and Implementing Quality Management Plans*. All pertinent elements of the QMP regulations and guidance are addressed in this document.

## ***Acknowledgments***

This QMP is the product of the EPA Office of Air Quality Planning and Standards. The following individuals are acknowledged for their contributions.

### **Principle Authors**

Dennis Mikel, OAQPS-EMAD-MQAG, Research Triangle Park, North Carolina  
Michael Papp, OAQPS-EMAD-MQAG, Research Triangle Park, North Carolina  
Dr. Les Hook, Oak Ridge National Laboratory, Oak Ridge, Tennessee  
Dr. Sigurd Christensen, Oak Ridge National Laboratory, Oak Ridge, Tennessee

### **Reviewers**

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

JoAnn Rice, Dr. Richard Scheffe, Dr. Marc Pitchford, Joe Elkins, Michael Jones

#### **Office of Research and Development**

Dr. Paul Solomon, Las Vegas, Nevada

#### **Parsons Corporation**

David Bush

#### **National Oceanic and Atmospheric Administration**

Jeffrey West

#### **College of Engineering, Center for Environmental Research and Technology**

Dennis Fitz, David Gemmill

#### **Comments and questions can be directed to:**

Dennis Mikel, OAQPS, RTP, NC

[mikel.dennisk@epa.gov](mailto:mikel.dennisk@epa.gov)

## *Acronyms and Abbreviations*

AIRS	Aerometric Information Retrieval System
APTI	Air Pollution Training Institute
ASTM	American Society for Testing and Materials
CAA	Clean Air Act
CFR	Code of Federal Regulations
DQA	data quality assessment
DQOs	data quality objectives
EDO	Environmental Data Operation
EMAD	Emissions, Monitoring, and Analysis Division
EPA	Environmental Protection Agency
FIPS	Federal Information Processing Standards
IMPROVE	Interagency Monitoring of Protected Visual Environments
LAN	local area network
LIMS	Laboratory Information Management System
MQAG	Monitoring and Quality Assurance Group
MQOs	measurement quality objectives
MSR	management system review
NAAQS	National Ambient Air Quality Standards
NAMS	national air monitoring station
NAREL	National Air and Radiation Environmental Laboratory
NARSTO	formerly North American Research and Stratospheric Transport of Ozone
OAQPS	Office of Air Quality Planning and Standards
PC	personal computer
PE	performance evaluation
QA/QC	quality assurance/quality control
QA	quality assurance
QAC	quality assurance coordinator
QAFR	quality assurance final report
QAO	quality assurance officer
QAPP	quality assurance project plan
QS	quality staff
QSSC	NARSTO Quality Systems Science Center
QMP	quality management plan
R&IE	Radiation and Indoor Air
SLAMS	state and local monitoring stations
SOP	standard operating procedure
TSA	technical system audit

## ***Tables***

<i><b><u>Number</u></b></i>	<i><b><u>Description</u></b></i>	<i><b><u>Page No.</u></b></i>
2.1	QAPP Elements Applicable to Various Programs	4
2.2	Types of Assessments	7
3.1	Core Ambient Air Training Courses	2
9.1	Assessment Schedule	1

## ***Figures***

<u><i><b>Number</b></i></u>	<u><i><b>Description</b></i></u>	<u><i><b>Section</b></i></u>	<u><i><b>Page</b></i></u>
1.1	Overview of the National Fine Particle Program	1.1	1
1.2	Phase I and II Supersites	1.2	2
1.3	Supersites Project Management Overview	1.2	3
1.4	Flow diagram illustrating major program stages and review	1.2	4
1.5	Supersites implementation general structure	1.3	7
6.1	Data Flow Diagram	6.1	3

## Quality Management Plan Identification and Approval

The attached QMP for the Supersite Research Monitoring Program is hereby recommended for approval and commits the resources and personnel to follow the elements described within.

### Office of Air Quality Planning and Standards

1) Signature: Richard Scheffe Date: 9/11/01

Dr. Richard Scheffe, Group Leader, Monitoring and Quality Assurance Group

2) Signature: Michael Jones Date: 09/05/01

Mr. Michael Jones, Supersite Project Officer

3) Signature: Dennis Mikol Date: 9/5/01

Mr. Dennis Mikol, Supersite Quality Assurance Coordinator

4) Signature: Joe Elkins Date: 9/11/01

Mr. Joe Elkins, OAQPS Quality Assurance Manager

5) Signature: Marc Pitchford Date: Aug 17, 2001

Dr. Marc Pitchford, OAQPS Senior Scientist, Supersite Technical Lead

### Office of Research and Development

1) Signature: Paul Solomon Date: 23 Aug 2001

Dr. Paul Solomon, ORD Senior Scientist Supersite Technical Lead

## Table of Contents

<i><b>Section</b></i>	<i><b>Page</b></i>	<i><b>Revision</b></i>	<i><b>Date</b></i>
<i>Foreword</i>	ii	1	08/08/01
<i>Acknowledgments</i>	iii	1	08/08/01
<i>Acronyms and Abbreviations</i>	iv	1	08/08/01
<i>Tables</i>	v	1	08/08/01
<i>Figures</i>	vi	2	08/08/01
 Title and Approval Page	 1/1	 2	 08/08/01
 Table of Contents	 1/2	 2	 08/08/01
1. Management and Organization		2	08/08/01
1.1 Supersites Program Background	1/9	3	08/08/01
1.2 Roles and Responsibilities	3/9	3	08/08/01
1.3 Principle EPA Coordinators	6/9	3	08/08/01
1.4 Research Groups	8/9	3	08/08/01
2. Quality System and Description		1	08/08/01
2.1 Supersites QA Applications	1/7	1	08/08/01
2.2 Quality Management Plan	1/7	2	08/08/01
2.3 Data Quality Objectives	2/7	2	08/08/01
2.4 Quality Assurance Project Plans	2/7	2	08/08/01
2.5 Standard Operating Procedures	2/7	2	08/08/01
2.6 Assessments	6/7	2	08/08/01
	7/7	2	08/08/01
3. Personnel Qualifications and Training		1	08/08/01
3.1 Personal Qualification	1/3	1	08/08/01
3.2 Training	1/3	1	08/08/01
3.3 Certification	3/3	1	08/08/01
4. Procurement of Items and Services		1	08/08/01
4.1 Sources of Funds	1/10	1	08/08/01
4.2 Procurement of Items	2/10	1	08/08/01
4.3 Procurement of Services	2/10	1	08/08/01
4.4 Assistance Agreements	4/10	1	08/08/01
4.5 EPA Exclusive Versus Discretionary Functions	4/10	1	08/08/01
5. Records and Documentation		2	08/08/01
5.1 Documents Hierarchy and Process	1/4	2	08/08/01
5.2 Document Responsibilities	2/4	2	08/08/01
5.3 Deposition and Storage of Documents and Records	3/4	2	08/08/01
5.4 Deposition of Reports	4/4	2	08/08/01
6. Computer Software and Hardware		1	08/08/01
6.1 Computer Systems Description	1/3	1	08/08/01
7. Planning and Implementation of Work Process		1	09/13/01
7.1 Project Goals and Objectives	1/6	1	08/08/01
7.2 Initial Planning and Conceptualization	3/6	1	08/08/01
7.3 Key Planning Personnel	5/6	1	08/08/01
7.4 Other Planning Activities	5/6	1	08/08/01



<i><b>Section</b></i>	<i><b>Page</b></i>	<i><b>Revision</b></i>	<i><b>Date</b></i>
8. Implementation of Work		1	08/08/01
8.1 Implementation Roles	1/2	1	08/08/01
9. Data Quality Assessments		1	08/08/01
9.1 Program Assessment Techniques	1/4	1	08/08/01
9.2 Reports to Management	2/4	1	08/08/01
9.3 Planning, Training and Authority	3/4	1	08/08/01
10. Data Quality Improvement		1	08/08/01
10.1 Quality Improvement Process	1/3	1	08/08/01
10.2 Quality Improvement Assurance	3/3	1	08/08/01
Glossary	1/4	1	08/08/01
Contact List	1/1	1	08/08/01
Appendix A - Procurement Policy Notice	1/11	1	08/08/01

## 1.0 Management and Organization

The purpose of this section is to document the overall policy, scope, applicability, and management responsibilities of the “Supersites” Program’s quality system. The section will provide a brief description of the Supersites Program and the organization and management of the programs as it relates to the quality assurance aspects.

### 1.1 Supersites Program Background

The Clean Air Act (CAA) requires EPA to revise or update the air quality standards based on review of the latest scientific information on known and potential human health effects associated with Particulate Matter (PM) levels found in the ambient air. In fulfilling this obligation, the EPA reviewed the air quality criteria, National Ambient Air Quality Standards (NAAQS) for PM and epidemiological evidence that shows an association between ambient concentrations of PM and a range of serious health effects. Based on the results of its review, the

EPA revised and promulgated new primary standards for the fine fraction of PM (i.e., particles with aerodynamic diameters less than or equal to [a nominal] 2.5  $\mu$ m, referred to as PM<sub>2.5</sub>) and the regulatory requirements for monitoring the chemical composition of these particles. In response to this promulgation, EPA has instituted a PM<sub>2.5</sub> network.

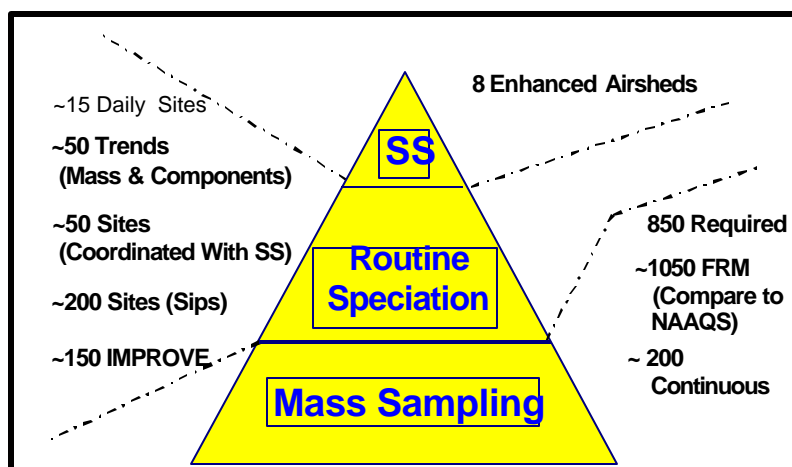


Figure 1.1 Overview of the National Fine Particle Network

Figure 1.1 illustrates the overall national fine particle network. The network is divided into three

tiers. The base is composed of the mass sampling network, for which the mass fine particulate data is collected for comparison to the national ambient air quality standards (NAAQS). The second tier, the Speciation Trends Network (STN) is intended to monitor and gather data on the chemical makeup of fine particles. These STN samplers will be placed at various national air monitoring stations (NAMS) and State and local air monitoring stations (SLAMS) across the Nation. The top tier, the “Supersites” Program is a grant based research program “designed to conduct special, detailed chemical and physical characterization studies in geographic areas with a range of characteristic PM<sub>2.5</sub> source-receptor and health risk situations<sup>1</sup>” This series of analytes is very similar to those measured within the Interagency Monitoring of

Protected Visual Environments (IMPROVE) program. In addition, several STN monitors will be placed at IMPROVE locations (or visa versa) in order to ascertain whether there are statistical and chemical links between these two national networks.

The goals of the Supersites Program took shape at a public PM Measurements Research Workshop held in Chapel Hill, N.C. on July 22 and 23, 1998. To commence the PM Supersites Program, EPA selected two initial sites: Atlanta GA and Fresno CA. These sites, henceforth referred to as Phase I Supersites, were non-competitively selected by virtue of ongoing and planned research activities, which align with those of the PM Supersites Program, and characteristics of the two airsheds. Six additional sites, and the Fresno Phase I site, henceforth referred to as Phase II Supersites, were competitively selected cooperative agreements awarded in January 2000. Figure 1.2 identifies both phase II Supersites and I. the Supersites will address objectives in three major areas:

*1) SIPs.... Support development of State Implementation Plans (SIP's) through improved understanding of source-receptor relationships leading to improved design, implementation, and tracking of control strategy effectiveness in the overall PM program;*

*2) health effects and exposure.....development of monitoring data and samples to support health and exposure studies to reduce uncertainty in National Ambient Air Quality Standards setting and to enable improved health risk assessments; and*

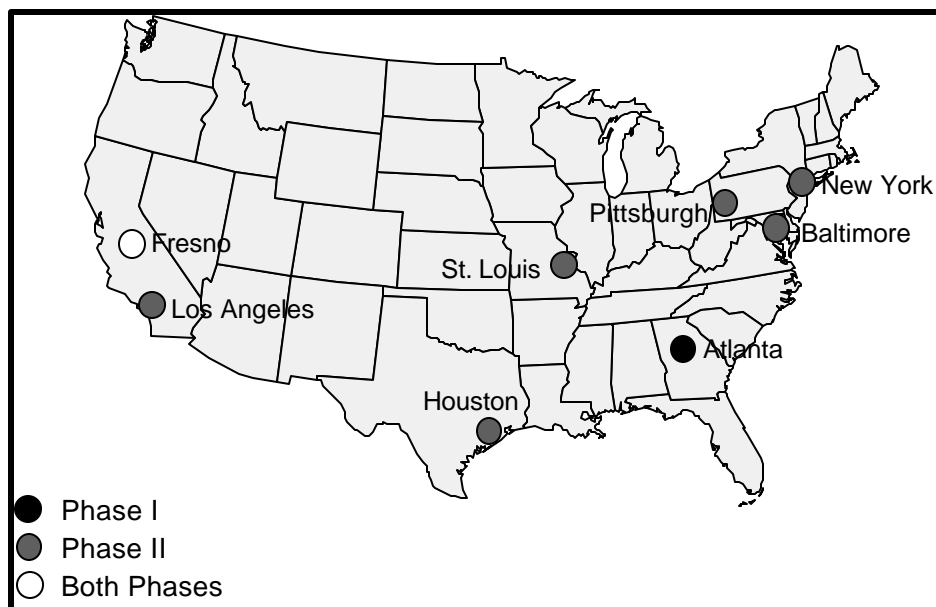


Figure 1.2 Phase I and II Supersites

*3)methods testing.... comparison and evaluation of emerging sampling methods with routine techniques to enable a smooth transition to advanced methods.*

Additional background information on the Supersites program can be found on the Ambient Monitoring and Technology Website (AMTIC) , (<http://www.epa.gov/ttn/amtic/Supersites.html>).

## 1.2 Roles and Responsibilities

### Program Management, Organization and Review

Figure 1.3 provides an overview of program management that will establish the communications and accountability essential for program planning, coordination and implementation.

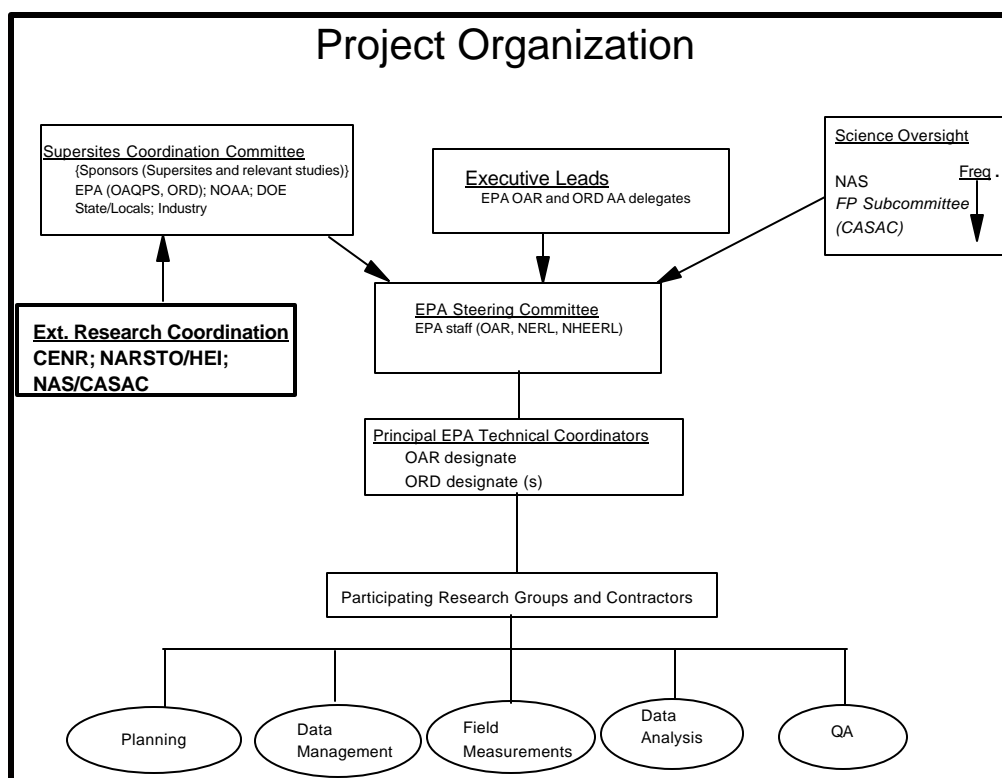


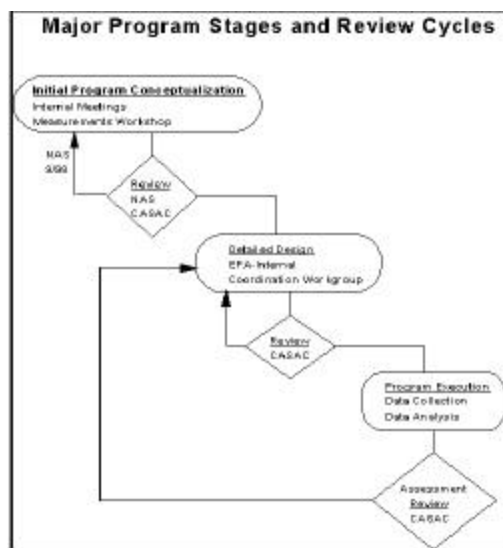
Figure 1.3 Supersites Project Management Overview

## Executive Leads

OAQPS and Office of Research and Development (ORD) will share in the overall administration and management of the program. The Assistant Administrators of both Offices and their designates will be accountable for all program objectives, including the integration of science research sponsored and conducted by EPA with the Supersites program.

## Supersites Coordination Committee

The Coordination Committee will extend beyond EPA to sponsors of related programs in other Federal agencies, industry and State and local agencies. The role of this Committee is to provide a forum for coordination and leveraging of resources by establishing and maintaining a dialogue among the members collectively who share similar needs and interests. In addition, the Coordination Committee would provide a valuable resource in reviewing Supersites plans and assessing progress.



**Figure 1.4 Flow Diagram Illustrating Major Program Stages and Review**

## Science Oversight

The Supersites represent an important component to foster greater integration across several science research programs. The National Academy of Sciences Committee on Research Priorities for Airborne Particulate Matter clearly has expressed a desire to see comprehensive science planning. The Technical Subcommittee on Fine Particle Monitoring of the Clean Air Scientific Advisory Committee (CASAC) (*hereafter referred to as the Subcommittee*) is

reviewing the Supersites Program and will provide advice and consultation. Program execution involves a sequence of activities starting with conceptualization, design and planning, and measurement deployment, with necessary reviews and assessments that feed back into program design. The proposed role of the Subcommittee within this sequence of events is shown schematically in Figure 1.4. Each of the major stages is also outlined briefly below. Following Subcommittee review in 1998, EPA established formal internal and external planning and design teams. Internally, EPA established a planning team composed of atmospheric science, regulatory and health effects and exposure specialists. In parallel, invitations were mailed to other Federal and State/local agencies and private industries active in relevant research to participate in a broader External Coordination Workgroup. EPA staff will be responsible for developing program plans and working with the external committee at a partnership level by providing early drafts and conducting meetings on an as needed basis. The design approach was based on developing a measurements strategy responsive to key questions (science and regulatory) and scientific hypotheses, taking advantage of the PM Measurements Workshop Report. EPA will be responsible for establishing and managing all administrative tasks related to program funding.

### **External Research Coordination**

The active work with the External Coordination Committee is one of several steps taken to optimize measurement resources across different organizations. The Subcommittee will be requested to review more detailed plans as part of the decision approval process.

Accordingly, the Supersites program will be responsive to advice generated by other venues explicitly dealing with larger science integration issues.

### **EPA Steering Committee**

Figure 1.5 provides a more detailed view of the program described in Figure 1.3 starting with the EPA Steering Committee. The EPA Steering committee is made up of program managers and science leads in OAQPS, NHEERL and NERL. This committee takes the advice and recommendations from the various stakeholder groups and provides internal EPA technical direction for the Supersites program technical coordinators. The Steering Committee builds consensus within EPA on technical direction and helps establish/prioritize resources to implement the program.

## **1.3 Principal EPA Technical Coordinators**

Internal EPA project management and technical coordinator teams that include regulatory, atmospheric sciences, health effects and exposure specialists will deal with resource management, communications, and technical issues. The principal coordinators are responsible for ensuring the implementation of the program. The specific duties of the coordinators as they relate to the development and implementation of the quality system are described below.

### **1.3.1 EPA Program Manager – R. Scheffe**

Dr. Richard Scheffe has oversight of the entire Supersites program. Dr. Scheffe interacts at all levels of the Supersites Program. His duties include:

- implementing and overseeing the EPA policy throughout this program ;
- communicating the goals of the program with the technical leads of the program;
- interacting directly with the Supersites Principal Investigators (PIs);
- communicating the progress of the program with management.

### **1.3.2 EPA Project Officer - M. Jones**

Mr. Jones is responsible for monitoring performance and ensuring compliance with agreement terms and conditions for each Supersites Project. His primary duties include:

- < review and approve progress reports and other deliverables;
- < maintain all programmatic, fiscal, technical deliverable, and communication records;
- < review and approve/ recommend approval (as appropriate) requests for changes to budget, schedule, work plan, and key personnel;
- < conduct site visit(s) for each project (programmatic / fiscal / technical).

### **1.3.3 EPA Technical Leads - P. Solomon and M. Pitchford**

Drs. Solomon and Pitchford are the technical coordinators for the Supersites program. As such, they work closely with the PIs of the Supersites program. They are responsible for the technical aspects of this program. As such, their responsibilities are:

- < coordinate with the PI the types of instruments at each Supersites;
- < coordinate meetings between PIs and EPA personnel;
- < provide technical guidance to the PIs and the other technical leads.

### 1.3.4 Quality Assurance Coordinator - D. Mikel

Mr. Mikel will oversee the quality assurance aspects of the Supersites Program. His primary responsibility is to ensure that a quality system is in place for each Supersites. Additional responsibilities include:

- < implementing and overseeing the OAQPS QA policy throughout this program ;
- < assisting in solving QA-related problems at any level of the program;
- < ensuring that an approved QAPP is in place for all environmental data operations associated with the program.
- < work with the Project QA manager to ensure that technical systems audits, audits of data quality, and data quality; assessments occur within the appropriate schedule and conducting or participating in these audits;
- < coordinate the QA Supersites Tele-conference group.

The QA Coordinator (QAC) has the authority to carry out these responsibilities and to bring to the attention of the project officer, program manager or technical leaders any issues related to these responsibilities.

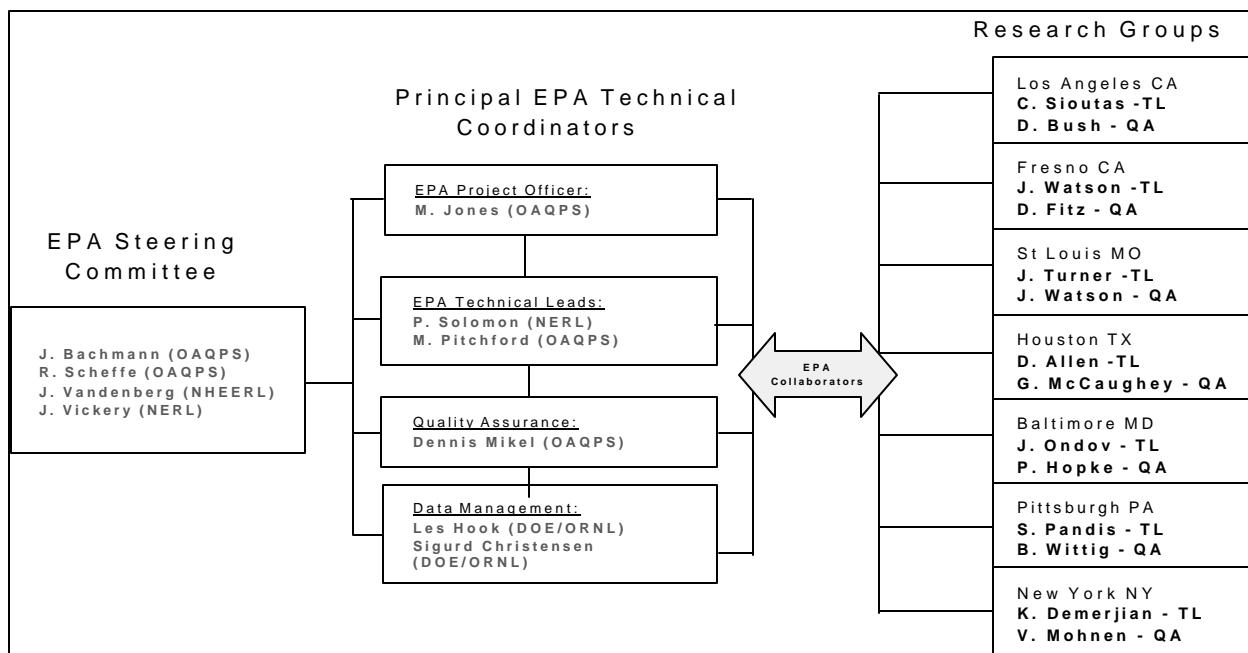


Figure 1.5 Supersites Implementation General Structure



### **1.3.5 Data Management - L. Hook and S. Christensen**

Drs. Christensen and Hook are responsible for working with all of the Supersites data managers and ensuring that they archive the data in the NARSTO Permanent Data Archive. Due to the nature of the data collected, EPA's Aerometric Information Retrieval System (AIRS) does not have neither capability nor the temporal flexibility to house the data from the Supersites. Section 6 will highlight the details of this archive. In addition, their responsibilities include:

- < leading the data management working group;
- < leading the technical discussions of efforts to develop consistent metadata (e.g., variable naming, units, methods, and flags);
- < ensuring that all data that are entered into the NARSTO archive have been quality assured;
- < attending annual Supersites meetings and updating the Supersites community on data management issues.

## **1.4 Research Groups**

Each Supersites is made up of a number of research scientists performing the environmental data collection activities as described in the Supersites specific grant proposal. Figure 1.5 identifies the technical leads, PIs and the QA Manager (QAM) for each Supersites. Both these individuals provide a focal point for the coordination of the research activities at the Supersites

### **Research Group Principle Investigators**

The PIs responsibilities include:

- < ensuring research scientists fulfill their obligations for development of QAPPs for their research environmental data operations;
- < ensuring communication between the research group and the EPA technical QAC;
- < assisting the research group QA lead in coordinating QA activities;
- < approving and implementing the Supersites QAPP for which he/she is responsible.

### **Research Group QA Manager**

The Research Group QAMs will have primary responsibility to ensure that a quality system is developed and implemented for the Supersites he/she is responsible. The QAM's responsibilities include:

- < developing and approving the Supersites QAPP for which he/she is responsible prior to implementing environmental data operations;
- < ensuring research scientists are aware of their obligations for development and implementation of QAPPs for their research environmental data operations;
- < establishing communications with the QAC and reporting progress on QA activities;
- < providing internal technical systems audits and assessments of researchers efforts;
- < ensuring that all Standard Operating Procedures (SOPs) are reviewed and finalized before the start of the program.

## References

1. Allbritton, D. and D. Greenbaum. 1998. *Atmospheric Observations: Helping Build the Scientific Basis for Decisions Related to Airborne Particulate Matter. Report of the PM Measurement Research Workshop*, Chapel Hill, North Carolina, 22-23-July. Prepared by Health Effects Institute and the Aeronomy Laboratory of the National Oceanic and Atmospheric Administration. Health Effects Institute, Cambridge, MA.  
<http://www.al.noaa.gov/wwwhd/pubdocs/PMMRW.pdf>

## **2.0 Quality System Description**

A quality system is defined as a structured and documented management system describing the policies, objectives, principals, organizational authority, responsibilities, accountability, and implementation of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. This section will describe the quality system applications used by the organization to implement effective quality assurance activities.

### **2.1 Supersites QA Application**

In order to meet its stated mission using environmental data, the Supersites PI must implement a QA program that assures that the data can be used for its intended purpose. The following elements will assist in the assurance of data quality and will be described in the following sections.

- QA management plans;
- Management systems reviews;
- Data quality objectives process;
- QA project plans;
- Standard operating procedures;
- Data quality assessments.

Various reviews to determine the successful application of QA in Supersites will be discussed in Section 9 and 10.

### **2.2 Quality Management Plans**

The Quality Management Plan (QMP) is part of the mandatory Agency-wide policy requires that all organizations performing work for EPA develop and operate management processes and structures for assuring that data or information collected are of the needed and expected quality for their intended use. The QMP describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing activities involving the Supersites Environmental Data Operation (EDO). This document represents the QMP for the Supersites program. The QMP will reside on the Air Monitoring Technology Information Center (AMTIC) web site for easy access to all Supersites cooperators. A hardcopy will also be filed with the OAQPS Document Control Manager. Approval for the QMP will include the OAQPS QA Manager, Mr. Joe Elkins and the Supersites QAC Mr. Dennis Mikel.

## 2.3 Data Quality Objectives (DQOs)

Data quality objectives (DQOs) are qualitative and quantitative statements derived from the DQO process that clarify project 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.

As described in section 1, the Supersites will address objectives in three major areas:

- < **SIPs.:** support development of State Implementation Plans through improved understanding of source-receptor relationships leading to improved design, implementation, and tracking of control strategy effectiveness in the overall PM program;
- < **health effects and exposure:** development of monitoring data and samples to support health and exposure studies to reduce uncertainty in National Ambient Air Quality Standards setting and to enable improved health risk assessments; and
- < **methods testing:** comparison and evaluation of emerging sampling methods with routine techniques to enable a smooth transition to advanced methods.

The goals of each Supersites are described on the AMTIC Supersites web page (<http://www.epa.gov/ttn/amtic/ssprojec.html>). In addition, each Supersites contains a number of sub-objectives which are carried out by various research organizations participating in the Supersites. OAQPS identifies the types of projects occurring in the Supersites Program as category 3 (see section 2.1.4). Category 3 projects do not require a formal DQO process but do require a determination of the quality of data needed for decision making. The quality of data will be defined in the QAPPs that are submitted for each Supersites project.

## 2.4 QAPPs

The QAPP is a formal document describing in comprehensive detail the necessary QA/QC, and other technical activities that must be implemented to ensure that the results of work performed will satisfy the stated performance criteria (DQOs).

The quality assurance policy of the EPA requires every Environmental Data Operation (EDO) to have written and approved QAPPs prior to the start of the EDO. It is the responsibility of the Research Groups participating in the Supersites Program to adhere to this policy. The technical lead and QA lead identified for each Research Group are responsible for assuring adherence to this EPA QA Policy and for approving the respective Supersites QAPP.

Each Supersite will produce one QAPP, incorporating all sub-projects. Due to the number of sub-projects in each Supersite the QAC will not review and approve SOPs. The research group QA lead will be responsible for assuring that SOPs are developed for each sub-project **in accordance with the approved QAPP.**

QAPPs are secured in a file by the grant ID number with the EPA Project Officer.

#### **2.4.1 Categories of QA Project Plans**

OAQPS will utilize a four-tiered project category approach to its QA Program in order to effectively focus QA. This approach was originally developed by the U.S. EPA, Air and Energy Engineering Research Laboratory (AEERL) and published by the EPA Risk Reduction Engineering Laboratory, Cincinnati, Ohio (EPA/600/9-89/087). Category I involves the most stringent QA approach, whereas Category IV is the least stringent. The following definition of the categories are quoted from the document listed above:

##### *Category I Projects*

Projects include EDOs that directly support rulemaking, enforcement, regulatory, or policy decisions. They also include research projects of significant national interest, such as those typically monitored by the Administrator. Category I projects require the most detailed and rigorous QA and QC for legal and scientific defensibility. Category I projects are typically stand-alone; that is, the results from such projects are sufficient to make the needed decision without input from other projects.

##### *Category II Projects*

Projects include EDOs that complement other projects in support of rulemaking regulatory, or policy decisions. Such projects are of sufficient scope and substance that their results could be combined with those from other projects of similar scope to provide necessary information for decisions. Category II projects may also include certain high visibility projects as defined by EPA management

##### *Category III Projects*

Projects include EDOs performed as interim steps in a larger group of operations. Such projects include those producing results that are used to evaluate and select options for interim decisions or to perform feasibility studies or preliminary assessments of unexplored areas for possible future work.

### *Category IV Projects*

Projects involving EDOs to study basic phenomena or issues, including proof of concepts, screening for particular analytical species, etc. Such projects generally do not require extensive detailed QA/QC activities and documentation. The number of elements required for each category is reduced as one proceeds from category I to IV as illustrated in Table 2-1.

OAQPS has designated the Supersites program as a category 3 project. The statement of the category will be placed on the QAPP signature and approval page, which will include signatures of the QAPP preparer, Task Lead, QA Lead and the QAC.

**Table 2-1 QAPP Elements Applicable to Various Categories**

<b>QAPP Element</b>	<b>Category Applicability</b>
Project Management	I, II, III, IV
A1 Title and Approval Sheet	I, II, III
A2 Table of Contents	I, II,
A3 Distribution List	I, II, III
A4 Project/Task Organization	I, II, III
A5 Problem Definition/Background	I, II, III, IV
A6 Project/Task Description	I, II, III, IV
A7 Quality Objectives and Criteria for Measurement Data	I
A9 Special Training Requirements/Certification	I, II, III
A10 Documentation and Records	I, II, III, IV
Measurement and Data Acquisition	I, II, III,
B1 Sample Process Design	I, II, III
B2 Sampling Methods Requirements	I, II, III, IV
B3 Sample Handling and Custody Requirements	I, II, III, IV
B4 Analytical Methods Requirements	I, II, III
B5 Quality Control Requirements	I, II
B7 Instrument Calibration and Frequency	I, II, III
B8 Inspection/Acceptance Requirements for Supplies and Consumables	I, II
B9 Data Acquisition Requirements	I, II, III
B10 Data Management	I, II, III
Assessment and Oversight	I, II, III
C1 Assessments and Response Actions	I, II
C2 Reports to Management	I, II, III
Data Validity and Usability	
D1 Data Review, Validation, and Verification Requirements	
D2 Validation and Verification Methods	
D3 Reconciliation and User Requirements	

## **2.4.2 QAPP Review and Approval**

QAPPs are reviewed and approved in accordance with *EPA QA/R5, Requirements for Quality Assurance Project Plans for Environmental Data Operations*. Copies of this document are available from the EPA Quality Staff (QS) Web site (<http://www.epa.gov/quality1/>). EPA Quality Staff encompasses all EPA staff that proves Quality Assurance for the agency. This includes Headquarters, OAQPS, Office of Research and Development (ORD) and the Regional Offices.

This document identifies and defines the elements that must be addressed in all formal QAPPs. The NARSTO QAPP model<sup>1</sup> was used as the template of all QAPPs for this program. This was a decision made by the Supersites QA Work Group, since many of the scientists were familiar with the format and had used the NARSTO format previously. The NARSTO QAPP format is similar to the EPA QA format, but is organized differently. All required sections of the EPA QA format are represented in the NARSTO format.

Review of the QAPP must include QAPP preparer, Research Group Task Lead and QA Lead and the QAC. Mr. Dennis Mikel, the QAC for the Supersites Program, will review and approve each QAPP for the required elements and the soundness of the QA/QC. The QAC will attempt to review QAPPs within 30 working days of submission. The QAC will provide written comments on each element. Through the QAPP review process, the QAC will determine whether the QAPP can be approved, and if not, will identify those elements requiring revision. If the QAPP requires revision, it will be sent back to the author. The revisions, which may be included in the QAPP or as an addendum, must be reviewed and approved by the QAC. All QAPP reviews are secured in a file by the grant ID number with the EPA Project Officer.

### *Conditional Approvals*

OAQPS does not encourage the use of conditional approvals; therefore, QAPPs may be conditionally approved only by the QAC. Conditional approval is defined as a QAPP that demonstrates that a quality system is in place and operational and that critical elements of the QAPP are provided in enough detail to allow the reviewer to determine that the data collected under the QAPP will be documented and of sufficient quality to meet the program data quality objectives.

### *QAPP Revision*

Any revisions required to the original QAPP can be included in a second or subsequent revision or an addendum. However, sometimes the scope of a project can change which may have the potential to affect the quality of the data. If these changes affect the collection of environmental data, an addendum to the approved QAPP must be submitted

that describes the changes and the appropriate QA/QC techniques necessary to meet the DQOs. The QAC must approve the changes.

### *QAPP Archive*

Upon completion of the Supersites Program, QAPPs will be filed with the OAQPS Document Control Officer (DCO) who will identify the document with a unique document control number (see section 5). All original copies of the QAPPs and any subsequent revisions will be secured by the DCO.

## **2.5 Standard Operating Procedures (SOPs)**

Standard operating procedures (SOPs) are written documents that detail the method for an operation, analysis, or action with thoroughly prescribed techniques and steps. SOPs are protocols for all routine activities, especially those that are involved in the EDOs, which generally involve repetitious operations performed in a consistent manner.

SOPs should ensure consistent conformance with organizational practices, serve as training aids, provide ready reference and documentation of procedures, reduce work effort, reduce error occurrences in data, and improve data comparability, credibility, and defensibility. They should be sufficiently clear and written in a step-by-step format to be readily understood by a person knowledgeable in the general concept of the procedure. Guidance for SOP development can be found in QS document entitled *Guidance for the Preparation of Standard Operating Procedures (SOPs) EPA QA/G-6*. Copies of this document are available at the QS Website ([http://www.epa.gov/quality1/qa\\_docs.html](http://www.epa.gov/quality1/qa_docs.html)).

SOPs must be written prior to the start of an EDO. The Research group QA Manager will be responsible for ensuring SOPs are developed. SOPs for data collection methods must be included in QAPPs either by reference, by inclusion of the actual method or be attached as an appendix. In general, approval of SOPs occurs during the approval of the QAPP.

Any change in a SOP during the EDO should be documented and filed by the research lead. SOPs will be reviewed during Technical Systems Audits (TSAs).



## 2.6 Assessments

There are several assessments tools that will be implemented by the QA system. Please see Chapter 9.1 for details. Assessments will be performed as the program begins and on a periodic basis after January 2001. Table 2-2 lists the types of assessments, assessor and assessment frequency.

**Table 2-2 Assessments**

Assessment Type	Assessor	Frequency
Technical Systems Audits	Project Level QA Managers	At the beginning of the project
Performance Audits	Project Level QA Manager	At the beginning of the project/annually after the first year
Network Review	EPA- OAQPS-QA Coordinator	At the beginning of the program
Performance Evaluations	EPA -ORIA-NAREL Lab	Throughout the life of the program
QAPP Review and Approval	EPA - OAQPS-QA Coordinator	Before projects begin
Data Quality Assessment	Project Level QA Managers	After data collection phase

## Reference

1. NARSTO Quality Planning Handbook, November 23, 1999, Oak Ridge National Laboratory, <http://cdiac.esd.ornl.gov/programs/NARSTO>

## **3.0 Personal Qualifications and Training**

This section will discuss the process put in place to provide training for the Supersites program. This chapter will outline the process involved and training available for air monitoring professionals.

The process of training the personnel whom will be the involved in the Supersites program will vary. The Supersites projects will be employing many research and well-known methods. For instance, Federal Reference Method PM<sub>2.5</sub> instrument will be employed at many locations. With these, State and Local agency professionals will be operating the instruments. For the research type of instruments, interns and graduate students from various colleges and universities will be operating the monitors. It is the responsibility of each Supersites project PI and QAM to provide training for all personnel involved in their projects. OAQPS provides numerous satellite classes and on-your-own courses that are free to air monitoring individuals. All persons working on this program are encouraged to take these courses.

### **3.1 Personal Qualifications**

Each Supersites program will make every effort to provide training to all who participate in this program. Personnel assigned to the Supersites Program should meet the educational, work experience, responsibility, personal attributes, and training requirements for their positions. Although OAQPS can provide training to all agencies, it cannot require the Supersites projects or any contractors to send their staff to EPA training courses. During the TSAs, the QAM for each project or its contractor will review records on personnel qualifications and training. All agencies should maintain these records in personnel files and will be accessible for review during audit activities.

### **3.2 Training**

Appropriate training is made available to persons supporting the Supersites program, commensurate with their duties. Such training may consist of classroom lectures, workshops, tele-conferences, and on-the-job training.

Over the last 2 years, a number of courses have been developed in cooperation with EPA 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 Staff (QS), <http://www.epa.gov/quality1/>

The courses mentioned below are open to all air monitoring personnel. EPA strongly encourages all state and local agencies and contractors to take these courses. Table 3.1 presents a sequence of core ambient air monitoring and QA courses for ambient air monitoring staff, and QA managers. The suggested course sequences assume little or no experience in QA/QC or air monitoring. Persons having experience in the subject matter described in the courses would select courses according to their appropriate experience level.

**Table 3.1 Core Ambient Air Training Courses**

Sequence	Course Title (SI = self instructional)	Source
1*	Air Pollution Control Orientation Course (Revised), SI:422	APTI
2*	Principles and Practices of Air Pollution Control, 452	APTI
3*	Orientation to Quality Assurance Management	QS
4*	Introduction to Ambient Air Monitoring (Under Revision), SI:434	APTI
5*	General Quality Assurance Considerations for Ambient Air Monitoring (Under Revision), SI:471	APTI
6*	Quality Assurance for Air Pollution Measurement Systems (Under Revision), 470	APTI
7*	Data Quality Objectives Workshop	QS
8*	Quality Assurance Project Plan	QS
9	Atmospheric Sampling (Under Revision), 435	APTI
10	Analytical Methods for Air Quality Standards, 464	APTI
11	Chain-of-Custody Procedures for Samples and Data, SI:443	APTI
*	Data Quality Assessment	QS
*	Management Systems Review	QS
*	Beginning Environmental Statistical Techniques (Revised), SI:473A	APTI
*	Introduction to Environmental Statistics, SI:473B	APTI
*	Statistics for Effective Decision Making	ASQC
	AIRS Training	OAQPS

\* Courses recommended for QA Managers

### **3.3 Certification**

No certificates are required for this program.

## **4.0 Extramural Agreements and Procurement of Items and Services**

OAQPS must ensure that the items and services it acquires are procured within EPA regulations, are delivered in a timely fashion, and are within the required specifications. The following sections will provide general information on OAQPS procurement procedures and provide personnel involved in the Supersites Program with the a description of the requirements

### **4.1 Source of Funds**

**4.1.1 State Assistance Grants:** Many SLAMS and NAMS will support the Supersites Program by operation of ancillary sites in the SLAMS/NAMS network. The source of funds is Section 103 and eventually Section 105 State Assistance Grants (STAG). Every year, funds will be allocated to the State and local air monitoring organizations to operate the PM<sub>2.5</sub> Federal Reference and Speciation Program. Funds are allocated to the EPA Regions who then allocate them to the State, local or Tribal agencies. These agencies then follow their own procurement policies to get the monitoring accomplished.

A portion of the STAG funds are allocated back to OAQPS for two activities

- 1 National speciation monitor contract- OAQPS set up a national contract to facilitate the purchase of speciation monitors
- 2 Analytical laboratory contract- OAQPS set up a national contract to perform all the filter preparation and analyses and reporting activities.

Each year OAQPS will submit a request for the appropriate allocation of funds for these activities based on the number of monitors being implemented (or planned) for that fiscal year.

**4.1.2 OAQPS Internal funds:** Each year OAQPS plans the activities it will pursue in the upcoming fiscal year. The OAQPS speciation monitoring and QA leads will work with various work groups and cooperators to prioritize the use of the environmental program management (EPM) funds. These funds may be used to purchase capital equipment or for contracting.

OAQPS, through the Memorandum of Agreement with the Office of Radiation and Indoor Air lab will provide contract funds to these labs. The use/ allocation of the funds will be negotiated during fiscal year planning.

## **4.2 Procurement of Items**

In EPA, only contracting officers (COs) are authorized to procure items and services, unless it is an impress fund transaction approved by the CO prior to the originators purchase of the item. The Federal Government is not bound by any commitments made by other than authorized personnel.

Requests for purchases begin at the yearly planning stages of the Speciation Program for the EPM funds. Purchases by contractors must be identified in the project scope of work for such purchases. All items should be identified and specifications that meet the government's minimum needs should be detailed. These specifications will be referred to during the procurement process and will assure that the OAQPS requestor receives the proper item and reduces the chances of purchase delays or incorrect purchases because of inadequate product specifications.

## **4.3 Procurement of Services**

Two types of mechanisms are primarily used to procure services, contracts and assistance agreements (grants, cooperative agreements, etc.). As mentioned in section 4.1, COs are the only individuals who can obligate funds.

When procuring services, one should follow the same basic procedure used for the procurement of items. There are certain activities that are of a policy- and decision-making nature that should remain the sole authority of EPA. The CMD should be contacted during the initial planning of the PR to discuss specific requirements for the procurement.

The Project Officer (PO) states the service that will be delivered, measures the quality of the service, and accepts the service. When a level-of-effort contract is the vehicle used in procuring services, the work assignment manager (WAM) provides the technical expertise for the work assignment and assumes responsibility for the QA requirements assigned to the PO. Two major tools to ensure that adequate service is provided are a well-defined statement of work (SOW) and a QAPP that includes reviews (audits).

The QAM or DQAO assists in this activity by providing knowledge and guidance on the QA requirements and aspects of any potential project. The QAM or DQAO will also approve the QA review form that is discussed in the next section.

**4.3.1 Contracts:** Contracts are used when the government derives sole benefit from a particular product or service. Contracts can be specific and can require a degree of lead-time for development. Depending upon the scope of the service, QA attributes can be developed that must be adhered to under the terms and agreements of the contract. Any

EPA initiated contracts are required to use some type of QA form to determine if the contract will require EDO and therefore requires a QMP, a QAPP assessments and reports. After the form is completed it must be reviewed by the (WAM/PO) and a QA officer. The form must be kept in the official contract file.

The Federal Acquisition Regulations, Title 48 of the Code of Federal Regulations, was recently amended to address contract quality systems requirements on a government-wide basis. The new FAR clause at 52.246-11, Higher-Level Quality Requirement, allows a Federal agency to select a voluntary consensus standard as the basis for its quality requirements for contracts and allows tailoring of the standard to more effectively address specific needs or purposes. Based on this FAR clause, EPA has selected ANSI/ASQC E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis for its environmental quality requirements and has tailored this standard to ensure that contractors demonstrate conformance to this national standard. The background and application of the new procurement policy as it relates to QA is included in **Appendix A must be followed**.

Due to these changes, 48 CFR 1546, a quality regulation that applies only to EPA, will be removed from the Code of Federal Regulations. The tailoring language allowed by 52 CFR 246-11 and pertinent requirements in 48 CFR 1546 will be included in the EPA Directive 1900, *Contracts Management Manual*. This procurement policy notice is being issued to ensure an orderly transition from 48 CFR 1546 to EPA Directive 1900 and contains tailoring language allowed by 52 CFR 246-11. It is in effect until the revisions to Directive 1900 are completed

Whenever the government enters into a contract, it is entitled to receive quality service. In order to define and measure this quality, the WAM/PO must develop a SOW that will accurately define the minimum acceptable requirements for the service or product. Methods used to determine quality (audits, quarterly interviews, random inspections, etc.) should be explained prior to project implementation so that the supplier will understand how quality will be assessed.

Part of the procurement process of certain types of large contracts include the use of a technical evaluation panel (TEP). When this form of contracting mechanism is used to solicit contracts in which a significant percent of the cost (> 25%) includes EDO, the TEP must include a QA representative, if possible, a representative from the group/branch processing the contract. Part of the TEP responsibilities will include rating each potential contractor against a standard set of criteria. A portion of these criteria can include various assessments such as on-site audits and the analysis of performance evaluation materials. Prior to the solicitation for bid, it must be determined what proportion of the TEP rating will be allocated to QA assessments. It is suggested that a minimum of 5% of the overall TEP rating be allocated to QA.

Depending upon the type of contract used to acquire a service, different types of QA methods for determining the quality of product or output may be used. However, in all cases, documentation is essential. POs/WAMS are responsible for documenting quality on a regular basis. EPA personnel must be aware of the "personal services" type of work characterized by an employer-employee relationship between government and contractor employees. These contracts are illegal in EPA. Personal services conflicts arise when government employees assume the right to instruct, supervise, or control a contractor's employee in how he or she performs work. It is the contractor's right to hire and terminate, to assign, and to organize and implement tasks as the contracting organization deems appropriate. OAQPS may tell the contractor what to do within the terms and agreements of the contract, but not how to do it.

#### 4.4 Assistance Agreements

Assistance agreements are used when both parties (EPA and the group providing the service) derive benefit out of the service. This usually occurs with grants or cooperative agreements where universities or states derive benefits from participating in EDOs. QA requirements are developed for all assistance agreements that include EDOs. OAQPS follows guidelines developed in the *EPA Assistance Administration Manual* (EPA-5700). Assistance agreement SOWs are usually developed jointly. However, once the SOW is completed, the parties must also agree on the quality standards for assuring the product or service. It is the responsibility of the WAM/PO to be knowledgeable of the EPA QA policy and to represent these standards during the development of the projects SOW. Special conditions are usually included in assistance agreements. The PO will list the conditions to which project participants must adhere. One of these conditions relates to QAPPs. Any assistance agreement that includes EDOs must include the following statement:

**A quality assurance project plan must be submitted within 90 days of this agreement and/or 30 days prior to commencement of any EDOs.  
Implementation dates will be adjusted based upon the above conditions.  
Costs associated with data collection are not allowable costs until the quality assurance project plan is submitted, nor will costs be reimbursed until the quality assurance program plan is approved.**

#### 4.5 EPA Exclusive Versus Discretionary Functions

The following information comes directly from *EPA Quality Manual for Environmental Programs 5360*.

Many quality system activities involving environmental data operations are inherently governmental functions and must be performed only by EPA personnel or by personnel explicitly



authorized by EPA based on statute, regulation, or by the terms of an extramural agreement. Such representatives may include other governmental personnel and with specific authorization, contractor personnel. When quality management tasks are performed by a contractor, the contract must be appropriately managed and must remain under the control of the authorized EPA contracting representatives. EPA cannot use cooperative agreements or grants to provide quality management activities such as QA and QC services for EPA because it is an inappropriate use of financial assistance (Office of General Counsel memorandum, August 2, 1994).

This section describes the quality management tasks necessary to comply with the Order and identifies those tasks that may be performed by non-government personnel under appropriate management controls.

Two types of quality management functions are described:

- C Exclusively EPA Functions - inherently governmental work which must be performed only by responsible EPA officials, including the QA Managers (QAMs), or authorized EPA representatives.
- C Discretionary Functions - activities that may be performed either by EPA personnel or by non-EPA personnel under the specific technical direction of and performance monitoring by the QA Manager or other responsible EPA or Government official under an approved contract, work assignment, delivery order, task order, etc.

In the situations involving the other associated functions, there may be instances involving sensitive contracting services, advisory and assistance services, and vulnerable contracting practices as defined by the Federal Acquisition Regulations, Office of Federal Procurement Policy (OFPP), and the EPA Contracts Management Manual (EPA Order 1900). Such situations are identified by *italicized text* in the following sections. In addition, management approval of services contracts as defined by OFPP Letter 93-1 must be obtained for many of the associated tasks.

Technical direction or other instructions to an extramural organization, relating to performance of an extramural agreement, shall be provided only by authorized EPA or other Government representatives in accordance with the terms of the applicable extramural agreement. Only authorized EPA or other Government representatives are to provide direction or instructions to an extramural organization providing quality systems support for environmental programs. This is to avoid such actions as:

- C the providing of directions or instructions that are inconsistent with the terms of an extramural agreement,
- C unauthorized access to confidential business information (CBI), or

- C unauthorized access to information that may allow an extramural organization to gain an unfair competitive advantage.

**4.5.1 Mandatory Quality Management Tasks and Descriptions:** This section describes the activities and tasks integral to an effective quality system. These tasks are required to implement EPA Order 5360.1 CHG 1.

Manage and Coordinate the Quality System

Exclusively EPA functions that must be performed by EPA QA personnel include:

- C managing the day-to-day implementation of the mandatory quality system.
- C acting as liaison between the organization and the QS on matters of QA policy.
- C coordinating with senior management the development of and preparation of the organization's Quality Management Plan.
- C coordinating with senior management changes to the Quality System as needed to assure its continued effectiveness and assisting in reporting the results annually to management and to QS in the QA Annual Report and Work Plan.
- C managing organization resources designated for the quality system.
- C maintaining records of pertinent quality system activities performed by the organization.

Review and Approve Procurement and Financial Assistance Documents for QA Requirements

Exclusively EPA functions that must be performed by EPA QA personnel include:

- C reviewing procurement and financial assistance documents (e.g., statements of work, scopes of work, applications for assistance, funding requests, and purchase requests) to confirm any need for QA requirements, providing any necessary special language or conditions for such QA requirements, and approving by signature the appropriate Quality Assurance Review Form.
- C participating directly or indirectly in the solicitation or agreement review process to advise the Project Officer on the suitability of the offer or quality system or quality assurance/quality control (QA/QC) approach for the particular project.
- C reviewing work assignments, delivery orders, and task orders to certify that appropriate QA/QC requirements have been established and that the necessary instructions are being communicated to the contractor to carry out the required QA/QC tasks. Approving by signature appropriate Quality Assurance Review Form (EPA Order 1900, Chapter 2).

### Review and Approve QA Planning Documents

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- C reviewing Quality Assurance Project Plans (QAPPs) for all projects, work assignments, delivery orders, task orders, grants, cooperative agreements, and interagency agreements involving data acquisition, data generation, and/or measurement activities that are performed on behalf of EPA.
- C approving all QAPPs for implementation in all applicable projects, work assignments, delivery orders, task orders, grants, cooperative agreements, and interagency agreements performed on behalf of EPA.
- C coordinating the correction of deficient QAPPs with the Project Officer and his/her management.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- C *reviewing, at the specific technical direction of the QAM, QA Project Plans and other QA-related planning documents, such as sampling and analysis plans, Data Quality Objectives (DQO) specifications, etc., and providing specific substantiated recommendations to the QAM on the adequacy of the QA approach in meeting the criteria provided by the QAM. (The reviews should identify specific technical deficiencies in the planning documents.)*

### Track and Report Quality System Deliverables

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- C tracking critical quality system deliverables for the organization and make periodic reports to senior management on the status of reporting actions and deliverables.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- C compiling/logging administrative and management information including turnaround times to correct deficient QAPPs, responses to audits (e.g., responses and corrective actions), and quality reviews of final reports.

### Manage Contractor Support Work Assignments, Delivery Orders, and Task Orders

Exclusively EPA functions that must be performed by EPA QA personnel include:

- C serving as the Contracting Officer Representative (for example, Project Officer, Work Assignment Manager, or Delivery Order Project Officer) for specific QA support contracts, work assignments, delivery orders, and task orders.

#### Plan and Conduct Management Assessments

Exclusively EPA functions that must be performed by EPA QA personnel include:

- C planning, directing, and conducting assessments of the effectiveness of the quality system being applied to environmental data operations and reporting results to senior management. Such assessments may be conducted using the Management Systems Review (MSR) process.
- C coordinating with senior management any revision of the quality system as necessary based on the findings of the assessment.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- C *providing technical support to the EPA QAM in the planning phase of management assessments. (Such activities are limited to the assembly and compilation of background information and data, guidance documents, technical reports, etc., available in the public domain, for use by EPA in designing the assessment goals and specifications.)*

#### Plan and Conduct Technical Assessments

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- C planning and directing with the responsible EPA project officials the implementation of periodic technical assessments of ongoing environmental data operations to provide information to management to assure that technical and quality objectives are being met and that the needs of the customer are being satisfied. Such assessments may include technical systems audits, surveillance, performance evaluations, and data quality assessments.
- C determining conclusions and necessary corrective actions (if any) based on the findings of the assessments.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- C *performing technical assessments of environmental data producing activities, both intramural and extramural (on-site and off-site) according to a specific plan approved by the QAM. Preparations for such assessments may include the acquisition or development of audit materials and standards. Results (findings) are summarized, substantiated, and presented to the QAM or authorized EPA representative.*

*A determination of whether an authorized Agency representative should accompany a contractor's personnel should be made on a case-by-case basis only after coordination between the responsible organization and contracting officer. Such coordination should include consideration of the purpose of the accompaniment and clear definition of the Agency representative's role and responsibility during the contractor's performance of the audit or technical assessment to avoid the appearance of a personal services relationship.*

#### Prepare and Present QA Training Materials and Courses

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- C *developing and presenting detailed guidance and training for QA/QC activities based on interpretation of Agency-wide requirements and guidance.*

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- C *providing or coordinating quality-related training for the organization in special skill areas identified by the Agency and not generally available to the organization.*
- C *providing allowable technical and/or logistical assistance in preparing and presenting quality-related technical training (within the Agency's implementation of special management and control measures and the constraints of potential for conflict of interest, of revealing confidential business information, or of appearing to be interpreting or representing Agency policy).*

#### Review and Approve Final Reports for Quality Documentation

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- C establishing criteria for the acceptability of quality documentation in the organization's published papers and reports; that is, defining what is required for an adequate discussion of the quality of the project results and the usability of the information reported.
- C approving for publication those papers and reports that meet the defined criteria.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- C *conducting a substantiated technical review of all reports produced by the organization using the qualitative and quantitative specifications obtained from the DQO process or other criteria provided by EPA. This quality review complements the peer review process.*

**4.5.2 Non-Mandatory Quality Management Tasks and Descriptions:** This section describes other activities and tasks integral to an effective quality system. They are not explicitly required to implement EPA Order 5360.1 CHG 1, but if implemented, they must be implemented as described below.

## 5.0 Records and Documentation

The responsibility of record keeping falls upon OAQPS, ORD and the individual Supersites Projects and their contractors. For this program, there are number of documents and records that need to be retained. A document, from a record 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..." EPA-OAQPS and ORD will adhere to this guideline. Section 5.1 will illustrate the process that will be implemented for storing documents and records. Since many agencies are involved, their documentation storage capabilities and processes will differ; however, at a minimum, all documents and records for this program will be securely stored. For more information on document control and storage, please see the individual agency QAPPs.

### 5.1 Document Hierarchy and Process

This section will outline the hierarchy of the documentation and illustrate the review process for the major documents created for this program.

**5.1.1 Hierarchy:** The Clean Air Act (CAA) and EPA Order 5360.1, July 1998 are the overarching documents for this program. As such, all authority to create programs and allocate funds is given in these documents. EPA Order 5360.1 gives the EPA authority to require all agencies that accept federal funds to create QMPs, QAPPs and Network Plans. OAQPS has the authority to require, review, comment and withhold funds if these requirements are not met. The order of hierarchy follows:

- < The Code of Federal Regulation, through the CAA and Order 5360.1 are the overarching authority.
- < The QMP encompasses the entire program. All agencies, OAQPS, ORD and the individual Supersites projects will adhere to the requirements and guidelines in the QMP. The QMP discusses the roles of each agency.
- < The QAPPs for individual agencies will govern that agency. The agency must adhere to the statements made in their QAPP.
- < The Network Plan will outline how the network will be implemented and document the location of each sampler with all ancillary data.

## **5.1.2 Document Creation and Review Process**

### **5.1.2.1 QMP**

The QMP for this program was generated by OAQPS-EMAD-MQAG. It has the overarching authority over all QAPPs, Network Plan and all other ancillary documents. This document has undergone thorough review by OAQPS, ORD, and the Supersites Project PIs and QA Managers.

### **5.1.2.2 QAPPs**

The individual Supersites PIs and QA Managers to describe their process of assuring the quality of the data write the QAPPs. OAQPS reserves the authority to review, make comments and approve the individual QAPPs.

### **5.1.2.3 Network Plan**

OAQPS requests that all Supersites project take electronic photographs of each site in the cardinal directions. These will be forwarded to OAQPS with all other siting data. OAQPS will create electronic resources that will include the following:

- < Electronic photos of the sampler in place;
- < Electronic photos of the area in all cardinal directions;
- < Maps of the area showing local sources (if known);
- < Coordinates of the location generated by Geographic Positioning Systems. The standard is +/- 10 meters.

This data will be compiled and placed in an accessible electronic database and distributed and stored by OAQPS. Any parties that wish to review the network will be able to obtain this data expeditiously.

### **5.1.2.4 Other Documents**

The responsibility of all other documents is detailed in the next section.

## **5.2 Documentation Responsibilities**

### **5.2.1 OAQPS –EMAD**

This division has oversight of the Supersites. As such, the documents that must be controlled and stored are under the jurisdiction of the Project Officer, who has the responsibility of storing and archiving all records that pertain to the requisition and deposition of contracts.



### **5.2.2 Supersites**

*Principle Investigators*- the PIs are responsible for the oversight of the field and laboratory documents and implementation of the QAPP. As such, he/she is responsible for the storage of all records and documents generated by the labs or field.

*Quality Assurance Managers* - The QA Managers are responsible for the archiving of all QA related documents created during any assessments by the manager or contractor in accordance with the QAPP.

*Individual Investigators* - The individual research investigators are responsible for the oversight of their instrument documentation. All calibration or maintenance data, notes, field information is their responsibility. As such, he/she is responsible for the storage of all records and documents generated by their field operations in accordance with their SOPs.

## **5.3 Deposition and Storage of Documents and Records**

This section will address the deposition, storage accessibility, and protection of documents and records. It is noted that the persons filling the roles mentioned above are responsible for the documents and record that they generate. These agencies will take full responsibility for the deposition of these records. Please note that all records and documents will be made available for review and scrutiny upon request for up to 5 years after the data were generated.

### **5.3.1 Field notebooks**

Notebooks will be utilized for recording results of field audits. Dates, times, field conditions, temperature, pressure and flow rates will be recorded. Each investigator will archive all field logs. Any computer-generated logs will be downloaded to their headquarters.

### **5.3.2 Lab Notebooks**

Notebooks will also be issued for the laboratory. These notebooks should be uniquely numbered and associated with the Supersites program. One notebook will be available for general comments/notes; others will be associated with, the temperature and humidity recording instruments, the refrigerator, calibration equipment/standards, and the analytical balances and all instruments used for this program. Laboratory notebooks review and archiving are the responsibility of the individual investigators or researchers. All logs must be maintained for at least 5 years after the data are generated.

### **5.3.3 Chain of Custody Forms**

Original Chain of Custody forms will be archived by the individual investigators.

### **5.3.4 Other Documents**

All other documents must be stored according to their QAPP.

### **5.3.5 Electronic data collection**

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, such as the output of the Fine Particle Federal Reference Method or Speciation samplers. Safe and secure handling and storage of electronic information must be assured through good data administrative practices, including periodic data backups, as described in their QAPP.

## **5.4 Deposition of Reports**

### **5.4.1 Data Reporting Package/Archiving and Retrieval**

All the information, electronic and written, will be retained for 5 years from the date the grantee submits its final expenditure report unless otherwise noted in the funding agreement. However, if any litigation, claim, negotiation, audit or other action involving the records has been started before the expiration of the 5-year period, the records will be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular 5-year period, whichever is later. For example, any data collected in calendar year 2001 (1/1/01 - 12/31/01) will be retained until, at a minimum, January 1, 2006, unless the information is used for litigation purposes.

## **6.0 Computer Software and Hardware**

There is an increasing dependence upon computers and computer related hardware in the collection of environmental data. Indeed, all environmental programs within and outside of the EPA use computers extensively to collect, store, validate and analyze environmental data. This section will outline briefly what computer systems will be employed throughout the Supersites program. This chapter will also describe the roles and responsibilities for system hardware and software.

### **6.1 Computer System Descriptions**

#### **6.1.1 EPA-OAQPS**

The QMP and Network Plan will be archived in Research Triangle Park, North Carolina. All communications and hardcopy information will also be housed at the EPA facility in Research Triangle Park, North Carolina. The QMP, final Supersites QAPPs will be posted on the EPA-OAQPS website, AMTIC.

#### **6.1.2 Supersites**

Individual Supersites will develop, operate, and maintain their computer systems as outlined in their individual site's QAPP or data management plan.

#### **6.1.3 NARSTO**

While participating in the flow of information from Supersites projects to the NARSTO Permanent Data Archive, NARSTO will employ three computer systems. Supersites data and metadata will be entered into, stored, and processed by the Data and Information Sharing Tool (DIST), an FTP site, and the NARSTO Quality Systems Science Center processing system. Please see Figure 6-1.

Data and Information Sharing Tool (DIST): DIST is a web-based index and clearinghouse of atmospheric measurement and chemistry data and metadata, made available by the NARSTO program. The DIST enables small groups of investigators to share project data in a secure environment and also provides data from numerous sources to the at-large research community. The data available through DIST may include measurement data, model outputs, images, and other information of interest to the atmospheric research community. Data are indexed using consistent metadata categories to support searching by fields such as project, location, date, keyword, and investigator. Data providers can easily enter metadata and add links to their data in this Web-based tool. The DIST is a key component in the flow of data from projects to the NARSTO Permanent Data Archive (PDA) with output capabilities that facilitate metadata and data archiving. The DIST can be accessed at <http://cdiac.esd.ornl.gov/programs/NARSTO/>.

The overall DIST system is robust in design and efficient in implementation. Users will find a convenient interface, similar to many existing web-based products, that includes a file manager and good help files. The system is implemented using Internet standards, including XML, and supports international metadata standards, including FGDC and Z39.50. DIST is based on commercial off-the-shelf software with many value-added improvements and is part of the ORNL Mercury Consortium, a group of independent data projects that work together to share improvements and reduce individual costs.

Supersites FTP site: The Supersites shared-access FTP site has two areas for accessing data files. One area is publicly accessible as an anonymous login site (<ftp://narsto.esd.ornl.gov>) and the other is an internal area with login and password limited access to directories for each Supersites project and working group. System administrators will distribute login names and passwords, create subdirectories and move files as directed by site users, and maintain and periodically backup the site. Appropriate security and access disclaimers are distributed to users and posted on the site.

Quality Systems Science Center processing system: This system accepts Supersites data provided in the Data Exchange Standard format, checks the format, calculates summary statistics, assembles documentation, and transmits the data to the NARSTO Permanent Data Archive (PDA). The Data Exchange Standard is documented in the NARSTO Data Management Handbook (<http://cdiac.esd.ornl.gov/programs/NARSTO/narsto.html#qsmg>), and also in Excel 97 templates designed to support creating these files. Files with related data are grouped into data sets for processing and archiving. A QSSC "Read and Verify" code reads the files in each data set, reproduces each file with an added section containing summary statistics for data in the file, produces files helpful in documenting the data set for archiving, verifies conformity to key provisions of the Data Exchange Standard, and produces a QA report indicating any deviations from the Standard that were found. If deviations were found, this QA report is sent back to the data originator so issues can be resolved. When the data set is complete and ready, documentation is assembled, and the data set is sent to the PDA for archiving.

NARSTO Permanent Data Archive (PDA): The PDA is maintained at the Langley Distributed Active Archive Center (DAAC) and operated by the NASA Langley Research Center, Hampton, Virginia. NARSTO data are maintained as part of their permanent data collection and are available to the public at no charge through a convenient Internet ordering system (<http://eosweb.larc.nasa.gov/>).

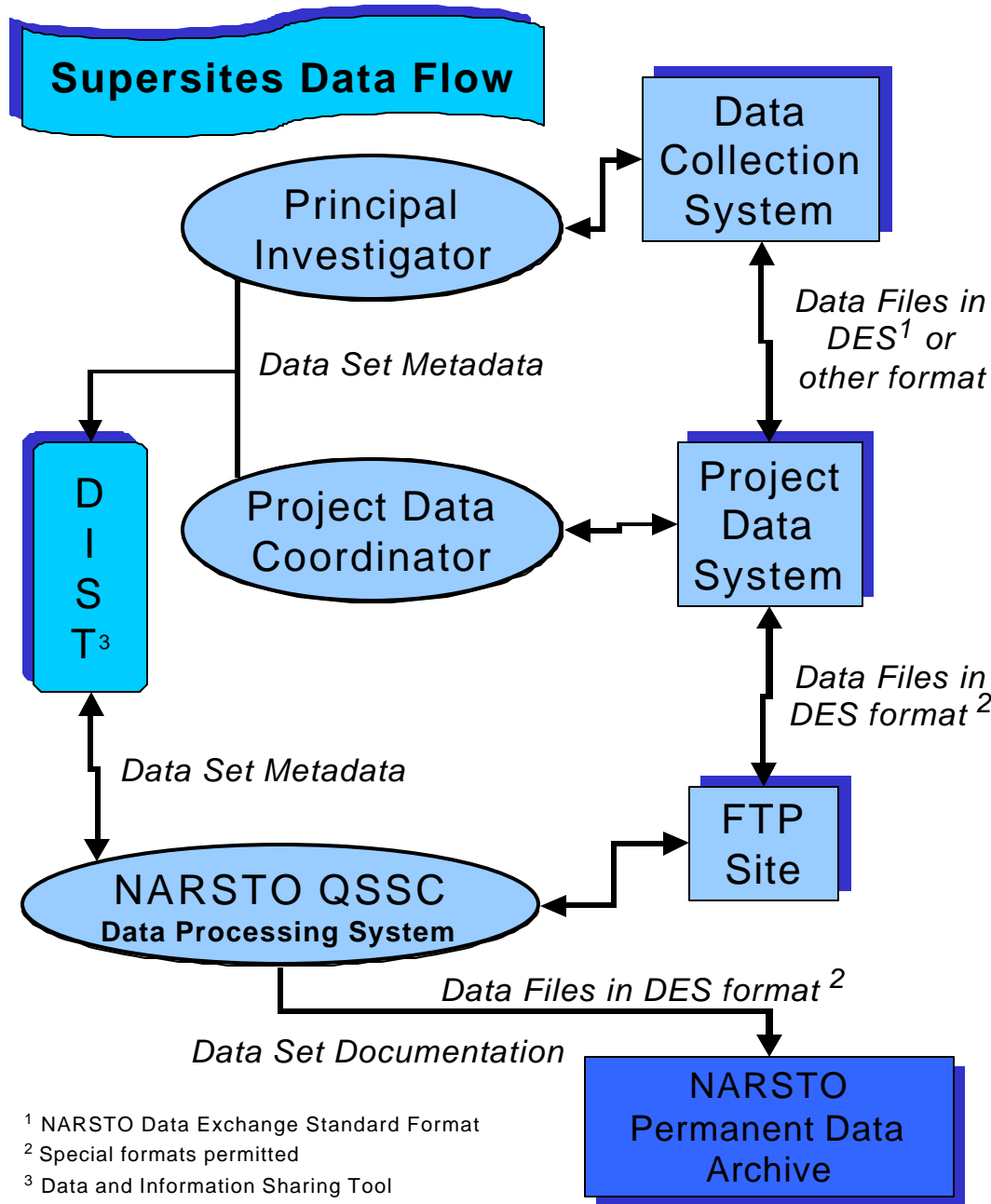


Figure 6-1. Data Flow Diagram

## 7.0 Planning and Implementation of Work Process

### 7.1 Project Goals and Objectives

This section outlines planning and implementation procedures that were employed in the Supersites program. This program has several diverse agencies that are interacting at several levels. Therefore, to ensure that the work is being performed and that the quality of the data is acceptable, clear communication must be employed for this program. The following sections outline how this is accomplished.

#### 7.1.1 Program Objectives

The program addresses the objectives in three major areas:

- < ***SIPs:** support development of State Implementation Plans (SIPs) through improved understanding of source-receptor relationships leading to improved design, implementation, and tracking of control strategy effectiveness in the overall PM program;*
- < ***health effects and exposure:** development of monitoring data and samples to support health and exposure studies to reduce uncertainty in National Ambient Air Quality Standards setting and to enable improved health risk assessments; and*
- < ***methods testing:** comparison and evaluation of emerging sampling methods with routine techniques to enable a smooth transition to advanced methods.*

These objectives are broad in scope and presented the challenge of developing specific data quality objectives within a National program responsive to many disciplines. Based on the original funding rationale, each of the Supersites study areas provided some support for implementation questions. Some of the sites added objectives related to research on health, exposure, and methods testing. Thus, while some aspects of the program were common to all locations, others, including duration, measurement frequency, and indicators measured may vary with specific objectives at differing locations. The Measurements Workshop Report (see Chapter 1 reference) provided numerous examples of overlapping data needs across diverse science disciplines that typically exhibit very limited interaction. A simple example includes the daily collection of chemically speciated data that assist both air quality model evaluations and exposure studies. Clearly, windows of opportunity exist for optimizing the use of environmental data to respond effectively to seemingly disparate objectives. An organized approach to building specific study objectives must be followed to ensure needs are met and resources optimized. Targeted program objectives were developed by:

- < starting from test hypotheses and questions that are generated by an integrated program planning team;

- < utilizing site/time based objectives where certain locations and study periods are optimized for specific topic areas; e.g.: specific airsheds optimized for source receptor and air quality model evaluation of specific airsheds optimized to support epidemiological and exposure studies;
- < emphasizing methods testing early, then transitioning to other objectives within a single airshed; including discrete or intensive sampling periods optimized to address specific test hypotheses;
- < requiring all investigators to follow existing quality assurance protocols in the development of QAPPs which includes requirements for developing DQOs. Optimizing objectives by location or time does not preclude some level of support at all locations to SIPs, health effects and exposure studies and methods testing, given the multiple uses of similar data.

### **7.1.2 Program Principles**

EPA staff adhered to the following organizational and guiding principles derived from the PM Measurements Workshop Report (Chapter 1 reference) in developing an overarching strategy for implementing the program:

- be designed as a “learning” rather than a “measurement” program;
- provide consistent and comparable, but not necessarily identical, measurements across the sites and the nation; be an investment that leverages the largest possible number of other governmental and private investments;
- have analysis and evaluation built in from the start;
- organize the measurements approach by asking; what are the major questions and hypotheses; what should be measured; where and when should the measurements.

The Supersites program must be flexible to adjust to and accommodate the unique needs of different research disciplines by planning across scientific disciplines (health effects, exposure and atmospheric science measurement needs) and regulatory agencies. Results must be developed in a timely manner to assist development of SIPs which are required as early as 2005, and review of the PM standard which is to be completed in 2002 and again in 2007. Therefore, program deployment is following a dual track staging with an initial establishment of two sites in 1999 and a gradual full site deployment accomplished in 2002. The rationale for this dual track deployment is to test technical and organizational elements of the program early in order to aid the optimization of the full program, and allow adequate planning and design so that the full program can provide the most relevant support for a mix of regulatory and research based needs.

Program planning and design to date consisted of the planning meeting, and report writing by the steering committee and attendees related to the PM Measurements Workshop, along with internal EPA meetings involving regulatory, atmospheric sciences, health effects and exposure specialists. More formal planning and design with a coordination group started the beginning of 1999. EPA staff recommended the establishment of two initial sites located in Atlanta, Georgia and

Fresno/Bakersfield, California in mid- 1999, which operated from 2 years or longer. Initial objectives for these sites was oriented toward source-receptor characterizations and testing non-routine monitoring methods and establishing logistical procedures, including assessment of resource needs, that will benefit subsequent deployment in other locations.

Preliminary feedback from the initial sites (Atlanta and Fresno) was factored into subsequent design of the full program, which benefited from more integrated planning among science disciplines and regulatory groups. Selection of remaining site locations was completed in the last calendar quarter, 1999 so that local agencies and universities could take into account the availability of Supersites in deploying their chemical speciation network. EPA staff recommends the deployment of the remaining six sites commencing in mid-2000.

## **7.2 Initial Planning and Conceptualization**

The development of this plan was discussed in the introduction above.

### **7.2.1 Program Planning and Design**

Following Subcommittee review scheduled for November 30, 1998, EPA established formal internal and external planning and design teams. Internally, EPA established a planning team composed of atmospheric science, regulatory and health effects and exposure specialists. In parallel, invitations were mailed to other Federal and State/local agencies and private industries active in relevant research to participate in a broader External Coordination Workgroup. EPA staff were responsible for developing more detailed program plans and working with the external committee at a partnership level by providing early drafts and conducting meetings on an as needed basis. The design approach was based on developing a measurements strategy responsive to key questions (science and regulatory) and scientific hypotheses, taking advantage of the PM Measurements Workshop Report. EPA also was responsible for establishing and managing all administrative tasks related to program funding. The active work with the External Coordination Committee is one of several steps (see Section 7) taken to optimize measurement resources across different organizations. The Subcommittee requested to review more detailed plans as part of the decision approval process.

### **7.2.2 Program Execution**

EPA manages program resources that result in funding vehicles to research groups and contractors that conduct much of the work. The actual work is being performed principally by university and other non-profit research groups with support as needed by contractor organizations. EPA assigned Technical Coordinators to the program to work closely with Project PIs. The limited number of Supersites locations demanded that a thoughtful and objective selection process be established. The initial assumptions underlying selections included the ability to capture unique airsheds in populated areas roughly defined through a combination of air chemistry, source distribution and geographical/meteorological characteristics. The following



selection criteria, which again draw on the PM Workshop Report, guided the selection of study areas.

- < **High concentrations of PM in unique and prototypical “airsheds”:** known or expected “high” concentration areas that *will approach* or exceed the PM NAAQS and affect substantial exposure to populations (serves SIPs and health effects and exposure). In the aggregate, these airsheds should reflect locations with varying meteorological, source composition and atmospheric properties, to allow for more comprehensive stressing of sampling methods, more sound statistical design for exposure/health research, and capture areas for varying dominance/mix of sources/atmospheric processes, including concentration regimes that approach the standard.
- < **Existence of ongoing/planned advanced monitoring:** availability of existing advanced field studies with an established expert monitoring support infrastructure to increase the chance of success, and leverage environmental measurement resources (serves predominantly SIPs). However, “under-served” locations lacking a historically strong support infrastructure would benefit from advanced measurements, and test the ability to start up a sophisticated measurement program. When viewed in the aggregate as a group of airsheds, a desirable balance of well-served, complemented with historically “under-served” locations provide potential rewards toward expansion of widespread measurement capability.
- < **Ongoing and planned health effects and exposure research studies:** Studies that benefit from Supersites measurements and foster greater coordination between measurements, atmospheric scientists and health and exposure science communities. EPA staff recommended that two sites in 1999 located in Atlanta, GA and Fresno/Bakersfield, CA be established. Both of these locations are likely to exhibit high PM levels, are associated with planned or ongoing major field sampling programs with expert technical personnel, and represent diverse airsheds (e.g., east versus west; predominant high sulfate versus high nitrate; predominant summer versus winter episodes). Moreover, it was imperative that the initial sites offer a high success probability to increase the usefulness of data early in the program.

These early needs included testing and intercomparisons of emerging sampling methods to expedite application to other areas, data to support EPA’s review of the PM standard and to elucidate source-receptor relationships for SIPs. Atlanta and Fresno provided excellent opportunities for conducting health effects and exposure research studies in the near and long term. Furthermore, both locations served as models for coordinating across university groups, industry and State/local agencies.

## **7.3 Key Planning Personnel**

### **7.3.1 Program Manager**

The Program Manager has the responsibility to make the final decision on the implementation of the program. He has the following responsibilities:

- < meet with the expert panel or/or CASAC to review the progress of the program;
- < direct OAQPS personnel listed below;
- < review the progress of the program and assure that it is moving forward as recommended by the expert panel.

### **7.3.2 Program Officer**

The Program Officer is the person who performs the following planning activities:

- < identify program schedules;
- < writes the level of effort proposals;
- < oversees the implementation of program from a technical perspective.

### **7.3.3 Quality Assurance Coordinator**

The QAC is responsible for the QA planning for the program. He is responsible for:

- < overseeing the overall QA for the program;
- < assess any data obtained from sources outside of the EPA that did not use approved QAPPs;

## **7.4 Other Planning Activities**

The following activities will facilitate the success of the program.

### **7.4.1 Communication**

OAQPS has the overall responsibility for the Supersites program. As such, the agency must assure that each agency within the program receives the goods, services and technical knowledge to perform their duties. In addition, all parties must be made aware of events and deadlines. Part of this is clear communication amongst all agencies. The following methods will be used to impart information to ensure proper planning.

#### **7.4.2 Tele-communications**

Tele-conferencing is an extremely useful tool to impart information and ensure that the planning process is moving forward. Drs. Les Hook and Sigurd Christensen lead the tele-conference working group for the data processing issues. This working group consists of OAQPS, NARSTO and Supersites data base managers. Drs. Hook and Christensen have guided this working group by informing the group concerning the development of the NARSTO data archiving process, data formatting, and metadata issues.

In addition, a working group formed in spring of 2000 to bring together the quality system for the Supersites program. This QA working group is led by Mr. Dennis Mikel, who is the Supersites QAC. The QA workgroup consists of OAQPS and ORIA and Supersites QA managers.

Dr. Joellen Lewtes, EPA ORD in Seattle, Washington leads the Organic Analysis Workgroup that has been overseeing the issues related to Organic Carbon research and analysis.

Dr. Peter McMurray, led the Supersites Size Distribution Committee, which summarized and compared the different measurements for particles and aerosols.

#### **7.4.3 Internet**

EPA supports and maintains the AMTIC web site on the Word Wide Web. The address for the Supersite Program is <http://www.epa.gov/ttn/amtic/ssprojec.html>. Guidance, special announcements and related documents are posted on this website. These documents can be downloaded from the File Transfer Protocol (FTP) areas of the web site. In addition, the EPA and all of the agencies involved in this program have electronic mail (email) capabilities, by which information can be transmitted and all affected parties can be informed of meetings and special events.

## **8.0 Implementation of Work**

Each Supersites group will develop a QAPP as described in Section 2.4.2 of this QMP. Since each Supersites group has developed their own QAPPs, ultimately each agency is responsible for the implementation of their program. This section will outline the individuals in each agency that will be required to implement the work.

### **8.1 Implementation Roles**

#### **8.1.1 Principal Investigator**

The PIs are responsible for all work to be performed. This includes:

- < ensuring that work is being performed according the approved QAPP;
- < development and implementation of procedures;
- < development of special or “critical” techniques that might deviate from the normal good laboratory practices; and
- < ensuring that quality assured data are transferred to the NARSTO QSSC in a timely manner.

#### **8.1.2 Quality Assurance Managers**

The QAMs oversee through internal TSAs and review of data, that procedures are being followed as specified by the project QAPP and SOPs. In addition, the QA managers must also:

- < identify operations needing SOP’s;
- < help prepare the procedures by writing and revising the QAPP;
- < review and approve SOP’s before they are implemented;
- < provide new tools to the monitoring or laboratory staff that may enhance or increase the productivity of the operation;
- < work with the PI in approving changes to procedures;
- < revise the QAPP to remove obsolete techniques and keep up-to-date procedures available to field and laboratory staff;
- < verify that changes made in the field, through TSAs, are performed as prescribed in the QAPP and SOP’s;
- < perform (or through a contractor) TSA and DQA.

### **8.1.3 Individual Investigators**

The investigators oversee their particular project or instrument. Any contractors or students working with or for them must follow the specified SOPs and QAPPs. In addition, the investigators must also:

- < prepare the procedures and SOPs for their instrument;
- < review and approve procedures before they are implemented;
- < provide training to their students or contractors before the instruments are operated;
- < work with the PI and QA manager in approving changes to procedures;
- < validate collected data and work with Data Manager to process data for site data system and archiving; and
- < actively engage other researchers in analyzing data.

### **8.1.4 Data Manager**

The Data Manager works with the project team to facilitate the data management, review, analysis, and archiving process. In addition, the Data Managers must also:

- < design, develop, and maintain a site data system suitable for site data acquisition, validation, and analysis activities;
- < assist investigators in collecting data and metadata, quality assuring data, formatting data files, and providing data sets to the NARSTO QSSC for archiving; and
- < participate in Supersites Data Management Working Group activities.

## 9.0 Data Quality Assessments

This section describes the quality-related activities necessary to support the Supersites program for acquisition, validation, assessment, and reporting.

### 9.1 Program Assessment Techniques

Assessment is an all-inclusive term used to denote any of the following: TSAs, performance audits, data quality assessments(DQAs), performance evaluations, Network Reviews and QAPP reviews. Definitions for each of these activities can be found in the Glossary. Table 10.1 provides information on the assessment type, assessor and frequency.

**Table 9.1 Assessment Schedule**

Assessment Type	Assessor	Frequency
Technical Systems Audits	Project Level QA Managers	At the beginning of the project
Performance Audits	Project Level QA Manager	At the beginning of the project/annually after the first year
Network Review	EPA- OAQPS-QA Coordinator	At the beginning of the program
Performance Evaluations	EPA -ORIA-NAREL Lab	Throughout the life of the program
QAPP Review and Approval	EPA - OAQPS-QA Coordinator	Before projects begin
Data Quality Assessment	Project Level QA Managers	After data collection phase

#### 9.1.1 Technical System Audit

The individual project QA managers for each project or their contractors will perform the TSAs. QA managers must not be involved in the routine data collection or analysis program. The results of the audits will be submitted to the QA manager who will review the results and institute corrective action if needed. The TSA results will then be incorporated into the QA final report (QAFR) that will be submitted to OAQPS.

#### 9.1.2 Performance Audits

Individual project QA managers for each project or their contractors will perform performance audits. The audits should commence at the beginning of the program in order to detect any problems with the instruments. Any deviations from the Measurement Quality Objectives (MQOs) as stated in the project QAPP will be reported to the project QA manager. Corrective actions will be performed as stated in the QAPP. Performance audits for the criteria pollutants are performed annually. The results will then be incorporated into the QA final report (QAFR) that will be submitted to OAQPS.

### **9.1.3 Network Review**

The EPA-EMAD-MQAG office will perform the network assessment in the first year of the Phase II project. The EPA QAC will request that all project QA managers or PIs submit electronic photographs to the MQAG. These pictures will be compiled to create the Network Plan. Maps will be generated through Geographic Information Systems (GIS) programs and will be saved to computer hard drives.

### **9.1.4 Performance Evaluations**

EMAD-MQAG is the lead agency for Performance Evaluations (PEs). The MQAG will be working with the Office of Indoor Air (ORIA) National Air and Radiation Environmental Laboratory (NAREL). NAREL will submit PEs to a majority of the laboratories during the first year of the study. The results from the PEs will then be submitted to MQAG-QAC who will share this information with the QA managers of each Supersite. This information will be included in the QAFRs.

### **9.1.5 QAPP Review and Approval**

EMAD-MQAG is the agency that will review and approval all QAPP. These will be submitted to the MQAG office with enough time for a thorough review prior to project start. Comments will be sent back to the submitting project for clarification and re-submission. When MQAG QA personnel are satisfied with the QAPP, then final approval will be determined. Data collected prior to QAPP approval must be flagged accordingly.

### **9.1.6 Data Quality Assessment**

Each project QA manager is tasked with writing a QAFR for their individual project. The QAFR will consist of the results of the performance and technical systems audits. In addition, the QA Managers will include their assessment of the data collected as stated in their QAPPs. Precision, Bias and accuracy data will be presented as stated in the QAPPs. The equations used in the QAPPs will be utilized to access the data sets. This will be submitted within two years after the end of the project to EMAD-MQAG. The QAFR will evaluate the data using the MQOs that are stated in the QAPP. EMAD-MQAG will create a final program QAFR that will summarize the quality of the Supersites experiments.

## **9. 2 Reports to Management**

As stated in Section 9.1, each of the QA managers is required to submit a QAFR for each project. The QAFR will evaluate the data using the MQOs that are stated in the QAPP. EMAD-MQAG will create a final program QAFR that will summarize the quality of the Supersites experiments.

## **9.3 Planning, Training and Authority**

The following sections will discuss process of planning, training and the authority of those whom will be performing assessments.

### **9.3.1 Planning**

The QMP is the first step towards having an effective planning process. This QMP will outline how assessors for this program will plan, schedule and implement assessments. At the beginning of the year, those who have been assigned to perform assessments will set out their tentative schedule for assessments. This schedule will first be submitted to the PIs and QA managers, who can modify schedule. After management approval, the schedule is submitted (by email) to the agencies that will be assessed. Usually, one month before the assessment, the agency to be assessed is notified by telephone of the exact dates and times. At this time, the assessment form (TSA forms) is submitted to the agency to be assessed (in writing or via email). This allows the agency the time to review the forms and gather the information needed to be presented to the assessors. This has a two-fold objective: it allows those to be assessed knowledge of what will be required and it can minimize the time that assessors are in the field and that managers and scientists are away from their other duties.

### **9.3.2 Training**

Training is essential to assessors in two ways: the assessor needs to understand the process by which data are generated, without this knowledge the assessment may be inadequate, and in order to communicate clearly with the agency that is being assessed, the assessor must be competent. Training fills these needs. A part of training that is not seen or documented is the fact that those chosen for assessment should have experience in the field in which they are assessing. Although most QA criteria and theory are universal, understanding the process by being experienced in working in that field is essential. It is the responsibility of the QA manger of each individual Supersites project to provide training for the assessment team. If the project decides to hire a contractor to perform assessments, the project PI and QA manager should have the confidence that this contractor can fulfil their duties as described in the QAPP and this QMP.

### **9.3.3 Authority**

All personnel that are chosen to conduct assessments to this program have the authority to do so through the EPA. OAQPS has the overall responsibility and authority over this program. It delegates this authority to perform assessments to all agencies/contractors that perform such duties. All personnel in this capacity have the right and responsibility to:



- identify problems;
- Identify and cite noteworthy practices that may be shared with others to improve the quality of their operations;
- propose recommendations for resolving quality problems;
- independently confirm implementation and effectiveness of solutions;
- report these finding to the Supersites PI or QA manager.

Reports of assessments are discussed in section 9.2.

#### **9.3.4 Disputes**

Occasionally, findings in an assessment report may be disputed by the researcher/investigator assessed. Any disputes that are announced should first be handled by the Supersites PI or QA manager. If this fails to satisfy the situation, then OAQPS has the final authority to make a decision concerning a dispute.

## **10.0 Quality Improvement**

This section will outline planning and implementation procedures that will be employed for improving the quality of the program. OAQPS and the QA managers from each Supersite have the responsibility to improve the quality of the program over an unspecified period of time. There can be no set dates on when this improvement can or will occur, however, OAQPS and the Supersites QA managers will make every effort to improve the system during the life of the Supersites program.

### **10.1 Quality Improvement Process**

This section will outline the process flow of the quality improvement paradigm.

#### **10.1.1 Assessment**

The assessments that are planned for the Supersites program are detailed in section 9.1 of this QMP. Once the assessment agency has completed an assessment, a report will be sent to the QA manager of the Supersites, who will review the results. Depending on the assessment report and the assessment scheme detailed in the QAPP, action may be deemed necessary and an assessment loop will be initiated.

#### **10.1.2 Assessment Report**

The assessment report will state the who, what, where and when of the assessment. The report will highlight the findings of the assessment. The QA manager will contact investigator where findings may be outside of the MQOs or requirements of the QAPP.

#### **10.1.3 Response**

The investigator has the right to respond in writing, or email. All responses will be reviewed by the assessor, QA manager and PI and will respond in kind. If any disputes arise from the assessment this will be dealt as detailed in section 9.3.4 of this QMP. In addition, the EPA has electronic mail (email) capabilities, by which information can be transmitted and all affected parties can be informed of meetings and special events.

#### **10.1.4 Final Assessment Report**

The final assessment report (QAFR) will be sent to OAQPS and the assessed agency. This report will highlight the findings of the assessment and recommendations.

### **10.1.5 Review, Compilation and Analysis**

Once OAQPS has received the final assessment reports from all of the Supersites, the EMAD QAC will compile the information and analyze the data. Any disputes concerning the assessments will be finalized at that time. The QAC will check the assessment reports to for outstanding issues raised by the reports. If any have not been resolved, then the QAC may recommend flagging of the data for a particular parameter.

### **10.1.6 OAQPS-QAFR**

The QAFR will be the final report. The report will highlight the major findings of the Supersites assessment and recommendations will be made in this report. In addition, the results from the NAREL PE will also be included into the QAFR.

## **10.2 Quality Improvement Assurance**

The OAQPS-QAFR and the QAFRs from each Supersite will assess the quality of the Supersites data set. Once the QAFRs are issued, the report will be sent to NARSTO for archive into the Supersites data area. Deficiencies that are not addressed will be noted in the reports. Any university, government or public researcher will be advised to read the QAFRs before they use the data in any analysis. This assures that the researchers understand the limitations of the data that they will use and should act responsibly in presenting their results to the scientific community.

---

## GLOSSARY OF QUALITY ASSURANCE AND RELATED TERMS

**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.

**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.

**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.

**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.

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

**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 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 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.

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

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

**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.

**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.

**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.

**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.

**NARSTO Program** — NARSTO is a public/private alliance, whose membership spans government, the utilities, industry, and academe throughout Mexico, the United States, and Canada. The NARSTO mission is to plan, coordinate, and facilitate comprehensive, long-term, policy-relevant scientific research and assessment of primary and secondary pollutant species emitted, formed, transformed, and transported in the troposphere over the North American continent. Member organizations support the mission through participation in workshops and meetings, financial support, or contribution of in-kind resources. Atmospheric research and assessment initiatives that support the mission may request to become NARSTO Technical Programs. Technical Programs agree to follow certain quality assurance and data management guidelines and send their data to the NARSTO Permanent Data Archive.

**NARSTO QSSC** — The NARSTO Quality Systems Science Center (QSSC) at the Oak Ridge National Laboratory assists NARSTO projects by consulting, reviewing quality system planning documents, and advising about data management issues. The QSSC is responsible for archiving data at the NARSTO Permanent Data Archive.

**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.

**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.

**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 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 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).

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

**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.

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

**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.

**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.

**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.

**Vendor** — 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: seller, contractor, subcontractor, fabricator, or consultant.

**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.

## Contact List

The following list is a compilation of contacts for the Supersites Program

Contact	Agency	Phone Number	Email
Rich Scheffe	OAQPS-EMAD-MQAG	919-541-4650	<a href="mailto:scheffe.rich@epa.gov">scheffe.rich@epa.gov</a>
Dennis Mikel	EPA-NARSTO	919-541-5511	<a href="mailto:mikel.dennisk@epa.gov">mikel.dennisk@epa.gov</a>
Jeffrey West	NOAA (NARSTO)	919-541-4635	<a href="mailto:west.jeffrey@epa.gov">west.jeffrey@epa.gov</a>
Michael Clark	ORIA-NAREL	334-270-7069	<a href="mailto:clark.michael@epa.gov">clark.michael@epa.gov</a>
Paul Solomon	ORD-Las Vegas	702-798-2280	<a href="mailto:solomon.paul@epa.gov">solomon.paul@epa.gov</a>
Marc Pitchford	OAQPS-EMAD-Las Vegas	702-798-0432	<a href="mailto:marcp@dri.edu">marcp@dri.edu</a>
Michael Jones	OAQPS-EMAD-MQAG	919-541-0528	<a href="mailto:jones.mike@epa.gov">jones.mike@epa.gov</a>
Les Hook	DOE (NARSTO)	865-241-4846	<a href="mailto:Hookla@ornl.gov">Hookla@ornl.gov</a>
Sigurd Christensen	DOE (NARSTO)	865-574-7394	<a href="mailto:swc@ornl.gov">swc@ornl.gov</a>
John Ondov	University of Maryland	301-405-1859	<a href="mailto:jondov@wam.umd.edu">jondov@wam.umd.edu</a>
John Watson	Desert Research Institute	775-674-7046	<a href="mailto:Johw@dri.edu">Johw@dri.edu</a>
David Allen	University of Texas	512-475-7842	<a href="mailto:Allen@che.utexas.edu">Allen@che.utexas.edu</a>
Constantinos Sioutas	University of California	213-740-0603	<a href="mailto:Sioutas@almaak.usc.edu">Sioutas@almaak.usc.edu</a>
Ken Demerjian	University of Albany	518-437-8705	<a href="mailto:Kld@asrc.cestm.albany.edu">Kld@asrc.cestm.albany.edu</a>
Spyros Pandis	Carnegie Mellon University	412-268-3531	<a href="mailto:Spyros@andrew.cmu.edu">Spyros@andrew.cmu.edu</a>
Jay Turner	Washington University	314-935-5480	<a href="mailto:Jrturner@seas.wustl.edu">Jrturner@seas.wustl.edu</a>



Project: Speciation QMP  
Appendix A  
Revision No:1.0  
Date: 9/13/01

## **Appendix A - Procurement Policy Notice For Contracting Officer's Representatives**

## **Procurement Policy Notice For Contracting Officer's Representatives**

### **1. Background**

The Federal Acquisition Regulations, Title 48 of the Code of Federal Regulations, was recently amended to address contract quality systems requirements on a government-wide basis. The new FAR clause at 52.246-11, Higher-Level Quality Requirement, allows a Federal agency to select a voluntary consensus standard as the basis for its quality requirements for contracts and allows tailoring of the standard to more effectively address specific needs or purposes. Based on this FAR clause, EPA has selected ANSI/ASQC E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, as the basis for its environmental quality requirements and has tailored this standard to ensure that contractors demonstrate conformance to this national standard.

Due to these changes, 48 CFR 1546, a quality regulation that applies only to EPA, will be removed from the Code of Federal Regulations. The tailoring language allowed by 52 CFR 246-11 and pertinent requirements in 48 CFR 1546 will be included in the EPA Directive 1900, *Contracts Management Manual*. This procurement policy notice is being issued to ensure an orderly transition from 48 CFR 1546 to EPA Directive 1900 and contains tailoring language allowed by 52 CFR 246-11. It is in effect until the revisions to Directive 1900 are completed.

### **2. Application**

This procurement policy notice applies to all Contracting Officer's Representatives, that is, all Project Officers, Deputy Project Officers, Regional Project Officers, Zone Project Officers, Delivery Order Project Officers, Work Assignment Managers, and Task Order Managers.

This procurement policy notice applies to all solicitations; task orders, work assignments, and other statements of work for contracts (including simplified procurement acquisitions) that involve environmentally related measurements (i.e., the collection and use of environmental data<sup>1</sup> and the design, construction, and operation of environmental technologies). Examples of environmentally related measurements are contained in Attachment 1.

---

<sup>1</sup>Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

### 3. General Requirements

Although this procurement policy notice applies solely to contracts, EPA requires that all recipients of funds (i.e., contractors, grantees, etc.) for work involving environmentally-related measurements comply with the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. To demonstrate conformance to this standard, EPA requires all recipients submit two types of documentation:

1. Documentation of the organization quality system (usually called a Quality Management Plan), and/or
2. Documentation of the application of quality assurance (QA) and quality control activities to a project-specific effort (usually called a Quality Assurance Project Plan).

Use of existing quality system documentation, such as documentation that a company is ISO 9000 certified, may be acceptable alternatives.

For small contracts, these two documents may be combined into a single document that describes the organization's quality system and the application of this system to the work performed under the contract. This can only be done with permission of the EPA QA Manager who will identify which elements should be addressed in this combined document.

Some contracts may cover activities of a program that are to be conducted at multiple locations or over a long period of time; for example, a large monitoring program that uses the same methodology at different locations. In this case, a Programmatic Quality Assurance Project Plan may be used to describe, in a single document, the general, common activities that are not site- or time-specific but are applied throughout the program. Project-specific information is then added to the approved Programmatic Quality Assurance Project Plan on a project-specific basis.

### 4. Directions for Pre-Award and Post-Award Activities

STEP 1. After consultation with the QA Manager (or the appropriate QA personnel<sup>2</sup>), complete the QA Review Form (as described in Section 2.5 of the *Contracts Management Manual*) and obtain the concurrence signature of the QA Manager.

---

<sup>2</sup>Appropriate QA personnel are defined in each EPA organization's Agency-approved Quality Management Plan. For simplicity, the use of the term QA Manager will refer to both the QA Manager and other approved QA personnel.

If QA requirements are not applicable to the procurement (indicated on the QA Review Form), the remaining Steps do not apply.

STEP 2. With the assistance of the QA Manager, determine what quality standards apply. Generally, ANSI/ASQC E4-1994 applies to the majority of EPA's work; however, standards other than ANSI/ASQC E4-1994 may also apply.

STEP 3. If ANSI/ASQC E4-1994 applies, identify (with the assistance of the QA Manager) whether the contract work will consist of:

- A. A single project,
- B. Multiple projects with different activities, or
- C. Multiple projects with similar activities.

A If the contract work consists of a *single project*, you must require one of the following:

- |                  |  |
|------------------|--|
| 1. Before Award: | A Quality Management Plan  |
| After Award:     | A Quality Assurance Project Plan for the contract<br>(Note: These are the default requirements.) |
| 2. Before Award: | QA Manager-specified documentation <sup>3</sup>  |
| After Award:     | A Quality Management Plan and a Quality Assurance Project Plan for the contract                  |
| 3. Before Award: | QA Manager-specified documentation <sup>3</sup>  |
| After Award:     | A Joint Quality Management Plan/Quality Assurance Project Plan for the contract                  |
| 4. Before Award: | A Joint Quality Management Plan Quality Assurance Project Plan for the contract                  |
| After Award:     | None   |

---

<sup>3</sup>QA Manager-specified documentation is defined in an EPA organization's Agency approved Quality Management Plan. This documentation must be consistent with Agency requirements defined in EPA Order 5360 (May 2000).

B. If the contract work consists of *multiple projects with different activities*, you must require one of the following:

1. Before Award: A Quality Management Plan  
After Award: A Quality Assurance Project Plan for each applicable project  
(Note: These are the default requirements.)
2. Before Award: QA Manager-specified documentation<sup>3</sup>  
After Award: A Quality Management Plan and a Quality Assurance Project Plan for each applicable project

C. If the contract work consists of *multiple projects with similar activities*, you must require one of the following:

1. Before Award: A Quality Management Plan  
After Award: A Quality Assurance Project Plan for each applicable project  
(Note: These are the default requirements.)
2. Before Award: A Quality Management Plan  
After Award: A Programmatic Quality Assurance Project Plan for the program (contract) and a project-specific supplement to the Programmatic Quality Assurance Project Plan for each applicable project
3. Before Award: A Quality Management Plan and a Programmatic Quality Assurance Project Plan for the program (contract)  
After Award: A project-specific supplement to the Programmatic Quality Assurance Project Plan for each applicable project

For each of the three cases (single project, multiple projects with different activities, or multiple projects with similar activities), the default requirements are listed as the first option (1). These requirements should be used unless the QA Manager concurs otherwise.

STEP 4. For each type of documentation identified in STEP 4, identify (with the assistance of the QA Manager) whether the documentation should be prepared in accordance

with the standard EPA requirements [i.e., *EPA Requirements for Quality Management Plans (QA/R-2)* and *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*] or whether other EPA-approved equivalent requirements will be used. The standard EPA requirements should be used unless the QA Manager concurs otherwise.

- STEP 5. If additional standards apply besides ANSI/ASQC E4-1994, identify (with the assistance of the QA Manager) what documentation is required to determine conformance to these standards.
- STEP 6. Provide the Contracting Officer with a list of documentation required before and after award (from cases A, B, and C in STEP 3) and if applicable, a list of any equivalent requirements to be used (STEP 4), and the Title, Numbering, Date, and any documentation required to demonstrate conformance for any additional standards (STEP 5).

The information that must be submitted to the Contracting Officer is contained in Attachment 2. It is recommended that you complete this form and provide it to the Contracting Officer with the QA Review Form (STEP 1).

- STEP 7. After award of the contract, if the work consists of multiple projects (cases B and C in STEP 3), complete a QA Review Form and Section 3 of Attachment 2 for each statement of work (e.g., work assignment, delivery order, task order).

Include in each applicable statement of work the requirement to submit the quality documentation needed after contract award. For example, if a project-specific supplement to the Programmatic Quality Assurance Project Plan is required for the project described in the statement of work, you must incorporate the requirement to develop this document into the statement of work.

## **5.0 Example of Activities Involving Environmentally-Related Measurements**

The following are some examples that involve environmentally-related measurements:

- C Activities that collect data to establish/determine the states/conditions of environmental or ecological systems and the health of human populations;
- C Activities that collect data to establish the ambient conditions in air, water, sediments, and soil in terms of physical, chemical, radiological, or biological characteristics;
- C Activities that collect data to establish/categorize radioactive, hazardous, toxic, and mixed wastes in the environment and to establish their relationships with and/or impact on human health and ecological systems;
- C Activities that monitor and quantify the waste and effluent discharges to the environment from processes and operations (e.g., energy generation, metallurgical processes, chemicals production), during either normal or upset conditions (i.e., operating conditions that cause pollutant or contaminant discharges);
- C Activities that use environmental data to develop environmental technology for pollution prevention, pollution control, waste treatment, storage, and disposal, and waste remediation;
- C Activities that use environmental data in mapping environmental process and conditions, and/or human health risk data, etc. (e.g., geological information system);
- C Activities that generate data from the evaluation of environmental technology used for pollution prevention; pollution control; waste treatment, storage, and disposal; and waste remediation;
- C Activities that generate/collect data to support enforcement and/or compliance monitoring efforts;
- C Activities that collect/generate data for the evaluation and/or demonstration of environmental technology (e.g., treatability and pilot studies);
- C Activities that investigate and collect data to determine chemical, biological, physical, or radioactive constituents in environmental and ecological systems, and their

behavior and associated interfaces in those systems, including exposure assessment, transport, and fate;

- C Activities that collect and/or generate data from the development and evaluation of methods for use in the collection, analysis, and use of environmental data;
- C Activities that involve the development, evaluation, and use of computers or mathematical models (and their input data) to characterize environmental processes or conditions;
- C Activities that use secondary data (i.e., environmental data that were collected for other purposes or obtained from other sources, including literature, industry surveys, compilations from computerized data bases and information systems) for the development and/or evaluation of computerized or mathematical models of environmental processes and conditions, and collect/generate data from the process; and
- C Activities that collect and/or use environmental data for monitoring/addressing concerns over the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical dosimetry, radiation dosimetry).



## 6.0 Contracts Clause and Tailoring Language Form

Use this form to provide direction to the Contracting Officer on the quality assurance activities that are required in your solicitation and contract.

1. List any additional quality standards besides *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E-4)*

Title: \_\_\_\_\_  
Numbering: \_\_\_\_\_  
Date: \_\_\_\_\_  
Documentation required to determine conformance:  
\_\_\_\_\_

2. a. Check all required documentation required before award of contract:

	Documentation	Specifications
9	Quality Management Plan	<u>EPA Requirements for Quality Management Plans (QA/R-2)</u> [dated ____] <sup>4</sup>
9	Joint Quality Management Plan/Quality Assurance Project Plan	<u>EPA Requirements for Quality Management Plans (QA/R-2)</u> [dated ____] and <u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u> [dated ____]
9	Programmatic Quality Assurance Project Plan	<u>EPA Requirements for Quality Management Plans (QA/R-2)</u> [dated ____] and <u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u> [dated ____]
9	Other Equivalent:	[Insert specification]

- b. If the standard specifications do not apply, identify equivalent specifications:
3. a. Select all documentation required after award of contract either at time of award or upon issuance of a statement of work:

<sup>4</sup>Note: we will fill in this date once the Federal Register Notice is published.

	<b>Documentation</b>	<b>Specifications</b>	<b>Due After</b>
<b>9</b>	Quality Management Plan	<u>EPA Requirements for Quality Management Plans (QA/R-2)</u> [dated ____]	Award of contract
<b>9</b>	Joint Quality Management Plan/Quality Assurance Project Plan	<u>EPA Requirements for Quality Management Plans (QA/R-2)</u> [dated ____] and <u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u> [dated ____]	Award of contract
<b>9</b>	Contract Quality Assurance Project Plan	<u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u> [dated ____]	Award of contract
<b>9</b>	Programmatic Quality Assurance Project Plan	<u>EPA Requirements for Quality Management Plans (QA/R-2)</u> [dated ____] and <u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u> [dated ____]	Award of contract
<b>9</b>	Quality Assurance Project Plan for each applicable project	<u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u> [dated ____]	Issuance of statement of work
<b>9</b>	Project-specific supplement to Programmatic Quality Assurance Project Plan	<u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u> [dated ____]	Issuance of statement of work
<b>9</b>	Other Equivalent:	<i>[Insert specification]</i>	<i>[Select one]</i> <b>9</b> award of contract <b>9</b> issuance of statement of work

- b. If the standard specifications do not apply, identify equivalent specifications.

**TECHNICAL REPORT DATA***(Please read Instructions on reverse before completing)*

1. REPORT NO. <b>EPA-454/R01-011</b>	2.	3. RECIPIENT'S ACCESSION NO.
AND SUBTITLE <b>Quality Management Plan for the PM Supersites Program</b>		5. REPORT DATE <b>09/01</b>
		6. PERFORMING ORGANIZATION CODE
7. AUTHOR(S) <b>Dennis Mikel, Michael Papp, Les Hook, Sigurd Christensen</b>		8. PERFORMING ORGANIZATION REPORT NO.
9. PERFORMING ORGANIZATION NAME AND ADDRESS  <b>U.S. Environmental Protection Agency Office of Air Quality Planning and Standards Research Triangle Park, NC 27711</b>		10. PROGRAM ELEMENT NO.
		11. CONTRACT/GRANT NO.
12. SPONSORING AGENCY NAME AND ADDRESS  <b>Director Office of Air Quality Planning and Standards Office of Air and Radiation U.S. Environmental Protection Agency Research Triangle Park, NC 27711</b>		13. TYPE OF REPORT AND PERIOD COVERED
		14. SPONSORING AGENCY CODE <b>EPA/200/04</b>
15. SUPPLEMENTARY NOTES		
16. ABSTRACT <b>The Quality Management Plan outlines the management structure for the Particle Matter Supersites Program. The guidance document gives details on how the Supersites Program will be implemented. The Supersites program is a multi-year research program that draws upon EPA OAQPS and Office of Indoor Air and university research groups throughout the country. This Plan outlines each agency's responsibilities and authority.</b>		
KEY WORDS AND DOCUMENT ANALYSIS		
a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
<b>Air Quality Monitoring Quality Assurance</b>	<b>Air Pollution Control</b>	
18. DISTRIBUTION STATEMENT  <b>Release Unlimited</b>	19. SECURITY CLASS ( <i>Report</i> ) <b>Unclassified</b>	21. NO. OF PAGES
	20. SECURITY CLASS ( <i>Page</i> ) <b>Unclassified</b>	22. PRICE