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Environmental Protection
Agency
Office of Air and Radiation

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

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July 2001

Quality Management Plan for the Fine Particle Speciation Trends Monitoring Program

Foreword

The following document is a Quality Management Plan (QMP) for the environmental data operations of the Fine Particle - 2.5 micron ($PM_{2.5}$) Speciation Trends Monitoring Program. The U.S. Environmental Protection Agency (EPA) Office of Air Quality Planning and Standards (OAQPS) staff developed this QMP to outline the roles of organizations involved in the Speciation Trends Network (STN). Please review this document and forward your comments and suggestions to the person listed in the Acknowledgment Section.

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 plan.

Acknowledgments

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

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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
CO	contracting officer
DQA	data quality assessment
DQAO	data quality assessment objective
DQOs	data quality objectives
EDO	environmental data operation
EMAD	Emissions, Monitoring, and Analysis Division
EPA	Environmental Protection Agency
EPM	environmental program management
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
OAQPS	Office of Air Quality Planning and Standards
ORIA	Office of Radiation and Indoor Air
PC	personal computer
PE	performance evaluation
QA/QC	quality assurance/quality control
QA	quality assurance
QAC	quality assurance coordinator
QAAR	quality assurance annual report
QAO	quality assurance officer
QAPP	quality assurance project plan
QMP	quality management plan
R&IE	Radiation and Indoor Environment
SLAMS	state and local air monitoring stations
SOP	standard operating procedure
SOW	statement of work
STAG	state assistance grant
STN	speciation trends network
TSA	technical system audit
WAM	work assignment manager

Tables

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Quality Management Plan Identification and Approval

The attached QMP for the Fine Particle Speciation Trends 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

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1) Signature: _____ Date: 13 June 2001

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1.0 Project/Task Organization

1.1 Introduction

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 the obligation of the law, the EPA recently 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 two new primary standards for the fine fraction of PM (i.e., particles with aerodynamic diameters less than or equal to 2.5 :m, referred to as $PM_{2.5}$) and the regulatory requirements for monitoring the chemical composition of these particles. In response to this promulgation, EPA has instituted a $PM_{2.5}$ network. Please see Figure 1.1, which illustrates the overall national fine particle network. As can be seen from the this figure, the second tier of the pyramid deals with the routine speciation. This QMP deals strictly with

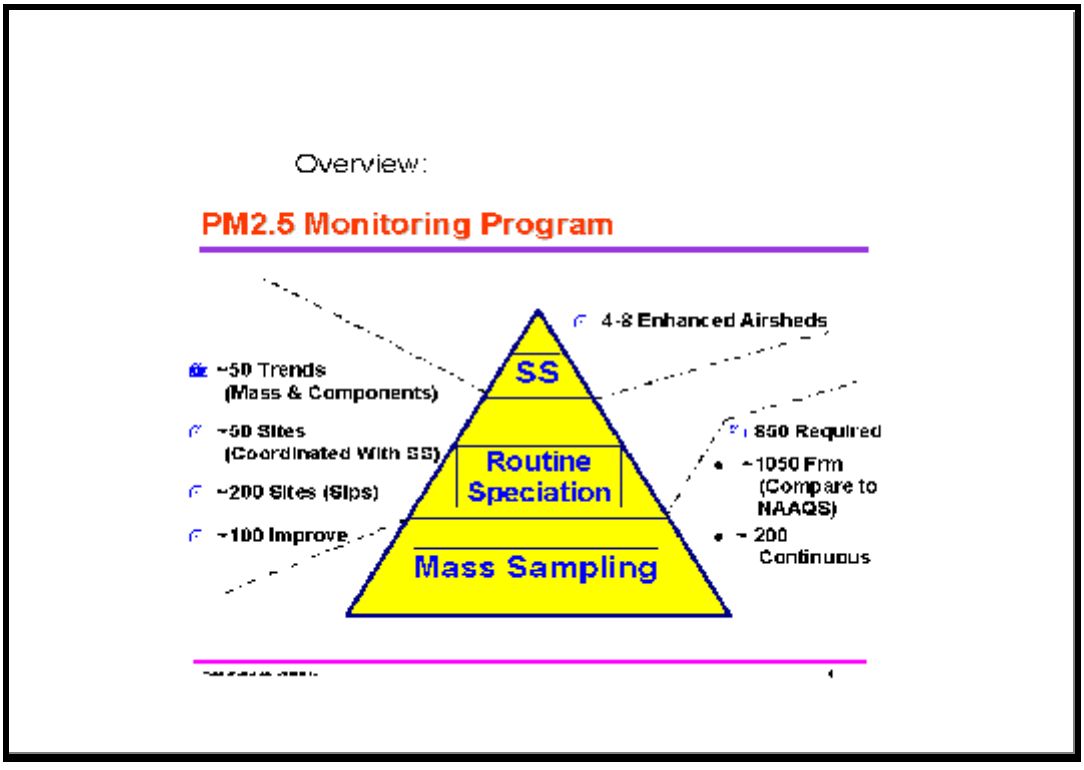

Figure 1.1 Overview of the National Fine Particle Network.

54 trends sites that are a portion of the routine speciation program.

In meeting the requirements to monitor and gather data on the chemical makeup of fine particles, EPA is establishing a Speciation Trends Network (STN). These STN samplers will be placed at various national air monitoring stations (NAMS) and State and local air monitoring stations (SLAMS) across the Nation. It is currently anticipated that 54 of these chemical speciation sites will be used to determine, over a period of several years, trends in concentration levels of selected ions, metals, carbon species, and organic compounds in $PM_{2.5}$. Further breakdown on the location or placement of the trends sites requires that approximately 20 of the monitoring sites be placed at existing Photochemical Assessment Monitoring Stations (PAMS). The placement of the remaining trends sites will be coordinated by EPA, the Regional Offices, and the state and local agencies. Locations will be primarily in or near larger Metropolitan Statistical Areas (MSAs). The remaining chemical speciation sites will be used to enhance the required trends network and to provide information for developing effective State Implementation Plans (SIPs). This QMP focuses on management and communication structure to assure data of adequate quality are produced by the 54 trends network sites.

As Figure 1 illustrates, the STN is a component of the National $PM_{2.5}$ Monitoring Network. Although the STN is intended to complement the activities of the much larger gravimetric $PM_{2.5}$ measurements network component (whose goal is to establish if NAAQS standards are being attained), STN data will not be used for attainment or non-attainment decisions. The programmatic objectives of the STN network are:

- *Annual and seasonal spatial characterization of aerosols;*
- *Air quality trends analysis and tracking the progress of control programs;*
- *Integration of chemical speciation data set with the data collected from the IMPROVE network; and*
- *Development of emission control strategies.*

Stakeholders in the STN will be those at EPA and State and Local agency investigators who are seeking to determine concentration trends of $PM_{2.5}$ chemical species over a period of 3 or more years and decision-makers at state and local levels who will use the data as input to models and for development of emission control strategies and determination of their long-term effectiveness. Other users will be public health officials and epidemiological researchers. However, expectations for data sets from the STN must be put in context. A number of limitations are recognized, (for instance, the 24-hour integrated sample approach, taken every 3rd day, is not suitable for determination of diurnal patterns and may have limited use to those who study health effects). EPA recognizes these data use limitations and limitations on the sampling and analysis methodologies. Thus, EPA does not rule out the possibility that objectives, requirements, and methods for speciation sampling may need to be adjusted in the future.

The STN is included in the monitoring requirements and principles set forth by the ***Federal Register***

(62 FR 38763), promulgated as part of the $PM_{2.5}$ National Ambient Air Quality

Standard (NAAQS) review completed in 1997. At a minimum, the STN will quantify mass concentrations and significant $PM_{2.5}$ constituents which include trace elements, sulfate, nitrate, sodium, potassium, ammonium, and carbon. 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.

EPA anticipates that approximately 250 sites will comprise the full chemical speciation network. In addition to the 54 sites for the trends network, another 200 sites will be implemented to enhance the required network and provide information for developing effective State Implementation Plans (SIPs). The non-trend sites will be allowed flexibility in terms of sampling frequency, site selection, site mobility, and addition of target species to address regional and local issues as needed. For example, some areas may choose to focus on specific episodes or seasons, such as a winter time wood smoke problem. EPA does not believe that a single nationwide approach to speciation sampling and analysis is the best approach for all locations. The EPA expects that most sites will follow a sampling and analysis program similar to the core STNs for their non-trend sites; however, alternative approaches will be considered on a case-by-case basis through negotiation by State agencies with EPA Regional Offices and Headquarters. EPA encourages State and Local Agencies to consider additional chemical analyses beyond the constituents specified for STN. For example, detailed analysis for compounds comprising the organic carbon fraction could provide valuable insight into development of more refined source-receptor relations, particularly in areas with significant carbon based aerosols. EPA also encourages the use of continuous monitoring techniques to the extent possible. Recent advances in measurement technologies have been proven reliable. This section of the QMP will focus on the agencies involved with this program and their roles and responsibilities.

1.2 Roles and Responsibilities

1.2.1 Office of Air Quality Planning and Standards: OAQPS is the organization charged under the authority of the Clean Air Act (CAA) to protect and enhance the quality of the nation's air resources. OAQPS sets standards for pollutants considered harmful to public health or welfare and, in cooperation with EPA's Regional Offices and the States, enforces compliance with the standards through SIPs and regulations controlling emissions from stationary sources. The OAQPS evaluates the need to regulate potential air pollutants, especially fine particles, and develops national standards.

Within OAQPS, the Emissions Monitoring and Analysis Division (EMAD), the Monitoring and Quality Assurance Group (MQAG) will be responsible for the oversight of the STN. MQAG has the following responsibilities for the STN:

- ensuring that the methods and procedures used in making air pollution measurements are adequate to meet the programs objectives and that the resulting data are of satisfactory quality;

- develop QMP and field Quality Assurance Project Plan (QAPP);
- Overall coordination of the monitoring and QA aspects;
- evaluating the performance, through mechanisms such as, technical systems audits, performance evaluations and management systems reviews, of organizations making chemical speciation measurements;
- implementing satisfactory quality assurance programs over federally funded ambient air quality monitoring networks;
- ensuring that national and regional laboratories are available to support such programs;
- ensuring that guidance pertaining to the quality assurance aspects of the fine particle speciation program are written and revised as necessary;
- rendering technical assistance to the EPA Regional Offices and air pollution monitoring community concerning fine particle sampling and analysis.

1.2.2 Office of Research and Development: The office of Research and Development (ORD) is charged with the research and development of the speciation sampler and technical oversight. ORD's role in the STN will be:

- oversee development and testing of new fine particle instrument designs;
- work closely with OAQPS to determine that the STN instruments are being operated in accordance to their design;
- evaluate ambient data as it is collected and work with the research community to ascertain the meaning of the results.

1.2.3 EPA Regional Office: EPA Regional Offices address environmental issues related to the states within their jurisdiction and to administer and oversee regulatory and congressionally mandated programs. The major quality assurance responsibilities of EPA's Regional Offices, in regards to the STN, are the coordination of quality assurance matters at the Regional levels with the State and local agencies. This is accomplished by the designation of EPA Regional Project Officers who are responsible for the fiscal and technical aspects of the program including:

- the Regional QA officer will be responsible for reviewing QAPPs for the EPA;
- acting as a liaison by making available the technical and quality assurance information developed by EPA Headquarters and the Region to the State and local agencies, and making EPA Headquarters aware of the unmet quality assurance needs of the State and local agencies.
- performing a thorough review of the STN within their region every three years.

1.2.4 National Air and Radiation Environmental Laboratory: The National Air and Radiation Environmental Laboratory (NAREL) in Montgomery, Alabama is one of two Office of Radiation and Indoor Air (ORIA) laboratories that will have a major role in the quality assurance system for the speciation program. NAREL will fill a specific and vital role in the quality assurance aspects of the program. These are briefly listed below: Details can be seen in Reference 2.

- validation of chemical speciation analytical laboratory performance (contract and state chemical speciation laboratories);
- SOP and QAPP review;
- Post Award PE Round Robin;
- Post Award on-site audit;
- Audit and PE Round Robin report to PO and OAQPS.
- Ongoing QA oversight program to evaluate continuing performance through an annual PE Round Robin study;
- maintenance of a repository of PE samples that could be used as double blind PEs by states, diagnostic tools by laboratories, etc.;
- performance of on-site audits of contract and state laboratories.
- Technical assistance to chemical speciation laboratories, states, DOPOs and PO regarding data quality (technical assistance may range from telephone calls for assistance on methodology to review of QC to determine data usability, to on-site performance audits).

1.2.5 Radiation and Indoor Environment National Laboratory The portion and Indoor Environment National Laboratory (R&IEL) is the other ORIA laboratory that will have a major role in the quality assurance system for the speciation program. The Las Vegas, Nevada office will fill specific and vital roles in the quality assurance aspects of the program. This is briefly listed below:

- R&IEL will provide the field QA for this program. This will consist of field TSAs, site visits and setting up collocated QA samplers in the field;
- provide observations of ongoing work to document conformance with specified field QAPPs;
- examine data after collection and determine how well the system performed;
- provide training for State and Local agencies on the operation of the STN samplers;
- demonstration testing of newly developed STN instruments.

1.2.6 Research Triangle Institute (RTI): Research Triangle Institute is the main laboratory for all speciation laboratory work. RTI will coordinate the pre-sampling, shipping, post-sampling activities. Much of the QA activities will be performed by RTI internally. The QA activities are detailed in RTI's Quality Assurance Project Plan[1.] Some of the QA activities are briefly listed below:

- processing of all Quality Control (QC) filters;
- analysis of all samples;
- tracking and record keeping of all samples as they move through the speciation program; participate in all TSAs, MSRs, and other audits;
- analyze the PEs when received from the NAREL laboratory;
- coordinate with sub-contractors and assure that the good laboratory practices and QA are performed;
- maintain adequate internal documentation and quality control;
- development of a laboratory QAPP;
- perform Level 0 and 1 validation on the data.

1.2.7 State and Local Air Monitoring Agencies: The state and local air monitoring agencies are tasked in operating the speciation samplers in the field. The agencies will work closely with RTI on shipping and receiving the speciation samples. Other activities include:

- select monitors from the national contract;
- write or adhere to a speciation field QAPP which must be approved by the EPA Regional QA officer;
- operate the samplers according to the accepted QAPP;
- store un-exposed filters in the manner described by the QAPP;
- Ship the exposed filters in a timely manner to RTI;
- maintain records of sampler operation;
- participate in any TSAs or Management Systems Reviews (MSRs)
- notify OAQPS, ORD or the DOPOs of any problems with the operation or design of the samplers;
- perform Level 2 and 3 validation on the data.

1.2.8 Delivery Order Project Officers: The Delivery Order Project Officers are Regional Office contacts who are liaisons between OAQPS, RTI and the State and Local agencies. The DOPOs facilitate the financial and planning aspects of the STN. There will be three DOPOs for the entire Nation: east, Midwest and west.

1.3 Key Personnel

Monitoring and Quality Assurance Group Leader – Dr. Richard Scheffe

Dr. Scheffe has overall responsibility for managing the STN. The direct responsibility for assuring data quality rests with management. Ultimately, the group leader is responsible for establishing QA policy and for resolving QA issues identified through the QA program. Major QA related responsibilities of the group leader include:

- approving the budget and planning processes;
- assuring that the program develops and maintains an adequate quality system.

The group leader delegates the responsibility of QA development and implementation in accordance with the OAQPS policy to the program manager and QA coordinator.

Program Manager -- Mr. James Homolya

Mr. Homolya is the designated as the OAQPS program manager of the STN. He is responsible for the OAQPS activities that are implemented as part of normal data collection activities. Responsibilities include:

- ensuring the implementation of the STN;
- communication with EPA Project Officers and EPA QA personnel on issues related to routine sampling and QA activities;
- understanding EPA monitoring and QA regulations and guidance, and ensuring all key personnel understand and follow these regulations and guidance;
- reviewing acquisition packages (contracts, grants, cooperative agreements, inter-agency agreements) to determine the necessary QA requirements;
- developing budgets and providing program costs necessary for EPA allocation activities;
- ensuring that all personnel involved in environmental collection have access to any training or QA information needed to be knowledgeable in QA requirements, protocols, and technology;
- recommending required management-level corrective actions.

Quality Assurance Coordinator - Mr. Dennis Mikel

Mr. Mikel will oversee the quality assurance aspects of the speciation program, as such will be designated the Quality Assurance Coordinator (QAC). His responsibilities include:

- coordinating the input to the QA Annual Report (QAAR);
- assisting in solving QA-related problems at any level of the program;
- ensuring that an updated QAPP is in place for all environmental data operations associated with the program;
- ensuring that technical systems audits, audits of data quality, and data quality assessments occur within the appropriate schedule and conducting or participating in these audits;
- tracking and ensuring the timely implementation of corrective actions;
- ensuring that a management system review occurs every 3 years;
- coordinate with the ORIA activities.

The QAC has the authority to carry out these responsibilities and to bring to the attention of the program manager or group leader any issues related to these responsibilities.

NAREL - Montgomery, Alabama Team Leader - Mr. Michael Clark

This Team is responsible for overseeing laboratory QA activities of the STN. His responsibilities include:

- implementing and overseeing the laboratory STN QA policy within the team;
- oversee analysis of the QA samples;
- reporting the QA data to OAQPS staff ;
- oversee the preparing of QA samples for the RTI laboratory;
- lead the MSRs and TSAs on the RTI laboratory.

R&IEL - Las Vegas, Nevada, Branch Manager - Mr. Emilio Braganza

The Las Vegas personnel are responsible for overseeing the field QA activities. His responsibilities include:

- participating in field training and certification activities;
- participating in the development of data quality requirements (field) with the appropriate QA staff;
- performing field TSAs and MSRs;
- oversee the verifying of all required field activities are performed and insure that measurement quality standards are met as required in the QAPP.

RTI Laboratory Program Director - Dr. R. K. M. Jayanty

Laboratory personnel are responsible for carrying out a required task(s) and ensuring the data quality results of the task(s) by adhering to guidance and protocol specified by the QAPP and SOPs for the lab activities. His responsibilities include:

- oversee participating in training and certification activities;
- participating in the development of data quality requirements (laboratory) with the appropriate QA staff;
- overseeing the writing and modifying of standard operating procedures (SOPs) and good laboratory practices (GLPs);
- oversee the preparing and shipping of all samples to the State and Local agencies;
- supervise the analysis of all samples;
- oversee the performing and documenting of preventative maintenance on laboratory equipment;
- overseeing the submission of final valid data to the Aerometric Information Retrieval System (AIRS) database;
- preparing and delivering reports to the OAQPS program manager and QA officer.

1.4 References

1. Quality Assruance Project Plan Chemical Speciation of PM2.5 Filter Samples, Research Triangle Park, NC, Document Number RTI/7565/00-02S

2. Quality Assurance Project Plan for the Quality Assurance Laboratory Role in the Particulate Matter (PM2.5) Chemical Speciation Project, U.S. Environmental Protection Agency Office of Radiation and Indoor Air, National Air And Radiation Environmental Laboratory, Draft 3, October 18, 2000.

3. Speciation Trends Network Quality Assurance Project Plan, U.S. EPA Document EPA-454/R-01-001

2.0 Quality System Description

This chapter will describe the principle components comprising the quality system and how they are used to implement the quality system. In addition, the latter part of this chapter will briefly discuss the monitoring system and how samples and data flow through the system.

2.1 Description of the Speciation Trends Program

Figure 2.1 illustrates the systems in place that have oversight of the ST N.

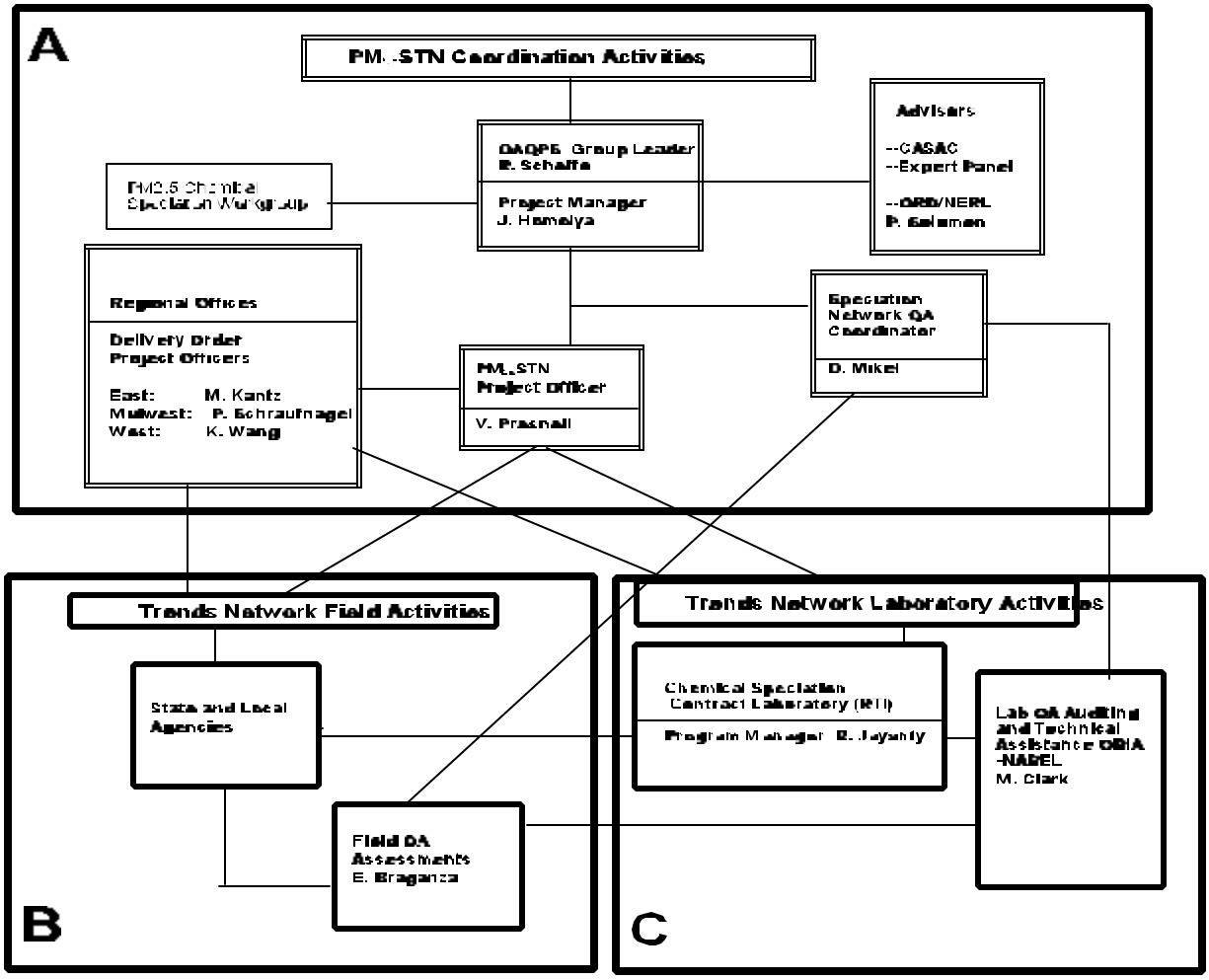

Figure 2.1 Description of the Speciation Trends Program

Figure 2.1 illustrates that there are two distinct systems in place for the STN: the QA system and

Monitoring System. The following sections will highlight these.

2.2 Quality Assurance System

2.2.1 OAQPS-EMAD: At the top of the QA structure is the OAQPS-QAC. It is the QAC's responsibility to oversee that QA is implemented into the program. The QAC will interact with a QA Workgroup that has formed. This QA workgroup consists of EPA, State and local agency, Regional Office, R&IEL and NAREL QA staff. They will meet periodically to discuss QA issues as they arise throughout the program. The QAC will also work directly with the ORIA offices. Assessment Reports will be given to the QAC on an annual basis. These will include the results of the assessments listed in Table 2.1 performed during the previous year. The ORIA offices; NAREL and R&IEL will have important roles in the QA system.. In addition, the MQAG may also perform MSR or TSAs on any of the agencies in the QA or monitoring system.

2.2.2 NAREL-Montgomery, Alabama: NAREL will have QA oversight of the RTI laboratory operations. As such, the laboratory will perform TSAs or MSRs on the RTI laboratory operation on an annual basis. In addition, the NAREL will create laboratory audit samples Performance Evaluations (PE) that will be forward to the RTI lab.

2.2.3 R&IEL – Las Vegas, Nevada: R&IEL will have QA oversight of the field operations. As such, the laboratory will perform TSAs and performance audits at state and local agency monitoring stations. At this time, the schedule and extent of the TSAs and performance audits are not known. When the audits are completed, the QA reports will be forwarded to OAQPS for review. At some time in the future, State Agencies and the Regional offices will be encouraged to perform these functions.

2.2.4 Regional Offices: The EPA Regional Offices will provide Network Reviews of the STN on each agency within their region once every three years.

Since EPA is providing funding for this program, the QA requirements fall under the auspices of EPA Order 5360.1 July, 1998. In short, this EPA order states that all extramural activities funded by the EPA must have minimum requirements in place at the beginning and carried through the project. In order to fulfill this EPA Order, the EPA has put the following QA components in place.

2.3 Quality Documents

The following are the documents, plans and guidelines by which the speciation trends program will be implemented.

2.3.1 Quality Management Plan: This QMP (described herein) outlines the management structure and how the QA system will be implemented. All entities listed in this QMP will adhere to these guidelines.

2.3.2 Quality Assurance Plans: All entities will develop QAPPs for their programs. This includes, RTI, R&IEL and NAREL. All state and local agencies will develop field QAPPs that will outline how their QA system will be implemented. OAQPS has written a draft field QAPP that can be used by the state and local agencies in drafting their individual QAPPs.

2.3.3 Assessments: There are several assessments tools that will be implemented by the QA system. The following table illustrates the implementation of assessments. Each of these assessments will be discussed in detail in Chapter 8.

Table 2.1 Assessments performed in the STN

Agency	Type of Assessment	Agency Assessed	Frequency
NAREL	TSA, MSRs and PEs	RTI	Annually
R&IEL	TSAs, Performance Audits	State and local agencies	Annually*
OAQPS-EMAD	TSAs	RTI, NAREL, State and Local agencies, Regional offices and R&IEL	As needed by EMAD determination
OAQPS-EMAD	MSRs	RTI, NAREL, State and Local agencies, Regional offices and R&IEL	As needed by EMAD determination
Regional Offices	Network Reviews	State and local agencies	Once every 3 years

* Not all instruments in the program will be audited every year. It is estimated that 25% of the instruments will be audited annually.

Assessments will be performed as the program begins and on a periodic basis after January 2001.

2.3.4 Quality Assurance Annual Report: Quality Assurance Annual Report (QAAR) will be provide to OAQPS-EMAD from R&IEL, NAREL and RTI. The QAARs will include the results from the assessments described in Table 2.1 and will include all QA data collected by these entities and summarized for a calendar year. These plans will also outline any assessments and corrective

actions needed to correct any deficiencies in their operations.

2.4 Description of the Monitoring System

This section will outline the monitoring system as illustrated in Figure 2.1. Data will be collected on the list of analytes below [1].

Table 2.2 List of Analytes

Method	Constituents
Gravimetry	mass
Ion Chromatography	nitrates, sulfates, ammonium, sodium ion and potassium
X-Ray Fluorescence	aluminum, antimony, arsenic, barium bromine, cadmium, calcium, cerium chlorine, chromium, cobalt, copper europium, gallium, gold, hafnium indium, iridium, iron, lanthanum lead, magnesium, manganese, mercury molybdenum, nickel, niobium, phosphorus potassium, rubidium, samarium, scandium, selenium, silicon, silver sodium, strontium, sulfur,tantalum terbium, tin, titanium,vandium wolfram, yttrium, zinc, zirconium
Thermal Optical Analysis	Elemental Carbon Carbonates Carbon Organic Carbon Total Carbon

As can be seen from Table 2-2, there are a number of analytes on the list. The speciation program will require two or three filter pack modules per instrument. Each of the modules will have a different filter medium and therefore, a different analytical method.

This section will outline the monitoring system as diagramed in Figure 2.2 and discuss how quality will be built into the overall speciation program process.

2.4.1Vendor: The filter vendor will ship packaged filters to the RTI laboratory. These will be logged in by the RTI shipping and receiving group and stored in a proper location.

2.4.2 RTI: The filters will be processed by RTI according to their QAPP and SOPs. These will be stored until needed in the field. The filters will then be logged out and shipped to the appropriate State and Local agency. Below is an outline of the RTI duties. Please note that these procedures will also be performed on any QA samples received from NAREL.

Pre-Sampling

< Receiving filters from the vendors;
< Checking sample integrity;
< Conditioning filters;
< Weighing filters;
< Storing prior to field use;
< Packaging filters for field use;
< Associated QA/QC activities;
< Maintaining microbalance and analytical equipment at specified environmental conditions;
< Equipment maintenance and calibrations.

Shipping/Receiving

< Receiving filters from the field and logging into database;
< Storing filters;
< Associated QA/QC activities .

Post-Sampling

< Checking filter integrity;
< Stabilizing/weighing filters;
< analysis of elements by X-Ray Fluorescence;
< thermal/optical analysis of quartz filters;
< extraction of ions from Nylon filters;
< Analysis of samples extracted;
< Data downloads from field samplers;
< Level 0 and 1 validation;
< Data entry/upload to AIRS;
< Storing filters/archiving;
< Associated QA/QC activities.

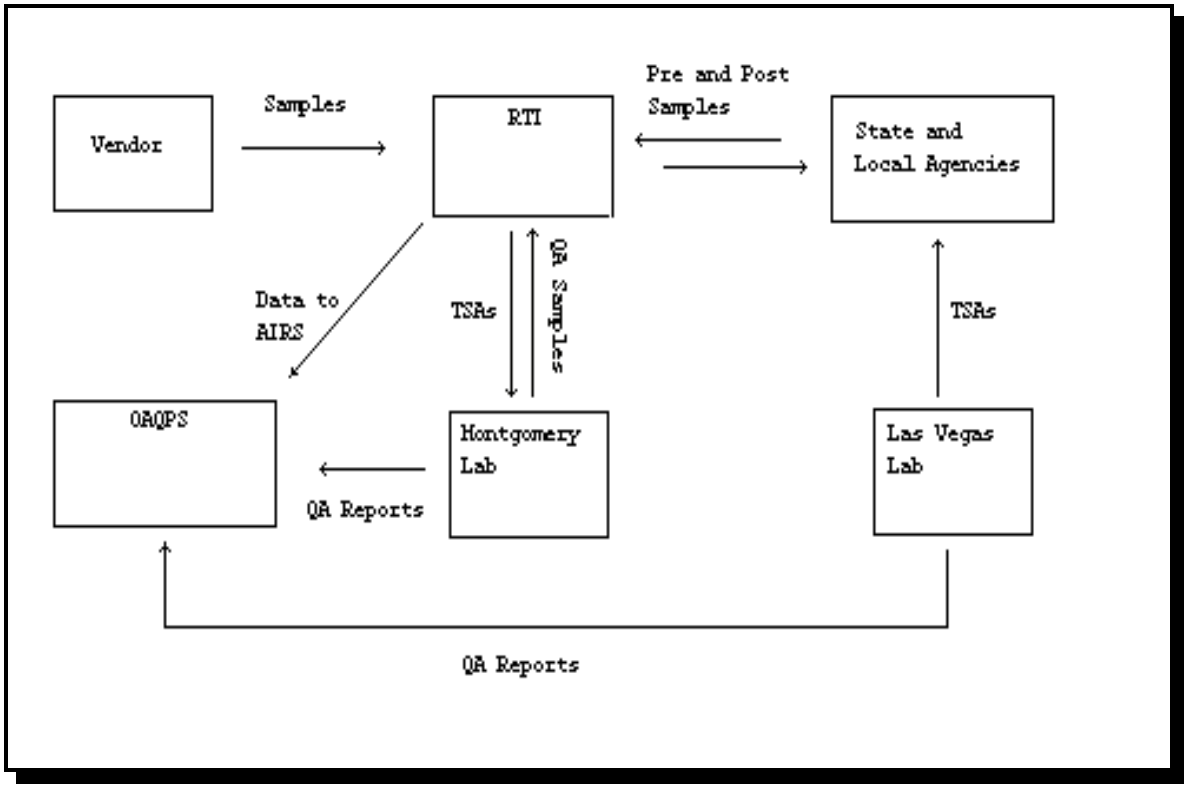

Figure 2.2 Data and Sample Flow Diagram

2.4.3 State and Local Agencies: The State and Local Agencies will received the pre-sampling filters from RTI. These will be stored until field use. After the sample run, the filters will be promptly shipped to RTI for final analysis. Record keeping of sampler operation and forwarding this information to RTI will be the responsibility of the State and Local Agencies.

2.4.4 OAQPS – AIRS: The EPA-OAQPS office will have the authority and responsibility for oversight of this program. The agency has two separate roles: collection and storage of the data into the AIRS database and oversight of the operation of the program. OAQPS will receive and review the QA reports that will be generated by the two ORIA laboratories. In addition, it will provide technical assistance to RTI, the State and Local Agencies and the ORIA laboratories.

2.5 References

1. Particulate Matter (PM2.5) Speciation Guidance Document, Final Draft, Edition 1, October 7, 1999, U.S. EPA document.

3.0 Personal Qualifications and Training

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

The process of training personnel will be a three pronged approach. First, the agencies must select persons who have the minimum qualifications to perform the duties. Second, the agencies must train the individuals for the basics of air monitoring theory and technique. 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. Lastly, OAQPS, in conjunction with R&IEL, is currently conducting fine particle sampler courses that are "hands on." Training on the operation and maintenance are taught at these classes.

3.1 Personnel Qualifications

OAQPS has the responsibility to provide training for this program. As such, OAQPS, in conjunction with the R&IEL will make every effort to provide training to all who participate in this program. Personnel assigned to the STN should meet the educational, work experience, responsibility, personal attributes, and training requirements for their positions. Although OAQPS will provide training to all agencies, it cannot require the state and local agencies or any contractors to send their staff to EPA training courses. During MSRs, EPA and its contracts will review records on personnel qualifications and training. All agencies should maintain these records in personnel files and have them accessible for review during audit activities.

3.2 Training

Appropriate training will be made available to employees supporting the fine particle speciation 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 *http://www.epa.gov/quality1*

The above mentioned courses are open to all air monitoring personnel. EPA strongly encourages all State and Local agencies and contractors to take these courses. Table 5.2 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. Courses not included in the core sequence would be selected according to individual responsibilities, preferences, and available resources.

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	QAD
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	QAD
8*	Quality Assurance Project Plan	QAD
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

OAQPS, in conjunction with ORIA – R&IEL have sponsored several "hands on" classes for State and Local Agencies to get a first look at the speciation samplers. This course lasts two days and is taught by the instrument vendors and EPA personnel. EPA issues training certifications for the successful completion of field and sample custody and data management training. Certification is based upon the qualitative and quantitative assessment of individuals adherence to the SOPs.

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 Speciation Program with the a description of the requirements

4.1 Source of Funds

4.1.1 State Assistance Grants: Since implementation of the STN is a State and local responsibility, the source of funds for the program are 103 and eventually 105 State Assistance Grants (STAG). Every year funds will be allocated to the State and local air monitoring organizations to operate the $PM_{2.5}$ Speciation Program. The STAG allocation for the Speciation Program was based upon estimates of setting up and implementing an ~ 200 sites network. The 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 speciation 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. These allocations or "taps" on the STAG funds are approved by the States.

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 ORIA labs (NAREL and R&IEL), 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

Within EPA, only contracting officers (COs) are authorized to procure items and services, unless it is a 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 STN for the EPA or STAG 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 STN'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. State and local funds are allocated through procurement and should follow
state and local procurement policies.

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 QA Project Plan (QAPP) that includes reviews (audits).

The QAC or DQAO assists in this activity by providing knowledge and guidance on the QA requirements and aspects of any potential project. The QAC 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 and a QAPP. After the form is completed it must be reviewed by the (WAM/PO) and a QAC. 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.

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. 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 for the STN, which a significant percent of the cost (> 25%) includes EDO, the TEP must include the QAC. Part of the TEP responsibilities will include rating each potential contractor against a standard set of criteria. A portion of this 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.

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 EDOs 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 such 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:

- Exclusively EPA Functions - inherently governmental work which must be performed only by responsible EPA officials, including the QA Managers (QAMs), or authorized EPA representatives.

- 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:

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

- managing the day-to-day implementation of the mandatory quality system.
- acting as liaison between the organization and the QS on matters of QA policy.
- coordinating with senior management the development of and preparation of the organization's Quality Management Plan.
- 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.
- managing organization resources designated for the quality system.
- 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:

- 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.
- participating directly or indirectly in the solicitation or agreement review process to advise the Project Officer on the suitability of the officer's quality system or quality assurance/quality control (QA/QC) approach for the particular project.
- 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:

- 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.
- 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.
- 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:

- *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:

- 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:

- 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:

- 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:

- 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.
- 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:

- *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:

- 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.
- 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:

- *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:

- 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:

- *providing or coordinating quality-related training for the organization in special skill areas identified by the Agency and not generally available to the organization.*

- *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:

- 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.
- 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:

- *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 will fall upon OAQPS, NAREL, R&IEL, State and Local agencies and RTI. For the STN, there are number of documents and records that need to be retained. A document, from a records management perspective, is a volume that contains information which describes, defines, specifies, reports, certifies, or provides data or results pertaining to environmental programs. As defined in the *Federal Records Act of 1950 and the Paperwork Reduction Act of 1995* (now 44 U.S.C. 3101-3107), records are: "...books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal Law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them..." EPA-OAQPS, NAREL, and R&IEL will adhere to this guideline. RTI will be strongly encouraged to adhere to this guideline as well. Section 5.1 will illustrates 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, there is one thing to which must to adhered, 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. Please See Figure 5.1 for an illustration of the documents that govern the STN program.

5.1.1 Hierarchy: The Clean Air Act (CAA) and EPA Order 5360.1, July 1998 are the 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. For the STN, OAQPS has the authority to require, review, comment and withhold funds if these requirements are not met. The order of hierarchy follows:

1. The Code of Federal Regulation, through the CAA and Order 5360.1 are the overarching authority.
2. The QMP encompasses the entire program. All agencies, R&IEL, NAREL, OAQPS, RTI and the state and local agencies will adhere to the requirements and guidelines in the QMP. The QMP discusses the roles of each agency.
3. The QAPPs for individual agencies will govern that agency. The agency must adhere to the statements made in their QAPP.
4. 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: Please see Figure 5.1 for structure of the documentation in this STN program.

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 will undergo thorough review by OAQPS, ORD, NAREL, R&IEL, and RTI. It will be made available for comments to the state and local agencies as well. Since changes may be made in this program, any revisions must be reviewed by all agencies.

QAPPs - The QAPPs written by the individual agencies to describe their process of assuring the quality of the data. OAQPS delegates the authority to review these individual QAPPs to the Regional QA officers.

Network Plan - OAQPS requests that all agencies that will operate a STN sampler will take electronic photographs of each site in the cardinal directions. These will be forwarded to OAQPS with all other siting data. OAQPS will create an database which will include the following:

< Electronic photo of the sampler in place;
< Electronic photos of the area in all cardinal directions;
< Maps of the area showing local sources (if known);
< All information required for the AMP 380 report;
< Coordinates of the location generated by Geographic Positioning Systems.

This data will be compiled and placed in a database. Since this data will also be entered in to the Aerometric Information Retrieval System (AIRS), the OAQPS database will be updated periodically. All of this data will be placed on Compact Disk (CD) and distributed and stored by OAQPS. Any parties that wish to review the network will be able to obtain this data expeditiously.

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

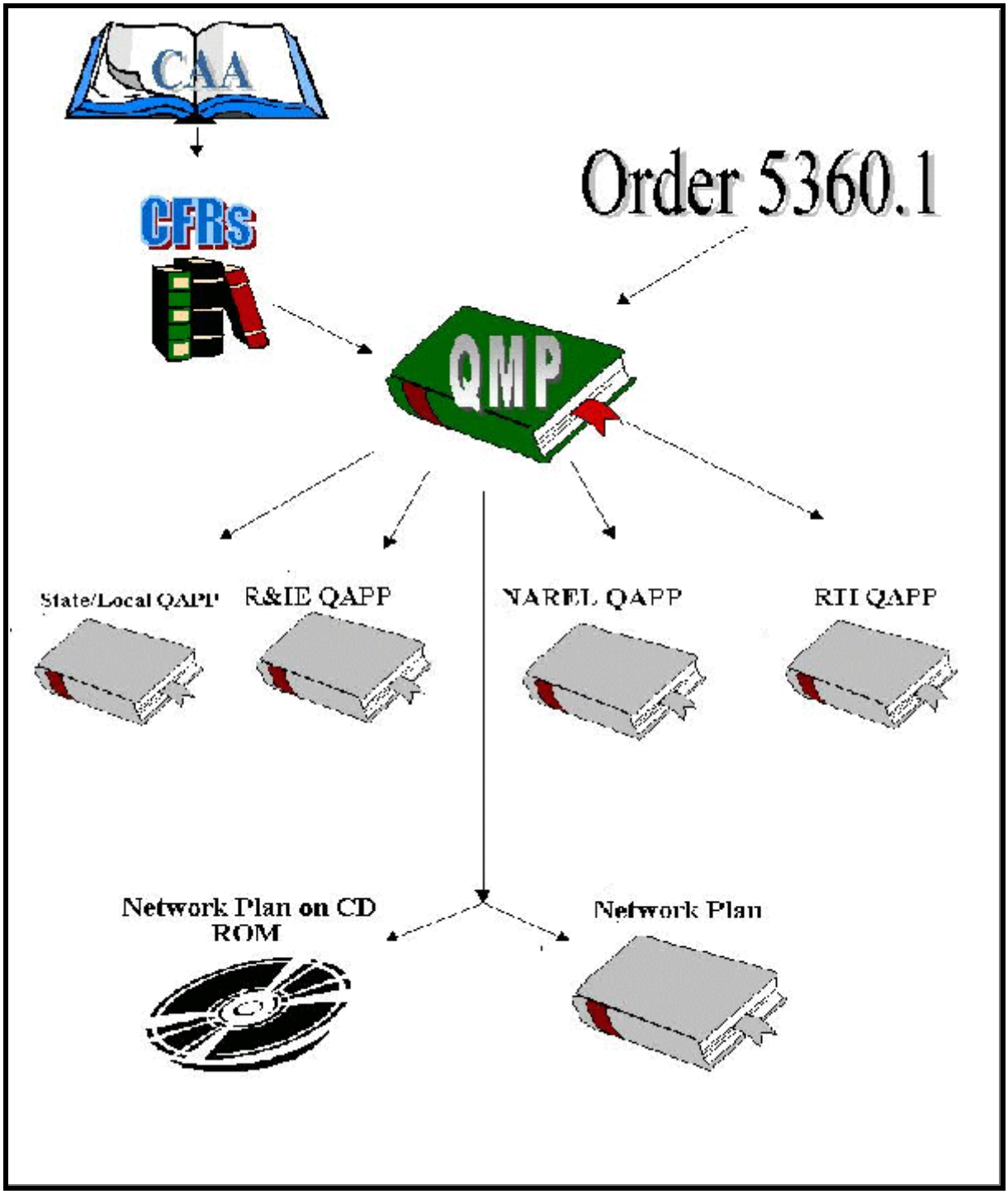

Figure 5.1 Hierarchy of Documents

5.2 Documentation Responsibilities

5.2.1 EPA OAQPS/Regional Offices: This division has oversight of the STN. As such, the documents that must be control and stored are under the jurisdiction of the DOPOs, the program manager and the QA coordinators are listed below.

DOPOs - The DOPOs has the responsibility of storing and archiving all records that pertain to the requisition and deposition of contracts and equipment to contractors, State and local agencies, or Regional offices. The DOPOs will store these documents as specified in this QMP.

Program Manager - The program manager is responsible for the overall operation and technical guidance for the program. The documents and records for under his/her jurisdiction, are reports to management, summaries of discussion and conference calls, technical guidance documents and any other data shared with all agencies involved.

QA coordinator - The QAC is responsible for the QA aspects of this program. As such, he is responsible for the QA documents related to QA conference calls The QAC is also responsible for the oversight and review of the STN QMP and all QAPPs created by the RTI, NAREL and R&IEL.

Regional QA Officers- The EPA Regional QA officers are responsible for the QA documentation related their individual QAPPs. In addition, these officers are responsible for the storage of the maintenance and operation documentation required to run a local program.

5.2.2 NAREL - Montgomery Alabama:

Project Manager - The project manager is responsible for the oversight of the laboratory QA at NAREL. As such, he/she is responsible for the storage of all records and documents generated by this lab. The NAREL approach uses bound notebooks to enter data on any stock solutions, working calibration or dilutions that are generated. It is the project managers responsibility to assure that all personnel under his jurisdiction keep these secured when not in use or overnight.

Quality Assurance Chemist - The QA chemist is responsible for the QA oversight of this laboratory. Any records created that pertains to duplicates, spikes or other QA samples will be under the QA chemist's jurisdiction.

5.2.3 R&IEL -Las Vegas, Nevada: The R&IEL approach uses bound notebooks to enter data on any flow rate or field performance evaluations. Standard TSA forms will be filled out in the field situation. The data will then be entered into spreadsheets/word processing programs on laptop.

Project Manager - The project manager, in cooperation with the QAC, is responsible for the oversight of the field QA. As such, he/she is responsible for the storage of all records and documents generated by field TSA or performance audits. The project managers responsibility to assure that all personnel under his jurisdiction keep the handwritten and electronic field reports locked when not in use or overnight.

Field Auditors - The field auditors are responsible for the collection of QA data at the monitoring locations during TSAs or field performance evaluations. Any records created on paper or in on laptop computer must be in the auditors presence when traveling or be in his/her locked room.

5.2.4 RTI -Research Triangle Park, North Carolina: The RTI will handle the bulk of the documentation and records for this program since the beginning and final deposition of all samples will be with RTI. RTI has fully documented their system in their QAPP. Below are responsible parties for documentation control.

Technical Area Supervisors - RTI has a two tiered level of management. The first tier has the program services manager, who is overall responsible lab operations and the QA Manager. The second tier is the Technical Area Supervisors. There are 7 Technical Areas, each with its own supervisor. Each is responsible for maintaining, quality handling, storage and retrieval of their area records.

5.2.5 State and Local Agencies: Each agency will retain copies of their documents and records pertaining to the operation, storage or handling of samples. These records must be made available for inspection and review by EPA or its designee.

5.3 Deposition and Storage of Documents and Records

This section will address the deposition, storage accessibility, 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.

Field notebooks- Notebooks will be utilized for recording results of field audits. Dates, times, field conditions, temperature, pressure and flow rates will be recorded. These will be archived along with the data generated by the field laptops in Las Vegas, Nevada. Please see the R&IEL QAPP and SOPs.

Lab Notebooks- Notebooks will also be issued for the laboratory. These notebooks will be uniquely numbered and associated with the speciation 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 instruments used for this program. RTI and NAREL will both be generating laboratory data. Therefore, they must maintain all records for at least 5 years after the data are generated.

Chain of Custody Forms- Original Chain of Custody forms must be retained by RTI and copies must be kept by the state or local agency.

Other Documents- All other documents must be stored according to their QAPP.

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. In order to provide a back-up, a hardcopy of automated data collection information will be stored for the appropriate time frame in project files.

5.3 Deposition of Reports

5.3.1 Annual Summary Reports: The annual reports will ensure that work performed by the agencies is accurately performed and that the statutory and contractual requirements are met.

RTI- RTI shall submit to EPA-OAQPS an annual summary report of all the speciation data collected within that calender year. The report will be submitted by April 1 of each year for the data collected from January 1 to December 31 of the previous year. The report will contain the following information:

Site and Monitoring Information.

- City name;
- county name and street address of site location;
- AIRS-AQS site code;
- AIRS-AQS monitoring method code.

Summary Data

- Annual arithmetic mean, and
- Sampling schedule used as once every 3-day schedule.

NAREL- NAREL shall submit to EPA-OAQPS an annual summary report of all the QA speciation data collected within that calender year. The report will be submitted by April 1 of each year for the data collected from January 1 to December 31 of the previous year. This report will include analysis of all PE samples and results of any MSRs or TSAs performed.

R&IEL- R&IEL shall submit to EPA-OAQPS an annual summary report of all the field performance evaluations and TSAs for data collected within that calender year. The report will be submitted by April 1 of each year for the data collected from January 1 to December 31 of the previous year.

5.4.2 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, most 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 STN. This chapter will also describe the roles and responsibilities for system hardware and software.

6.1 Computer System Descriptions

6.1.1 RTI: RTI will have the most extensive computer system for this operation. The pre-sampling, post sampling filter data and sample run information will be housed in the RTI Oracle data base.

6.1.2 EPA-OAQPS: Once the data has been validated by RTI and reviewed by the State and Local agencies, the data will be delivered to the AIRS database. The AIRS database is a long term data storage main-frame computer. It is housed at the EPA facility in Research Triangle Park, North Carolina.

6.1.3 NAREL: The NAREL will have a database system that will house the QA sample information analyzed by NAREL. The QA database will be on Local Access Network (LAN) that is maintained by the NAREL computer group.

6.1.4 R&IEL: The ORIA Las Vegas data will mostly consist of audit reports and TSA reports. As audit reports are written, they will be download to PC hardrive of the auditors.

6.2 Roles and Responsibilities

6.2.1 EPA Systems: All EPA databases are governed by EPA directive 2100 including the Year 2000 compliance, security and privacy requirements. Each of the EPA agencies have their own LAN (R&IEL, NAREL and OAQPS). These are password protected and maintained by the System Administrators (SA) for each agency. The EPA's SA have the responsibility of ensuring that the computer hardware used for this program meets the technical requirements. These include:

- quality expectations (i.e., configuration testing);
- control to changes to hardware;
- the SA's follow their QMP for developing, validating, verifying software so that it meets EPA Directive 2182;
- evaluate purchased software before it is utilized by EPA scientists;
- ensure that data and information produced by the EPA are collected and archived in a safe and secure manner.

6.2.2 RTI: RTI is currently developing a Data Base Management System (DBMS) based on Microsoft SQL server. This system will be utilized by RTI to manage, store analyze the database as the data are collected. The final database will be tested and follow the guidelines set down by EPA Directive 2182. The RTI has a data base Technical Supervisor who is tasked to perform the following duties:

- quality expectations (i.e., configuration testing);
- control to changes to hardware;
- follow their QAPP for developing, validating, verifying software so that it meets EPA Directive 2182;
- evaluate purchased software before it is utilized by RTI scientists;
- ensure that data and information produced for the EPA are collected and archived in a safe and secure manner.

7.0 Planning

This section will outline planning and implementation procedures that will be employed in the STN. This program has several diverse agencies that are will be 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 will outline how this will be accomplished.

7.1 Project Goals and Objectives

As stated in Section 1, the STN is a component of the National $PM_{2.5}$ Monitoring Network. The programmatic objectives of the STN network are:

- *Annual and seasonal spatial characterization of aerosols;*
- *Air quality trends analysis and tracking the progress of control programs;*
- *Integration of chemical speciation data set with the data collected from the IMPROVE network; and*
- *Development of emission control strategies.*

It has been decided that $PM_{2.5}$ chemical species over a period of 3 or more years would be sufficient for statistical analysis of the data. This data will be utilized as input to models and for development of emission control strategies and determination of their long-term effectiveness. Public health officials and epidemiological researchers will also use the data to test health based research.

In the early stages of this program, an expert panel met on May 18-19, 1998 in Las Vegas, NV, to review the EPA's revised guidance document on the speciation network. Members of the panel were: Drs. Tom Cahill, Phil Hopke, Lara Gundel, John Ondov, and Petros Koutrakis. Mr. Robert Stevens, who is also a panel member, did not attend the meeting, but he submitted his comments in writing. Members of the speciation group, which consists of EPA staff and representatives from several states, also participated in this meeting. Below is a summary of the expert panel recommendations[1].

- Identification of types of data: Speciation data will be required in three major categories; ions, semi-volatile organics and metals;
- these data will be used to support SIP implementation and source characterization;
- the sampling frequency should be increased from once every 6^{th} day to once every 3^{rd} day;
- there should be at least 3 years of data collected.
- the number of sites can be supported with no more than 55 sites;
- there should be a phased in approach to the program; and
- the data should be collected around the nation.

The expert panel meets from time to time to assess the progress of the STN program. Milestones we set by the expert panel by which EPA would adhere. The following is a description of the milestones;

1. First Year, Network Design and Objectives: During the first year, the EPA staff focused its efforts on the design of the speciation network. In 1998, at the Seattle meeting, the expert panel had the opportunity to review the objectives of the network and the list of measurement parameters.
2. Second Year, Sampler Intercomparison Field Studies: Since the Seattle meeting, a series of field studies have been conducted to evaluate the performance of the candidate sampling devices. In addition, the EPA staff has initiated the process of contracting the laboratories designated to perform the sampler preparation and chemical analysis.
3. Third Year, Intercomparison Completion and Implementation of the First Ten Sites: The focus should be on the completion of the sampler tests, completion of the sampling and analysis protocols, and start-up of the first ten sampling sites. An effort should be made to develop an implementation plan for the speciation network and to set up a managerial structure. It is important to present a structured plan outlining the responsibilities and duties of the participating groups.
4. Fourth Year, Development of State Expertise in Particulate Data Interpretation: Research scientists have a tremendous experience in particle sampling and to, some extent, in chemical analysis methods; however, the state scientists have little experience in analyzing particulate data. Therefore, before the end of the fourth year, a plan should be presented to provide training to state scientists in source apportionment methodologies and their interpretation.

The EPA has accepted these recommendations and have begun to implement them on this abovementioned schedule. Below is a list of the key personnel and their responsibilities.

7.2 Key Planning Personnel

7.2.1 Monitoring and Quality Assurance Group Leader: The group leader has the responsibility to make the final decision on the implementation of the program. He/she has the following responsibilities:

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

7.2.2 Program Manager: The program manager is the person who performs the following planning activities:

1. identify program schedules;
2. writes the level of effort proposals;
3. oversees the implementation of program from a technical perspective.

7.2.3 Delivery Order Project Officer: The DOPOs are responsible for the following planning activities;

1. identify program schedule, in terms of deliverable goods;
2. work with the program manager on the level of effort;
3. oversee the financial implementation of the program.

7.2.4 Quality Assurance Coordinator: The QAC is responsible for the QA planning for the program. He/she is responsible for:

1. overseeing the overall QA for the program;
2. making sure that proper QA is being performed;
3. meet with other QA members via meetings and tele-conferences
4. assess any data obtained from sources outside of the EPA that did not use approved QAPPs;

7.3 Other Planning Activities

The following activities will facilitate the success of the program.

OAQPS must assure that each agency within the program receives the proper training, equipment, 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.

7.3.1 Tele-communications: Tele-conferencing is an extremely useful tool to impart information and ensure that the planning process is moving forward. For the past 12 months, Mr. James Homolya has led tele-conference working group for the speciation program. The working group has consisted of OAQPS, Regional EPA and State and Local Agency staff. Mr. Homolya has guided this working group by informing the group concerning the development of the speciation samplers, discussion of the laboratory operations and the time lines of implementation of the samplers into the field.

Recently, a new working group has been formed to bring together the quality system for the speciation program. This QA working group will be led by Mr. Dennis Mikel, who has been designated as the STN-QA coordinator. The QA workgroup consists of OAQPS and ORIA staff.

7.3.2 Internet: EPA supports and maintains a web site on the Word Wide Web. Guidance documents, special announcements and related documents are posted on the 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. Any persons interested in the program may find information at the following location: *http://www.epa.gov/ttn/amtic/amticpm.html*.

7.3.3 Data Analysis: Preliminary data analysis will be performed by RTI as described in their QAPP[2]. However, it is OAQPS technical staff will also review and analyze the data sets. Results and summaries will be presented a various seminars and technical workshops.

7.4 References:

1. Koutrakis, Petros, Chair, Speciation Expert Panel. *Recommendations of the 1999 Expert Panel on the EPA Speciation Network, Final Summary-08/03/99*

2. Quality Assruance Project Plan Chemical Speciation of PM2.5 Filter Samples, Research Triangle Park, NC, Document Number RTI/7565/00-02S

8.0 Implementation of Work

Each organization involved in this program will develop a QAPP that will describe the process and work performed for their program. The state and local agencies' QAPPs will be submitted to EPA Regional Offices, which will review, provide comments and finally approve their QAPPs. On the other hand, RTI's, NAREL's and R&IEL's QAPPs will be submitted to OAQPS for review, comments and final approval. Since each agency/laboratory has developed their own QAPPs, ultimately each agency is responsible for the implementation of the program in their county, state or laboratory. This section will outline the individuals in each agency that will be required to implement the work.

8.1 Implementation Roles

8.1.1 Program Manager: The program managers are responsible for overall work to be performed. These include:

< ensuring that work is being performed according the agency QAPP;
< development and implementation of procedures;
< standardization of techniques;
< development of special or "critical" techniques that might deviate from the normal good laboratory practices;

8.1.2 Quality Assurance Managers: The QA managers oversee through internal TSAs and review of data that procedures are being followed as specified by the agency QAPP. In addition, the QA managers must also:

< identify operations needing procedures;
< help prepare the procedures by writing and revising the QAPP;
< review and approve procedures before they are implemented;
< provide new tools to the monitoring or laboratory staff that may enhance or increase the productivity of the operation;
< control the release, change and use of planned procedures;
< work with the program manager 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, as performed as prescribed in the QAPP.

9. Data Quality Assessments

This section describes the quality-related activities necessary to support the speciation network operations and the associated data acquisition, validation, assessment, and reporting.

Important benefits of regular DQAs include the opportunity to alert the management of data quality problems, to propose viable solutions to problems, and to procure necessary additional resources. Management should not rely entirely upon the MSRs and TSAs for their assessment of the data. The MSR and TSA only occur annually. Quality assessment, including the evaluation of the technical systems, the measurement of performance, and the assessment of data, is conducted to help insure that measurement results meet program objectives and to insure that necessary corrective actions are taken early, when they will be most effective.

9.1 Program Assessment Techniques

Assessment is an all-inclusive term used to denote any of the following::TSAs, performance evaluation audits, management systems review, data quality assessments(DQAs). Definitions for each of these activities can be found in the Glossary. Table 10.1 provides information on the parties implementing the assessment and their frequency.

Table 9.1 Assessment Schedule

Agency	Type of Assessment	Agency Assessed	Frequency
NAREL	TSA, MSRs and PEs	RTI	Annually
R&IEL	TSAs, Performance Audits	State and local agencies	Annually*
OAQPS-EMAD	TSAs	RTI, NAREL, State and Local agencies, Regional offices and R&IEL	As needed by EMAD determination
OAQPS-EMAD	MSRs	RTI, NAREL, State and Local agencies, Regional offices and R&IEL	As needed by EMAD determination
Regional Offices	Network Reviews	State and local agencies	Once every 3 years

* Not all instruments in the program will be audited every year. It is estimated that 10% of the instruments will be audited annually.

9.1.1 Technical System Audit: Initially, the TSAs will be performed by the ORIA laboratories. The results of the TSAs will be included in the QAAR reports that will be submitted to OAQPS. Other agencies will submit their reports to OAQPS as well. Information on how these will be conducted can be found in EPA QA/R- 5 document.

9.1.2 Network Reviews: Network Reviews will be performed by EPA Regional staff on each State and Local Agency once every three years. Network Reviews for criteria pollutants are performed once every three years. The EPA Regional offices will be tasked to review the speciation network at the same time as the criteria pollutant Network Review. The Regional offices will notify OAQPS of any anomalies in the network.

9.1.3 Management System Review: Management System Review will be conducted by the EPA-EMAD- MQAG staff. The MSR will be performed annually. The RTI laboratory and selected EPA Regional office will be reviewed annually.

9.1.4 Data Quality Assessments: The EPA-EMAD-MQAG will produce a Data Quality Assessment report during the first year and every three years thereafter. This assessment will be performed using standard statistical tests to ascertain the uncertainty of the data.

9. 2 Reports to Management

The NAREL and R&IEL laboratories will submit assessments and reports performed by the organization, in particular, the QAARs. The NAREL QAAR will report on the TSAs, QA sample data and the effectiveness of the quality system. The R&IEL QAAR will focus on the TSAs and field audits that have been performed throughout the year.

Network Review performed by the Regional Offices should be forwarded to OAQPS for inclusion in the QAAR.

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 management, who can modify the schedule. After management approval, the schedule is submitted in writing (or 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 or MSR forms) are 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 fill 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. Below is a list of assessment training that will be provided in this program.

< OAQPS will continue to offer satellite course on QA and QC, as well as programs that update the state and local agencies on the STN.
< NAREL, R&IEL will continue to offer training classes to the personnel that will be performing assessment to the STN.

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 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 EPA Regional Offices or directly to OAQPS.

Reports of assessments are discussed in section 9.2.

9.3.4 Disputes: Occasionally, findings in an assessment report may be disputed by the agency assessed. Any disputes that are announced by an agency should first be handled by the Regional Offices. If this fails to satisfy the situation, then OAQPS has the final authority to make a decision concerning a dispute. In the case of assessments made by NAREL and R&IEL, OAQPS has the authority to discuss and satisfy disputes.

10.0 Quality Improvement

This section will outline planning and implementation procedures that will be employed for improving the quality of the program. OAQPS has 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 will make every effort to improve the system over a period of many years. The following figures illustrates the quality improvement process that OAQPS will institute for this program.

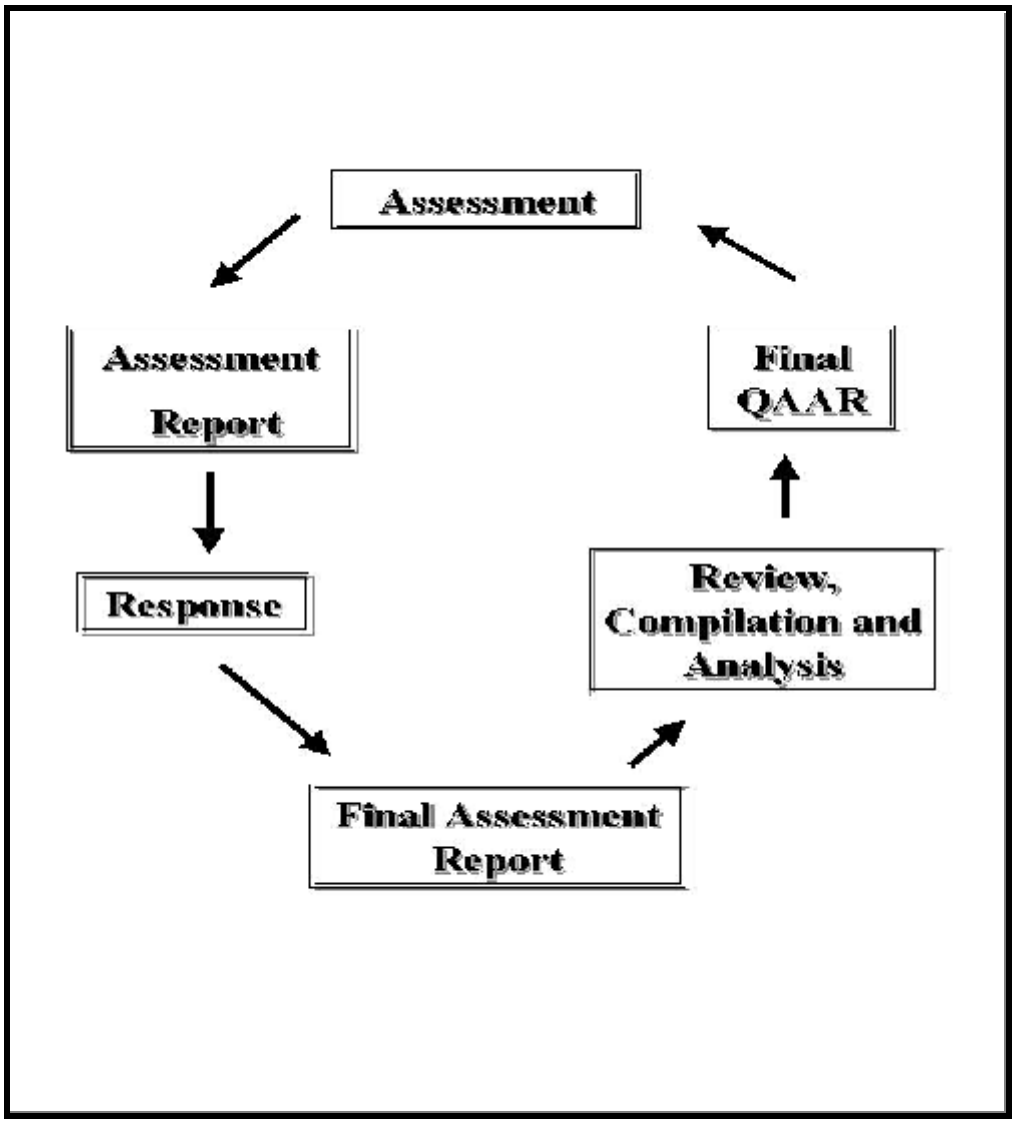

Figure 10.1 Data Improvement Flow Diagram

10.1 Quality Improvement Process Flow

This section will outline the process flow of the quality improvement paradigm as diagramed in figure 10.1.

10.1.1 Assessment: The assessments that are planned for the STN are detailed in section 9 of this QMP. Once the assessment agency has completed the assessment, a report will be sent to the assessed agency.

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 and allow the assessed agency the ability to respond to all assessment findings (usually 45 days).

10.1.3 Response: The assessed agency has the right to respond in writing, or email. All responses will be reviewed by the assessment agency 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 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.

10.1.4 Final Assessment Report: The final assessment report 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, the agency will review the findings, compile the information and analyze the data. Any disputes concerning the assessments will be finalized at that time.

10.1.6 Final QAAR: The final QAAR will be the final report for a given calendar year. This report, created by OAQPS, will highlight the major findings of the assessment and recommendations will be made in this report. This report will then be sent to all Regional Offices, RTI, NAREL, R&IEL, CASAC and the expert panel. Any other parties that wish to obtain this report must contact the person listed in the forward of this QMP. Regional offices will be required to forward this report to the state and local agencies.

10.2 Quality Improvement Assurance

The QAAR and the assessment reports will ensure that quality will continually improve by allowing the assessed agencies the ability to participate, review and have input into the final reports. Once the assessment reports are issued, the assessment agencies will note where improvement needs to be addressed. When the next assessment is performed, the previous deficiency will be noted and brought to the assessed agency's attention. At that time, the assessed agency must provide proof that the previous year's assessment deficiencies were addressed between the assessments. Any deficiencies that were not addressed will be documented in the next assessment report. Deficiencies that are not

addressed over a one year period will be noted by OAQPS. OAQPS will request that the Regional Offices contact the management of the assessed agency and take action as needed. This assures that OAQPS management will have resolution to deficiencies and that these deficiencies do not remain un-addressed. This above mentioned process will allow OAQPS and all stakeholders the ability to evaluate planning, implementation of programs, and evaluate the effectiveness of the program.

In the case of action items that threaten the quality of the data, the assessment team will identify who (organizationally) is responsible for improvements. If immediate action is needed, EPA-OAQPS gives the authority to the assessment agency to follow-up (within two weeks) to ensure that corrective action are taken and adverse conditions to quality are remedied as soon as practical

Staff members at all agencies are encouraged to identify and establish communications between all agencies. This includes state and local agencies to OAQPS and from any assessment agency to the state and local agencies. Staff members are encouraged to bring any improvements to the assessment agencies during the assessments and to discuss the most practical and cost effective remedies for any problem.

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.

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

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.

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

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.

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

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.

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

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 Fine Particle Speciation Program.

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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[1] and the design, construction, and operation of environmental technologies). Examples of environmentally-related measurements are contained in Attachment 1.

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).

[1]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.

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 an 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[2]), 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.

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
   (Note: These are the default requirements.)

2. Before Award: QA Manager-specified documentation[3]
   After Award: A Quality Management Plan and a Quality Assurance Project Plan for the contract

3. Before Award: QA Manager-specified documentation[3]

[2]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.

[3]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).

	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

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[3]
	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.

Attachment 1
Example of Activities involving Environmentally-Related Measurements

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

- Activities that collect data to establish/determine the states/conditions of environmental or ecological systems and the health of human populations;
- Activities that collect data to establish the ambient conditions in air, water, sediments, and soil in terms of physical, chemical, radiological, or biological characteristics;
- 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;
- 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);
- Activities that use environmental data to develop environmental technology for pollution prevention, pollution control, waste treatment, storage, and disposal, and waste remediation;
- Activities that use environmental data in mapping environmental process and conditions, and/or human health risk data, etc. (e.g., geological information system);
- Activities that generate data from the evaluation of environmental technology used for pollution prevention; pollution control; waste treatment, storage, and disposal; and waste remediation;
- Activities that generate/collect data to support enforcement and/or compliance monitoring efforts;
- Activities that collect/generate data for the evaluation and/or demonstration of environmental technology (e.g., treatability and pilot studies);
- 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;
- 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;
- Activities that involve the development, evaluation, and use of computers or mathematical models (and their input data) to characterize environmental processes or conditions;
- 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

- 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).

Attachment 2
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	EPA Requirements for Quality Management Plans (QA/R-2) [dated _____][4]
9	Joint Quality Management Plan/Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated _____] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated ____]
9	Programmatic Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated ____] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated ____]
9	Other Equivalent: _____	*[Insert specification]* _____

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

[4]Note: we will fill in this date once the Federal Register Notice is published.

3. a. Select all documentation required after award of contract either at time of award or upon issuance of a statement of work:

	Documentation	Specifications	Due After
9	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated _____]	Award of contract
9	Joint Quality Management Plan/Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated _____] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated ____]	Award of contract
9	Contract Quality Assurance Project Plan	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated _____]	Award of contract
9	Programmatic Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated _____] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated ____]	Award of contract
9	Quality Assurance Project Plan for each applicable project	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated _____]	Issuance of statement of work
9	Project-specific supplement to Programmatic Quality Assurance Project Plan	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated _____]	Issuance of statement of work
9	Other Equivalent: _____	*[Insert specification]* _____	*[Select one]* **9** award of contract **9** 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.	2.	3. RECIPIENT'S ACCESSION NO.
EPA-354/R01-009		

4. TITLE AND SUBTITLE	5. REPORT DATE
Quality Management Plan for the Fine Particle Speciation Trends Monitoring Program	07/01
	6. PERFORMING ORGANIZATION CODE

7. AUTHOR(S)	8. PERFORMING ORGANIZATION REPORT NO
Dennis Mikel	

9. PERFORMING ORGANIZATION NAME AND ADDRESS	10. PROGRAM ELEMENT NO.
U.S. Environmental Protection Agency Office of Air Quality Planning and Standards Research Triangle Park, NC 27711	11. CONTRACT/GRANT NO.

12. SPONSORING AGENCY NAME AND ADDRESS	13. TYPE OF REPORT AND PERIOD COVERED
Director Office of Air Quality Planning and Standards Office of Air and Radiation U.S. Environmental Protection Agency Research Triangle Park, NC 27711	14. SPONSORING AGENCY CODE EPA/200/04

15. SUPPLEMENTARY NOTES

16. ABSTRACT

The Quality Management Plan that outlines the management structure for the Fine Particle Speciation Trends Network (STN) Monitoring Program. The guidance document gives details on how the STN Program will be implemented. The STN program is a multi-year program that draws upon EPA OAQPS, Office of Indoor Air (ORIA), Regional offices and State and Local Air Pollution Agencies. This Plan outlines each agency's responsibilities and authority.

. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Air Quality Monitoring Quality Assurance	Air Pollution Control	

18. DISTRIBUTION STATEMENT	19. SECURITY CLASS *(Report)*	21. NO. OF PAGES
Release Unlimited	Unclassified	
	20. SECURITY CLASS *(Page)*	22. PRICE
	Unclassified	