Quality Assurance Guidance Document

Quality Management Plan
for the National Air Toxics Trends Stations

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Forward

EPA Order 5360.1 Chg 2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, provides requirements for the conduct of quality management practices, including quality assurance (QA) and quality control (QC) activities, for all environmental data collection and environmental technology programs performed by or for this Agency.

In accordance with EPA Order 5360.1 Chg 2, EPA requires that environmental programs be supported by a quality system that complies with the American National Standard ANSI/ASQC E4-2004*, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.*

Correspondingly, EPA meets ANSI/ASQC E4-2004 through the requirement for quality management plans (QMPs). The QMP is a means of documenting how an organization will plan, implement, and assess the effectiveness of its quality assurance and quality control operations applied to environmental programs; in this case, the National Air Toxics Trends (NATTS) program

 This QMP was generated using the EPA Quality Assurance (QA) regulations and guidance as described in *EPA QA/R-2*, *EPA Requirements for Quality Management Plans* and the accompanying document, *EPA QA/G-2*, *Guidance for Developing, Reviewing and Implementing Quality Management Plans.* All pertinent elements of the QMP regulations and guidance are addressed in this plan. This QMP documents the Quality System developed by the Office of Air Quality Planning and Standards (OAQPS) for implementing the NATTS program and the minimum level of quality assurance activities required by monitoring organizations implementing the program. This document is not a substitute for the QMP requirements at the monitoring organizations but may be useful in their development.

Please note that national monitoring programs are not static entities; programs change over time. OAQPS staff will, from time to time, review this document and make changes and revision. This QMP will most likely be reviewed on a 5 year cycle.

Acknowledgments

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

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Acronyms and Abbreviations

AAMG	Ambient Air Monitoring Group
ALAPCO	Association of Local Air Pollution Control Officials
AMTIC	Ambient Monitoring Technology Information Center
APTI	Air Pollution Training Institute
AQS	air quality system
ASQ	American Society for Quality
ASTM	American Society for Testing and Materials
AT	air toxics
ATMAC	Air Toxics Monitoring Advisory Committee
CAA	Clean Air Act
CFR	Code of Federal Regulations
CO	contracting officer
DQOs	data quality objectives
EDO	environmental data operation
EMAD	Emissions, Monitoring, and Analysis Division
EPA	Environmental Protection Agency
EPM	environmental program management
FTP	file transfer protocol
GLP	good laboratory practice
GPRA	Government Performance Reporting Act
HAPs	hazardous air pollutants
LAN	local area network
LIMS	laboratory information management system
MQOs	Measurement Quality Objectives
MSR	management system review
NATA	National Air Toxics Assessment
NATTS	National Air Toxics Trends Stations
OAQPS	Office of Air Quality Planning and Standards
ORD	Office of Research and Development
ORIA	Office of Radiation and Indoor Air
PC	personal computer
PT	proficiency testing
PO	Project Officer
QA/QC	quality assurance/quality control
QA	quality assurance
QAC	quality assurance coordinator
QAAR	quality assurance annual report
QAPP	quality assurance project plan
QMP	quality management plan
QS	quality system
SLT	state/local/tribal
SOP	standard operating procedure
SOW	statement of work
STAG	state assistance grant
STAPPA	State and Territorial Air Pollution Program Administrators
TSA	technical system audit
UATS	urban air toxics strategy
UATMP	urban air toxics monitoring program
WAM	work assignment manager

Tables

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Quality Management Plan Identification and Approval

The attached QMP for the National Air Toxics Trends Assessment Monitoring Program is hereby recommended for approval and commits the resources and personnel to follow the elements described within.

Office of Air Quality Planning and Standards

1) Signature_____Date_____

Mr. Michael Jones, NATTS Program Lead, Ambient Air Monitoring Group

2) Signature_____Date_____

Mr. Dennis Mikel, NATTS Quality Assurance Coordinator

3) Signature_____Date_____

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1.0 Project/Task Organization

1.1 Introduction and Background

There are currently 188 hazardous air pollutants (HAPs), or air toxics (AT), regulated under the Clean Air Act (CAA) that have been associated with a wide variety of adverse health effects, including cancer, neurological, reproductive and developmental effects, as well as eco-system effects. These air toxics are emitted from multiple sources, including major stationary, area, and mobile sources, resulting in population exposure to these air toxics as they occur in the environment. While in some cases the public may be exposed to an individual HAP, more typically people experience exposures to multiple HAPs and from many sources. Exposures of concern result not only from the inhalation of these HAPs, but also, for some HAPs, from multi-pathway exposures to air emissions. For example, air emissions of mercury are deposited in water and people are exposed to mercury through their consumption of contaminated fish.

Our current Government Performance Results Act (GPRA) commitments specify a goal of reducing air toxics emissions by 75% from 1993 levels to significantly reduce the risk to Americans of cancer and other serious adverse health effects caused by airborne toxics. Because of our limited tools to assess the impacts of these emissions on public health and the environment, we are focusing on reducing emissions to the extent possible. However, as we develop new assessment tools and begin to address the risk associated with these emissions as required by the CAA, we will be modifying that goal to one that focuses on risk reductions associated with exposure to air toxics. In working toward this risk-based goal, we will focus on the cumulative effects of air toxics in urban areas, the multi-media effects of air toxics on water bodies, on populations whose water and food are affected by the deposition of persistent and bio-accumulating air toxics, and the effects on sensitive populations and economically disadvantaged communities. We have a long-term goal of eliminating unacceptable risks of cancer and other significant health problems from exposures to air toxics emissions and to substantially reduce or eliminate adverse effects on our natural environment.

1.1.1 National Air Toxics Assessments and the Role of Ambient Monitoring

EPA finalized the Urban Air Toxics Strategy (UATS) in the Federal Register on July 19, 1999[1]. The UATS states that emissions data are needed to quantify the sources of air toxics impacts and aid in the development of control strategies, while ambient monitoring data are needed to understand the behavior of air toxics in the atmosphere after they are emitted. Since ambient measurements cannot practically be made everywhere, modeled estimates are needed to extrapolate our knowledge of air toxics impacts into locations without monitors. Exposure assessments, together with health effects information, are then needed to integrate all of these data into an understanding of the implications of air toxics impacts and to characterize air toxics risks.

The EPA implemented the National Air Toxics Assessment (NATA), key to the success of which are four principle activities:

▶ development of source-specific standards and sector-based standards, including section 112 standards, i.e. Maximum Achievable Control Technology, Generally Achievable Control Technology, residual risk standards, and section 129 standards. **-** National, regional, and community-based initiatives to focus on multi-media;
▶ assessment of cumulative risks, such as the Integrated UATS, Great Waters, Mercury initiatives, Persistent Bio-accumulative Toxics, Total Maximum Daily Load initiatives, and Clean Air Partnerships.
▶ identification of areas of concern, characterize risks and track progress. These activities include improving emissions inventories, air quality and exposure modeling, and continued research on effects and assessment tools, leading to improved characterizations of air toxics risk and reductions.
▶ promoting education and outreach.

The success of the NATA critically depends on our ability to quantify the impacts of air toxics emissions on public health and the environment. All of these activities are aimed at providing the best technical information regarding air toxics emissions, ambient concentrations, and health impacts to support the development of sound policies for NATA. Specifically, these activities include:

▶ the measurement of air toxics emission rates from individual pollution sources;
▶ the compilation of comprehensive air toxics emission inventories for local, State, Tribal and national domains;
▶ the analysis of patterns and trends in ambient air toxics measurements;
▶ the estimation of ambient air toxics concentrations from emission inventories using dispersion modeling;
▶ the estimation of human and environmental exposures to air toxics, and;
▶ **the measurement of technically consistent ambient concentrations of air toxics at trends monitoring sites throughout the nation, through the development and implementation of a National Air Toxics Trends Station (NATTS) program.**

This QMP focuses on the role of ambient measurement data as one key element of the assessment process, i.e., NATA, and describes the key considerations for focusing the quality aspects of the NATTS monitoring effort.

The anticipated analytical uses of ambient monitoring data should be kept in mind when designing the measurement network. Specifically, we anticipate that the NATTS data will be used for:

▶ **tracking trends in ambient levels to facilitate tracking progress toward emission and risk reduction goals, which is the major objective of this program;**

- ▸ directly evaluating public exposure & environmental impacts in the vicinity of monitors;
- ▸ providing quality assured HAPs data for risk characterization;
- ▸ assessing the effectiveness of specific emission reduction activities;
- ▸ evaluating and subsequently improving air toxics emission inventories and model performance.

Since it is not possible to monitor everywhere, we must develop a monitoring network which represents air toxics problems on a national scale and which provides a means to obtain data on a more localized basis, as appropriate and necessary. The appropriateness of a candidate monitoring site with respect to the data uses described above was a key consideration in identifying sites for the national network.

1.1.2 National Air Toxics Trends Network

OAQPS, in conjunction with the EPA Regional Offices and State, Local, Tribal (SLT) air pollution control agencies, have developed the NATTS. Figure 1-1 and Table 1-1 provides the location of the NATTS as of the publication date of this QMP. It is possible that this network will expand and contract as needed. It is the expected that the core stations will be operated initially, over a six year period for assessments of national trends.

Table 1-1 NATTS Sites

Urban Sites		Rural
E. Providence,RI	Chicago, IL	Chittenden County, VT
Boston (Roxbury), MA	Houston (Deer Park), TX	Hazard, KY
New York, NY	St. Louis, MO	Chesterfield, SC
Rochester, NY	Bountiful, UT	Mayville, WI
Washington, DC	San Jose. CA	Grand Junction, CO
Decatur, GA	Phoenix, AZ	La Grande, OR
Tampa, FL	Seattle WA	Harrison County, TX
Detroit, MI		

Urban Sites

Rural Sites
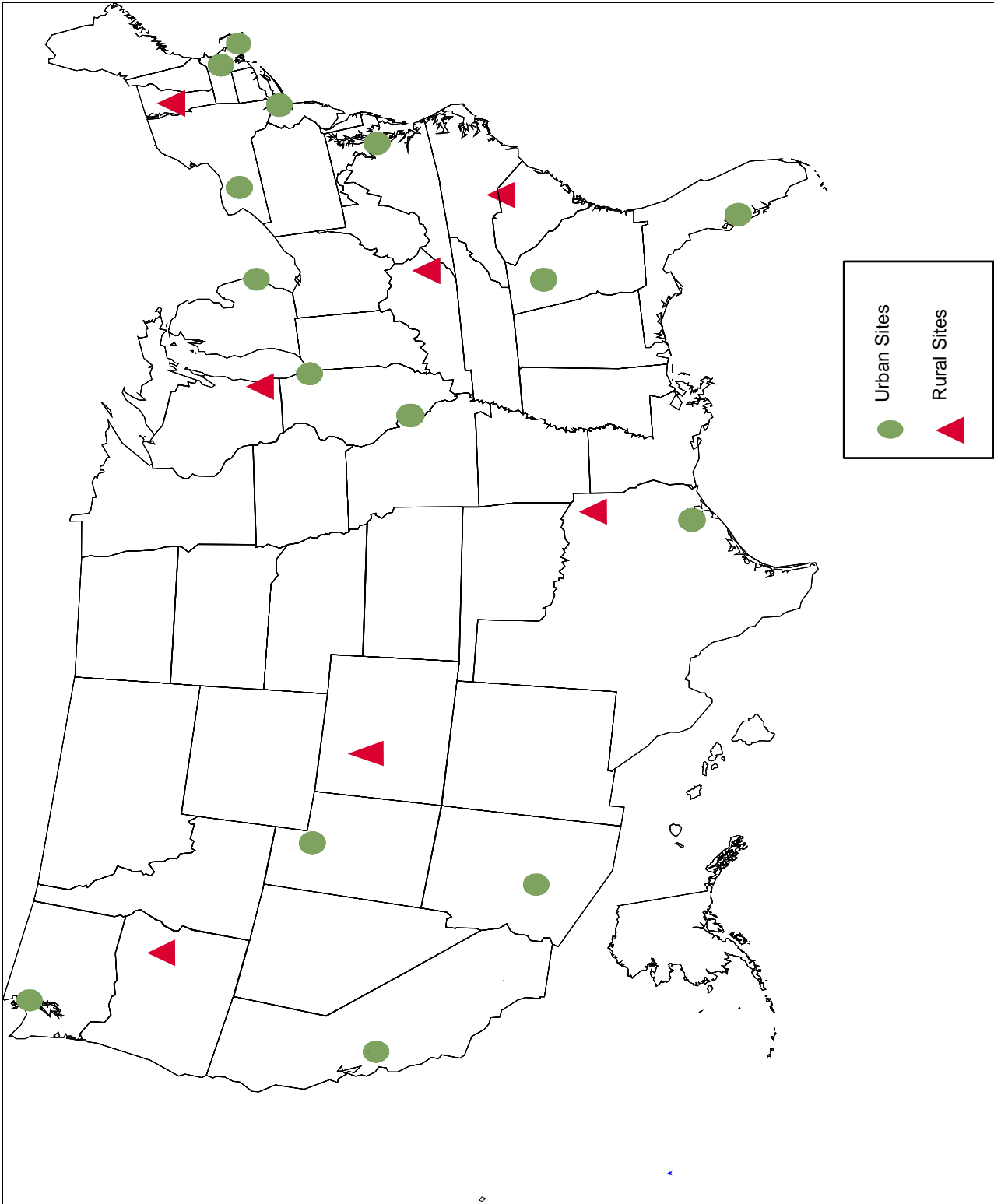
There are 33 HAPS identified in the draft UATS [1], which are listed in Table 1-2. They are a subset of the 188 toxics identified in Section 112 of the CAA which are thought to have the greatest impact on the public and the environment in urban areas. These chemicals can be grouped into several general categories which include volatile organic compounds (VOCs), metals, aldehydes and semi-volatile organic compounds (SVOCs).

Table 1-2 List of Analytes

Required	Core	Max
Benzene, hexavalent chromium*, acrolein, 1, 3 butadiene, arsenic and formaldehyde * Method still under development.	Benzene, 1,3-butadiene, carbon tetrachloride, chloroform, 1,2-dichloropropane, dichloromethane, tetrachloroethylene, trichloroethylene, vinyl chloride, arsenic, beryillium, cadmium, hexavalent chromium*, lead, manganese, formaldehyde and acrolein	Acrylonitrile, benzene, 1,3-butadiene, carbon tetrachloride, chloroform, 1,2 dibromomethane, 1,3-dichloropropene, 1,2-dichloropropane, ethylene dichloride, ethylene oxide, dichloromethane, tetrachloroethane, tetrachloroethylene, trichloroethylene, vinyl chloride, arsenic, beryillium, cadmium, hexavalent chromium*, lead, mercury, manganese, nickel, acetaldehyde, formaldehyde and acrolein, 2,2,7,8 tetrachlorobenzo-p-dioxin, coke oven emissions, hexachlorobenzene, hydrazine, polycyclic organic matter, polychloronated biphenyls, quinoline

Sampling for these compounds can be performed by a variety of ways. A Technical Assistance Document[2] has been developed which details the proven analytical methods for many of these compounds. If an agency pursues a method that is not detailed in the TAD, the acceptance of the method will be based upon whether it can achieve the Measurement Quality Objectives (MQOs) for the specific, relevant target compound(s) in Table 1-2. The MQOs are listed in detail in Appendix A. The SLT agencies will have to provide the technical information to EPA prior to implementing instruments and laboratory analytical techniques not suggested in the TAD. In addition, OAQPS may perform research and development of new methods as is warranted.

1.2 Roles and Responsibilities

The following organizations and committees are an integral part of the NATTS Monitoring Program. The management structure is illustrated in Figure 1-2.

1.2.1 EPA Air Toxics Monitoring Advisory Committee (ATMAC): The ATMAC is comprised of EPA Air Program Office and Regional representatives that meet regularly to address programmatic, technical, and resource allocation matters.

1.2.2. STAPPA / ALAPCO Air Monitoring Steering Committee: The Steering Committee advises EPA on programmatic, technical, and resource allocation matters.

Figure 1-3 Overview of NATTS Management
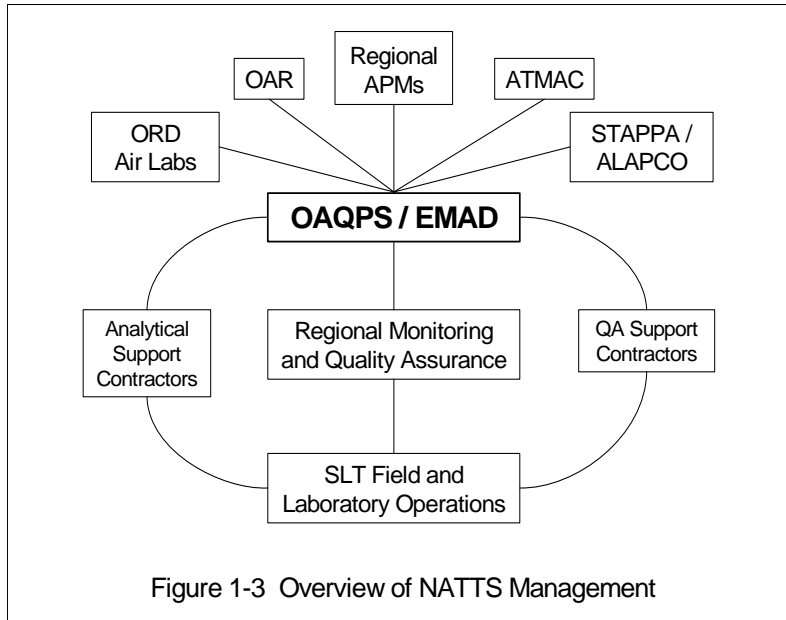
1.2.3 Office of Air Quality Planning and Standards: OAQPS is the organization charged under the authority of the (CAA) to protect and enhance the quality of the nation's air resources. OAQPS sets standards for pollutants considered harmful to public health or welfare and, in cooperation with EPA Regional Offices and the SLTs, enforce compliance with the standards through regulations controlling emissions from stationary sources. OAQPS evaluates the need to regulate potential air pollutants and develops national standards.

Within OAQPS, the Emissions Monitoring and Analysis Division (EMAD) has the following responsibilities for the NATTS:

- ▸ provide overall programmatic oversight and management;
- ▸ ensure 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 quality and technical assistance documents;
- ▸ evaluate the performance, through mechanisms such as, Proficiency Testing (PT), Technical Systems Audits (TSAs) and Management Systems Reviews (MSRs) of organizations making air toxics measurements;
- ▸ implement satisfactory quality assurance programs over federally funded ambient air quality monitoring networks;
- ▸ ensure that guidance pertaining to the quality assurance aspects of the air toxics monitoring program are written and revised as necessary;
- ▸ render technical assistance to the EPA Regional Offices and air pollution monitoring community concerning sampling and analysis.

1.2.4 Office of Research and Development: The Office of Research and Development (ORD) is charged with the research and development of the air toxics methods, samplers and technical oversight. ORD's role in the NATTS will be to:

- ▸ oversee development and testing of new air toxics instrument designs;

▸ evaluate ambient data as it is collected and work with the research community to ascertain the meaning of the results.

1.2.5 EPA Regional Office: EPA Regional Offices address environmental issues related to the states within their jurisdiction, administer and oversee regulatory and congressionally mandated programs, and provide direct feedback / input to the program management function. The major quality assurance responsibilities of EPA Regional Offices, in regards to the NATTS, are the coordination of quality assurance matters at the Regional levels with the SLT Agencies, and providing technical assessments and performance evaluations. This is accomplished by the designation of EPA Regional QA managers, who are responsible for:

▸ reviewing QMP and QAPPs from the SLT agencies;
▸ acting as a liaison by making available the technical and quality assurance information developed by EPA Headquarters and the Region to the SLT agencies;
▸ making EPA Headquarters aware of the unmet quality assurance needs of the SLT agencies.

1.2.6 Office of Radiation and Indoor Air: The Office of Radiation and Indoor Air (ORIA) laboratory in Las Vegas, Nevada will likely assume a support role in the NATTS. Specifically, the ORIA laboratory will offer their services to certify the concentrations of VOCs in calibration cylinders before they are utilized by the SLT agencies.

1.2.7 QA Support Contractors: OAQPS will contract QA support for two activities: 1) the creation of "single blind" Proficiency Testing (PT) samples that will be sent to all NATTS analytical laboratories, and 2) provide Technical System Audits (TSAs) at all NATTS sites and laboratories that are involved in the program. The TSAs will be on-site inspections of all monitoring stations and laboratories within the program. An annual report on all performance evaluations and TSAs will be developed within the February-March time frame of the following calendar year.

1.2.8 State, Local and Tribal Air Monitoring Agencies: The SLT agencies are tasked in operating the samplers in the field and in some cases, analyzing the samples at their own or contract laboratory facilities. Other duties include:

▸ write and adhere to an AT field/laboratory QAPP which must be approved by the EPA Regional QA Manager;
▸ store un-exposed samples in the manner described by the QAPP;
▸ maintain records of sampler operation;
▸ participate in all TSAs, analyze all PT samples submitted to them by independent QA Contract Lab or MSRs;
▸ perform Level 0,1, 2 and 3 validation on the data;
▸ submit data to the Air Quality System (AQS) within 90 days after the end of the calendar quarter;
▸ participate in meetings and teleconference calls led by OAQPS or the EPA Regional offices.

1.2.9 Analytical Laboratories

The SLT agencies will either analyze or contract for the analysis of NATTS samples collected by their agency. During contract development, SLT agencies must ensure that the analytical laboratories:

▸ write or adhere to a laboratory QAPP and standard operating procedures (SOPs);
▸ implement the QA/QC requirements described in NATTS QA documentation;
▸ participate in any TSAs, analyze all PT samples submitted to them by independent QA associated with the NATTS;
▸ perform Level 0,1, 2 and 3 validation on the data;
▸ submit their data to the National AQS or to the agency which they support.

1.2.10 Technical Workgroups

From time to time, analytical and quality issues arise that need attention and discussion. OAQPS will work with the SLT and Regional offices to create technical workgroups to address these issues when they occur.

1.3 Key QA Personnel

OAQPS Program Manager

The Program Manager is responsible for the OAQPS activities that are implemented as part of normal data collection activities.   Responsibilities include:

▸ review and approval of the NATTS QMP;
▸ communication with EPA Regional Project Officers and EPA QA personnel on issues related to monitoring and QA activities that need to be resolved on a higher level;
▸ understanding EPA monitoring and QA regulations and guidance, and ensuring all key personnel understand and follow these regulations and guidance;
▸ reviewing contracts, grants, cooperative agreements, inter-agency agreements to determine the necessary QA requirements;
▸ developing budgets and providing program costs necessary for EPA allocation activities;
▸ interacting with and convening the ATMAC.

OAQPS Quality Assurance Coordinator

The Quality Assurance Coordinator (QAC) will oversee the national quality assurance aspects of the NATTS. His/her responsibilities include:

▸ developing and revising the NATTS QMP;

▸ establishing and implementing a QA communication program;
▸ developing and revising the model QAPP;
▸ coordinating QA Annual Report (QAAR);
▸ assisting in solving QA-related problems at any level of the program;
▸ ensuring that TSAs, PTs, audits of data quality, and data quality assessments occur within the appropriate schedule and conducting or participating in these audits.

EPA Regional Quality Assurance Managers

The EPA Regional QA Managers, or their designees, will oversee the quality assurance aspects of the NATTS in their regions. His/her responsibilities and include:

▸ assisting in solving QA-related problems with NATTS program in their region;
▸ reviewing and approving the initial and all revised QAPPs written by NATTS programs in their region;
▸ participating in TSAs and data quality assessments that occur within a Region's jurisdiction.

SLT Monitoring QA Manager and Analytical Laboratory QA Manager

The SLT QA Managers will oversee the quality assurance aspects of their agency's NATTS. His/her responsibilities include:

▸ working with the NATTS SLT management to establish a QA/QC program;
▸ creating and updating the QAPP and submitting it to the EPA Regional QA Manager;
▸ coordinating the Level 0, 1 and 2 data validation;
▸ coordinating the receipt and analysis of PT samples;
▸ participating in TSAs and data quality assessments that occur within the appropriate schedule;
▸ participating, when necessary in NATTS QA conference calls;
▸ addressing any issues that arise from analyses of independent PT samples and the TSAs.

1.4 References

1. Federal Register Notice, Chapter 64, Section 38705, National Air Toxics Program, The Integrated Urban Strategy, July 19, 1999, http://www.epa.gov/ttn/atw/urban/fr19jy99.pdf
2. Technical Assistance Document for the National Ambient Air Toxics Trends and Assessment Program, May 5, 2005, http://www.epa.gov/ttn/amtic/airtox.html

2.0 Quality System

This section will discuss and outline the Quality System (QS) that has been established for the NATTS. The goal of the NATTS QS is to provide monitoring data of adequate quality to achieve the purposes for which it's collected. This is done by following the EPA's model for a quality system. This systematic approach is illustrated in Figure 2.1.   Each of these steps will be discussed in this section.
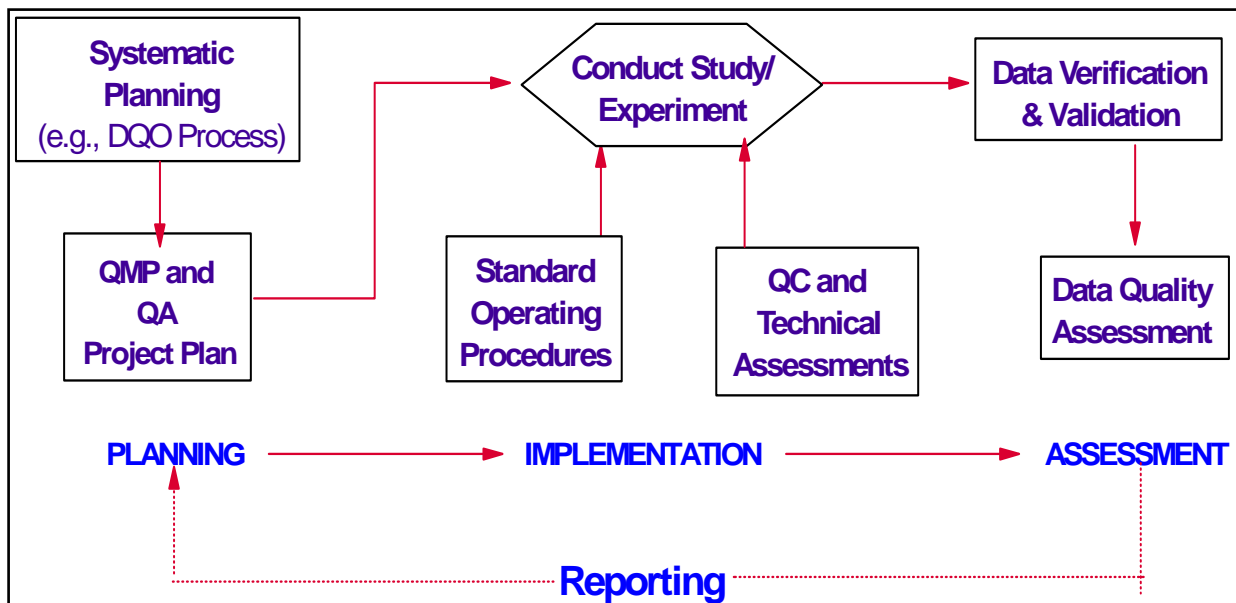
Figure 2.1 Illustration of the Quality System for NATTS

2.1 Quality System Planning Activities

2.1.1 Data Quality Objectives for the NATTS

The first step in the QS is systematic planning, realized through the development of Data Quality Objectives (DQOs). Since the program will not generate complete, error-free data, there will be some probability of making a decision error. The main goal of the DQO process is to find a workable balance between the degree to which data are complete and error free, and acceptable levels of decision errors. To find the balance, the possible errors need to be carefully defined. This usually needs to be done with the recognition that there will be a range, often called the gray zone, where it is impractical to control decision errors.

The DQO process described in EPA QA/G-4[1] document provides a general framework for ensuring that the data collected by EPA meets the needs of the intended decision-makers and data users. The process establishes the link between the specific end use of the data with the data

collection process and the data quality (and quantity) needed to meet program goals. This process was applied to one of the primary goals of the NATTS, namely to identify and assess trends in ambient HAP concentrations. This is not to say that the NATTS data cannot be used for other purposes, rather that the development of the quality system, data quality indicators (precision, bias, completeness) and their resultant measurement quality objectives were based upon detecting the trends mentioned above.

In 2001 a workgroup representing data users, decision-makers, state and local parties, and monitoring and laboratory personnel developed the DQOs through a series of conference calls. Since it would not be feasible to develop DQOs for every toxic compound measured in the NATTS, and in the interest of simplicity and consistency in the MQOs, the highest risk drivers were selected for the development of the DQOs: benzene, 1,3-butadiene, arsenic, chromium, acrolein, and formaldehyde.

The workgroup established the following trends objective of the National Air Toxics Monitoring Program:

> *To be able to detect a 15% difference (trend) between two successive 3-year annual mean concentrations within acceptable levels of decision error.*

The following statements provide more detail of the DQO:

> *If there is no true decrease in the three-year average concentrations, then the probability of observing a mean concentration for years four through six that is at least 15 percent below the observed mean concentration from years one through three should be no more than 10 percent.*

> *If there is a true decrease in the three-year average concentrations of at least 30 percent, then the probability of observing a mean concentration for years four through six that is less than 15 percent below the observed mean concentration from years one through three should be no more than 10 percent.*

> *Equivalently, the second statement could read that:*

> *If there is a true decrease in the three-year average concentrations of at least 30 percent, then the probability of observing a mean concentration for years four through six that is at least 15 percent below the observed mean concentration from years one through three should be at least 90 percent.*

A detailed document on the development of DQOs for the NATTS can be found in the Technical Assistance Document for the National Air Toxics Trends Network[1], Section 3.3.1.

In summary, based on variability and uncertainty estimates used in the DQO process, the

specified air toxics trends DQOs should be met for monitoring sites that satisfy the goals of:

- 1-in-6 day sampling frequency with at least an 85% quarterly completeness; and
- measurement precision controlled to a Coefficient of Variance (CV) of no more than 15%.

The quality system described in this QMP and the SLT QAPPs will reflect these DQOs.

2.1.2 Quality Management and Project Plan Development

QMP Development

Since the NATTS program has specific objectives that are dependent on obtaining consistent and high quality data across the nation, EPA Headquarters has assumed responsibility for the development of the QMP for this program. Similar to the $PM_{2.5}$ Speciation QMP, the NATTS QMP provides a minimum set of requirements that will be followed by all monitoring organizations participating in the NATTS. The QMP will cover only the technical elements applicable to the program and will not supersede a SLT monitoring organization's QMP. OAQPS began development of the NATTS QMP in 2002 and submitted it for review to the major program stakeholders.   In 2003 OAQPS was provided with additional resources to implement a more comprehensive quality system starting in calendar year 2004, thus requiring this revision.

Quality Assurance Project Plan Development

As with the QMP, QAPPs are required for any Environmental Data Operation (EDO) using EPA funds. The purpose of the QAPP is to document planning results for EDOs and to provide a project-specific "blueprint" for obtaining the type and quality of environmental data needed for a specific decision or use. All aspects of planning, implementation, assessment and reporting described in Figure 2.1 should be discussed in the QAPP. The NATTS participants are required to develop QAPPs for their monitoring organization. In order to provide some consistency in the development of the quality system, the OAQPS QA team developed a Model QAPP[2] that was distributed to the NATTS managers in late 2002. This document was designed and written to be a guide for the NATTS managers to develop their individual QAPPs for their projects. The EPA Regional offices are required to approve the NATTS QAPPs.

2.2 Quality System Implementation Activities

2.2.1 SOPs

To ensure nationally consistent data of adequate quality (meeting the DQOs), the correct execution of specific sampling and analytical methodology is required. The methods selected must consider the following data quality indicators:

- detectability - being able to measure the concentrations ranges required for the program;
- completeness- being able to collect the quantity of data necessary;
- precision – being repeatable to an acceptable level;
- bias – being able to maintain a concentration that does not systematically deviate from the true concentration.

The NATTS DQOs provide a means to determine the acceptable ranges of these data quality indicators. From the DQOs one can develop MQOs for various phases of the measurement process (sampling/analysis) which, once established, can help an organization select or develop methods that will meet these measurement quality objectives (see next section). This is the theory behind the use of a performance based measurement system. Currently, there are only a few sampling and analytical methods available that will meet the DQOs for the NATTS. Section 4 of the NATTS TAD[3] provides strongly suggested guidance for the consistent use of sampling and analysis methods for the NATTS. Through QAPP reviews and technical systems audits, significant method deviations that are implemented and could affect the quality of the data will be identified and discussed to ensure that the methods will meet the DQOs.

As part of the QAPP development process, NATTS participants are required to develop SOPs at a level of detail specific to their EDO. As an example, it is not appropriate to simply reference TO-15 in the QAPP as the method for use since there are a number of options included in that method that any organization would have to select as the option used for their procedure.

If contractors are used by the NATTS monitoring organization, then the contractors must submit their SOPs to the NATTS monitoring organization for incorporation into the QAPP prior to EPA Regional office review and approval.

2.2.2 Quality Control through the Development of Measurement Quality Objectives

In order to achieve the DQOs, organizations need to be able to define the appropriate indicators of data quality and identify measurements that can be made to provide estimates of these indicators. The MQOs are currently in draft form, due to current on hexavalent chromium and acrolein. Please note that a number of these are required, namely, the MQOs that are discussed in this section. The other MQOs are considered guidance; meeting the guidance MQOs will allow agencies to adhere to the required MQOs and provide the NATTS program a more consistent product. The required quality indicators include:

Precision - a measure of mutual agreement among individual measurements of the same property usually under prescribed similar conditions, expressed generally in terms of standard deviation. It is important that the estimate of precision (and bias) be as inclusive of the total data collection system, meaning that the estimate include imprecision related to field, preparation, handling and laboratory operations. Precision will be assessed through the use of collocated sampling, duplicate filters and a number of laboratory techniques. In order to achieve the NATTS DQOs total precision should be controlled to 15% coefficient of variation (CV).

Bias- the systematic or persistent distortion of a measurement process which causes error in one direction. At present, the NATTS program does not have a good method to quantify total measurement system bias especially the portion of bias associated with sampling in the field. Bias will be assessed through the implementation of a proficiency test (PT) program, and standards certifications which will be able to provide assessments of laboratory bias issues. Since 2001, OAQPS has been reinventing the mail-able National Performance Evaluation Program to a through-the-probe audit activity for the criteria pollutants. Trailers and/or mobile laboratories visit a monitoring site and challenge the monitors with audit gases through the inlet instead of the back of the monitor. OAQPS will look at augmenting the current NPEP trailers/labs with the equipment to provide similar audits to the NATTS sites.

Completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions. In order to achieve the NATTS DQOs a completeness goal of 85% is required. The completeness goal will obviously be affected by data quality but more importantly detectabilty. There may be cases where the concentrations at certain sites will be below the detection limits of the current methods available for monitoring so even if a sample is collected it may not be detected and therefore effect the completeness statistic.

Detectabilty - the determination of the low range critical value of a characteristic that a method specific procedure can reliably discern. Method detection limits (MDLs) have been established but the technique for their quantification, and the frequency of assessment must be agreed upon.

Comparability - a measure of confidence with which one data set can be compared to another. This is achieved by setting DQOs and establishing the correct MQOs for the data quality indicators above. If the acceptance criteria are achieved the data should be comparable.

Representativeness - Representativeness is a measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition. The current NATTS network, which is based on a number of logistical and resource considerations, is currently set at 22 urban and rural sites.

2.2.3 Technical Assessments

An assessment is an evaluation process used to measure performance or effectiveness of a system and its elements and is an all inclusive term used to denote audits, performance evaluations, proficiency tests, management systems audits, peer review, inspection or surveillance.

2.2.3.1 Technical Systems Audits (TSA) and Instrument Performance Audits (IPAs) – A technical systems audit is a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management and reporting aspects of a quality system.   Instrument performance audits provide checks of some of the critical features of instruments (e.g., flow rates, temperature probes, etc.) by challenging the sampling instruments against independent standards.

- **Laboratory TSA -** EPA, using contractors and EPA Regional Offices, will attempt to perform 12 audits a year of the laboratories performing analysis for the NATTS. It is expected that audits of all laboratories would be completed in 2 years. An audit check sheet will be developed in order to provide a consistent evaluation across all laboratories.   Reports on these audits will be included in an Annual QA Report.
- **Field TSA/IPA –** EPA, using contractors and EPA Regional Offices, will perform TSAs/IPAs on field activities at schedules similar to the lab TSA and will implement both lab and field TSA in one visit, if possible.
- **Internal TSA –** Monitoring organizations, as part of the internal quality system procedures, may perform technical systems audits of the environmental data operations as described in their QAPP.

2.2.3.2 Proficiency Tests (PT) - A PT is a type of assessment in which a sample, the composition of which is unknown to the analyst, is provided to test whether the analyst/laboratory can produce analytical results within the specified acceptance criteria. OAQPS will implement quarterly PT studies for the NATTS program laboratories using the following process:

1. Decide on the **audit constituents** and the **concentration levels**.
2. Find an independent organization to develop the PT samples. The organization (vendor) that creates the PT samples must not perform analysis for any of the NATTS SLT agencies.
3. The independent organization/vendor will certify the audit concentration and constituents through the National Institute of Standards and Technology (NIST). PT materials will be developed and sent to NIST for analysis and certification. The appropriate confidence limit window would be identified.   This information would be reported from NIST to OAQPS for independent verification of the audit concentration.

2.2.3.3 Calibration Cylinder Certification -OAQPS, in conjunction with Office of Air and Radiation (ORIA) laboratory in Las Vegas, Nevada, will be implementing a program where the VOC calibration cylinders will be sent from the NATTS analytical laboratories to ORIA for certification. In the future, if the laboratories agree to the process, OAQPS could perform a national purchase of calibration cylinders and certify their concentration prior to use by the laboratories.

2.2.3.4 Through the Probe Performance Evaluation –Since 2001, OAQPS has been reinventing the mailable National Performance Audit Program to a through the probe audit activity. Trailers and/or mobile laboratories visit a monitoring site and challenge the monitors with audit gases through the inlet instead of the back of the monitor. OAQPS will consider providing similar audits to the NATTS sites for VOCs and aldehydes in the near future.

2.3 Quality Assurance Reports

OAQPS will hire a contractor to create a Quality Assurance Annual Report (QAAR). The QAAR will document the information of the MQOs and independent assessments that are performed within a calendar year. These results will then be compared against the MQO criteria for this program. The annual report will be utilized by OAQPS, EPA Regional Offices and NATTS stake-holders to assess the status of the program. If problems are identified, corrective steps by the NATTS SLT agencies, with the input of the EPA Regional offices, will be undertaken.

After the first 3 years of NATTS monitoring, a more interpretive DQA will be performed to determine whether the assumptions and data quality requirements used to develop the DQOs are being achieved.

2.4 References

1. Guidance for the Data Quality Objectives Process, EPA/600/R-96/055, http://www.epa.gov/quality/dqos.html
2. Quality Assurance Guidance Document -- Model Quality Assurance Project Plan for the National Air Toxics Trends Stations, EPA 454/R-02-007, http://www.epa.gov/ttn/amtic/airtxfil.html
3. Technical Assistance Document for the National Ambient Air Toxics Trends and Assessment Program, May 5, 2005, http://www.epa.gov/ttn/amtic/airtox.html

3.0 Personal Qualifications and Training

3.1 Personnel Qualifications

Personnel assigned to the NATTS should meet the educational, work experience, responsibility, personal attributes, and training requirements for their positions. EPA does not identify specific attributes necessary to qualify for participation in the NATTS program; it remains the responsibility of the SLT monitoring organizations and those organizations employed in their service. During TSAs and MSRs, EPA will review records on personnel qualifications and training documentation. All agencies should maintain these records in personnel files and have them accessible for review during audit activities.

3.2 Training

There are no formal requirements for NATTS training. The SLT monitoring organizations and those organizations employed in their service will be responsible for ensuring that appropriate training will be made available to employees supporting the NATTS, commensurate with their duties. For the SLT agencies that are implementing the Urban Air Toxics Monitoring Program (UATMP), the UATMP Contractor provides field standard operating procedures (SOPs) and direct training when they assist the SLT agencies in setting up the UATMP samplers. Training for other types of NATTS samplers may be available through sampler manufacturers.

EPA has implemented training courses on the use of VOCDat, a software tool for the analysis of volatile organic compounds which has been expanded to the NATTS program. In addition the contractor supporting this software provides telephone support and has been authorized to perform batch uploads. VOCDat can be found at the following website
http://www.sonomatech.com/sti/projects.htm

The EPA sponsored Air Pollution Training Institute (APTI)
http://www.epa.gov/oar/oaq.apti.html does provide some air toxics training that would be beneficial to monitoring organizations.

4.0 Procurement of Items and Services

The following sections will provide general information on procurement procedures in the NATTS Program.

4.1 Source of Funds

4.1.1 State Assistance Grants: Since implementation of the NATTS is a State and Local responsibility, the source of funds for the program are awarded as Section 103 State Assistance Grants (STAG). Every year, funds are allocated to the EPA Regions who then allocate them to the SLT agencies. These agencies then follow their own procurement policies to get the NATTS monitoring accomplished.

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

1. **UATMP laboratory contract-** OAQPS implements a national contract to support SLTs that desire to perform air toxics and Photochemical Assessment monitoring. The UATMP contractor provides the sampling equipment, SOPs, sample material, analyses and reporting to the agency. The contractor also validates, verifies and submits the data to AQS.

2. **QA/QC** - The performance evaluations and technical systems audits are funded through STAG funds. These are described in Section 2.2.3 of this document.

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 from 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. NATTS monitoring and QA leads will work with various workgroups and cooperators to prioritize the use of EPA environmental program management (EPM) funds. These funds may be used to purchase capital equipment or for contract support activities.

4.2 Procurement of Items

4.2.1 EPA Procurements: 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.

4.2.2 Monitoring Organization Procurements – The grant requirements developed for the NATTS monitoring organizations will provide some level of detail on the appropriate procurements for the Program. This detail would include the types of monitoring equipment and analytical equipment and consumables necessary to meet the implementation activities and MQOs of the NATTS program. Monitoring organizations shall follow the procurement policies associated with the EPA grant conditions and the procurement policies that are described in their local QMP.

4.2.3 Contractor Procurements – Procurements by contractors must be identified in the project scope of work for such purchases. All items should be identified and specifications that meet the NATTS minimum needs should be detailed. These specifications will be referred to during the procurement process and will assure that the requestor receives the proper item and reduces the chances of purchase delays or incorrect purchases because of inadequate product specifications.

4.3 Procurement of Services

Two types of mechanisms are primarily used to procure services, contracts and assistance agreements (grants, cooperative agreements, etc.).

4.3.1 Contracts

Contracts are used when the requestor derives sole benefit from a particular product or service.

4.3.1.1 EPA Contracts - Whenever the government enters into a contract, it is entitled to receive quality service. In order to define and measure this quality, the work assignment manager or the project officer (WAM/PO) must develop a scope of work (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 includes the use of a technical evaluation panel (TEP). Part of the TEP responsibilities will include rating each potential contractor against a standard set of criteria. A portion of the 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.

Any EPA initiated contracts are required to use some type of QA form to determine if the contract 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.

EPA contracts for the NATTS program include:

- Laboratory and field technical systems audits and instrument performance audits (See section 2.2.3.1);
- Development and distribution of PT samples (See section 2.2.3.2);
- Through the probe audits (See section 2.2.3.4);
- Development and revision of data analysis software (VOCDat);
- Guidance document development or revision (NATTS TAD).

4.3.2 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.

EPA assistance agreement recipients must implement or have implemented a quality system conforming to the E-4[2] . This quality system shall be applied to all environmental programs within the scope of the assistance agreement(s). Environmental programs include direct measurements or data generation, environmental modeling, compilation of data from literature or electronic media, and data supporting the design, construction, and operation of environmental technology. This requirement is consistent with and for all environmental programs operating under the EPA Quality System such as:

1. All applicants for EPA assistance shall submit a QMP prepared in accordance with the specifications provided in EPA Requirements for QMPs Quality Management Plans (QA/R-2) (EPA 2001), or documentation determined by EPA to be equivalent to R-2, which describes the quality system implemented by the applicant. The NATTS agency QMPs shall be reviewed and approved by the EPA Regional Quality Assurance Manager (or designee), as a condition for award of any assistance agreement. The QMP must be submitted as part of the application. If the QMP is not submitted as part of the application and EPA decides to fund the project, EPA will include a term and condition in the assistance agreement. This term and condition requires the recipient to submit the QMP within a specified time after award of the agreement and notifies the recipient that they may not begin work involving environmental programs until the EPA Project Officer informs them that the QMP has been approved.

2. Monitoring organization participating in the NATTS, in most cases, are already participating in ambient air monitoring activities and are required to have a QMP on file at the EPA Regional Office. The monitoring organizations must revise their QMP to include quality system components for NATTS.

3. The Assistance Agreement requires the recipient to submit a QAPP to EPA for review and approval by the EPA Regional Office Project Officer and EPA QAM before undertaking any work involving environmental measurements or data generation. QAPPs shall be prepared using EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA 2001).

4. Approval of the recipient's QMP by the EPA Project Officer and the EPA QAM, may allow delegation of the authority to review and approve QAPPs to the recipient based on procedures documented in the QMP.

EPA has the following requirements and guidance documents available to assist applicants and recipients in complying with these requirements:

- EPA Requirements for Quality Management Plans (QA/R-2) (EPA 2001)

- EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA 2001)

- EPA Guidance on Quality Assurance Project Plans (QA/G-5) (EPA/600/R-98/018, February 1998)

The documents may also be downloaded from the Quality Staff Home Page under the heading, "EPA Quality System Documents", at URL: http://www.epa.gov/quality .

4.4 References

1. Policy and Program Specifications for the Mandatory Agency-wide Quality System, EPA Order 5360.1 A2, May 2000, http://www.epa.gov/quality1/qa_docs.html
2. ANSI/ASQC E4-1994, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, American National Standard, January 1995.

5.0 Records and Documentation

The responsibility of record keeping will fall upon OAQPS, QA support contractors, SLT agencies and their contractors. For the NATTS, 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."   Section 5.1 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 all must be adhered; all documents and records for this program will be securely stored. More detailed information on document control and storage must be adequately described in individual agency QAPPs.

5.1 Document Hierarchy

This section will outline the hierarchy of the documentation and illustrate the review process for the major documents created for this program. Figure 5.1 illustrates the hierarchy of quality system documentation.

5.1.1 Policy Tier: The American National Standard (ANSI/ASQC E4-1994, *Specifications and Guideline for Quality Systems for Environmental Data Collection and Environmental Technology Programs* provides a national consensus standard and the basis for the EPA Agency-wide Quality System. From this standard the EPA Order 5360.1 A2 Policy and Program Requirements for the Mandatory Agency –wide Quality System is developed. EPA Order 5360.1 A2 require all agencies that accept federal funds to create QMPs and QAPPs. In addition, Assistance agreement policies (40 CFR 30, 31 and 35) describe conformance to EPA QA policies. Within the OAQPS Ambient Air Quality Monitoring Programs, QA policies more specific to the Ambient Air Program are included.

5.1.2 Program Tier: At the organization/program level, the QMP is developed for the NATTS and describes how the program shall comply with the requirements of EPA Order 5360.1 A2. The elements illustrated in figure 5.1 would be documented in the QMP. Since the NATTS program has specific objectives that are dependent on consistent and comparable data quality across the nation, EPA Headquarters has assumed responsibility for the development of the QMP for this

program. Similar to the PM$_{2.5}$ Speciation QMP, the NATTS QMP will provide a minimum set of requirements that will be followed by all monitoring organizations participating in the NATTS. The QMP will only cover the technical elements applicable to the program and will not supersede but augment a SLT QMP. This document will undergo thorough review by all stakeholders.
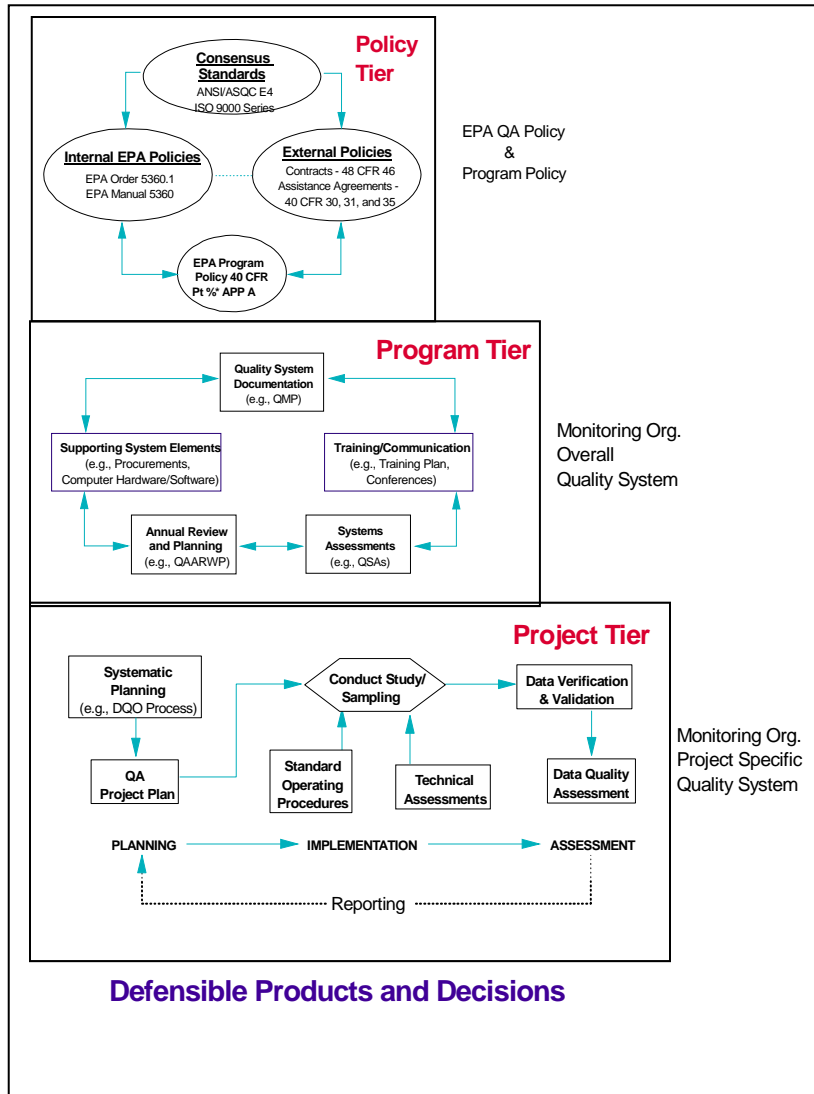
5.1.3 Project Tier: The project level (lowest tier) is where specific projects are implemented and how the quality of that data is controlled and assessed to meet specific program objectives. The major documents written in the project Tier are the QAPP and SOP.   In order to provide some consistency in the development of the quality system, the OAQPS QA team developed a model QAPP that was distributed to the NATTS managers in late 2002. This document was designed and written to be a guide for the NATTS managers to develop their individual QAPPs for their projects. The EPA Regional offices are required to approve

the QAPP.

Figure 5.1 Hierarchy of the EPA Quality System

5.2 Document Creation and Control Process

Table 5-1 represents the categories and types of records and documents which are applicable to document control. Information on key documents in each category follow. It should be noted that the list contains documents that may not be applicable to particular organizations and therefore is not meant to be a list of required documentation. This list should also not be construed as the definitive list of record and document types.

Table 5-1 Types of Information that Should be Retained Through Document Control

Categories	Record/Document Type
Management and Organization	Monitoring Agency Information Organizational Structure Quality Management Plan Personnel qualifications and training Document control plan Support contracts
Site Information	Network description Site characterization file Site maps/pictures
Environmental Data Operations	QA Project Plan Standard Operating Procedures (SOPs) Field and laboratory notebooks Sample handling/custody records Inspection/ Maintenance records
Raw Data	Any original data (routine and QC)
Data Reporting	Data/summary reports Journal articles/papers/presentations
Data Management	Data algorithms Data management plans/flowcharts
Quality Assurance	Control Charts Data quality assessment QA Reports System Audits Network reviews Corrective actions

5.2.1 Management and Organization

Documentation for many of the document types listed in Table 5-1 for this category can be found in a single document, the QMP, which is the blueprint for how an organization's quality management objectives will be attained. If NATTS monitoring agencies have been participating in the Ambient Air Quality Monitoring and accepting assistance agreement funds then a QMP for that organization should already be completed.

5.2.2 Site Information

Site information provides vital data about each monitoring site. Historical site information can help determine and evaluate changes in measurement values at the site. The QAPP should include specific documentation of site characteristics for each monitoring station. This information will assist in providing objective inputs into the evaluation of data gathered at that site. Typically, the site identification record should include:

1. data acquisition objective (e.g., air quality standards monitoring);
2. station type;
3. instrumentation checklist (manufacturer's model number, pollutant measurement technique, etc.);
4. sampling system;
5. spatial scale of the station (site category--i.e., urban/industrial, suburban/commercial, etc.; physical location--i.e., address, coordinates, etc.);

6. influential pollutant sources (point and area sources, proximity, pollutant density, etc.);
7. topography (hills, valleys, bodies of water, trees; type and size, proximity, orientation, etc. picture of a 360° view from the probe of the monitoring site);
8. atmospheric exposure (unrestricted, interferences, etc.);
9. site diagram (sample flowsheet, service lines, equipment configuration, etc.);
10. site audits.

Network Plan – the OAQPS contractor that performs the TSAs will take electronic photographs of each site in the cardinal directions. This information will be forwarded to OAQPS with all other siting data. OAQPS will create a database that will include the following:

▸ photographs of all sites;
▸ drawings of the area, including nearby sources;
▸ geographic information system maps of the area showing local sources (if known);
▸ coordinates of the location generated by geographic positioning system.

5.2.3 EDOs

A quality assurance program associated with the collection of ambient air monitoring data must include an effective procedure for preserving the integrity of the data. There are basically four phases of an overall quality assurance program:

• data collection - includes testing, preparation and identification of the sample, strip charts, or other data;
• sample handling - includes protection from contamination and tampering during transfer between individuals and from the sampling site to the evidence locker (i.e., chain of custody);
• analysis - includes storage of samples prior to and after analysis as well as data interpretation;
• preparation and filing of test report - includes evidentiary requirements and retention of records.

Failure to include any one of these elements in the collection and analysis of ambient air monitoring data may undermine the credibility of any report based on these data.

Environmental data operations include all the operations required to successfully measure and report a value within the data quality objectives. Documentation for environmental data operations would include:

QAPPs - These documents show environmental data operations are planned, implemented, and assessed during the life cycle of a program, project, or task. As mentioned in the assistance agreement sections of 40 CFR parts 30.54 (Non-State and Local Gov.) and 31.45 (State and Local Gov.) quality assurance programs must be established. In addition to the grant requirements, 40 CFR Part 58 Appendix A states that each quality assurance program must be described in detail in accordance with the *EPA Requirements for Quality Assurance*

Project Plans for Environmental Data Operations.

SOPs- Standard operating procedures are written documents that detail the method for an operation, analysis, or action with thoroughly prescribed techniques and steps. It is officially approved as the method for all routine activities, especially those that are involved in the environmental data operations, which generally involve repetitious operations performed in a consistent manner. SOPs should be written by individuals performing the procedures that are being standardized. Individuals with appropriate training and experience with the process need to review the SOPs, it should be approved by the supervisor of the personnel responsible for writing the document. For documentation purposes, the approving official should sign and date the title page of the SOP. In addition, the NATTS agencies must have a document control system for their SOPs and QAPPs. This consists of a numbering system that allows updates to the documents without the need of re-writing the entire document.

Field and laboratory notebooks- Any documentation that may provide additional information about the environmental data operation (e.g., calibration notebooks, temperature records, site notes, maintenance records etc.). Manual recording of data are sometimes required for ambient air tests. Standardized forms should be utilized to ensure that all necessary information is obtained. These forms should be designed to clearly identify the process tested, the date and time, location of the test station, and operating personnel. This information may determine the credibility of the data and should not be erased or altered. Any errors should be crossed out with a single line, and the correct value recorded above the crossed-out number.

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.

5.2.4 Raw Data

Raw data includes any original factual information from a measurement activity or study recorded in laboratory work sheets, records, memoranda, notes, or exact copies thereof and that are necessary for the reconstruction and evaluation of the activity or study. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. For automated information systems, raw data is considered the original observations recorded by the information system that are needed to verify, calculate, or derive data that are or may be reported. Organizations should critically review the NATTS and create a list of what the organization considers raw data and provide a means to store this information in a manner that is readily accessible.

5.2.5 Data Reporting, Handling and Storage

In addition to samples and field records, the report of the analysis itself may serve as material evidence. Just as the procedures and data leading up to the final report are subject to the rules of evidence, so is the report. Written documents, generally speaking, are considered as hearsay, and are not admissible as evidence without a proper foundation. A proper foundation consists of introducing testimony from all persons having anything to do with the major portions of the test and analysis. Thus the field operator, all persons having custody of the samples, and the analyst would be required to lay the foundation for the introduction of the test report as evidence.

To ensure compliance with legal rules, all test reports should be filed in a safe place by a custodian having this responsibility. Although the field notes and calculations are not generally included in the summary report, these materials may be required at a future date to bolster the acceptability and credibility of the report as evidence in an enforcement proceeding. Therefore, the full report including all original notes and calculation sheets should be kept in the file. Signed receipts for all samples, strip charts, or other data, should also be filed.

The original of a document is the best evidence, and a copy is not normally admissible as evidence. Microfilm, snap-out carbon copies, and similar contemporary business methods of producing copies are acceptable in many jurisdictions if unavailability of the original is adequately explained and if the copy was made in the ordinary course of business.

In summary, although all original calculations and test data need not be included in the final report, they should be kept in the agency's files. It is a good rule to file all reports together in a secure place. Keeping these documents under lock and key will ensure that the author can testify at future court hearings that the report has not been altered.

5.2.6 Data Management

Much of the data collected for the NATTS will be collected through the use of automated systems. These systems must be effectively managed and documented by using a set of guidelines and principles by which adherence will ensure data integrity.

5.2.7 Quality Assurance

Quality assurance information is necessary to document the quality of data. This information should be retained in a manner that it can be associated with the routine data that it represents. QA Information include:

- ▸ **Control charts** – This tool is used to track information over long or short periods of time. By placing values along a grid, the performance of different aspects can be monitored.
- ▸ **Data quality assessments (DQAs)**- These assessments are a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection

design and to determine the adequacy of the data set for its intended use.
- ▸ **QA Reports -** Reports pertaining to the quality of data, usually related to some aggregate (quarterly, yearly etc.) focusing on measurement quality attributes and data quality objectives.
- ▸ **Evaluation/Audits**- Assessments of various phases of the environmental data operation must be performed and must be discussed in an agency's QAPP.

5.3 Documentation Responsibilities

5.3.1 EPA OAQPS: This office has oversight of the NATTS. As such, the documents that must be control and stored that are under their jurisdiction. The Program Manager and the QA coordinator document responsibilities are defined below.

Program Manager - The program manager is responsible for the overall operation and technical guidance for the program. The documents and records 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 oversight and review of the NATTS QMP, TSA and PT data and the documents that are utilized to create the QAAR.

5.3.2 QA Support Contractor: Standard TSA forms will be filled out in the laboratory and field situation. The data will then be entered into spreadsheets/word processing programs on laptop.

5.3.3 State, Local and Tribal 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.

5.3.4 Deposition and Storage of Documents and Records: 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. Resolution of all issues that arise from it, or until the end of the regular 5-year period, whichever is later.

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 NATTS. This chapter will also describe the roles and responsibilities for system hardware and software.

6.1 Computer System Descriptions

6.1.1 EPA-OAQPS: Once the data has been validated by SLT agency or UATMP Contractor and reviewed by the SLT agencies, the data will be delivered to the AQS database. The AQS database is now housed in a long term data storage facility located at the EPA Computer Center in Research Triangle Park, North Carolina.

6.1.2: QA Support Contractors: The QA support contractors will have computer systems that will be adequate for their operations.

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

6.1.4 State, Local and Tribal Agencies: The SLT computer systems will vary from agency to agency. The agencies will purchase and maintain computer systems that are adequate for their field and laboratory operations

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 (ORIA and OAQPS). These are password protected and maintained by the System Administrators (SA) for each agency. The EPA 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 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 QA Support Contractor: The support contractors will utilize a Data Base Management System (DBMS). This system will be utilized by the contractors 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 contractors will have a database 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 UATMP Contractor scientists;
▸   ensure that data and information produced for the EPA are collected and archived in a safe and secure manner.

6.2.3 State/Local/Tribal Agencies: Each SLT agency will be encouraged to create a DBMS for their agency. The current versions of analytical equipment such as gas chromatographs/mass spectrometers and Inductively Coupled Plasma/mass spectrometers create data that are shunted directly to computer systems. The SLTs will be responsible for:

▸   ensuring that raw outputs from spectrometers and chromatographs are stored in a secure manner;
▸   allowing these raw and meta data that are generated to stored in long term fashion (i.e., compact disk or hard drives)
▸   allowing the raw and meta to be shared among the QA and data review staff.

7.0 Planning

This section will outline planning and implementation procedures that will be and were employed for the NATTS. 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 NATTS is a component of the NATA. The programmatic objectives of the NATTS network are to:

- **tracking trends in ambient levels to facilitate tracking progress toward emission and risk reduction goals, which is the major objective of this program;**
- directly evaluating public exposure & environmental impacts in the vicinity of monitors;
- providing quality assured data AT for risk characterization;
- assessing the effectiveness of specific emission reduction activities;
- evaluating and subsequently improving air toxics emission inventories and model performance.

The DQOs require that air toxics data over a period of 6 or more years would be sufficient for statistical analysis of the data. This data can also 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.

The following milestones are described below.

1. First Year, Network Design and Objectives (2002): During the first year, the EPA staff focused its efforts on the design of the NATTS network and creating the DQOs.   In 2002, an EPA/SLT air toxics steering committee reviewed the objectives of the network and agreed upon the initial monitoring locations.
2. Second Year, Setup of the Initial Network (2003): The focus was on writing the QAPPs, completion of the monitoring stations and sampler tests, completion of the sampling and analysis protocols, and start-up of the first 22 sampling sites.
3. Third Year, Startup of the Network (2004): The network was placed into operation and the assessment portion (TSAs and PTs) of the QS was put into place.
4. Fourth Year, Assessment Review and Data Interpretation (2005): The emphasis for the fourth year will be to review the information from the assessments and to work with the NATTS community to improve the program. OAQPS will work with the NATTS

community and agencies to implement an annual air toxic workshop. This workshop will be the appropriate venue to analyze and review the NATTS program and plot the course for the next year. In addition, the QMP will be finalized and the first QAAR will be written.

5.   Fifth Year and Beyond, Program Improvement and Analysis(2006-): NATTS community will work on meeting the DQOs and performing data analyses. The annual toxics workshop will be continued.

7.2 Key Planning Personnel

The key planning personnel are detailed in Section 1.3 of this document. Please refer to that section for information on their planning activities.

7.3 Other Planning Activities

The following activities will facilitate the success of the program.

All parties must be made aware of events and deadlines and adhere to those deadlines if possible. To facilitate this work, clear communication must be established 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. The QAC has begun a tele-conference group that consists of OAQPS, Regional EPA and SLT agency staff. The OAQPS QAC will guide this working group by informing the group concerning method development, assessment results and discussion of the laboratory operations and the time lines of implementation of the program.

7.3.2 Internet: EPA supports and maintains a web site on the Word Wide Web. Guidance documents, special announcements, newsletter 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/airtxfil.html.*

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 SLT agencies' QAPPs will be submitted to EPA Regional Offices, which will review, provide comments and finally approve their QAPPs.   On the other hand, the UATMP Contractor's quality documents 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 city, 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 SLT 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 through use of SOPs;
- development and approval 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;
- if contract laboratories are used, then it is the QA managers responsibility that the contractor write a QAPP and SOPs that can be incorporated into the agency-submitted QAPP.

9.0 Data Quality Assessments

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

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, PTs and MSRs. 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
QA Support Contractor	TSA and PTs	SLT Agencies and all their support contractors	PT samples quarterly*, Initially, TSAs once every two years. To be determined after 2005.
Regional Offices	Network Reviews	SLT agencies	Once every 5 years
EPA-OAQPS	MSRs	Regional Offices	Annually

* If the agencies are able to meet the bias requirements, then the PT will be submitted semi-annually.

9.1.1 Technical System Audit: The TSAs are a thorough on-site investigation of the SLT laboratory and field operations. The TSAs will performed at each agency and their support contractors once every two years. Since many of the NATTS agencies rely on the UATMP for laboratory support, this contractor will be assessed annually. The TSA assessor will submit their reports to the agency assessed and to OAQPS. 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.

9.1.2 Network Reviews: Network Reviews will be performed by EPA Regional staff on SLT agencies once every five years. The EPA Regional offices will be tasked to review the NATTS 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: MSRs will be conducted by the EPA-EMAD-AAMG staff. The UATMP Contractor and selected EPA Regional office will be reviewed annually.

9.1.4 Proficiency Testing: The PT samples are blind samples that are created by an independent OAQPS contractor. The samples are sent to each analytical laboratory with instruction on how to extract each sample. The SLT laboratories analyze the samples and report their findings to the PT contractor. The results are forwarded to the SLT, Regional Offices and OAQPS for review.

9. 2 Reports to Management

The QA Support Contractors will submit assessments and reports performed by the organization, to OAQPS. The OAQPS QAC and contractors will annually compile the information, along with estimates of precision and bias and publish an annual QA report. The QAARs will be placed on OAQPS' Ambient Monitoring Technology Information Center (AMTIC) website for national distribution.

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 outlines 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 forms (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: the agency is notified of what will be required and efforts of the assessors and the agency will be minimized.

9.3.2 Training: Training is essential to assessors in two ways: 1) the assessor needs to understand the process by which data are generated. Without this knowledge, the assessment

may be inadequate, and 2) in order to communicate clearly with the agency that is being assessed, the assessor must be competent. OAQPS will continue to offer satellite courses on QA and QC, as well as programs that update the state and local agencies on the NATTS. SLT agencies will continue to train operators.

9.3.3 Authority: All personnel that are chosen by EPA to conduct assessments for 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.

9.3.4 Disputes: Occasionally, findings in an assessment report may be disputed by the agency assessed. OAQPS has the final authority to make a decision concerning a dispute. In the case of assessments made by QA support contractors or the EPA Regional offices, OAQPS has the authority to discuss and resolve disputes.

10.0 Quality Improvement

This section will outline planning and implementation procedures that will be employed for improving the quality of the program. All agencies participating in the NATTS have the responsibility to improve the quality of the program over an unspecified period of time. There can be no set dates on when this improvement can or will occur, however, all agencies will make every effort to improve the system over a period of many years. The discussion below follows the QS cycle that is illustrated in Figure 5.1.

10.1 Assessments

The assessments that are planned for the NATTS 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.

10.1.1 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 14 days).

10.1.2 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 resolved 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 tele-conferences.

10. 2 Reporting

10.2.1 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.

10.2.2 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.

10.2.3 QAAR: The OAQPS QAAR will be the final QA 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, UATMP Contractor, QA support contractors and the SLT agencies participating in the NATTS. In addition, the report will be posted on the AMTIC website.   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.

10.3 Quality Improvement and Planning

The QAAR, TSA and PT assessment reports will highlight any problems within the calendar year.   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 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 has the authority to follow-up to ensure that corrective action are taken and adverse conditions to quality are remedied as soon as practical

 One of the goals of the assessment reports are to compare those results to the DQOs. The assessment reports allow the stakeholders in this program to reevaluate whether the DQOs for the program are obtainable. If the DQOs are being met, then this goes into future planning process for the program.

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.

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.

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 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, non-technical 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.

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.

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

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

1. REPORT NO. EPA-454/R02-006	2.	3. RECIPIENT'S ACCESSION NO.
4. TITLE AND SUBTITLE Quality Management Plan for the National Air Toxics Trends Stations Monitoring Program	5. REPORT DATE 09/05	
	6. PERFORMING ORGANIZATION CODE	
7. AUTHOR(S) Dennis Mikel, Michael Papp, Michael Jones	8. PERFORMING ORGANIZATION REPORT NO.	
9. PERFORMING ORGANIZATION NAME AND ADDRESS U.S. Environmental Protection Agency Office of Air Quality Planning and Standards Research Triangle Park, NC 27711	10. PROGRAM ELEMENT NO.	
	11. CONTRACT/GRANT NO.	
12. SPONSORING AGENCY NAME AND ADDRESS Director Office of Air Quality Planning and Standards Office of Air and Radiation U.S. Environmental Protection Agency Research Triangle Park, NC 27711	13. TYPE OF REPORT AND PERIOD COVERED	
	14. SPONSORING AGENCY CODE EPA/200/04	

15. SUPPLEMENTARY NOTES

16. ABSTRACT

The Quality Management Plan for the National Air Toxics Trends Stations details the management structure National Air Toxics Trends Monitoring Program. The guidance document gives details on which organizations will be involved with the national program. It details the responsibilities and rights of each organization that will be involved in the national trends network. An important discussion point is the Quality Assurance Assessment and Improvement System.

.   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 Release Unlimited	19. SECURITY CLASS *(Report)* Unclassified	21. NO. OF PAGES 55
	20. SECURITY CLASS *(Page)* Unclassified	22. PRICE