QUALITY MANAGEMENT PLAN

FOR THE

AIR PROTECTION DIVISION

Diana Esher, Director

Revised: January 2014

Air Protection Division (APD) Quality Management Plan

Concurrences and Approvals

Concurrences:

Amy Johansen APD Quality Assurance Coordinator (3AP00)

Signature:

changen

Marcia Spink, Associate Director Office of Air Programs (3AP00)

Signature:

nia K. Spink

Kathleen Cox, Associate Director Office of Permits & Air Toxics (3AP10)

Signature:

at la

Zelma Maldonado, Associate Director Office of Air Enforcement & Compliance Assistance (3AP20)

Signature:

Cristina Fernandez, Associate Director Office of Air Program Planning (3AP30)

Signature:

ho

Alice Chow, Associate Director Office of Air Monitoring & Analysis (3AP40)

Signature:

. Chow lico

Carol Febbo, Associate Director Office of Air Partnership Programs (3AP50)

Signature:

Date:

Date:

Date:

2414 Date:

Date: 1/30/14

4 Date:

Date:

TABLE OF CONTENTS

1. MANAGEMENT AND ORGANIZATION

- 1.1 APD Quality Assurance Policy
 - 1.1.1 Purpose and Background
 - 1.1.2 APD Quality Management Policy
- 1.2 Scope of the APD Quality Management Plan

2. DESCRIPTION OF APD's QUALITY SYSTEM

- 2.1 Data Quality Objectives
- 2.2 Quality Assurance Project Plans
- 2.3 Secondary Data Quality Assurance
- 2.4 Standard Operating Procedures
- 2.5 Roles and Responsibilities
 - 2.5.1 APD Director
 - 2.5.2 APD Quality Assurance Coordinator
 - 2.5.3 APD Project Officers
 - 2.5.4 APD Data Quality Management
 - 2.5.5 Regional Quality Assurance Manager
 - 2.5.6 OASQA Quality Assurance Team
- 2.6 Communications
- 3. PERSONAL QUALIFICATIONS AND TRAINING
- 4. PROCUREMENT OF ITEMS AND SERVICES
- 5. DOCUMENTATION AND RECORDS
- 6. COMPUTER HARDWARE AND SOFTWARE
- 7. PLANNING
 - 7.1 Program Specific Planning
 - 7.2 Data Quality Planning
- 8. IMPLEMENTATION OF WORK PROCESSES
 - 8.1 Procedures for Insuring Work Performed According to the Plan

Terry Simpson, Regional Quality Assurance Manager Environmental Assessment and Innovation Division (3EA00)

Signature:

Date:

Approval for Implementation:

Diana Esher, Director Air Protection Division (3AP00)

Signature:

ana SIL

2/10/2014 Date:

David Arnold, Deputy Director Air Protection Division (3AP00)

Signature:

ind

Date:

- 8.2 Changes to the Plan
- 8.3 Responsibility
- 9. ASSESSMENT AND RESPONSE
- 10. QUALITY IMPROVEMENT
 - 10.1 Regional Quality System Audit

APPENDIX A Air Protection Division's Organizational Chart

ACRONYMS

ACS	Annual Commitment System
AFS	Air Facility Subsection
AIRS	Aerometric Information Retrieval System
APD	Air Protection Division
AQS	Air Quality Subsection (of the AIRS database)
CAA	Clean Air Act
DQOs	Data Quality Objectives
EPA	Environmental Protection Agency
HAPS	Hazardous Air Pollutants
IAGs	Interagency Agreements
NACAA	National Association of Clean Air Agencies
NCore	National Core Multi-Pollutant Monitoring Station
NEI	National Emissions Inventory
OAR	Office of Air and Radiation
OASQA	Office of Analytical Services and Quality Assurance
OEAM	Office of Ecological Assessment and Management
OECA	Office of Enforcement and Compliance Assistance
ORC	Office of Regional Counsel
PAMS	Photochemical Air Monitoring System
PO	Project Officer
QA	Quality Assurance
QAC	Quality Assurance Coordinator
QAPP	Quality Assurance Project Plan
QAT	Quality Assurance Team
QMP	Quality Management Plan
QSA	Quality System Audit
RTPNC	Research Triangle Park North Carolina
RQC	Regional Quality Council
RQAM	Regional Quality Assurance Manager
RQAO	Regional Quality Assurance Officer
RQMP	Regional Quality Management Plan
SLAMS	State and Local Air Monitoring System
SPM	Special Purpose Monitors
SOP	Standard Operating Procedure
TSA	Technical Systems Audit

1. MANAGEMENT AND ORGANIZATION

1.1 APD Quality Assurance Policy

1.1.1 Purpose and Background

The purpose of this document is to define and describe the total Quality Management system of the Air Protection Division (APD), including the Division policies and responsibilities. This document is intended to assist the APD Project Officers (POs) and Managers in the uniform implementation of Quality Assurance (QA) requirements for all environmental data collection activities.

APD is strongly committed to good science and to the implementation of a sound quality management system. This commitment is consistent with the goals of the Administrator's Quality Assurance Policy Statement, EPA Order 5360.1 A2 ("Policy and Program Requirements for the Mandatory Agency-Wide Quality System"), and the Quality Management Plan for EPA Region III.

APD has already developed and integrated QA practices into its data collection activities. These practices are specifically designed to generate and process data of known and acceptable quality in a cost-effective manner.

1.1.2 APD Quality Management Policy

The policy of APD is that appropriate QA activities shall be conducted within the Division to insure that all environmental data generated and processed shall be: scientifically valid, of adequate statistical quality, of known precision and accuracy, of acceptable completeness, representativeness, and comparability, and where appropriate, legally defensible. This goal can be achieved by insuring that appropriate QA procedures are used throughout the data collection process from project design through data usage.

APD policy shall comply with EPA Order 5360.1 A2 which requires a Quality Assurance Project Plan (QAPP) for all environmental data collection activities. Environmental data collection activities are defined as the collection or generation of information or measurements resulting from any field data collection activity, laboratory analyses or models involving the assessment of chemical, physical or biological factors relating to the environment. Data collection activities include those activities in which data is generated both by and for the Division and/or with Division funds.

EPA Order 5360.1 A2 also applies to the use of environmental data collected for other purposes or from other sources (so called, secondary data), including literature, industry surveys, compilations from computerized data bases, and information systems, results from computerized or mathematical models of environmental processes and conditions.

Specifically it is the policy of APD that:

• The generation of environmental data shall occur only in accordance with the procedures set forth in relevant generic or project-specific QAPPs. For any specific environmental data collection activity, the QAPP will specify the detailed procedures required to assure the generation of quality data. All QAPPs must be approved prior to data collection, except in the unlikely event that environmental data is generated for an emergency situation. In this case, an evaluation of the procedures used to generate the data will be made at the earliest opportunity following the emergency situation.

• All environmental data generated shall be of known and acceptable quality. The data quality information developed with all environmental data shall be documented and available.

• All APD environmental data collection programs shall insure that acceptable QA requirements are included and implemented in all applicable data collection activities conducted directly by or funded by the APD.

• The intended use(s) of the environmental data shall be defined before the data collection activities begin, so that appropriate QA standards may be applied to that activity. The level of data quality shall be determined by considering the prospective data needs of all identified data users. Data Quality Objectives (DQOs) shall be established to insure the utility of the environmental data for its intended use(s), and as a guide for preparation of the QAPP. Intended data uses, level of quality, specific QA activities, and data acceptance criteria related to data quality needs shall be described in each data collection activity's QAPP.

• The APD will require any external organization that performs work for programs administered by the Division to have a quality system that is documented in an approved QMP.

1.2 Scope of the APD QMP

The APD QMP is applicable to all Division programs that implement environmentally related data-gathering activities. This includes field and laboratory data-generated activities or investigations that involve the determination of chemical, physical, or biological characteristics related to the environment, as established in EPA Order 5360.1 A2, use of data generated by other organizations to establish criteria, standards, or the promulgation of guidance or regulations requiring the collection of data by grantees or the regulated community.

The following air programs meet the criteria established by the definition of environmentally related data and data gathering activities and are covered by the APD QMP:

- Mobile Sources Program
- Hazardous Air Pollutants
- Grants Program
 - o Clean Air Act (CAA), Sections 105 and 103
 - o Toxic Substances Control Act, Title 3 (Radon)
- Acid Rain Program
- Permits
- Enforcement
- Provisions for Nonattainment Areas
- Initiatives related to climate change and energy conservation
- Radiation Program
- Radon and Indoor Air Programs
- Ambient Air Monitoring

It is the APD policy that QA issues be addressed during all appropriate planning, design, implementation and assessment phases of a program or project. Quality Assurance is applicable to the following program components within the APD. These are:

- Development of policies or guidance that involve data collection activities
- Development of methods or protocols
- Analytical method validation
- Monitoring
- Emissions Inventories
- Laboratory activities
- Data quality assurance
- Information Management
- Permitting

- Compliance and enforcement
- · Procurement of supplies and services
- Oversight
- Training

Not all programs will include all of the program components listed. However, it is the APD policy that when these components are part of a program, the appropriate QA activities are incorporated.

2. DESCRIPTION OF APD's QUALITY SYSTEM

Sections A.2. and A.8. of the Region III Quality Management Plan (RQMP) mandate that a total Quality Management System be created and implemented by each Division. This chapter of the APD QMP describes the tools that are used to insure uniform implementation of QA requirements for all environmental data collection activities, and defines the roles and responsibilities of those directly or indirectly involved with environmental data collection activities.

The APD QMP describes an integrated system of responsibilities for implementing QA requirements. This system includes APD management, the APD Quality Assurance Coordinator (APD QAC), POs, the APD Data Quality Manager, the Regional Quality Assurance Manager (RQAM), the Regional Quality Assurance Officer (RQAO), and the Analytical Services and Quality Assurance Branch Quality Assurance Team (QAT). The roles and responsibilities of each element of this integrated system are defined here in Chapter 2.

2.1 Data Quality Objectives

DQOs are statements of the quality of environmental data required to support Division decisions or actions. DQOs establish the level of risk or uncertainty that the Division is willing to accept in the environmental data to be used to make a defensible decision. DQOs represent a major planning step, accomplished through a formally structured process, whereby it is determined which environmental data are required to accomplish the objectives of sampling/analysis, what data quality is required, and what is the appropriate balance between time, resources and data quality. Simply stated, DQOs set forth the whole reason why sampling or analysis is occurring. Once the QAPP states these clearly, the other major elements of a QAPP follow much more easily than if DQOs are not clear. Clearly stated, DQOs enable the whole team involved in writing, reviewing and implementing the QAPP to effectively conduct their respective roles in development and implementation of the QAPP.

2.2 Quality Assurance Project Plans

QAPPs shall be written to insure that:

• The level of data quality needed will be determined and stated before the data collection begins; and

• All environmental data generated and processed will reflect the quality and integrity established by the project DQOs.

A QAPP documents the data quality objectives or "acceptance criteria" for a project, identifies the critical measurements to be performed, and discusses the QA activities to be conducted during the sampling, analytical and validation phases of the project. All QAPPs will adhere to the most recent version of the Agency's Requirements for Quality Assurance Project Plans (EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5) and any relevant Regional QAPP Guidance.

Effective management of a data collection program and/or project requires periodic assessment of the quality of data being obtained to establish a basis for determining when and if corrective action is needed. To insure that this assessment occurs, all environmental monitoring planned or conducted by APD shall have an associated QAPP reviewed by the PO, or other qualified entity, and, as appropriate, the APD QAC.

QAPPs for continuing environmental or project-specific grant programs are submitted by grantees directly to the PO for review. The PO reviews the QAPP to ensure that the appropriate goals and objectives are identified in the DQOs. Where States participate in national air quality monitoring programs under CAA grants, and input the data from those programs into the AIRS AQS data system, the APD data specialist is responsible for all QA related to that process.

APD compliance and enforcement programs may use generic or site-specific QAPPs for their environmental data collection activities. These QAPPs are frequently prepared by other agencies supporting the Division's compliance and enforcement activities or occasionally by outside contractors.

Regardless of who reviews the continuing environmental or project-specific QAPPs, the POs are ultimately responsible for their approval, and for maintaining the appropriate QA documentation in the project/grant files.

2.3 Secondary Data Quality Assurance

All secondary data provided to the APD and used in projects is required to have quality assurance documentation prior to its use in projects. Metadata, the descriptors or qualifiers that document the quality assurance path of data accompany APD funded projects as much as possible. APD managers, staff and/or extramural agreement holders analyze and document these descriptors to ensure data usability. In those cases where the pedigree of the data cannot be determined, a disclaimer is included to clearly indicate that the data was used without these descriptors.

Guidance on the collection and evaluation of secondary data can be found from the following sources:

Uniform Federal Policy for Quality Assurance Project Plans: Evaluating Assessing and Documenting Environmental Data Collection and Use Programs, EPA Publication Number EPA-505-B-04-900A, March 2005

Guidance for Quality Assurance Project Plans, EPA QA/G-5, December 2002

US EPA Region 2 Guidance for the Development of Quality Assurance Project Plans for Environmental Monitoring Projects, April 12, 2004

2.4 Standard Operating Procedures

Standard Operating Procedures (SOPs) are documented methods for performing certain routine or repetitive tasks. Occasionally, APD is involved with environmental data collection. Activities include (but are not limited to): sample setup and collection, sample handling and custody, site setup, site assessments, instrument calibrations, preventive and corrective maintenance, quality control, data management and data validation. SOPs are expressed in terms of fixed protocols which must be followed. SOPs should outline modifications to published methods, as appropriate, for the application or facilities at hand. The EPA <u>Guidance for Preparing Standard Operating Procedures (SOPs)</u> (EPA QA/G-6) shall be used to determine the appropriate format for individual SOPs. In addition, various SOPs exist throughout the Division related to administrative and SIP processes and are required to be updated every other year.

2.5 Roles and Responsibilities

Anyone in APD who is directly or indirectly involved with environmental data collection activities has responsibility for insuring data quality. This will include POs, supervisors, program managers and senior managers. In addition, the Office of Analytical Services and Quality Assurance (OASQA) plays a supporting role for insuring data quality related to State air quality monitoring as a result of CAA grant commitments.

2.5.1 APD Director

The Director of the APD has overall responsibility for the APD QA program. This includes the development, implementation and continued operation of all QA activities. Specifically the Director of the APD has the following responsibilities:

• Ensuring that all intermural and extramural projects involving the generation of environmental data are performed in accordance with the APD QMP.

 Ensuring that resources needed to implement QA requirements are identified and provided.

• Ensuring that adequate procedures are in place to address QA requirements in all applicable program operations, including those delegated to state agencies.

· Cooperating with QA reviews or audits.

 Taking appropriate corrective actions based on recommendations contained in review finding's reports.

2.5.2 APD Quality Assurance Coordinator

The APD QAC is delegated the responsibility by the Director of the APD for ensuring that the implementation of QA requirements by the APD is in accordance with this QMP and the Regional QMP. The APD QAC reports to the Director of the APD and works closely with the APD POs, the RQAM, the RQAO and the OASQA QAT. Specifically the APD QAC has the following responsibilities:

• Serving as the official APD contact for QA and QC matters.

• Coordinating all APD QA matters with the RQAM to insure that all QA policies and methods are in accordance with current EPA national and regional guidelines.

• Identifying APD QA and QC needs, and respond to APD QA and QC problems or questions with the assistance of the RQAM, the RQAO and the OASQA QAT.

• Assessing APD training needs, and arranging and developing training courses where appropriate, in coordination with the RQAM.

Serving as the official APD representative on the Regional Quality Council.

• Coordinating staff interviews and file reviews with the RQAM during QA assessments of the APD.

2.5.3 APD Project Officers

The APD POs have the primary responsibility for insuring that environmental data generated for projects which they administer or oversee is collected in accordance with the procedures established in this QMP. APD POs include all individuals responsible for direct environmental data generation (i.e., the program itself collects samples for analysis) as well as individuals who generate environmental data indirectly through the administration of permits or orders or who administer projects supported by EPA through contracts, grants or interagency agreements (IAGs). APD POs fulfill this responsibility in cooperation with the APD QAC and other Division staff, as appropriate.

Specific responsibilities of the POs depend on the nature of the data collection activity and on the specific program for which data is being collected. All POs will insure that each data collection activity conducted or funded by the APD and administered or overseen by the PO is done only after a QAPP is reviewed and approved. QAPPs can exist in two basic forms: (1) a project-specific QAPP prepared for a particular data collection activity, or (2) a program (particulate matter, ozone, etc.) QAPP, modified, as needed, by the user for a specific data collection project, and reviewed and verified every 3-5 years.

Many of APD continuing environmental grant programs (i.e., State program grants under Section 105 of the CAA) may require only a generic QAPP from the grantee. This generic QAPP is reviewed for completeness by the PO, or air monitoring staff or other qualified entity. Other APD grant programs may involve project-specific QAPPs (i.e., grants to universities and citizens groups). These project-specific QAPPs will be processed as described above for generic QAPPs, except that the grant POs may also perform a technical review of the QAPP in addition to the other responsible reviewers.

Regardless of who reviews the generic or site-specific QAPP for a particular grant of direct data collection activity, the PO has the responsibility for requesting that an appropriate and timely review be done and ultimately for their approval. The PO is also responsible for ensuring that original copies of the QMP, QAPP and QMP/QAPP approval documentation, and technical documents (e.g. work plans, technical reports, audit reports, monitoring plans and reports) are contained in the grant or project files.

2.5.4 APD Data Quality Management

In accordance with grants issued under Sections 105 and 103 of the CAA, States collect air quality data in conjunction with the following air quality monitoring programs, and input the data from these programs into the Aerometric Information Retrieval System (AIRS) Air Quality Subsection (AQS) data system.

- PAMS Photochemical Air Monitoring System
- SLAMS State and Local Air Monitoring System
- NCore National Core Multi-Pollutant Monitoring Station
- SPM Special Purpose Monitoring

The APD Air Monitoring Staff are responsible for ensuring data quality related to State data input from these monitoring programs into the AIRS AQS database. The operation of the monitoring systems themselves should be covered under a state QMP and QAPP. The APD Air Monitoring Staff provide recommendations for approval of the State QAPPs associated with data collection and operation of those monitoring systems. All State QMPs are reviewed and approved by the RQAM.

The APD Air Monitoring Staff and/or the APD Grant PO for the Section 105 and 103 grants is ultimately responsible for ensuring that states develop QMPs and QAPPs for all environmental data collection activities covered under the grant, and that copies of QMPs, QAPPs and their approval documentation is maintained in the project or grant files.

2.5.5 Regional Quality Assurance Manager

The RQAM and the OASQA QAT are responsible for overseeing the implementation of the RQMP. Specifically, these responsibilities include:

· Reviewing and approving the APD QMP.

· Distributing Agency QA guidance documents, policies, and procedures.

• Conducting formal reviews and assessments of QA activities within the APD in cooperation with the Regional Quality Council (RQC) and the OASQA QAT. The results of these reviews and assessments are provided to the Division in the form of a report.

Assessing Regional QA training needs and arranging, developing and / or
presenting training courses on QA topics. The assessment of APD training needs,
and the arrangement and development of training courses will be done, where
appropriate, in coordination with the APD QAC the RQC, and the RQAM.

• As noted above, the RQAM is responsible for the review and approval of all State QMPs.

2.5.6 OASQA Quality Assurance Team

The OASQA QAT is located within Environmental Assessment and Innovation Division, and its functions consist exclusively of QA. Specifically, their responsibilities include:

Providing assistance to the APD on QA and QC issues.

Assisting the RQAM in conducting internal assessments of the APD QA program.

• Provides assistance in QAPP review, training, and data validation.

2.6 Communications

To be effectively implemented, the APD QMP must not only be completed, circulated and updated, but understood by those responsible for its implementation. This will be accomplished through effective communications.

The APD QAC will keep the Director of the APD and other senior managers appraised of QA issues as they arise. The APD QAC will be responsible for attending meetings of the RQC and communicating the results of those meetings to APD management and POs.

3. PERSONNEL QUALIFICATIONS AND TRAINING

Only APD personnel who are trained and qualified in QA procedures will be used to collect environmental data in the field, or act as project managers for grants or contracts. APD managers and staff who may oversee or be directly involved in these activities will be offered basic training in QA concepts to assist them with the proper implementation of their responsibilities. In addition, these managers and staff are required to draw upon their educational background, professional experience, and on-the-job training. There any many Agency-wide on-line training courses on QA and QM and are available at EPA's Quality System website. QA training courses specific to air quality are available through EPA's Air Pollutant Training Institute website.

Training needs will be identified by the APD QAC, the RQAM, and the RQC; and the resultant training will be targeted to the particular needs of APD staff. Currently available training programs will be utilized or specific training will be requested from the RQAM.

Training courses listed in the training section of the RQMP will be offered to all POs and QA personnel.

4. PROCUREMENT OF ITEMS AND SERVICES

Environmental data used in APD may be obtained in several ways. APD may use EPA staff, grantees (including states), contractors, and private sector resources to sample and analyze environmental conditions. A QAPP (generic or project-specific) is required for each method of environmental data collection. QMPs are also required for continuing environmental program grants.

5. DOCUMENTATION AND RECORDS

Documents such as Work Plans, QAPPs and other project related reports are submitted to the PO. All POs shall maintain a current file of each QAPP (and related documentation) under their management until such time as the QAPP may be sent to a central file room or archived according to Agency guidelines.

Documents for data submissions are grouped into two (2) categories. The first category consists of ongoing projects (e.g. Section 105 grants), where data are submitted on a periodic basis throughout the length of the project. The second category consists of fixed projects, i.e., those projects where data are submitted only once at the end of the project. Copies of national guidance or requirements documents that are specific to the programs administered by the APD will be maintained by the APD QAC or by the POs within the APD that are responsible for the administration of that program. When new guidance and requirements documents are received, obsolete or superceded guidance and requirements will be removed from all users' possession. For enforcement personnel involving evidentiary records, appropriate chain of custody and confidentiality procedures are implemented. Where appropriate, this includes stamping all paper and electronic confidential records as "Enforcement Confidential" and

following chain of custody procedures presently being developed in the Region, and in accordance with:

http://www.epa.gov/apti/coc/

http://www.epa.gov/otaq/emisslab/testproc/120.pdf

6. COMPUTER HARDWARE AND SOFTWARE

APD works with State data collected as emissions data from mobile, point and area sources, and with air quality (i.e., ambient air) data collected from air monitors. In addition to this, States are also required to report certain Title V (permits) and enforcement-related information. States input this data into several national data systems. Originally AIRS was the recipient of this data, with the Air Facility Subsection (AFS) of AIRS getting the emissions data from point and area sources, and the Title V and enforcement-related information. The Air Quality Subsection (AQS) of AIRS received the data from the air monitoring programs. States are required to have QMPs and QAPPs associated with the collection of this data. The emissions data of AFS has been folded into a new national database called the National Emissions Inventory (NEI), which was created to consolidate some of the emissions reporting. This system contains emissions data collected by states related to point and area sources, mobile sources and Hazardous Air Pollutants (HAPS). Research Triangle Park North Carolina (RTPNC) is responsible for the maintenance and operation of the NEI, as well as maintaining data quality within the system. A OA/OC software package is provided to states by RTPNC as part of those responsibilities. The Title V and enforcement-related information is still in AFS. Enforcement data is pulled at least quarterly by APD's AFS data manager and checked for errors or missing information. The AFS data manager resolves any discrepancies with a telephone call to the States.

States measure ambient air quality via a number of monitoring systems including the PAMS, the NCore and the SLAMS, and input the data into AIRS AQS.

7. PLANNING

7.1 Program Specific Planning

APD negotiates annual targeted and indicator performance measures with both the Office of Air and Radiation (OAR) and the Office of Enforcement and Compliance Assistance (OECA). These performance measures are based upon the annual program guidance developed by OAR and OECA, and are captured and tracked in the Annual Commitment System (ACS) database. OAR's and OECA's national program guidance in turn is based on EPA's five-year Strategic Plan's Goals. By performing the targeted and indicator measures, APD contributes to the stated goals of OAR and OECA. In addition, APD may prepare "strategic plans" for submission to the Regional Administrator that details how the Division will contribute to various Regional initiatives.

7.2 Data Quality Planning

The APD is committed to sound science, and therefore strives to generate environmental data that are of adequate quality to support decisions. The primary vehicle for insuring adequate data quality at the project level is the QAPP. QA is a necessary component of any project plan involving the collection or use of environmental data.

Developing DQOs is a fundamental part of this planning process and the completion of the QAPP. The Quality Assurance Division guidance document <u>Guidance on Systemic</u> <u>Planning Using the Data Quality Objectives Process</u>, (EPA QA/G-4) will be used where appropriate to establish the desired data certainty requirements based on the decision(s) to be made.

For planning purposes, all units within the Division currently rely on the OASQA for requisite QA expertise. Typically, advice and assistance may be requested on reviewing project-specific QMPs and QAPPs and to provide training for POs and managers.

8. IMPLEMENTATION OF WORK PROCESSES

8.1 Procedures for Insuring Work Performed According to the Plan

All programs within APD that directly collect environmental data or that require data to be collected by others must prepare a QAPP to be followed in the data collection process. These plans are contained within the project/grant files and are available for review. In APD, these plans may be reviewed by the OEAM, OASQA or other qualified entity prior to APD approval.

For grant programs administered by APD, a QMP is required as a condition for approval of any grant involving environmental data collection. Currently, the review and approval of grantee QMP's is done by the RQAM.

8.2 Changes to the Plan

Revisions to an approved project-specific QAPP may be required for a variety of reasons, and at a minimum every 3-5 years. Other reasons for revision may include the fact that the QAPP expires, key individuals involved in the sampling and analysis change, protocols change, or DQOs change.

8.3 Responsibility

The APD is committed to an empowered staff and is fortunate to have many senior POs. These POs are responsible for the management of their assigned projects, including the implementation of the necessary QA procedures. APD management expects that all data used within its programs have been generated under the umbrella of an adequate QA protocol. Thus, at key points in a given project, the POs are expected to brief management of the progress and/or results of their work, including evidence and certification that the work was completed in accordance with an approved work plan. For enforcement cases, the Office of Regional Counsel (ORC) may check to insure that proper QA procedures were followed before proceeding to use the data in an enforcement action.

APD grant POs are responsible for insuring that QMPs are submitted by grantees who are engaged in data collection activities for approval by EPA.

9. ASSESSMENT AND RESPONSE

In order to assess the effectiveness and insure successful implementation of its quality management system, APD will rely on a coordinated system of internal and external management reviews and audits.

In addition to the formal procedures outlined below, APD will attempt to correct any problem with its quality system when problems are discovered through other, informal processes.

In accordance with the provisions of 40 CFR Part 58, APD is required to annually conduct comprehensive management/technical system audits (TSA) of at least one third of its State and local agencies ambient air monitoring programs. These audits include, but are not limited to, inspections of various air monitoring sites; performance audits of air monitoring instrumentation; an assessment of QA/QC procedures applied by the State agency; an assessment of the State agency's air quality data collection and data reporting procedures via the Agency's AIRS-AQS database; and conducting interviews of the State agencies' air monitoring program management and staff on matters related to the aforementioned air monitoring program areas. The air monitoring program staff of APD's Air Quality Analysis Branch performs these activities under the directions of the audit procedures developed jointly by EPA and the National Association of Clean Air Agencies (NACAA) as described in the EPA Quality Assurance Handbook for Air Pollution Measurement, Volume II - Ambient Air Specific Methods. In FY 2012, APD (via commitment to the EPA Office of Air and Radiation) will perform comprehensive management/technical system audits of the air monitoring programs administered by the State of Maryland and the Commonwealths of Pennsylvania and Virginia. The results of APD's audit activity will be reported to EPA-HQ via the AQS database.

10. QUALITY IMPROVEMENT

10.1 Regional Quality System Audit (QSA)

QSAs are the independent assessment of the APD's quality management system, and are performed by a review team under the direction of the RQAM. This review team consists of the RQAM, a member of the Regional Quality Assurance Council, the OASQA QAT and other personnel as specified by the RQAM. APD is committed to using the results of this assessment process to correct any identified deficiencies and address any operational adjustments necessary for the improvement of environmental data collection, analytical procedures and the Quality Management Plan (QMP) itself.

The APD fully supports the use of the QSA process to determine if its quality system is operating in an acceptable manner, as described in this QMP. The Regional QSA is planned and performed on a frequency determined during annual planning by the RQAM and the RQC. The QSA process is designed to:

- identify and examine the critical linkages among the processes and the participants in data collection and use which are necessary to assure that the quality of the data meets established requirements, and
- identify where the quality system is working well and where improvements should be considered by management.

The principal results of the QSA process are findings, which include areas that need improvement to be in compliance with the QMP or with Agency QA policy. The APD response to the findings report will document the Division's plan for correction of the identified deficiency.

The review team will present its findings and recommendations in a report to the APD Director. Within 30 days of report issuance, APD will respond in writing to the review team's report. The APD response will address the assessment findings and recommendations and will establish a schedule for implementation of any corrective measures and improvement actions of its data quality and the quality management systems.

The APD QAC will be responsible for developing and overseeing any corrective action plan developed as a result of a QSA. Copies of audit reports and corrective action plans will be maintained by the APD QAC.

APPENDIX A Air Protection Division's Organizational Chart

144



