U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Quality Management Plan

May 20, 2020

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Research Triangle Park, NC

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OAQPS Management Approvals

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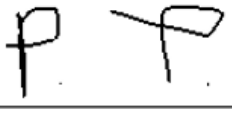
X 

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Acronyms and Abbreviations

ADP	Action Development Process
AQAD	Air Quality Assessment Division
AQI	Air Quality Index
AQS	Air Quality System
AQPD	Air Quality Policy Division
CAA	Clean Air Act
CBI	confidential business information
CFR	*Code of Federal Regulations*
CO	carbon monoxide
COR	Contracting Officer Representative
CSN	($PM_{2.5}$) Chemical Speciation Network
DAHS	Data acquisition and handling system
DQA	data quality assessment
DQI	Data Quality Indicator
DQOs	data quality objectives
EDO	environmental data operation
EPA	Environmental Protection Agency
EPAAR	EPA Acquisition Regulations
FAR	Federal Acquisition Regulations
FSP	Field Sampling Plan
GHG	greenhouse gas
GIS	geographical information systems
HAP	hazardous air pollutant
HEID	Health and Environmental Impacts Division

IMPROVE	Interagency Monitoring of Protected Visual Environments
IT	information technology
ITG	Information Transfer Group
MQOs	measurement quality objectives
MSR	management system review
MTG	Measurement Technology Group
NAAQS	National Ambient Air Quality Standards
NATA	National Air Toxics Assessment
NATTS	National Air Toxics Trends Stations
NCore	National Core Monitoring Network
NESHAP	National Emission Standards for Hazardous Air Pollutants
NIST	National Institute of Standards and Technology
NO_2	nitrogen dioxide
NPAP	National Performance Audit Program
NSR	New Source Review
NSPS	New Source Performance Standard
O_3	ozone
OAQPS	Office of Air Quality Planning and Standards
OEI	Office of Environmental Information
OID	Outreach and Information Division
OMB	Office of Management and Budget
ORD	Office of Research and Development
PAMS	Photochemical Assessment Monitoring Stations
Pb	lead
PE	performance evaluation
PEP	performance evaluation program

$PM_{2.5}$	particulate matter (PM) with an aerodynamic diameter of ≤ 2.5 µm
PM_{10}	particulate matter (PM) with an aerodynamic diameter of ≤ 10 µm
PO	Project Officer
PSD	Prevention of Significant Deterioration
PWS	Performance Work Statement
QA	quality assurance
QA/QC	quality assurance/quality control
QAARWP	quality assurance annual report and work plan
QARF	Quality Assurance Review Form
QS	Quality System
QSA	quality systems assessment
QAM	quality assurance manager
QAO	quality assurance officer
QAPP	quality assurance project plan
QMP	quality management plan
RACT/RACM	reasonable available control technology/reasonable available control measures
SAP	Sampling and Analysis Plan
SIP	State Implementation Plan
SLAMS	State and local monitoring stations
SLT	State, local and Tribal
SO_2	sulfur dioxide
SOP	standard operating procedure
SOW	statement or scope of work
SPPD	Sector Policies and Programs Division
TIP	Tribal Implementation Plan
TOCOR	Task Order Contracting Officer Representative
TSA	technical systems audit

WAM	Work Assignment Manager

1 Management and Organization

1.1 QA Policy Statement

The Environmental Protection Agency's (EPA's) mission is to protect human health and the environment. To accomplish that mission, EPA utilizes environmental information from a variety of sources. Almost everything EPA does is directly dependent upon the collection and use of environmental data as defined in EPA Order CIO 2105.0 *Policy and Program Requirements for the Mandatory Agency-Wide Quality System,* Section 8 (b).

The Office of Air Quality Planning and Standards (OAQPS) Quality Policy (Figure 1-1) is consistent with EPA Order CIO 2105.0.

> It is OAQPS policy that all environmental data and information collected and/or used in the process of decision-making are of known and documented quality, suitable for its intended use, with all aspects of collection and analysis thoroughly documented; such documentation being verifiable and defensible. This policy applies to all data collected under environmental operations and environmental technology activities performed directly by or for OAQPS. This includes Federal, State, Tribal and local partners under interagency and financial assistance agreements; contractors funded by EPA; regulated entities and potentially responsible parties. The Director, Senior Leadership and managers ensure adequate allocation of resources (intramural and extramural money, travel and training funds, and personnel) to achieve the OAQPS Quality Policy.

Figure 1-1. OAQPS Quality Policy

Environmental data include information collected directly from measurements, produced from models, compiled from other sources such as data bases or literature; any measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology (CIO 2105-P-01-0). Environmental data also includes data derived from samples collected from the environment, the results of other analytical testing of environmental conditions, and process data or physical parameters collected from the operation of environmental technologies (ANSI/ASQ E4-2014).

Environmental technology is an all-inclusive term used to describe pollution monitoring, measurement and control devices and systems, waste treatment processes and storage facilities, and site remediation processes and their components (CIO 2105-P-01-0). This term applies to hardware-based systems and methods and techniques used for pollution prevention, pollution reduction, or containment of contamination to prevent further movement of contaminants (ANSI/ASQ E4-2014).

Environmental data operations (EDOs) are any work performed to obtain, use, or report environmental data or environmental technologies.

1.1.1 Delegated Authority

To ensure the OAQPS quality assurance (QA) policy is uniformly applied across the Office, the OAQPS Quality Assurance Manager (QAM) is delegated the authority and responsibility for the implementation of the OAQPS Quality Management Plan (QMP). The authority covers intramural and extramural environmental data operations as a result of:

a. OAQPS in-house environmental measurement activity;
b. Contracts and Interagency Agreements;
c. Grants and Cooperative Agreements;
d. Partnerships with industry, state, local and tribal (SLT) offices, and Regional offices.

It is EPA policy that all environmental programs administered by EPA or directly for EPA through EPA-funded extramural agreements shall be supported by individual quality systems (QS) that comply fully with the American National Standard ASQ/ANSI E4:2014: *Quality Management Systems For Environmental Information And Technology Programs - Requirements With Guidance For Use*.

1.2 OAQPS Organizational Structure

The OAQPS Organizational Structure, as shown in Figure 1-2, is headed by the Director of OAQPS. There are five Divisions, each headed by a Director. The organizational structure and lines of communication of the OAQPS QS are shown in Section 1.3 and in Figure 1-3.

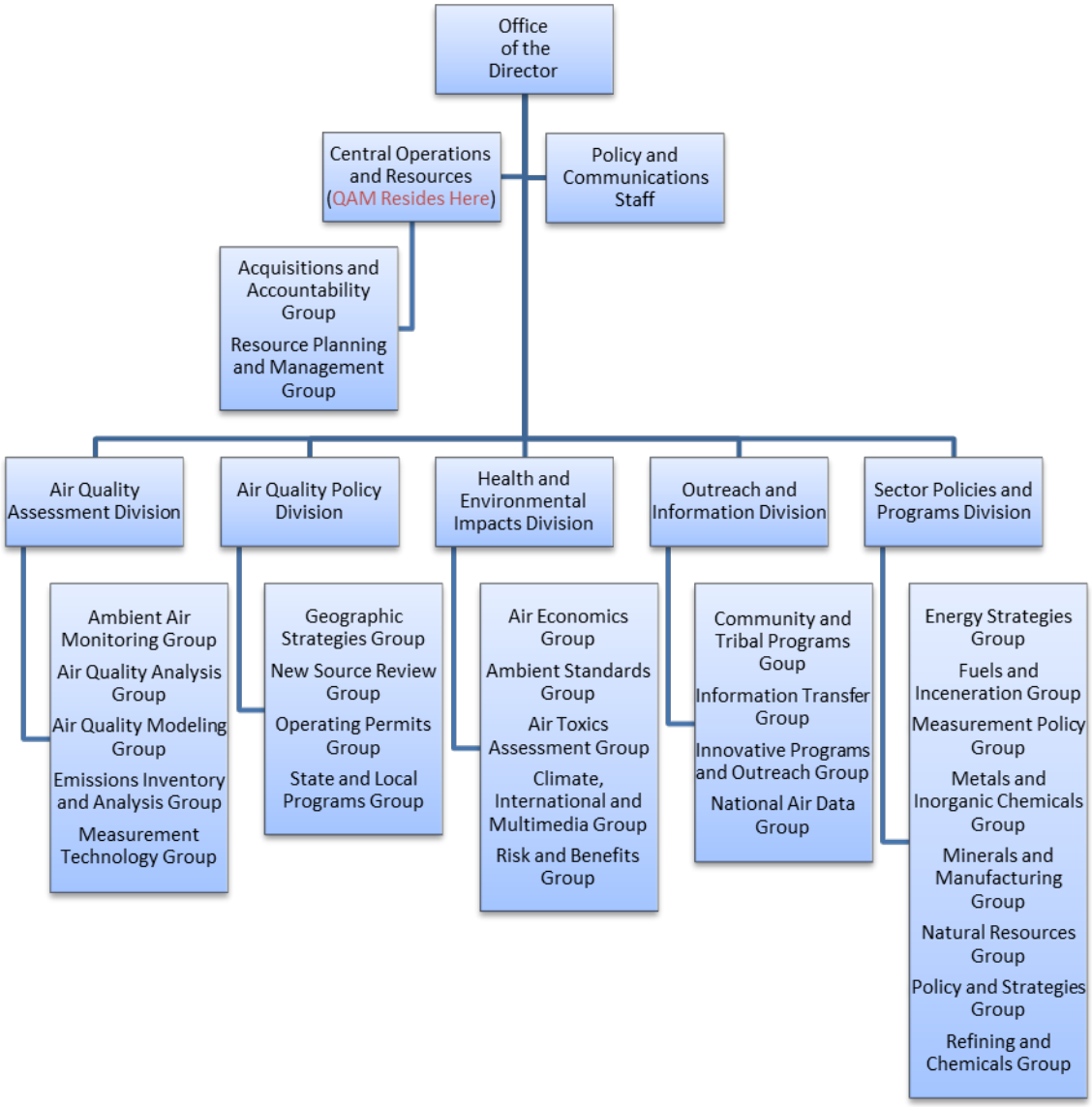


Figure 1-2 OAQPS Organizational Chart

More detail about the Groups within each Division can be found in Appendix A of this document.

1.2.1 Office of the Director

The OAQPS is part of EPA's Office of Air and Radiation (OAR). Its primary mission is to preserve and improve air quality in the United States. To accomplish this, OAQPS

- compiles and reviews air pollution data

- develops regulations to limit and reduce air pollution
- assists states and local agencies with monitoring and controlling air pollution
- makes information about air pollution available to the public, and
- reports to Congress the status of air pollution and the progress made in reducing it.

The strategic vision of OAQPS is to lead and manage national air quality programs to protect public health and the environment from air pollution. Strategic goals in support of this vision include:

- Developing a well-rounded and self-assured staff;
- Effectively communicating the purpose, benefit, and success of our program;
- Establishing and maintaining cooperative working relationships with partners and stakeholders to build consensus; and
- Identifying practical solutions based on verifiable data.

1.2.1.1 Science Advisor

Within the Office of the Director is the OAQPS Science Advisor. The OAQPS Science Advisor manages OAQPS input into ORD research planning and review for projects relevant to interactions between air quality and climate change and participates in relevant Agency research planning, in coordination with the ORD and Office of Policy (OP) in support of the NAAQS, air toxics programs, and economic analyses.

1.2.1.2 Workforce and Organizational Development

Also within the Office of the Director is an Associate Director for OAQPS responsible for directing, formulating, and evaluating human capital, workforce development, and organizational development policies for OAQPS and implementing a succession plan to develop the next generation of leaders for the office.

1.2.2 Central Operations and Resources

The Central Operations and Resources (CORE) office manages the development of program goals, objectives and plans and develops systems for tracking and assessing program progress, including headquarters, regional, SLT resource and program management systems. It manages program resources, including budget, contracts, and human resources, and coordinates cross-cutting information resources management and administrative support services. The CORE is also responsible for the following functions:

- Managing QA at the Office level;
    - The OAQPS QAM resides in CORE and serves as the coordinator (not the supervisor) of the QA staff in each of the five divisions.
- Managing long-range and strategic planning processes, including implementation of the Government Performance and Results Act (GPRA);
- Developing and managing OAQPS portions of Headquarters and Regional program progress tracking systems, including development of performance measures;

- Managing OAQPS human resource activities, including timekeeping, awards, ethics, liaison with the servicing human resources office, labor-management issues, and office-wide human resource initiatives (e.g., training and development, intern and mentoring programs, health and productivity management programs, etc.); and
- Managing office-wide administrative support services, including health and safety, facilities, conference support, Freedom of Information Act, bankcards, copy center, the Senior Environmental Employee program, confidential business information (CBI), and records management.

1.2.3 Policy and Communications Staff

The PACS Director is the principal OAQPS staff member responsible for advising the OAQPS Director and other senior Air program officials on political and policy-related matters with outside parties including Congress, industry, environmental groups, and state and local elected officials. PACS functions as a primary advisor to the OAQPS Director on air quality policy issues and is the lead OAQPS group responsible for Congressional, press and other communications matters.

PACS has the following principal responsibilities:

- Coordinating responses to all Congressional inquiries (including follow-up questions from Congressional hearings) and staff briefings, as well as Congressional hearings;
- Providing a policy level review on all office-level correspondence, reports, and regulatory packages;
- Serving as the focal point for all OAQPS media contacts and for media event planning for OAQPS;
- Tracking all on-going OAQPS projects and develops and disseminates the communications materials for all the rules, guidance, and program reports developed by OAQPS;
- Writing speeches and developing briefings by the Director, OAQPS, and other EPA officials on OAQPS-related issues; and
- Coordinating rapid response to requests from the White House, the Administrator's Office, the Office of the Assistant Administrator for Air and Radiation, the Office of Public Affairs, and the Office of Congressional and Intergovernmental Relations.
- Facilitating communication and information flow on program and policy issues between Washington headquarters offices and OAQPS;
- Tracking and ensuring OAQPS policy, regulatory, and other key packages proceed through the review and signature process in a timely fashion;

1.2.4 Air Quality Assessment Division

The Air Quality Assessment Division (AQAD) drives sound air quality management policy, decision making and accountability assessment through the strategic application of technical and

analytical leadership promoted through open collaboration with other OAQPS divisions, other OAR offices, the Office of Research and Development (ORD), other federal agencies, State, Local, and Tribal (SLT) agencies, and outside groups. The AQAD leads by promoting multi-pollutant approaches to air quality management through comprehensive integrated evaluations of multiple sectors, spatial scales, and pollutants, meteorology, climate, and the implications of interactions among them; and by advancing the state of the art in emissions, modeling, ambient and source measurements, and data analysis techniques. AQAD:

- Continually improves the assessment of emissions, ambient data, and air quality modeling to enhance the design, implementation and evaluation of air quality management programs and related control strategies;
- Produces timely and meaningful assessments of pollutant trends and impacts, providing the public with clear and transparent information that can be effectively used to help them better understand the air quality in their area, how it can affect their health, and how changes in their activities can reduce emissions and improve air quality;
- Establishes and promotes a framework for accountability by developing and applying methods and definitive data bases for evaluating air quality management programs to determine progress, need for mid-course corrections and achievement of environmental goals, including attainment of the national ambient air quality standards (NAAQS) and other air quality benchmarks;
- Creates and maintains value-added predictive tools and analyses, improving both the quality of analytical results and the timeliness of critically needed information for regulatory and policy decision making;
- Improves the credibility and transparency of our technical assessments by infusing and demonstrating quality throughout our analytical systems, methods and data;
- Strengthens the basis for air rules and policies across OAR by leading technical collaboration across EPA, and other federal agencies (e.g., NOAA, NASA and CDC) and promoting multi-pollutant, multi-media solutions to environmental issues; and
- Works closely with other OAQPS divisions and EPA offices to ensure integration of regulations, policies and guidance to facilitate effective program implementation.

1.2.5 Air Quality Policy Division

The Air Quality Policy Division (AQPD) develops policies, regulations, and strategies for integrated air quality management of criteria pollutant and hazardous air pollutant programs, and visibility protection in coordination with other OAQPS Divisions. These policies and strategies are targeted, as appropriate, to SLT, regional, national, and multi-national scale air quality issues. Additionally, AQPD:

- Develops attainment and maintenance policies, strategies, and implementation programs under Part D of Title I of the Clean Air Act, to guide the implementation efforts of the federal, SLT air management agencies;

- Manages and assures the integration of the national air quality permit programs, including operating permits and pre-construction permits (nonattainment new source review and prevention of significant deterioration);
- Develops and promotes the application of innovative policies and strategies designed to reduce criteria pollutants and visibility impairment in national parks and wilderness areas;
- Monitors the effectiveness of air quality management programs and assesses the need for ongoing changes to the programs;
- Establishes and maintains cooperative working relationships with federal, SLT agencies, as well as other key stakeholders, including industry and public health and environmental protection groups, to facilitate effective development and implementation of regulations, policies, and guidance; and
- Works closely with other OAQPS divisions and EPA offices to ensure integration of regulations, policies and guidance to facilitate effective program implementation.

1.2.6 Health and Environmental Impacts Division

The Health and Environmental Impacts Division (HEID) provides expertise on the health and ecological effects of criteria and toxic air pollution and on the assessment of exposures and risks related to these pollutants. HEID:

- Conducts quantitative exposure and risk assessments, develops integrated policy assessments, and conducts rulemakings to review and revise, as appropriate, NAAQS to protect public health and the environment;
- Conducts quantitative exposure and risk assessments for air toxics programs, including sector-based regulations and national-scale assessments;
- Develops and improves exposure and risk models for criteria and air toxic pollutants, including models for multimedia, multipollutant assessments;
- Analyzes the benefits, economic impacts and cost of improving air quality, including developing benefit/cost estimates for NAAQS, hazardous air pollutant standards, new source performance standards and other regulatory actions and legislative proposals, as well as providing economic analytical support for other EPA offices;
- Participates in relevant Agency research planning, in coordination with the ORD and Office of Policy (OP) in support of the NAAQS, air toxics programs, and economic analyses;
- Reviews the scientific literature and assesses the policy implications of the linkages between climate change and air pollution in support of regulations and policy initiatives, including those focused on short-lived climate forcers;

- Coordinates efforts across OAQPS and with other agencies to assess and address international transboundary air pollution and its impacts on U.S. and global air and environmental quality;
- Assesses the distribution of air pollution exposures and risks among different socio-demographic groups and susceptible/vulnerable populations;
- Coordinates efforts across OAQPS and with other offices and agencies to develop improved indicators for public health and the environment; and
- Works closely with other OAQPS divisions and EPA offices to ensure integration of regulations, policies and guidance to facilitate effective program implementation.

1.2.7 Outreach and Information Division

The mission of the Outreach and Information Division (OID) is to improve air quality and public health by:

- Managing data systems critical to implementing air quality programs across the United States;
- Training SLT air agencies on Clean Air Act (CAA) regulations and policies;
- Assisting tribal leaders, small businesses, environmental justice communities, and state and local air agency staff in implementing and better understanding CAA regulations and related policies; and
- Working closely with other OAQPS divisions and EPA offices to ensure integration of regulations, policies and guidance to facilitate effective program implementation.

The direction and daily work of OID is managed by the division director. Assisting in that work is the associate director, who is also responsible for overseeing the contract, administrative, and travel budgets.

OID is a recognized leader in:

- Training SLT air agency staff;
- Coordinating with tribal and environmental communities;
- Operating and maintaining critical agency information systems; and
- Developing and running innovative voluntary programs.

1.2.8 Sector Policies and Programs Division

The Sector Policies and Programs Division (SPPD) leads the development of comprehensive and cost-effective emission reduction strategies and regulations governing air emissions from stationary sources, including technology and health-based standards and voluntary or non-regulatory initiatives. SPPD:

- Collaborates with other OAQPS divisions, the broader Agency, and external stakeholders to devise strategies and regulations using a combination of market-based mechanisms, alternative compliance options and incentives to achieve environmental goals.

- Builds on our growing understanding of pollutant interactions to optimize control requirements and maximize control efficiencies across CAA-mandated programs;
- Coordinates control requirements in time and content to reduce or eliminate conflicts and redundancies among them and to minimize multiple trips back to the same industries;
- Designs mechanisms to maximize flexibility while maintaining accountability for results;
- Reduces the administrative burdens to industries, SLTs, and EPA;
- Enhances the overall cost effectiveness of environmental improvements while reducing the overall burden to affected industries; and
- Works closely with other OAQPS divisions and EPA offices to ensure integration of regulations, policies and guidance to facilitate effective program implementation.

1.3 Quality Management System Structure

In accordance with EPA Order CIO 2105.0, overall responsibility for the OAQPS QS resides with the Assistant Administrator (AA). The responsibility for developing and documenting OAQPS QA policies, procedures and guidance; overseeing the implementation and assessment of the OAQPS QS; and providing QA training has been delegated to the OAQPS QAM. The QAM is located in CORE and is independent of environmental data operations.

1.3.1 OAQPS QA Team

The OAQPS QA Team is made up of the OAQPS QAM and five Divisional QA Leads. The QA Team is responsible for ensuring that OAQPS management and staff understand and adhere to the OAQPS QMP. Delegated QA officers (DQAOs), discussed in Section 1.4.4, reside in each Division.

Figure 1-3 represents the OAQPS QS organizational structure and lines of communication of the OAQPS QA Team.

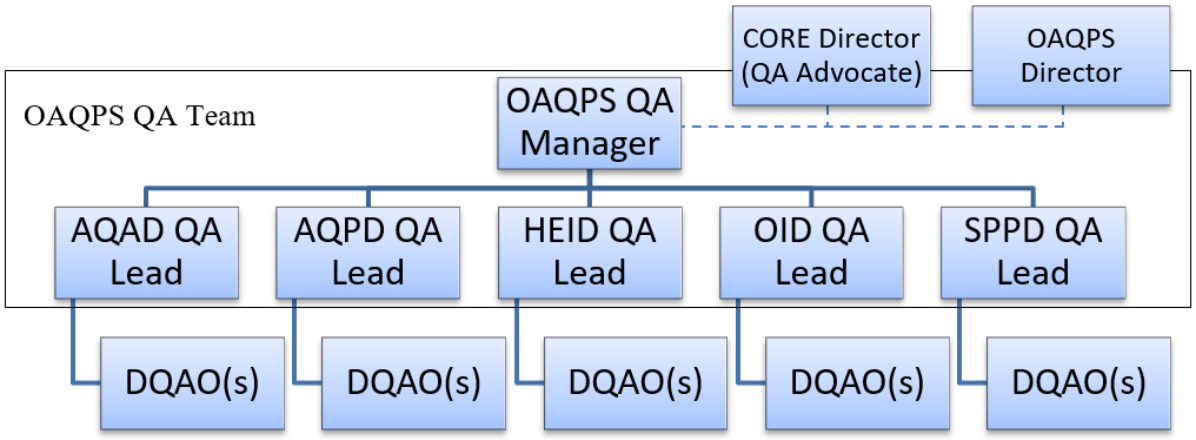


Figure 1-3. Organizational Structure and Lines of Communication of the OAQPS Quality System

1.4 Individual Quality Systems Roles, Responsibilities and Authorities

Although the responsibility to implement the OAQPS QS resides with all OAQPS staff and managers involved in generation or use of environmental data, the following positions have key roles and authorities.

1.4.1 OAQPS QAM

The OAQPS QAM has responsibility for oversight and implementation of OAQPS and Agency QA policies. The primary focus of this oversight is to ensure the development and implementation of quality management systems, related policies and procedures for OAQPS, consistent with the OAQPS mission; make certain the OAQPS QMP contains processes and procedures to ensure the quality and integrity of data and information is of the appropriate use for decision making; execute due diligence by conducting annual reviews to provide assurance of documentation of OAQPS's environmental information products (i.e., QMP, quality systems assessment (QSA), Quality Assurance Project Plan (QAPP), Quality Assurance Review Form (QARF), etc.), and assure the accuracy of the information contained in these environmental information products. The QAM responsibilities are incorporated into her performance agreement.

The specific responsibilities of the OAQPS QAM are to:

- Oversee implementation of the OAQPS QS and ensure that all OAQPS components and applicable programs comply fully with the requirements of CIO 2105.0, *Policy and Program Requirements for the Mandatory Agency Wide Quality System*;
- Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the OAQPS Agency-approved QMP;

- Ensure that all environmental programs implemented through extramural agreements comply fully with applicable QA and QC requirements;
- Ensure that all proposed and final regulations supported by environmental data during their development or implementation include the application of sufficient and adequate QA and QC activities during the collection and use of such data;
- Perform management and technical audits of OAQPS organizations and extramural programs conducting environmental programs to determine the conformance of their mandatory QSs to their approved QMPs and the effectiveness of their implementation;
    - Ensure that deficiencies highlighted in the assessments are appropriately addressed;
- Identify program-specific QA and QC training needs for all levels of management involved in EDOs and staff and provide for this training;
- Develop and conduct annual reviews of the OAQPS QMP;
- Prepare Quality Assurance Annual Report and Work Plan (QAARWP);
- Review and approve QMPs, QAPPs and QA Documents for OAQPS;
- Represent OAQPS on Agency, Interagency and National QA policy issues;
- Participate in contract awards as prescribed by contracting regulations; and
- Perform management and technical audits of OAQPS and extramural programs.

The QAM has the authority to carry out these responsibilities and to bring to the CORE Director's attention any issues associated with these responsibilities including any problems that may affect the QAM's level of independence.

1.4.1.2 OAQPS QAM QA Document Approval Authority

EPA Order 2105.0 authorized OEI to develop, coordinate and direct the implementation of the Agency-wide QS, thereby delegating OEI the authority to approve the OAQPS QMP. The OAQPS QAM delegations include the authority to approve QA documents for OAQPS. EPA recognizes two key documents for use in planning QA activities: QMPs and QAPPs. Other QA documents that may be associated with QAPPs include Sampling and Analysis Plans (SAPs) or Field Sampling Plans (FSPs). These QA documents are described in Section 7. The OAQPS QAM has exercised authority to delegate limited approval authority for some project-level QA documents to OAQPS personnel, DQAOs who are discussed in Section 1.4.4.

While Division DQAOs perform many of these reviews, the OAQPS QAM retains authority for approving the following QA Documents:

- OAQPS Contract and Program-level QA Documents;
- QMPs developed by contractors and grantees using EPA funds;
- Interagency Agreement QA Documents;
- QA Documents prepared by EPA personnel (i.e., not prepared by contractors or grantees);
- QA Documents for EPA-lead sampling events not involving grant or contract support for field sampling where OAQPS is a partner;
- QA Documents currently in review with the OAQPS QA Program; and

- Enforcement actions, as appropriate. Refer to the individual enforcement action for information about EPA's QA document approval authority.
    - Special considerations for enforcement actions:
        - For enforcement actions such as Administrative Orders (AOs) or Administrative Orders on Consent Decrees (AOCs), QA Document approval authority may differ from guidelines presented here. Refer to the individual Order for information about EPA's QA document approval authority.
        - Note: It is recommended that QA requirements are specified in each Order. Additionally, it is recommended that each Order specify the EPA person(s) responsible for approving QA documents prepared by the responsible parties or potentially responsible parties; and

In addition, the OAQPS QAM retains authority for approving QARFs for all contract/procurement actions. Table 1-1 illustrates the hierarchy of QA document approval authorities. For more information about QA requirements for contract actions, see Section 4.

Table 1-1. QA Document Approval Authority Hierarchy

QA Documentation Review Authority	Level	QA Documentation
OEI	Organizational	OAQPS QMP
OAQPS QAM Only		OAQPS Contract Level QA Documents Grantee QMPs (EPA Funded) IAG QA Documents
OAQPS QAM or Delegate	Project-Level	QARFs QMPs QAPPs Sampling and Analysis Plans (SAPs) Field Sampling Plans (FSPs) SOPs

1.4.2 QA Advocate

The QA Advocate, who is the Director of CORE, has certain QA responsibilities including providing:

- Direct access to the OAQPS Director and the Senior Management Team on important QA issues;

- A mechanism for conflict resolution; and
- Advocacy for QA on the Senior Management Team.

1.4.2.1 Conflict Resolution

The Director of CORE has the authority to conduct independent oversight of all programs undertaken by the OAQPS, both intramural and extramural, and to report findings and corrective actions to the OAQPS Director. After first being addressed at the Group level and Division level disputes may be taken to the CORE Director by the QAM or QA Division Leads for resolution consistent with CIO 2105.0, *Policy and Program Requirements for the Mandatory Agency-Wide Quality System*. EPA policy and any applicable regulations on quality requirements in extramural agreements. Any QA disputes requiring the involvement of the CORE Director will be documented by the QAM to include a summary of the issue, including documentation, positions of the disputants, and the resolution of the dispute. The report shall be reviewed by the disputants and Director of CORE for clarity and copies of the report shall be distributed to OAQPS Senior Management.

1.4.3 Quality Assurance Division Leads

The QA Division Leads are the main points of contact within each of the five OAQPS Divisions. Each QA Division Lead regularly attends their Division Staff meetings and is either a Group Leader or on the immediate Division Director's staff. The QA Division Leads, along with the QAM make up the QA Team. The QA Division Leads responsibilities include:

- Attending the OAQPS QA team meetings;
- Coordinating the implementation of the OAQPS QMP;
- Acting as a conduit for QA information to Division staff;
- Representing the Division's interests on the QA Team while understanding cross Office/Division perspectives;
- Assisting the QAM in developing QA policies and procedures;
- Coordinating the Division's input to the QMP and the QAARWP, and
- Representing Division QA activities at routine Division staff meetings

Each QA Division Lead has the authority to carry out these responsibilities and bring to the attention of his or her respective Division Director any issues related to these responsibilities.

1.4.4 Delegated QA Officers

EPA OAQPS personnel working in each Division are versed in their respective regulatory requirements and/or familiar with pertinent project goals necessary to support program decisions. It is in OAQPS's best interest to leverage this knowledge base. As such, when certain training requirements are met, the OAQPS QAM may delegate authority to an individual, to approve project-level QA documents such as QAPPs, FSPs and SAPs.

Within each Division in the immediate office or at the Group level reside one or more delegated QA Officers (DQAOs). Some of the DQAO's have delegated authority to review and approve

project level QA documentation including contractor QMPs, QAPPs, and SOPs while others only review Quality Assurance Review Forms (QARFs) to determine the level of QA documentation required at the Task Order (TO) level.

The DQAO represents the OAQPS QAM by reviewing, approving and signing project-level QA documents. Signing QA documents is an Agency action; therefore, DQAOs must adhere to certain requirements outlined in the required training.

When approving a project-level QA document, the DQAO must include the title of DQAO on the signature line in addition to any other titles specified by the project manager, WACOR, or TOCOR, as appropriate, or an SOP document.

If a team has more than one team member who is a certified DQAO, only one person may be designated as the DQAO for the project. That person alone has authority to act as the DQAO for the project.

DQAO's are responsible for tracking and maintaining copies of all QA documents that they review and/or approve. Periodically (not more frequently than quarterly), the DQAO will provide the OAQPS QAM with the following information:

1. QA Document Review Status—a list of documents in review or already reviewed including review type (new document or annual review), approval status (approved or not approved) and approval date, if approved;
2. QA Documents Reviewed—electronic copies of all QA documents reviewed in pdf format. All approved QA documents must include the approval signatures & dates; and
3. Review checklists—copies (preferably electronic) of completed OAQPS QA checklists for each accompanying QA document.

If the review/approval status for a QA document has not changed since the last reporting period, it is not necessary to report on that QA document status until or unless its status changes.

To maintain project-level QA document approving authority, the DQAO agrees to:

1. Complete the training requirements for DQAOs (see Section 3.2).
2. Ensure appropriate EPA-approved project-level QA document(s) are in place prior to collection, generation or use of environmental data or environmental technology, except under circumstances requiring emergency response immediate action to protect human health and the environment or operations conducted under police powers (See Section 2.4.1.34 Conditional Approvals);
3. Review the project-level QA documents using the OAQPS QAPP Review checklist or if not a QAPP (See Section 7 for a discussion of other types of QA documents), other checklist;
4. Maintain independence of the data generation activities;
5. Track all QA documents that are reviewed, noting whether the documents were approved;
6. Maintain a file of all reviewed and/or approved QA documents and their companion checklists;

7. For QA documents that are deemed approvable by the DQAO, sign and date the project-level QA documents and create an electronic file (PDF) of the entire document, including all attachments and the completed signature page;
8. Report project-level QA document review and approval status to the OAQPS QAM, as requested; and
9. Provide information as requested by the OAQPS QAM to support periodic QSAs of the project-level QA document reviews and approvals

1.4.5 OAQPS Director

The OAQPS Director ensures that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the OAQPS Agency-approved QMP; and that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) that are commensurate with the quality management responsibilities assigned by of EPA Policy CIO 2105.0, *Policy and Program Requirements for the Mandatory Agency Wide Quality System* and the OAQPS Agency-approved QMP.

1.4.6 OAQPS Deputy Director

The OAQPS Deputy Director is the OAQPS Scientific Integrity Official (SIO). The OAQPS SIO coordinates with the Office of Air and Radiation (OAR) SIO to ensure staff and managers are trained on the scientific integrity policy and acts as a liaison when/if matters within OAQPS need to be referred to the OAR SIO.

1.4.7 Division Directors

QA is an integral part of every OAQPS Program that is associated with the collection or use of environmental data. Division Directors are responsible for providing and managing adequate resources to ensure that all environmental data in support of their respective programs are of known quality, defensible and adequate for the intended use.

The Division Directors' QA responsibilities also include:

- Ensure that Division staff follow the OAQPS QMP;
- Reviewing, coordinating Division input to, and approving the OAQPS QMP;
- Appointing one QA Division Lead to the OAQPS QA Team; and
- Appointing employees within the Division as appropriate to become trained to perform DQAO functions or delegating this appointment function to Group Leaders.
- Assist the QAM with any dispute resolutions coming up through that divisions staff.

1.4.8 Managers and Supervisors

EPA Order CIO 2105.0 requires that the performance agreements of all supervisors, senior managers, and appropriate staff have quality management responsibilities assigned by the QA Orders and this QMP reflected appropriately in the critical element(s) within their PARS.

1.4.9 Program and Project Managers

Any OAQPS employee (staff or manager) with immediate managerial, administrative or technical control of a project, program or extramural agreement involving the generation or use environmental data is responsible for ensuring the OAQPS QS is employed for all activities involving environmental data. This includes specifying the quality of the environmental data required for each project, securing the appropriate approvals of the QMP/QAPP, ensuring environmental data that are generated/used are defensible and of known quality, and requesting the appropriate resources needed from management. These requirements are applicable to a variety of titles or functions, including:

- Project Managers;
- Project Leads
- Task Managers;
- Work Assignment Managers (WAM);
- Contracting Officers (CO);
- Contracting Officer's Representatives (COR);
- Contract Specialists;
- Grant Specialists;
- Contract Project Officers; and
- Grant Project Officers.

1.4.10 OAQPS Staff and Other Support Staff

All staff, contractors and cooperators, are vital for the proper functioning of the quality system. Key responsibilities for staff involved in operations subject to QA requirements are:

- Awareness of the quality management system (e.g., completing all required QA training which at a minimum cover EPA QA Policy);
- Participation in the quality management system through, but not limited to, following procedures, identifying quality issues, proposing solutions, developing standard operating procedures and work instructions, and following quality assurance project plans;
- Identifying and reporting evolving quality concerns. The concerns may be reported to the Quality Assurance Manager, Division Directors, Group Leaders and Office Director. Access can be through meetings, telephone conversations, electronic mail, or other communication methods; and
- Participation in the resolution of the quality concerns.

1.4.11 Other Roles/Positions Identified in the QMP

Some key positions, mentioned in this QMP, are assigned to individuals within OAQPS. The names of these individuals are listed in Table 1-2.

Table 1-2. Current Representatives for Key Positions Identified in the OAQPS QMP

OAQPS Position	Representative	Contact Information
OAQPS Director	Peter Tsirigotis	Tsirigotis.Peter@epa.gov 919.541-5616
OAQPS Deputy Director Scientific Integrity Official	Mike Koerber	Koerber.Mike@epa.gov 919.541.5557
OAQPS Quality Assurance Manager	Jenia McBrian	McBrian.Jenia@epa.gov 919.541.0371
OAQPS Quality Advocate	Jeff Whitlow	Whitlow.Jeff@epa.gov 919.541.5523
Peer Review Coordinator	Robert Hetes	Hetes.Bob@epa.gov 919-541-1589

1.5 Technical Activities and Programs Requiring the Application of Quality Management Practices

In order to support its mission, OAQPS funds and implements many Environmental Data Operations (EDOs) and these must be supported by a QS. OAQPS serves as a major focal point for activities in fulfillment of the Clean Air Act (CAA). It utilizes contractors, grantees, other federal agencies, EPA Regional, and SLT agency support to generate necessary technical data and reports of findings.

OAQPS EDOs include all phases of the data collection activities, such as field sampling, laboratory analysis, data management, modeling, assessment, and reporting. These data, along with secondary data, which may be collected under different data quality criteria, are interpreted and reported and are also used in modeling efforts to perform additional interpretation and assessment. OAQPS EDOs include:

- Developing regulations under the various Clean Air Act programs e.g.,
  - New Source Performance Standards;
  - National Emission Standards for Hazardous Air Pollutants;
  - Maximum Achievable Control Technology Standards;
  - Generally Available Control Technology standards for area sources; and
  - Section 129 emission standards or under other federal statutes.
- Reviewing and revising the NAAQS;
- Assessing and improving the effects of air pollution through both ambient and source monitoring;

- Developing environmental indicators and new methods for ambient and source monitoring;
- Developing and distributing guidelines for regulatory air quality models including the establishment of preferred air quality models and techniques;
- Developing emission factors and emission standards;
- Developing emissions inventories and providing technical guidance on development of emission inventories by others;
- Conducting comprehensive studies to determine the nature, magnitude, transport and fate of air pollution emissions currently and in the future;
- Evaluation and demonstration of remedial actions and control strategies for air pollution;
- Assessments of health and ecological effects, exposure and risk, extent and trends of air pollution contamination;
- Sampling and analysis of a host of air pollution constituents, from both continuous automated instruments and manual instruments; and
- Mapping and landscape characterization techniques through various remote sensing platforms and meteorological and physical parameters.

1.6 Secondary Data (Secondary Use of Data)

OAQPS uses secondary data in many of its assessments and models. Secondary data can be considered data that are utilized for a purpose other than that for which they were initially collected. A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. The OAQPS secondary data policy is discussed in Section 7.

2 OAQPS Quality System

2.1 Description and Implementation

The OAQPS QS is accordant with the Agency-wide QS policies and procedures and provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. Agency-wide QS documents, including specifications for EPA organizations; internal EPA directives; specifications for non-EPA organizations; and general guidance are publicly available and posted on EPAs Agency-wide Quality System Documents website.

The quality management tools described in this section enable OAQPS to conduct program and project-specific planning, verify and document the integrity of the work products, evaluate the effectiveness of the quality system, and report on that effectiveness to senior management and the Enterprise Quality Management Division (EQMD).

Functionally, OAQPS has a centralized QA Program that consolidates the QA decision-making, assessment (auditing), guidance, and training functions in a central core, yet allows delegation of authority for day to day QA activities and project-level QA document approval to staff in the various Divisions.

The OAQPS QS is overseen by the OAQPS QAM, who maintains independence from environmental data operations and is afforded access to the OAQPS Director and/or Deputy Director, if needed.

The independence of the OAQPS QAM, QA Staff and other delegated QA representatives is not only required by national EPA policy, but is vitally important to OAQPS's implementation of its QS, allowing the OAQPS QAM (or delegated QA representatives) the authority to advocate the importance and relevance of quality in EPA's work. The QAM can serve without any potential conflicts of interest due to the position's location in CORE, outside any sub-group that collects and/or uses environmental data directly, and with explicit ties to the Director and Deputy Director.

2.1.1 Quality Management Plan

EPA Policy requires that all Agency organizational units document their QA program in an approved QMP. The document describes the QS in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing activities involving EDOs. The QMP is developed for use by all OAQPS staff, as detailed in Section 1. The OAQPS QMP will reside on the OAQPS QA SharePoint site for easy access to all OAQPS staff, and be made publicly available on the EPAs website. The OAQPS QMP must be approved by the OAQPS QA Manager, Division Directors, and the OAQPS Director. It is then submitted for approval by the Director of the Quality Staff in OEI. This approval is valid for up to five years provided there are no major changes to the organization's QS during the interim.

The QMP will be reviewed every September by the QA Team to determine if the information remains relevant to the Office. Any required change(s) will include an update to the revision

number of the QMP. A description of the major changes will be sent via E-mail to all OAQPS staff, appropriately archived, and will be included in the QAARWP. If necessary, training materials will be revised to reflect the changes. The revised QMP will be posted on the OAQPS QA SharePoint and the obsolete version archived. Every 5 years based upon the original approval date, the QMP will undergo a thorough review in its entirety and go through the approval cycle.

2.2 Mission, Policy and Scope

OAQPS primary mission is to preserve and improve air quality in the United States. To accomplish this mission, OAQPS uses environmental information from a variety of sources. Nearly all OAQPS program work is directly dependent upon the collection and use of environmental data. The OAQPS Quality Policy (Figure 1-1) is supported by OAQPS's QS which requires that all environmental data used in Agency decision-making are scientifically sound, defensible and of known and documented quality and are of appropriate and adequate quality for the intended purpose.

Generally, the following policies apply to all environmental data collection, generation or use conducted by OAQPS personnel and its contractors, grantees, and interagency agreement recipients:

- Appropriate QA planning documents (e.g., Quality Management Plan (QMP), Quality Assurance Project Plan (QAPP), Sampling and Analysis Plan (SAP), Field Sampling Plan (FSP), or Statements of Work (SOW) are developed and approved prior to the initiation of data any environmental data collection, generation and/or use.
- Intended use(s) and data quality objectives (DQOs) of environmental data are identified prior to data collection, generation and/or use in the appropriate QA planning document(s). Note that not all projects require the formal DQO process, however DQOs should be identified based upon the intended us of the data. See Section 2.4.1.1 for more information about DQOs.
- Implementation of projects and tasks involving any environmental data collection, generation and/or use conforms to information provided in approved QA planning documents.
- Oversight of any environmental data collection, generation and/or use is performed by an individual or organization that is independent of any environmental data collection, generation and/or use activities and any identified deficiencies are promptly corrected.
- Programs and projects that use existing data or data from secondary sources must have an approved QAPP (or equivalent QA document). The QA document must specify the QS that will be used to determine the suitability of the data for the proposed use.
- QA oversight is performed, ensuring that all programs generating environmental data as well as those used in Agency decision-making are providing usable and defensible results.

The specifics of each of these requirements are the scope and content of this QMP.

2.3 Plan, Do, Check Model

OAQPS has adopted the Plan, Do, Check, Act (PDCA) quality model as the foundation of its QS. The PDCA quality model is an iterative four-step approach for managing, planning, implementing and administering continuous improvement over the lifecycle of any OAQPS activity, including all work processes and work products.

The elements of the PDCA quality model are summarized below and detailed further in Sections 7 through 10 of this document.

- PLAN establishes the objectives and processes necessary to deliver results in accordance with the desired output or goals. Planning includes project organization, securing resources, and defining roles and responsibilities of participants.
- DO is the implementation or execution of the planned activity, following standard protocols or procedures for direct data acquisition, acquisition of data from existing or other sources (e.g. combining multiple sources of secondary data), and modeling.
- CHECK monitors and measures the process performance through the assessment of the project to identify any differences or deviations from the implementation of the plan and the expected results, targets, objectives or goals established in the planning phase.
- ACT is action taken for correcting significant differences between actual and planned results. This step includes a root cause analysis to determine where to apply the changes that will create improvement of the process or product.

Application of the PDCA quality model is appropriate for all OAQPS environmental operations, administrative activities and extramural agreements. PDCA serves as the theme for this QMP and its approach is integrated into all aspects of this document.

2.4 OAQPS QA Applications and Tools

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

Figure 2-1 illustrates the EPA Quality System with three connected groups of components, which lead to defensible products and decisions:

1. Policy/Regulations – These components address quality-related policies and regulations that EPA organizations and non-EPA organizations must address.

2. Organization/Program – These components address the management and implementation component of the individual Quality System. The components are applied across an entire organization (e.g., a Regional Office or a National Research Laboratory) or to a specialized, complex, large, or highly visible programs (for example, EPA's Great Lakes National Program).

3. Project – These components address the project-specific components that are applied to individual projects (within an organization or program) to ensure that the project objectives are achieved. Figure 2-1 also shows some of the quality management tools EPA has developed to assist in developing and implementing a quality system. These tools are described in this Section.

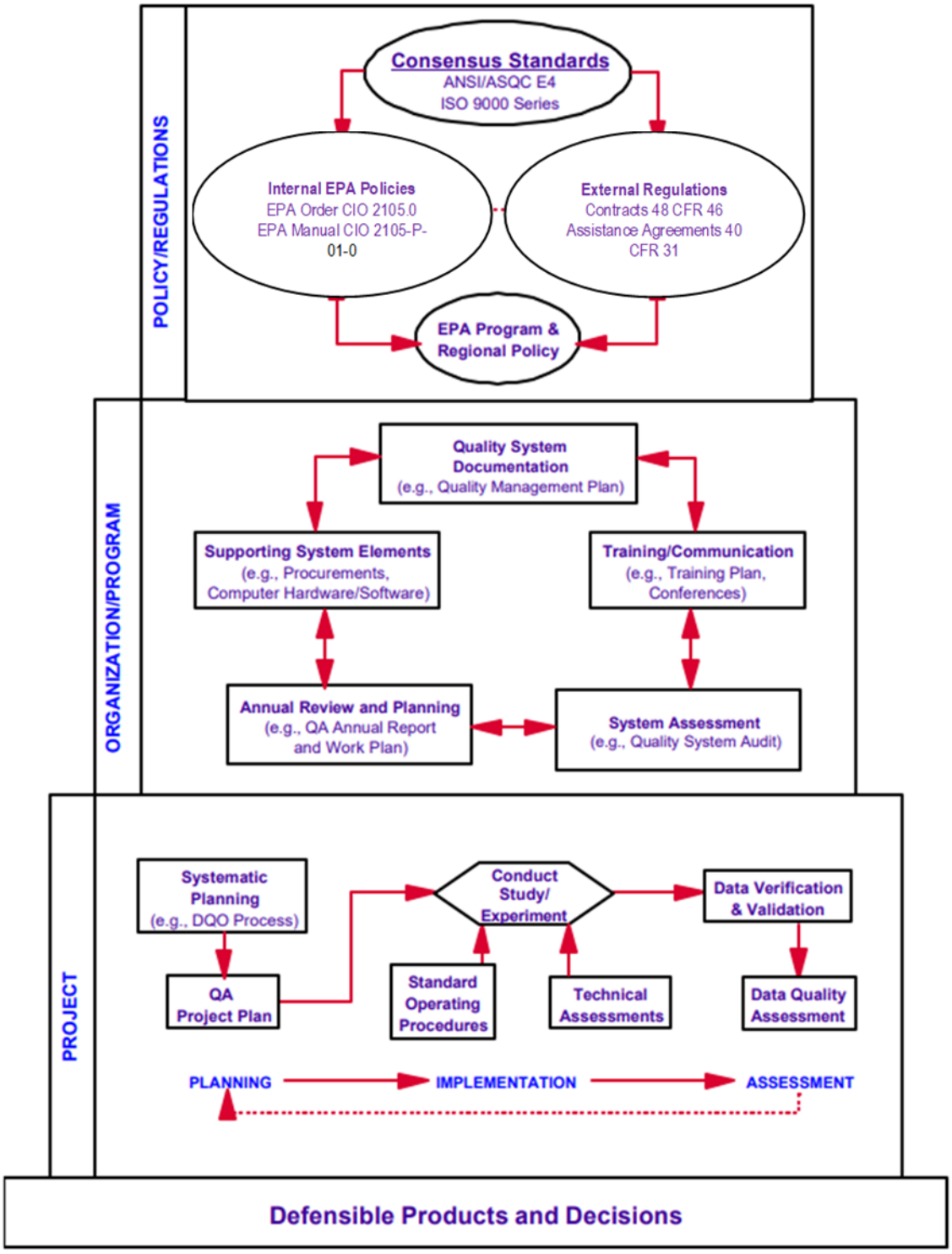


Figure 2-1. EPA Quality System Components and Tools

2.4.1 Systematic Planning

A systematic planning process using a graded approach is a normal part of OAQPS project planning and includes considerations of the cost-effectiveness and realistic capabilities of the EDO. The basic elements of systematic planning include the following elements:

- Organization: Identification and involvement of project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc.
- Project Goal: Description of the project goal, objectives, and study/project questions and issues.
- Schedule: Identification of the project schedule, resources, milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements).
- Data Needs: Identification of the type of data needed and how the data will be used to support the project's objectives.
- Criteria: Determination of the quantity of data needed and specification of performance or acceptance criteria for measuring quality.
- Data Collection: Description of how and where the data will be obtained (including existing data) and identification of any constraints on data collection.
- Quality Assurance: Specification of needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both field and laboratory, audits, technical assessments, performance evaluations, etc) or of existing data.
- Analysis: Description of how the acquired data will be analyzed, evaluated, and assessed against its intended use and the quality performance or acceptance criteria.

The following subsections provide an overview of the OAQPS planning processes and links to policy and reference documents to guide in project planning and assessments.

2.4.1.1 Data Quality Objectives (DQOs)

The DQO process is an example of the systematic planning process and is designed to generate *performance criteria* for the collection of new data. In general, performance criteria represent the full set of specifications that are needed to design a data or information collection effort such that, when implemented, generate newly collected data that are of sufficient quality and quantity to address the project's goals.

Acceptance criteria are specifications intended to evaluate the adequacy of one or more existing sources of information or data as being acceptable to support the project's intended use. The generation of acceptance criteria is discussed in the development of QAPPs (Guidance for Quality Assurance Project Plans EPA QA/G-5) (U.S. EPA, 2002d).

DQOs are qualitative and quantitative statements that:

- Clarify the intended use of the data;
- Define the type, quality and quantity of data used to support the decision;
- Identify the conditions under which the data should be collected; and

- Specify tolerable limits on the probability of making a decision error due to uncertainty in the data.

By applying the DQO process to the development of a quality system, the EPA guards against committing resources to data collection efforts that do not support a defensible decision.

It is the responsibility of the OAQPS Project Officer or Contracting Officer Representative (COR) to define the project's allowable uncertainty, if applicable.

DQO development should be a normal part of the project planning process and must be accomplished based on cost-effectiveness and realistic capabilities of the measurement process, which includes both direct and indirect data acquisition. To facilitate this determination, the EPA Quality Staff developed EPA QA/G-4, Guidance on Systematic Planning Using the Data Quality Objectives Process, which is posted on the Agency-wide QS Documents website.

The DQO process assists the user in defining the purpose for an environmental data operation and sets the framework for the design, implementation, and QA of the project. Once DQOs are defined, a QA program can be developed. By using the DQO process to plan EDOs, EPA can improve the effectiveness, efficiency, and defensibility of decisions in an effective manner.

2.4.1.2 Data Quality Indicators (DQIs)

Performance and acceptance criteria are often expressed in terms of data quality indicators (DQIs). The principal indicators of data quality are precision, bias, accuracy, representativeness, comparability, completeness, and sensitivity. Refer to EPA QA/G-5 Guidance for Quality Assurance Project Plans for guidance on DQIs.

2.4.1.3. Quality Assurance Project Plans (QAPPs)

The QAPP is a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of work performed will satisfy the stated performance and acceptance criteria. The information in this section applies equally to in-house and extramural QAPPs. QAPPs are not required for projects that do not include EDOs, such as a conference or communications effort.

The EPA quality system related regulations require contracts, grants and agreements have written and approved quality assurance project plans prior to the start of the environmental data operations. Section 2.1 of the *EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5)* requires "all work funded by EPA that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be implemented in accordance with an approved QA Project Plan."

The COR (includes WACOR/TOCOR), PO, or Project/Program Lead is responsible for ensuring the quality documentation is present, accurate, and in the project file. This responsibility extends to the QAPP, the results of the QAPP process, and any other required QA documentation. If QAPP requirements are not satisfied, the COR or PO, with the Contracting Officer or Grant Officer and QAM as applicable, will determine the appropriate actions.

Please see *EPA Requirements for Quality Assurance Project Plans* (QA/R-5) and *Guidance for Quality Assurance Project Plans* (G-5) when preparing QAPPs for OAQPS projects. To facilitate QAPP preparation, QAPP templates are posted on the OAQPS QA SharePoint site.

For additional guidance on project planning, please refer to *EPA Quality Management Tools for Projects* posted on the EPA Quality Management website.

2.4.1.3.1 QAPP Planning, Preparation, Review and Approval

The following subsection outlines the process for QAPP planning, preparation, review and approval. Figure 2-2 presents a flow chart of this process.

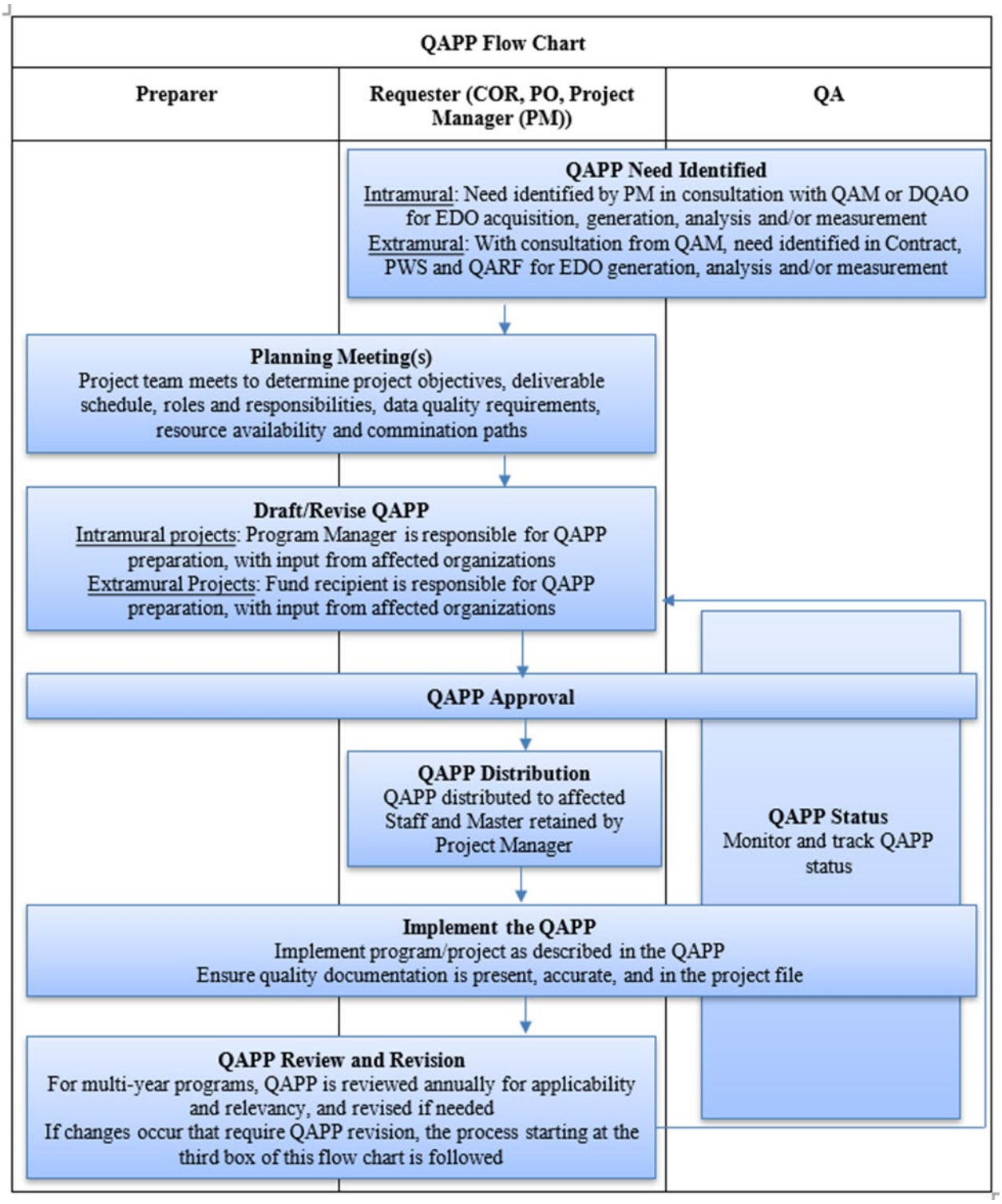


Figure 2-2. QAPP Flow Chart

2.4.1.3.2 QA Categories: The Graded Approach

Because of the diversity of work conducted by OAQPS, a "one size fits all" approach to quality specifications will not work across the Office. Therefore, the OAQPS implementation of the EPA QS is based on a graded approach, where QSs vary according to the specific objectives and needs of the organization or program. For example, the quality practices needed in a research program are different from those in a regulatory compliance program because the purpose or intended use of the data is different.

The QAPP is documentation of the application of QA and QC activities to an activity-specific effort: The level of detail of the QAPP should be based on a graded approach so that the level of detail varies according to the nature of the work being performed and the intended use of the data. As a result, an acceptable QAPP for some EDO's may require a qualitative discussion of the experimental process and its objectives while others may require extensive documentation to adequately describe a complex environmental program.

Every project differs in its scope, time requirements, and complexity. OAQPS utilizes four QA categories ranging from Category I (the most stringent and requiring all QAPP elements) to Category IV (the least stringent and requiring only a few QAPP elements). See Table 2-1 for the list of QAPP elements and how they apply to each of the QA Categories discussed, below.

The following describes QA Categories I through IV.

- **Category I** Projects produce results that are autonomous. These projects are of sufficient scope and substance that their results could be used to directly support rulemaking, enforcement, regulatory, policy decisions, compliance or other litigation. These projects require the most rigorous and detailed QA, as the resulting data must be both legally and scientifically defensible. Such projects are of critical importance to the Agency goals and must be able to withstand legal challenge.
    - Examples include:
        - Standards establishment, review or revision
        - Projects of significant national interest (e.g., regulatory actions and emergency sampling events)
- **Category II** Projects are those that complement other projects in support of regulatory or policy decisions. Such projects are of sufficient scope and substance that their results could be combined with those from other projects of similar scope to provide the necessary information for decisions. In addition, projects that do not fit this pattern, but have high visibility, would also be included in this Category.
    - Examples include:
        - Non-regulatory air quality monitoring
        - Modeling analyses to support policy and regulatory decisions
- **Category III** Projects are those that are interim steps in a larger group of steps or projects. Such projects include those producing results that are used to evaluate and select

options for interim decisions, or to perform feasibility studies or preliminary assessments of unexplored areas for possible future work.

    - Examples include:
        - Scoping study preceding method development
        - Secondary data research project

- **Category IV** Projects are those involved in studying basic issues, including proof of concepts, screening for particular analytical species, etc. These projects are non-regulatory and typically limited in their scope.
    - Example:
        - Literature reviews

To determine the appropriate QA Category and associated QAPP requirements for an extramural project, the OAQPS QAM or the DQAO must be consulted to review the Statement of Work (SOW) or Performance Work Statement (PWS) and complete the QARF indicating the level of QA required for the project. QAPPs are also required for intramural projects involving EDOs and the OAQPS QAM or the DQAO must be consulted to determine the level of QA required for the project or Program.

If the project is a Category I, it is the Project Officer or COR's responsibility to develop a systematic planning process (may be the DQO Process) with the principal investigators and cooperators. For all projects that require Category I QAPPs, a separate document is required that includes the DQOs or other formal systematic plans. DQOs for the other three categories of QA project plans can be included in the QAPP.

Table 2-1, below, outlines the number of QAPP elements required for each QA category for non-modeling QAPPs. Note that the requirements are reduced as one proceeds from Category I to IV.

For modeling QAPPs, the graded approach should be used throughout the model development and/or application process. This involves examination of the scope, rigor, and complexity of the modeling analysis that is necessary to meet the intended use of the modeling results, accounting for the necessary degree of confidence as well as timing and resource constraints.

Table 2-1. QAPP Elements Applicable to Each QA Category

Element		QA Category Applicability
Project Management		
A1	Title and Approval Page	I, II, III, IV
A2	Table of Contents	I, II, III
A3	Distribution List	I, II
A4	Project/Task Organization	I, II, III
A5	Problem Definition/Background	I, II, III
A6	Project/Task Description	I, II, III, IV
A7	Quality Objectives and Criteria for Measurement Data	I, II, III, IV
A8	Special Training Requirements/Certification	I
A9	Documentation and Records	I, II, III
Measurement/Data Acquisition		
B1	Sample Process Design	I, II, III, IV
B2	Sampling Methods Requirements	I, II, III
B3	Sample Handling and Custody Requirements	I, II, III
B4	Analytical Methods Requirements	I, II, III, IV
B5	Quality Control Requirements	I, II, III, IV
B6	Instrument Calibration and Frequency	I, II, III
B7	Inspection/Acceptance Requirements for Supplies and Consumables	I, II
B8	Data Acquisition Requirements	I, II, III, IV
B9	Data Management	I, II
Assessment and Oversight		
C1	Assessments and Response Actions	I, II, III, IV
C2	Reports to Management	I, II, III, IV
Data Validation and Usability		
D1	Data Review, Validation, and Verification Requirements	I, II, III
D2	Validation and Verification Methods	I, II
D3	Reconciliation and User Requirements	I, II, III

Program Managers, Project Managers, CORs (TOCORS/WACORS), with consultation from the QAM or the DQAO, are required to designate the category of the QAPP. The statement of the category will be placed on the QAPP signature and approval page which will include signatures

of the QAPP preparer, Program Manager/COR, and the QAM or the DQAO. Other personnel, depending upon the nature of the QAPP, may need to sign the approval page.

2.4.1.3.3 QAPP Review and Approval

For extramural projects, the QAPP must be reviewed by the Project Lead or COR. For internal projects, the QAPP must be prepared by the Project Lead. After review (extramural) or preparation (internal), the QAPP must be reviewed and approved by either the QAM or the DQAO prior to the beginning of a project or program and then annually thereafter. If statistical analyses are included in the QAPP, it is recommended that the plan be reviewed by a statistician.

> QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.
>
> EPA Order 2105.0 (6.a.7).

The QAM or the DQAO will review each QAPP for the required elements and the soundness of the quality assurance/quality control (QA/QC). The QAM or the DQAO should review QAPPs within 30 working days of submission. The QAM or the DQAO will provide written comments on each element using the OAQPS QAPP checklist, posted on the OAQPS QA SharePoint site, which shall be used to facilitate and document the review process. Through the QAPP review process, the QAM or the DQAO will determine whether the QAPP can be approved and, if not, will identify those elements requiring revision. If the QAPP requires revision, it will be sent back to the author. The revisions, which may be included in the QAPP or as an addendum, must be reviewed and approved by the QAM or the DQAO.

2.4.1.3.4 Conditional Approvals

OAQPS does not encourage the use of conditional approvals; therefore, QAPPs may be conditionally approved only by the QAM. When a situation requires immediate action to protect human health and the environment or operations conducted under police power, the OAQPS QAM may grant conditional approval to a QAPP to permit some work to begin while non-critical deficiencies in the QAPP are being resolved. Conditional approval is defined as a QAPP that demonstrates that a QS is in place and operational and that critical elements of the QAPP are provided in enough detail to allow the reviewer to determine that the data collected under the QAPP will be documented and of sufficient quality to meet the program data quality objectives. Based upon the need to implement an EDO, a memo will be developed and signed by the QAM which provides for conditional approval while identifying the QAPP areas that require revision and a date by which these revisions must be made.

Subject to this exception, the 'COR (TCOR/WACOR), or Project/Program Manager, as applicable, is responsible to ensure that no environmental data operations are performed before the QAPP is approved.

2.4.1.3.5 QAPP Revision

Although the approved QA Project Plan must be implemented as prescribed; it is not inflexible. Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. When such changes occur, the approving official shall determine if the change significantly impacts the technical and quality objectives of the project. When a substantive change is warranted, the originator of the QA Project Plan shall modify the QA Project Plan to document the change and submit the revision for approval by the same authorities that performed the original review. Only after the revision has been received and approved (at least verbally with written follow-up) by project personnel, shall the change be implemented.

For programs or projects of long duration, such as multi-year monitoring programs or projects using a generic QA Project Plan, the QA Project Plans shall be reviewed at least annually by the EPA Project Manager (or authorized representative). When revisions are necessary, the QAPP must be revised and resubmitted for review and approval by the Project Leader or COR.

2.4.1.3.6 QAPP Archive

Upon completion of a project, QAPPs should be filed within the Project Lead's Division filing system.

2.4.1.3.7 Extramural Quality Assurance Project Plans

The Grant and Federal Assistance Regulations, 40 CFR Parts 30.54 and 31.45, document the QA requirements when the project entails EDOs. One of the four categories of QAPPs, as determined by the Project Lead or COR, will be required. Mandatory approval signatures include the QAPP preparer, Project Lead or COR, and the OAQPS QAM or DQAO.

2.4.1.4 Standard Operating Procedures

SOPs may describe technical and administrative operational elements. Whatever the context, SOPs shall thoroughly describe steps and techniques for the activity and will be sufficiently clear to be understood by a person with knowledge in the general concept of the procedure or process. Any limitation on the use or applicability of a specific SOP shall be documented in the SOP itself. Definitions of and guidance for preparing SOPs is found in EPA QA/G-6 (2007), *Guidance for Preparing Standard Operating Procedures*.

SOPs must be written by personnel who are deemed technically competent by management, based on their knowledge, skills, and abilities. SOPs for data collection methods must be included in QAPPs either by reference or by inclusion of the actual method. If a method is referenced, it must be stated that the method is followed exactly, or an addendum that explains changes to the method must be included in the QAPP. If a modified method will be used for an extended period, the method should be revised to include the changes to appropriate sections. In general, approval of SOPs occurs during the approval of the QAPP. Individuals with appropriate training and experience with the particular procedures and/or methods in the QAPP must review

the SOPs. Internal OAQPS SOPs must be approved by the Project or Program Lead and the QAM or program DQAO.

An SOP cannot be revised during an EDO without the consent of the Project Lead or COR. If the modification is accepted, it must be documented in a letter to the Project Lead or COR, addended to the existing QAPP and reported in the next progress report. When a revised procedure has been approved, the obsolete procedure must be removed from the work area and replaced with the revised procedure. The Project Lead is responsible for assuring the revised procedure is the one being followed.

2.4.1b SPPD-Specific Systematic Planning

As discussed above, quality documentation, which may be a QAPP, is a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of work performed will satisfy the stated DQOs. The information in this section applies equally to quality documentation for both SPPD internal and extramural projects. The Grant and Federal Assistance Regulations, 40 CFR 1 Parts 30.53 and 31.45, document the QA requirements when the project entails EDOs. One of the two categories of quality documentation, as determined by the Project Lead or COR in consultation with the QAM or DQAO, will be required. Quality documentation is not required for projects that do not include EDOs.

As stated in in the previous section, the EPA's QA policy requires every EDO to have written and approved quality documentation prior to the start of the EDO. The Project Lead or COR and is responsible for addressing this Policy. The Project Lead or COR is responsible for providing copies of the approved quality documentation to everyone who has a major responsibility in the EDO and explaining the elements of the quality documentation to these individuals.

2.4.1b.1 SPPD Documentation Review and Approval

Quality documentation, such as a QAPP, will be prepared, reviewed and approved as described in the previous Section.

2.4.1b.2 SPPD Revision of the Quality Documentation

The QAPP review and revision process will follow the process described in the previous Section.

It should be noted that the issuance of work assignments/task orders that are a continuation of a project conducted under a previous work assignment/task order may not require revision of the quality documentation from the previous work assignment/task order, provided the scope of the project has not changed such that the DQOs associated with that project have changed and the quality documentation addresses the work required to be performed during the work assignment/task order. The QAPP must be reviewed and reapproved in order to make and document this determination.

2.4.1b.3 SPPD Archiving of the Quality Documentation

Upon completion of a project, all quality documentation will be filed within the Project Lead's Division filing system. An electronic copy of the QARF, SOW (or PWS) and QAPP are also kept on the server by the SPPD QA team.

2.4.1b.4 SPPD Categories of QA Documentation

SPPD utilizes QA Categories I and II in its QA Program to effectively focus QA for regulations. The Project Lead or COR, with consultation from the QAM or DQAO, is required to designate the category of the project. CORs should use the following definitions to determine the appropriate category for their project.

- SPPD Category I Projects
    - As described previously, Category I projects require the most detailed and rigorous QA and QC project plan elements that are needed for legal and scientific defensibility. These additional plan elements are not required for Category II Projects. Category I projects are typically those in which SPPD directs an EPA contractor to conduct measurements. Projects meeting these criteria are required to follow the criteria developed by the Emissions Measurement Center (EMC) for establishing appropriate project specific quality documentation, such as a QAPP.
        - Clarification: MTG oversees method development and appropriate QA for the methods used to collect stationary source emissions test data. Because Category I Projects are projects where methods are used to collect direct measurements, the project will need to meet the criteria of the methods. These criteria are developed by the EMC. MTG will not be advising SPPD on QAPPs, but the same criteria MTG develops for the methods and the QA in the methods must be used in SPPD's QAPPs as well. It will be SPPD's responsibility to ensure SPPD's QAPPs follow the criteria developed by the EMC.
- SPPD Category II Projects
    - All other SPPD projects involving EDOs that do not meet the requirements for Category I projects are required to have Category II quality documentation. Because SPPD receives data from outside sources (non-direct measurements), not all QAPP elements listed in Table 2-1 are relevant to the quality documentation for SPPD Category II projects. Elements that are not relevant to SPPD Category II projects include:

        A8 Special Training Requirements/Certification

        B1 Sample Process Design

        B2 Sampling Methods Requirements

        B3 Sample Handling and Custody Requirements

        B4 Analytical Methods Requirements

        B6 Instrument Calibration and Frequency

        B7 Inspection/Acceptance Requirements for Supplies and Consumables

    - Previous versions of the OAQPS QMP that predate this document specified SPPD Category II QAPPs include Elements A1, A4, A6, A7 and D1 with a description of each element. As of the effective date of this QMP, SPPD Category II QAPPs will contain all elements from Table 2-1 with the notation "Not Applicable" for those sections that do not apply.
- SPPD In-house Quality Documentation
    - All EDOs including those involving no funds (FTEs only) accomplished by OAQPS staff must be covered by approved quality documentation prior to the start of the EDO. Mandatory approval signatures include the Principal Investigator and the OAQPS QAM or DQAO.

2.5 Assessments of Quality

The following applies to OAQPS both when OAQPS is performing or is receiving an assessment.

Debriefings should occur for assessments and include all personnel audited and the audited organizations management. The debriefing provides the audited agency with an overview of the major negative as well as positive findings of an audit. A negative finding would be one that has the potential for affecting the quality of the data, the decisions made with the data, or does not follow EPA QA Policy or requirements. A finding should be tied to an adverse condition or data quality issue. Minor negative findings or "observations" that are identified in order to improve an audited organizations QS do not need to be discussed at the debriefing.

There may be times when organizations dispute the findings of the auditing agency. During the debriefing, the auditor may be provided with additional information that he/she did not receive or observe while performing the assessment. If this is the case, the finding may be retracted. If the additional information does not change the auditor's opinion of the finding it should remain a finding. The debriefing needs to be as positive as possible. Discussions on disputed issues should be limited to provide additional factual information and limit any adversarial discussions. The audited organization will have an opportunity to dispute the finding in writing during the audit reporting stage.

A formal report for an assessment will be developed by the auditing organization. As in the debriefing, the report will highlight the positive and negative findings. The report should require the audited agency to address the findings by providing corrective actions for each finding and a time frame by which the corrective action will be implemented. A disputed finding must be formally addressed by the audited organization. This response should provide enough detail to determine whether the finding should be retracted. If the additional information does not change the auditor's opinion of the finding, it should be left as a finding and the issue referred to upper management of both the audited and auditing organization to resolve. In order to "close-the-loop" on disputed findings, an additional memo on the resolution of the disputed issues must be completed and filed with the audit report.

2.5.1 Quality Systems Assessments

Quality system assessments are designed to provide objective feedback about the quality system at the organizational level, and two types are performed in OAQPS: quality system assessments

(QSAs), and management systems reviews (MSRs). QSAs are performed on established quality systems while MSRs are performed on developing quality systems with an objective of providing technical assistance for improving a quality system. Please refer to EPA QA/G-3, *Guidance on Assessing Quality Systems* for more information on planning and conducting QS assessments.

2.5.2 Technical Systems Audits

Technical Systems Audits (TSAs) are focused, thorough, and systematic assessments that measure the performance of the work at a project or program level and with respect to the established technical guidelines, SOPs, and project requirements as defined in QAPPs or other QA documents. These audits include document reviews (i.e., QAPP review prior to completing a milestone) and may include qualitative audit of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of environmental data generation, use and reporting. EPA's *Guidance on Technical Audits and Related Assessments for Environmental Data Operations* (QA/G-7) should be used to prepare for and conduct a TSA.

TSAs should be scheduled throughout the project life cycle to identify potential problems early in the project and allow for timely corrective action. The types of TSAs that may be considered and applied for a particular project will vary; some options are:

- Laboratory Analysis
- Field Sampling
- Field Testing/Monitoring
- Data Package Completeness Reviews
- Assessment of Data Validation Reports

A project or a program should conduct a TSA no less than one per year and/or as required by regulation. The review findings and corrective actions shall be documented by the project or program representative in the end-of-year project report. The project manager, WACOR, or TOCOR, as appropriate, is responsible for ensuring that the identified TSA is accomplished and properly documented for a project. In addition, the project manager, WACOR, or TOCOR, as appropriate, is responsible for providing a summary of the TSA and its outcomes to the OAQPS QAM.

2.5.3 Data Review, Verification and Validation

Data review, verification and data validation are essential, prerequisite assessments conducted before an overall data quality assessment (DQA) can be completed for a project's environmental data. These assessments are necessary for data users to understand the potential qualitative and quantitative biases of environmental data and how decision-making may be impacted as a result of the biases.

Personnel performing data verification and validation of both direct and non-direct measurements as well as using existing available data must have professional knowledge of principles (e.g., chemical, biological, etc.), theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices.

Extensive knowledge of the principles and practices of QA and familiarity with the project specific DQIs is also necessary. EPA QA/G-8 *Guidance on Environmental Data Verification and Data Validation*, November 2002, reissued January 2008 provides general guidance on data verification and validation processes.

All project-level QA planning documents (i.e., QAPPs, SOPs) must clearly describe the specific processes, including SOPs for data verification and data validation for environmental data generated or existing data used during the project and identify the individuals or organizations responsible for the completion of the data verification and data validation. Quality documents containing statements such as "data will be validated" do not sufficiently describe the data verification and data validation process. Data review, data verification and data validation, as defined in EPA QA/G-8, are not usually provided in conjunction with analytical services (including data analysis, physical sample analysis, modeling outputs, etc) unless they are specifically requested and required in the QAPP or other QA documents and must therefore be specifically incorporated into program quality documents.

Project Managers are responsible for ensuring that the data received from either internal or external sources are reviewed, verified and validated prior to proceeding to data quality assessment. This includes existing data. The specific procedures and title(s) of the individual(s) responsible for data review, verification and validation shall be included in the project's QA documentation, including requirements for documenting and reporting the results of the data review, verification and validation. These requirements must be included in the statements of work in solicitations and post-award Task Orders SOWs.

2.5.4 Data Quality Assessment

A DQA is the scientific and statistical evaluation of data to determine if data obtained from environmental data operations are of the right type, quality, and quantity to support their intended use. The DQA is a required element of all QAPPs and completes the data life cycle by providing the assessment needed to determine if the planning objectives were achieved, a key step prior to making Agency decisions.

DQAs are designed to examine one or more of the components of the data, namely: planning (design), generation (methods), and usability (quality). EPA's guidance documents *Data Quality Assessment: A Reviewer's Guide*, QA/G-9R and *Data Quality Assessment: Statistical Methods for Practitioners*, QA/G-9S should be used to plan and conduct DQAs, with additional guidance available in QA/G-9, *Guidance for Data Quality Assessment Practical Methods for Data Analysis EPA*.

The EPA Project Manager is responsible for ensuring a DQA is performed to determine whether the data are of sufficient quality for their intended purpose. The level of effort for a particular DQA will be commensurate with the QA Category, project objectives and intended use of the data.

2.6 QA Support Systems for OAQPS Programs

EPA's responsibility, under the CAA as amended in 1990, includes: setting NAAQS for pollutants considered harmful to the public health and environment; ensuring that these air

quality standards are met or attained through national standards and strategies to control air emissions from sources; and ensuring that sources of toxic air pollutants are well controlled.

OAQPS is the organization charged under the authority of the CAA to protect and enhance the quality of the nation's air resources. OAQPS evaluates the need to regulate air pollutants and develops national standards; works with monitoring organizations to develop plans for meeting these standards; monitors national air quality trends and maintains a database of information on air pollution and controls; provides technical guidance and training on air pollution control strategies; and monitors compliance with air pollution standards.

2.6.1 Ambient Air Quality Network Program

Oversight of the ambient air quality networks is provided by OAQPS. These Networks include:

- State or Local Air Monitoring Stations (SLAMS) Network
- National Core (NCore) Network
- Photochemical Assessment Monitoring Stations (PAMS)
- $PM_{2.5}$ Chemical Speciation Network (CSN)
- National Air Toxics Trends Network (NATTS)
- Interagency Monitoring of Protected Visual Environments (IMPROVE)
- Clean Air Status and Trends Network (CASTNET)
- National Atmospheric Deposition Network (NADP)
- Urban Air Toxics Monitoring Program (UATMP)

The principle network is the SLAMS which consists of a network of monitoring stations whose size and distribution is largely determined by the monitoring requirements for NAAQS comparison and the needs of SLT air monitoring organizations to meet their respective tribal/state implementation plan (TIP/SIP) requirements. The TIP/SIP provide for the implementation, maintenance, and enforcement of the NAAQS in each air quality control region within a tribe/state. The principal pollutants, also called criteria pollutants, monitored in the SLAMS network are particulate matter (PM_{10} and $PM_{2.5}$), SO_2, CO, NO_2, O_3, and Pb.

As illustrated in Figure 2-3, the ambient air monitoring networks are designed to collect data to meet five basic objectives:

1. Prevent air pollution emergency episodes;
2. Provide air pollution data to the general public in a timely manner;
3. Support compliance with air quality standards and emission strategy development;
4. Provide trends analyses; and
5. Support air pollution research.

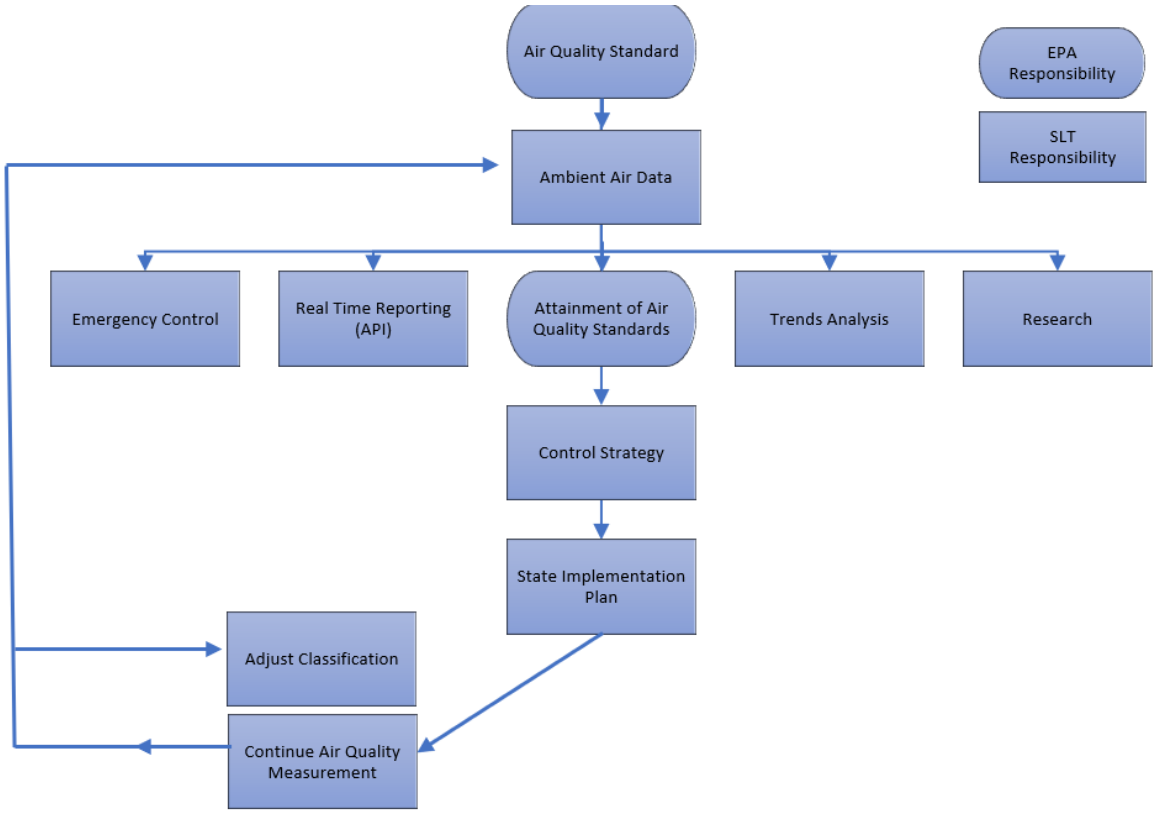


Figure 2-3 Ambient Air Quality Monitoring Process

2.6.1.1 Ambient Air Program Organization

While OAQPS provides oversight of and technical assistance to the ambient air quality networks, federal, SLT agencies all have important roles in developing and implementing air monitoring programs. Figure 2-4 identifies the major entities involved in the Ambient Air Quality Monitoring Program, the organizational structure, and the lines of communication. The responsibilities of each organization follow.

In general, most formal QA communication occurs in the pathway illustrated in the Figure 2-2. Primary QA organizations (PQAOs) are identified because each EPA Region consists of many PQAO's and each PQAO may consist of one SLT monitoring organization or be a consolidation of several monitoring organizations.

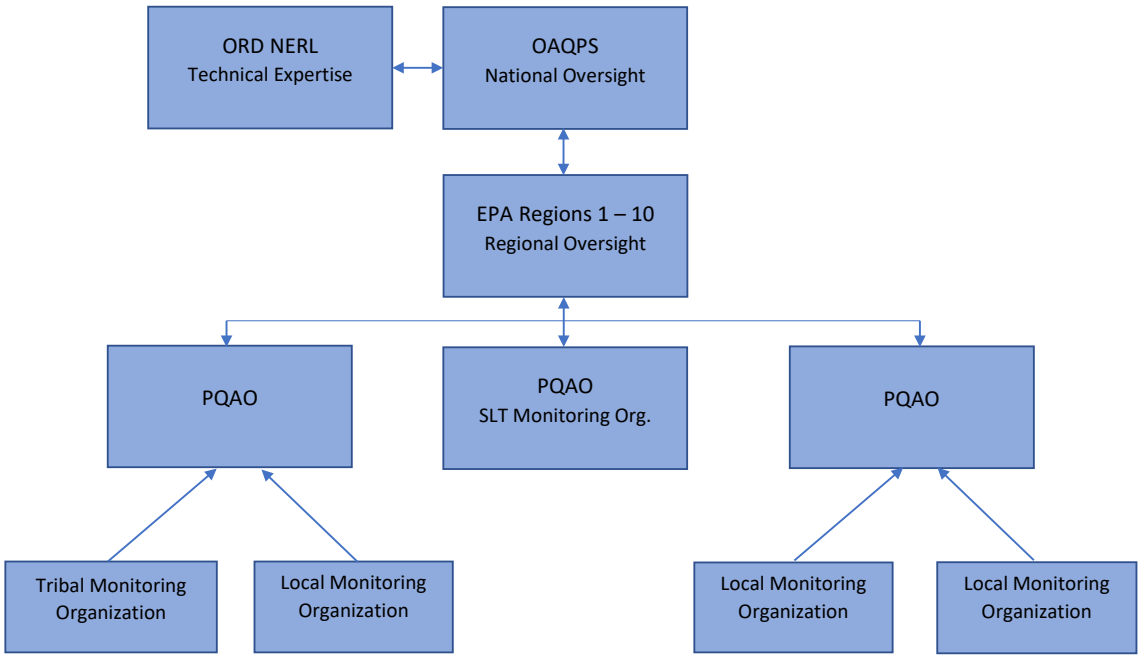


Figure 2-4. Program Organization and Lines of Communication

2.6.1.1.2 OAQPS

Within the OAQPS AQAD, the AAMG is responsible for the oversight of the Ambient Air Quality Monitoring Network and its QA program. AAMG, relative to QA, has the responsibility to:

- Develop a satisfactory QS for the Ambient Air Quality Monitoring Network;
- 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 appropriate quality;
- Manage the National Performance Audit Program (NPEP (which includes NPAP, PM2.5 PEP and Pb-PEP)));
- Perform DQAs of organizations making air pollution measurements of importance to the regulatory process;
- Ensure that guidance pertaining to the QA aspects of the Ambient Air Program are written and revised as necessary; and
- Provide technical assistance to the EPA Regional Offices and the air pollution monitoring community.

2.6.1.1.3 EPA Regional Offices

EPA Regional Offices play a critical role in addressing environmental issues related to the monitoring organizations within their jurisdiction and administering and overseeing regulatory and congressionally mandated programs. In addition, one Region serves a rotating two-year term as Lead Region for air quality monitoring and serves to coordinate and communicate monitoring issues to and from Headquarters and the other Regions.

The major QA responsibilities of EPA's Regional Offices regarding the Ambient Air Quality Program are the coordination of QA matters between the various EPA offices and the monitoring organizations. This role requires that the Regional Offices:

- Distribute and explain technical and QA information to the monitoring organizations;
- Identify QA needs of the monitoring organization to EPA Headquarters that are "national" in scope;
- Conduct TSAs of PQAOs as directed by CFR
- Provide personnel and the infrastructure to implement CFR mandated programs;
- Provide the personnel with knowledge of QA regulations and with adequate technical expertise to address ambient air monitoring and QA issues;
- Ensure monitoring organizations have approved QMPs and QAPPs prior to routine monitoring;
- Approve or delegate authority to approve QAPPs and QMPs;
- Evaluate the capabilities of monitoring organizations to measure the criteria air pollutants by implementing network reviews and technical systems audits of primary QA organizations (PQAOs);
- Assess data quality of monitoring organizations within its region; and
- Assist monitoring organizations in defining primary QA organizations within their jurisdiction and in assigning sites to a primary QA organization.

2.6.1.1.4 Monitoring Organizations and Primary QA Organizations

40 CFR Part 58 defines a monitoring organization as a "state, local or other monitoring organization (such as tribes) responsible for operating a monitoring site for which QA regulations apply," and a PQAO as a monitoring organization or a group of monitoring organizations that share a number of common "QA Factors".

The major responsibility of the monitoring organization is the implementation of a satisfactory monitoring program, which would naturally include the implementation of an appropriate QA program. Implementation of an appropriate QA program includes the development and implementation of a QMP and QAPPs for the Ambient Air Quality Monitoring Program. It is the responsibility of monitoring organizations to implement QA programs in all phases of the data collection process, including non-direct measurements, the field, its own laboratories, and in any consulting and contractor laboratories which it may use to obtain data.

Monitoring organizations may be identified for reasons such as:

- Distinguishing geographic regions (e.g. CA Districts);
- Distinguishing different entities or sources of funds (e.g., tribal funds versus state/local funds);
- Identifying organizations receiving funds directly from EPA; and

- Identifying organizations that have different methods or objectives for monitoring.

Therefore, if the monitoring organization accepts federal funds for monitoring, it will be identified as a monitoring organization that will be required to submit a requisite QMP and QAPPs to cover its monitoring activities. This does not eliminate it from consolidating to a PQAO with other organizations that it shares common factors.

A PQAO is a monitoring organization or a group of monitoring organizations that share several common "QA Factors". More complete information on PQAOs are found in 40 CFR Part 58, Appendix A.

The number and type of monitors and sites in a PQAO have very important implications to QA activities. For some pollutants, the number of monitoring sites in a PQAO may be used to determine the number and frequency of quality control checks, including the number of collocated monitors and the audit frequencies for the NPAP and the $PM_{2.5}$ and Pb PEP. Data assessments for completeness, precision and bias are aggregated at the PQAO level. The 5 common factors previously listed (a through e) are the key criteria to be used when an agency decides the sites to be considered for aggregation to a PQAO. There are cases where SLT monitoring organizations have consolidated to one PQAO. The requirement does not intend that all 5 factors must be fulfilled but that these factors are considered. However, common procedures and a common QAPP should be considered key to making decisions to consolidate sites into a PQAO. However, the QAPP(s) of the monitoring organizations must refer to the PQAO that the monitoring organization is affiliated with. EPA Regions will need to be aware of monitoring organizations consolidating to a PQAO and have documentation on file to this effect. It is strongly suggested that when an opportunity for QAPP revisions arise that monitoring organizations that have consolidated develop one overarching QAPP that cover both organizations.

2.6.1.2 The Ambient Air Monitoring Program Quality System

At the highest level, standards and regulations determine what QA is required for the monitoring program and, therefore, set the stage for program and project specific guidance. In addition to EPA Policies and QS requirements, the standards and regulations pertinent to the Ambient Air Quality Monitoring Program include 40 CFR Part 35 and 2 CFR 1500.11 which are not specific to air monitoring, documents like the CAA and 40 CFR Parts 50, 53 and 58 which are specific to ambient air monitoring. Part 50 and 53 may have MQOs listed that will be in a Monitoring Organizations QS, but 40 CFR Part 58, Appendix A is where the requirements reside for ambient monitoring.

Figure 2-5 represents the stages of the Ambient Air Quality Monitoring QA Program, which are consistent with the requirements for all of OAQPS as outlined throughout this document.

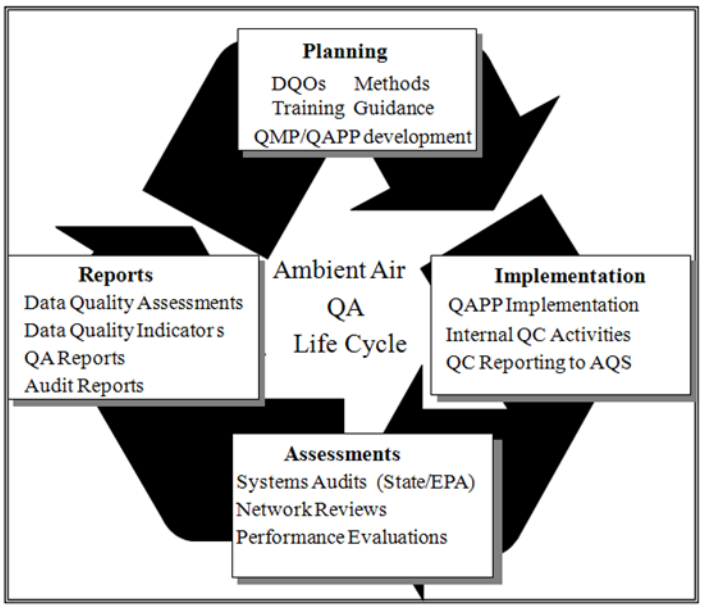


Figure 2-5. Ambient Air Quality Monitoring QA Program

2.6.1.3 Planning

QAPPs, QMPs and TSAs: For the Ambient Air Monitoring Program, preparation of QAPPs and QMPs are the responsibility of each monitoring organization. EPA Regions approve these documents and the submission and approval dates are reported to the EPA Air Quality System (AQS). In some circumstances QAPPs may be delegated to monitoring organizations for approval. Technical system audits are conducted by the EPA Regions to evaluate adherence to QAPPs.

DQOs and MQOs: As NAAQS come up for review for criteria pollutants, OAQPS reviews the data to determine if current DQOs are being met. If a DQO has not yet been developed, OAPQS will implement the DQO process. The majority of the ambient air monitoring programs have formal DQO for the collection of the data.

Once a DQO is established, the quality of the data must be evaluated and controlled to ensure that it is maintained within the established acceptance criteria. MQOs are designed to evaluate and control various phases (sampling, preparation, analysis) of the measurement process to ensure that total measurement uncertainty is within the range prescribed by the DQOs. MQOs can be defined in terms of DQIs (See Section 2.4.1.2).

- For each of MQO/DQI, acceptance criteria are developed for various phases of the EDO. Various parts of 40 CFR Parts 50 and 58 have identified acceptance criteria for some of these indicators. Tables of the most critical MQOs have been developed for the ambient air program and are presented both in the QA Handbook for Ambient Air Measurements Volume II –Ambient Air Monitoring Program as well as the technical assistance documents for the specific monitoring programs, which re posted on the Ambient Monitoring Technology Information Center (AMTIC).

Methods: Reference methods and measurement principles have been written for each criteria pollutant. For comparison to the NAAQS, monitoring organizations must use methods that are designated as a Federal Reference Method (FRM), Federal Equivalent Method (FEM) or an approved regional monitor (ARM) for $PM_{2.5}$. ORD NERL implements the FRM/FEM designation program and provides technical assistance in the $PM_{2.5}$ ARM process. Approved FRM/FEM methods refer to individual monitoring instruments that either provide a real-time pollutant concentration or a sample for further laboratory analysis and must be operated minimally as required in 40 CFR Part 50. Since these methods cannot be applied to the actual instruments acquired by each monitoring organization, they should be considered as guidance for detailed SOPs that are developed by monitoring organizations as part of an acceptable QAPP. Guidance methods for the non-criteria pollutants can be found in program specific technical assistance documents that are modified to SOPs specific to a monitoring organization.

Training: OAQPS has formal training and certification programs for the performance evaluation programs it implements. Training is also provided through national ambient air monitoring conferences, EPA regional office meetings, regional planning organizations (RCORs) and through various Centers like the Tribal Air Monitoring Support (TAMS) Center or the Air Pollution Training Institute.

Guidance: The *QA Handbook for Ambient Air Measurements Volume II –Ambient Air Monitoring Program* as well as many other guidance documents have been developed for the Ambient Air Quality Monitoring Program. Many of the monitoring networks have developed technical assistance documents and generic QAPPs to help guide personnel in the important aspects of these programs. These documents are posted on the Ambient Monitoring Technical Information Center (AMTIC) Website.

2.6.1.4 Implementation

Federal regulation provides for the implementation of several qualitative and quantitative checks to ensure that the data will meet the DQOs. Each of the checks attempts to evaluate phases of measurement uncertainty. The checks include precision and accuracy checks; xero/span checks; annual certifications; and calibrations. Specific information about these and other checks can be found in 40 CFR Part 58 Appendix A and in the *QA Handbook for Ambient Air Measurements Volume II –Ambient Air Monitoring Program*.

2.6.1.5 Assessments and Reports

Assessments for the Ambient Air Quality Monitoring Program include:

- Onsite TSAs of SLT ambient air monitoring programs to assess compliance with established regulations governing the collection, analysis, validation, and reporting of ambient air quality data. Both EPA and state organizations perform TSAs and they are required in the Ambient Air QA Requirements (40 CFR Part 58 Appendix A);
- Network Reviews to determine how well a particular air monitoring network is achieving its required air monitoring objective(s) and how it should be modified to continue to meet its objective(s) (40 CFR Part 58.10);

- Regional level data assessments to evaluate the attainment of the DQOs and reports of these assessments or reviews. These assessments include DQAs of precision, bias, and accuracy at the monitor, PQAO and National level; QC Reporting to AQS; QA reports that assess DQOs; and the analysis of performance evaluation samples.

Table 2-2. Ambient Air Quality Monitoring Program Performance Evaluations

Program	PE Program Overview
NPAP	The NPAP provides audit standards for gaseous pollutants either as devices that the site operator connects to the back of the instrument or are sampled through a probe. Flow audit devices and lead strips are also provided through NPAP.
$PM_{2.}$ PEP	The strategy is to collocate a portable FRM $PM_{2.5}$ air sampling audit instrument with an established primary sampler at a routine air monitoring site, operate both samplers in the same manner, and then compare the results.
Pb-PEP	The strategy is to collocate a portable FRM Pb air sampling audit instrument with an established primary sampler at a routine air monitoring site, operate both samplers in the same manner, and then compare the results
NATTS PT	A NATTS proficiency test (PT) is a type of assessment in which a blind sample is provided to a laboratory to test whether the analyst/laboratory can produce analytical results within the specified acceptance criteria.
SRP	Upon certification of the NIST Standard Reference Photometer (SRP) by ORD, it is shipped to the EPA Regions to certify the SRP that remains stationary in each Regional Lab. These Regional stationary SRPs are then used to certify the ozone transfer standards that are used by the SLT monitoring organizations.
PAMS Cylinder Certs	EPA developed a system to certify the standards used by the monitoring organizations to calibrate their PAMS analytical systems. The standards are prepared by a contract laboratory, then sent to an independent laboratory for analysis and certification, then compared to the vendor concentrations ensure they meet the contractually required acceptance tolerance.
CSN/IMPROVE $PM_{2.5}$ Speciation and gravimetric PEs & lab TSAs	$PM_{2.5}$ CSN and IMPROVE PEs are developed in ambient air; therefore, the true concentration is unknown. Samples are collected for gravimetric analysis, elements by x-ray fluorescence, cations and anions by ion chromatography, and elemental and organic carbon. The samples are analyzed by contract laboratories for both the CSN and IMPROVE Networks, as appropriate, and the reported concentrations are analyzed to determine general agreement among the laboratories. OAQPS also implements TSA's of IMPROVE and CSN laboratories.
Protocol Gas	EPA Protocol Gases are used in QC activities (i.e., calibrations, audits etc.) to ensure the quality of data derived from ambient air monitors used by every state in the country.

All concentration data require data assessments at the Regional level to evaluate the attainment of the DQOs and reports of these assessments or reviews. These assessments include:

- DQAs of precision, bias, and accuracy at the monitor, PQAO and National level

- Annual AQS AMP251, AMP256, and AMP450 and AMP600 reports to evaluate the precision and accuracy of data against the acceptance criteria
- QA reports, which provide an evaluation of QA/QC data for a given time period to determine whether DQOs were met. These reports are produced for several monitoring programs and may be performed annually or at 3-year time intervals ($PM_{2.5}$)
- Meetings and Calls at various national meetings and conference calls can be used as assessment tools for improving a network.
    - It is important that information derived from the avenues of communication are appropriately documented.

2.6.2 National Emissions Inventory

The National Emissions Inventory (NEI) is created to provide the EPA, federal, SLT decision makers, and the national and international public the best and most complete estimates of criteria air pollutant and precursor (CAP) and HAP emissions. While the EPA is not directly obligated to create the NEI, the Clean Air Act authorizes the EPA Administrator to implement data collection efforts needed to properly administer the NAAQS program. Therefore, OAQPS maintains the NEI program in support of the NAAQS. Furthermore, the Clean Air Act requires states (or their delegates) to submit emissions to the EPA as part of their SIPs that describe how they will attain the NAAQS. The NEI is used as a starting point for many SIP inventory development efforts and for states to obtain emissions from other states needed for their modeled attainment demonstrations.

While the NAAQS program (and the CAA) is the basis on which the EPA collects CAP emissions from the SLT air agencies, the CAA does not require collection of HAP emissions. For this reason, the HAP reporting is voluntary. Nevertheless, the HAP emissions are an essential part of the NEI program. These emissions estimates allow EPA to assess progress in meeting HAP reduction goals described in the Clean Air Act amendments of 1990. These goals seek to lessen the negative impacts to people of HAP emissions in the environment, and the NEI allows the EPA to assess how much emissions have been reduced since 1990.

To create the NEI, the EPA takes many steps that result in a release of the NEI every three years, with both updates to the triennial inventories and interim-year inventories created as needed to support EPA projects. Each of these steps is listed below along with identification of oversight needs and points of internal coordination for QA and QC activities.

EPA and SLTs are working to create business rules and build data collection computer software that streamlines emissions data collection from regulated entities (i.e., industry). Currently, EPA and SLTs collect emissions data from regulated entities under a variety of authorities under numerous programs using a variety of formats and different reporting schedules. Harmonizing reporting is expected to provide a single consolidated website where integrated emissions inventory information could be found in a consistent and transparent fashion. While the CAER software development process doesn't involve EDOs, its description is included here for completeness.

2.6.2.1 Collection of emissions data and inputs from external data partners

For this step, a process exists to collect data from SLT air agencies as well as from the Department of Interior's Bureau of Ocean Energy Management (BOEM). State and local agencies are required to submit CAP data in accordance with the Air Emissions Reporting Rule (AERR); 40 CFR 51 Subpart A. Tribes can voluntarily submit the data unless they have been delegated the authority for their territory by the state, in which case the same requirements apply. States may also delegate to local air agencies. The rule requires that some emissions sources be reported as point sources (individual facilities), other sources be reported as nonpoint emissions (county totals), and mobile data be reported as model inputs for all states except California, which is required to submit mobile emissions because they use a customized EPA-approved mobile source model. All SLT air agencies can voluntarily submit HAPs and GHG emissions. In addition, SLT air agencies and forestry agencies can provide data regarding the timing, location, and activity levels for prescribed burning and wildfires, which the EPA uses to create an "events" inventory of the emissions from these fires. In the case of offshore oil and gas platforms, the BOEM computes emissions from these sources and sends data to EPA.

The format and required data fields for submission are specified by the AERR. In most cases, the Emissions Inventory System (EIS) is the required mechanism for submitting the data to the EPA. In some cases (e.g., fires activity, nonpoint input data, new tools), collection of data is managed through other techniques including email and SharePoint. The collection step includes EPA staff communication of changes to SLTs about the required or voluntary aspects of reporting. In addition, EPA staff review data and communicate with the SLT agencies as needed to ensure complete collection.

2.6.2.2 Collection of emissions data from other federal programs (point, nonpoint, mobile, events)

To help achieve completeness in the NEI, the NEI team staff and contractors collect and use other federal data sources to augment where the SLT data may be incomplete for point sources. In addition, EPA staff and contractors collect and use a variety of data sources at the state and/or county levels as a starting point for estimating county-level activities for the nonpoint and mobile data categories. Coordination is needed between EPA staff and contractors who assist with some of these activities.

2.6.2.3 Development of emissions calculation methods (nonpoint and commercial marine vessels for ports and county totals)

For all nonpoint categories and commercial marine vessels, NEI team staff lead the development, QA, and publishing of emissions methods, models and tools for use in the NEI. These methods, models and tools can include custom software, Microsoft Access databases, and Microsoft Excel spreadsheets. For some specific nonpoint sectors (e.g., fertilizer ammonia, biogenic vegetation and soils, and agricultural burning), the EPA ORD has active research improving emissions estimation methods on which the NEI team staff rely to estimate emissions. In many cases, SLT air agencies choose to use these EPA-developed methods as a means of meeting their AERR reporting requirements for those sectors. Coordination is needed among EPA staff, contractors, and SLT agency staff.

2.6.2.4 Development of augmentation factors to calculate emissions of one pollutant based on emissions of another pollutant (point, nonpoint, events)

EPA staff uses various data sources to create pollutant ratios for the purpose of computing emissions of one pollutant (e.g., a HAP volatile pollutant) from another pollutant for which data are available from a SLT agency (e.g., volatile organic compounds). This step is needed when SLT agency data are incomplete (as is the case for PM components), when SLT agencies provide a summed pollutant but pollutant components are needed for NEI (e.g., SLT can report total chromium but NEI publishes trivalent chromium and hexavalent chromium), or to augment for unreported HAPs scaling from reported criteria air pollutants. These ratios can be based on a variety of internal and external data sources, including the SPECIATE database, emission factors from WebFIRE, non-EPA emission factors, source test data, emissions reported from other similar sources, and from the peer-reviewed literature.

Additionally, EPA staff apply factors from the SPECIATE database and a cross-reference assignment to sources to calculate the PM model species (organic carbon, elemental carbon, sulfate, nitrate, and crustal/other) and label DIESEL PM. Coordination is needed among the NEI team staff and with the EMT staff.

2.6.2.5 Development of inputs to tools and models (mobile, nonpoint, events)

EPA staff and EPA contactors create inputs for the models and tools used to estimate emissions for mobile sources, nonpoint sources, and events. This task involves data processing and manipulation of other data sources to convert the information into the formats and resolution needed by the models and tools. Coordination is needed between EPA staff and contractors.

2.6.2.6 Using models and tools to create emissions (point airports, point rail yards, point ports, mobile, events, nonpoint)

EPA staff, EPA collaborators, and contractors use models and tools that take input data and create emissions estimates. For aircraft and support equipment at airports, the EPA uses a Federal Aviation Administration (FAA) model. For rail yards, the EPA relies on a system developed by the Eastern Research Technical Advisory Committee (ERTAC) whose members also gather the input data and run the tools for use in the NEI. For point source ports, the EPA relies on programs that process satellite-based tracking data for commercial marine vessels. For onroad mobile sources and nonroad equipment, the Office of Transportation and Air Quality (OTAQ) publishes the Motor Vehicle Emissions Simulator (MOVES), which OAQPS uses to estimate emissions for the NEI. For events (prescribed burning and wildfires), the EPA adapts a series of models developed by the US Forest Service, known collectively as BlueSky/SMARTFIRE. For nonpoint sources, OAQPS uses tools that EPA staff and contractors develop as described above. Coordination is needed between EPA staff and EPA collaborators or between EPA staff and contractors who run these tools and models and deliver the output data for evaluation and use by EPA staff.

2.6.2.7 Compilation of inventory data into a data release

EPA staff use the EIS to compile the emissions inventory data into a data release, which involves selecting the best available data from all the individual datasets loaded into EIS. EPA staff make sure that any data not submitted to EIS directly are loaded into the EIS. EPA staff design a "selection" that specifies the priority order of available datasets for each pollutant and emissions process. EPA staff run the EIS to create a "selection" of data, and then they evaluate it to ensure that the intended data outcomes have been achieved. NEI team staff must coordinate during the selection process among themselves and with the EIS system owners. Depending on QA findings after the data selection, multiple selections may be run.

2.6.2.8 Public release of data (summaries, website, and posting data outside EIS firewall)

NEI team staff use the EIS to create emissions summaries and provide data electronically outside of the EIS firewall. Summaries and other data releases must be checked for consistency with the raw NEI data, with one another, and to ensure that each of the summaries or data tables provided externally match the formats and content required for the individual distribution mechanisms that they support. Examples of distribution mechanisms include the Air Emissions Inventory website, the Qlik NEI Report, the Air Emissions Modeling website, EnviroFacts, and the Facility Registry Service (FRS).

2.6.3 Trends Analyses

2.6.3.1 Emissions Trends

The emissions trends process uses NEI data across the years to create emissions trends by aggregated emissions sectors called "Tier 1", including projections for some sectors from the last NEI year to the most recently ended calendar year. For some sectors and years, special datasets are used to improve estimates beyond what had been developed for a historical inventory year. In addition, missing years for some sectors are interpolated to provide data for each Tier 1 group and year. For some criteria pollutants, elemental carbon, organic carbon, and some HAPs, the EPA uses other categorizations than the Tier 1 groups to supply emissions trends for other purposes including the ORD Report on the Environment and international reporting requirements.

2.6.3.1.1 Compilation of data sources

The emissions trends staff lead gathers all the data to be used for emissions trends and puts the data into a consolidated dataset for processing using custom computer programs. The compilation is maintained over time to be modified with data updates rather than compiling the data anew each time the trends data are produced. Modifications include adding additional years of data as well as replacing past years with improved or corrected versions of data for those years. QA is needed to make sure that the compiled data matches the totals of the original data. Coordination is needed between the emissions trends staff lead, the NEI team staff, and sometimes the EMT staff depending on the sources of data used for an update to the emissions trends.

2.6.3.1.2 Development and implementation of aggregation and augmentation software and approaches

EPA staff use the latest map of source classification codes to Tier 1 categories or other categories as needed. EPA staff develop updated crosswalks of the codes to special categories that are needed for other purposes to ensure that any new codes in a new inventory are included. EPA staff develops and tests software programs (e.g., SAS programs) that aggregate the compiled data sources into the appropriate categories. Coordination or manager oversite is needed to ensure categories are defined appropriately.

2.6.3.1.3 Public release of data (summaries and website)

EPA staff use custom software programs and the EIS to create emissions summaries and provide data electronically on the website. Summaries and other data releases must be checked for consistency with one another and to ensure that each of the summaries or data tables provided externally match the formats and content required for the individual distribution mechanisms that they support. Examples include the Air Emissions Inventory website, the Convention on Long-range Transboundary Air Pollution (LRTAP), and the Report on the Environment. The EIS data manager also publishes data from the EIS system to database locations outside the EPA firewall for sharing data with some users.

2.6.3.2 Air Quality Trends

EPA develops an air quality trends report and accompanying data summaries that are published annually on the AirTrends website. To assess trend in ambient concentrations, EPA staff retrieves ambient monitoring data from the Air Quality System (AQS). The current national ambient air quality monitoring network is comprised of thousands of measurement sites located across the country that report data to AQS. This network is developed through state and local air quality agencies and is based on well-established network design and monitor siting criteria. The primary purpose of the national air monitoring network is to provide the data necessary to assess protection of public health and the environment.

2.6.3.2.1 Trends methodology

EPA staff query AQS for the relevant annual summary statistics for each criteria pollutant, along with information necessary for assessing annual completeness. Because the aim is to assess trends in actual concentrations, data flagged as influenced by exceptional events are included. Only summary statistics that meet minimum annual completeness criteria are used. Trend sites, which are used in national or regional trends assessments, must have valid annual summary statistics for at least 75 percent of the years during the trend period. In addition, trend sites must not be missing more than two consecutive years of data. Simple linear interpolation is employed to fill in for missing years. Missing end years are replaced with the value of the nearest year. The interpolated data set is used for assessing national and regional trends. The uninterpolated data set is used for assessing trends at individual sites. A nonparametric test is used to detect statistically significant trends.

2.6.3.2.2 Public release of data (summaries and website)

EPA publishes an annual, interactive air trends report available from the AirTrends website. The online report features a suite of visualization tools that enable citizens, policymakers and stakeholders to view and download detailed information by pollutant, geographic location and year. The report content can easily be shared across social media sites. Data, source code, and documentation are available for download at the air trends report GitHub repository https://github.com/USEPA/Air-Trends-Report.

2.6.4 Emissions Inventory Modeling Platform

The OAQPS Emissions Modeling Team (EMT) develops emissions modeling platforms to support air quality modeling performed by the EPA for various regulatory and analytical purposes. Regulatory purposes include analysis of transport across state boundaries to support Transport SIPs and modeling of projected future-year ambient air quality for Regulatory Impact Analyses. Other analytical purposes include model development by the Office of Research and Development and the NATA.

The emissions modeling platform consists of the emission inventories, the ancillary data files, and the approaches and tools used to transform inventories for use in air quality modeling. Many emissions inventory components of an emissions modeling platform are based on the NEI, although there can be differences between the platform inventories and an NEI as a result of addressing technical issues, public comments, and the incorporation of newly available data and improved methods. Emissions modeling platforms include all CAPs and most HAPs available from the NEI. Different chemical mechanisms are used by different air quality models, each of which has its own input formats and requirements, and so each emissions modeling platform must adapt to the requirements of the model(s) that it will be supporting. For instance, some air quality models require as input hourly and gridded emissions of chemical species that correspond to CAPs and specific HAPs. Other air quality models, such as dispersion models, have different spatial and temporal allocation requirements and may not include chemical speciation.

2.6.4.1 Collection of emissions data from countries in the gridded modeling domain

In addition to the NEI, the EPA uses other countries' emissions data to augment the inventories, since the gridded modeling domains usually cover areas over Mexico and Canada. Additionally, for some hemispheric modeling projects, the EPA collects data from countries throughout the Northern Hemisphere. In additional to emissions inventory data, these data can include factors for temporal allocation, spatial allocation, or chemical speciation. Coordination is needed between EPA staff, other countries, and contractors who assist with some of these activities.

2.6.4.2 Ancillary data development (speciation, gridding, temporal allocation, growth/contraction to future year, controls impacts in future year)

Ancillary data development includes the collection, manipulation, and use of other data sources to create input files for the SMOKE system. For speciation, the EMT staff rely on the SPECIATE database for the raw data needed to develop speciation profiles. EMT staff and contractors use the Speciation Tool to aggregate the SPECIATE data to the grouped chemical

species needed for air quality models. To assign the speciation profiles to emissions sources, the EMF staff collaborate with stakeholders and contractors to build a speciation cross-reference file.

For temporal allocation, the EMT staff and contractors maintain temporal allocation factors and cross-reference files to map the temporal allocation factors to emissions sources. EMT staff and contractors periodically review the temporal allocation factors, find areas of needed improvement, research improved methods, and implement new factors and cross references.

For spatial allocation, the EMF staff relies on numerous geographic datasets available from other federal agencies including the Census Bureau and the US Geological Survey as a starting point for creating spatial allocation factors. EMT staff and contractors use the Spatial Allocator to create spatial surrogates for gridded modeling domains or for census tracts (for dispersion models). To assign the spatial surrogates to emissions sources, the EMT staff members collaborate with stakeholders and contractors to build a spatial surrogate cross-reference file.

For future-year growth and contraction estimates, the EMF staff and contractors rely on data from various federal sources including the Department of Energy and the Department of Agriculture. Data such as fuel usage or animal populations can be mapped to be used as a surrogate for emissions growth and contraction of the emissions sectors for which those surrogates apply. Emissions are also reduced in the future due to emissions control requirements, and EMT staff and contractors mine information available from EPA regulations, SLT regulations, facility closure databases, and consent decrees to determine future emissions reductions. The efforts for controls include coordination across different parts of EPA, with SLTs, and with contractors. In the case of a Regulatory Impact Assessment (RIA), EMT staff rely on other staff across OAR to develop “control scenarios,” which are provided to OAQPS via a Control Strategy Tool module in the EMF.

For some emissions sectors, namely utilities and mobile sources, models are available to project future emissions. OAQPS relies on OAP staff and contractors to run the Integrated Planning Model (IPM) for future-year utility emissions. EMF staff and contractors use OTAQ’s MOVES model for future year emissions estimates for onroad vehicle and nonroad equipment sources. Coordination is needed among EPA staff in different offices and multiple contractors to ensure the quality of the results.

2.6.4.3 Setting up and managing emissions modeling cases

When preparing emissions for air quality models, EPA and contractor users of SMOKE and EMF must ensure that the correct input data files are used as well as the correct SMOKE settings. The EMF allows all collaborators to see the selected input files and settings, which facilitates communication across the team to promote quality. The inputs and settings need to be customized for each emissions sector processed through SMOKE, which can have dozens of separate runs to process emissions for all sectors. Once all sectors have been processed, the EPA and contractor users of SMOKE and EMF merge the results together to create the input files for the air quality models.

2.6.4.4 Running emissions models

EPA contractors run SMOKE to process emissions, and SMOKE creates numerous summary files and log files that are then analyzed by EMT staff and contractors. As SMOKE generates outputs, the EMT staff and contractors use standard QA checks to make sure that the results are what is expected based on the inputs data and other settings chosen.

2.6.4.5 Public release of data (packaging platforms, creating summaries, website)

EPA staff and contractors gather all the input files, programs, and scripts into data packages for posting on the Air Emissions Modeling website and sometimes put onto disk drives of collaborators and customers. Summaries and other data releases must be checked for consistency with one another and to ensure that each of the summaries or data tables provided externally match the formats and content required for the individual distribution mechanisms that they support.

2.6.6 Air Quality Modeling

The Air Quality Modeling Group within OAQPS is responsible for:

- Conducting air quality modeling and related evaluations and analyses integral to regulatory and policy decisions within the Office of Air and Radiation (OAR) for multiple pollutants, sources and spatial scales (e.g., international, national, regional, and local, etc.);
- Completing regulatory updates to the EPA's *Guideline on Air Quality Models* (also published as Appendix W of 40 CFR Part 51) including development, maintenance and updates to the EPA's preferred dispersion model, AERMOD, that informs various regulatory programs under the Clean Air Act (CAA); and
- Collaborating with the research community within EPA and externally to promote policy relevant improvements in the atmospheric models to better inform regulatory and policy decisions.

Air quality models use mathematical and numerical techniques to simulate the physical and chemical processes that affect air pollutants as they disperse and react in the atmosphere. These models are important to our air quality management system because they are widely used by agencies tasked with controlling air pollution to both identify source contributions to air quality problems and assist in the design of effective strategies to reduce harmful air pollutants. The air quality models used to inform CAA programs will include: (1) dispersion models that use mathematical formulations to characterize the atmospheric processes that disperse a pollutant emitted by a source, and (2) photochemical models that simulate the changes of pollutant concentrations in the atmosphere at regional, national and global scales using a set of mathematical equations characterizing the chemical and physical processes in the atmosphere.

AQMG applies both dispersion and photochemical models to inform regulatory and policy decisions within OAR and is responsible for determining the EPA preferred air quality models and techniques to be used to inform regulatory programs under the CAA through its *Guideline on Air Quality Models*. Each of these work areas is discussed below along with identification of

internal coordination for QA and QC activities.

2.6.6.1 Dispersion Model Applications

Dispersion models are commonly used to determine compliance with NAAQS, and other regulatory requirements such as NSR and PSD regulations. OAQPS addresses the regulatory application of these models in EPA's *Guideline on Air Quality Models* (also published as Appendix W of 40 CFR Part 51). Consistent with the *Guideline*, AQMG conducts dispersion modeling to inform regulatory and policy decisions within OAR and to assist Regional offices in their approval of compliance demonstrations for PSD and SIP actions that assess source culpability and control strategies. These dispersion model applications include the following:

1) Review of the NAAQS;
2) Policy development and legal requirements for implementation programs under the Clean Air Act (CAA); and
3) Communication and outreach efforts.

These dispersion applications inform projects that involve federal rulemakings with technical support documents and model evaluation reports being developed and made available on project specific EPA websites or generally available on EPA's Air Modeling - Reports and Journal Articles website. The dispersion models used by AQMG are specified in the *Guideline* as "EPA preferred models" with full documentation provided as part of the Action Development Process (ADP) including proposed and final rulemakings with public review and comment. An overview of the ADP process is provided in Section 2.9.7.

An example would include the use by the Agency as part of its Risk and Exposure Assessment (REA) for the SO_2 NAAQS Review which fully documents the dispersion model use for this REA and includes model performance evaluation that justifies its use.

For dispersion model applications, the project level QAPP is developed that refers to the need for pollutant concentration inputs based on dispersion modeling. That project level QAPP will reference the AQMG's Dispersion Model Application QAPP that will ensure quality assured modeling inputs for that particular regulatory and/or policy application.

2.6.6.2 Photochemical Model Applications

AQMG conducts photochemical modeling to inform regulatory and policy decisions in OAR including the following:

1) Review of the NAAQS;
2) Policy development and legal requirements for implementation programs under the Clean Air Act (CAA); and
3) Communication and outreach efforts.

These photochemical applications typically inform projects that involve federal rulemakings with technical support documents and model evaluation reports being developed and made available on project specific EPA websites or generally available at the Support Center for Regulatory Atmospheric Modeling (SCRAM) website. The photochemical models used by AQMG are

subjected to separate peer-review processes with justification for their use being determined and documented as part of the ADP including proposed and final rulemakings with public review and comment.

An example would include the application of the Office of Research and Development's Community Multi-scale Air Quality Model (CMAQ) that is subjected to periodic peer-review as it evolves with scientific input from modeling community and stakeholders. It was recently used by the Agency as part of its Tier 3 Motor Vehicle and Emission Fuel Standards with the technical support document that fully documents the photochemical model application for this rulemaking and includes model performance evaluation that justifies its use for this particular action.

For photochemical model applications, the project level QAPP is developed that refers to the need for pollutant concentration inputs based on photochemical modeling. That project level QAPP will reference the AQMG's Photochemical Model Application QAPP that will ensure quality assured modeling inputs for that particular regulatory and/or policy application.

2.6.6.3 Development, Maintenance, and Updates to Preferred Air Quality Models

EPA's OAQPS determines the air quality models and techniques to be used to inform regulatory programs under the CAA through its *Guideline on Air Quality Models*. The *Guideline* was originally published in April 1978 to provide consistency and equity in the use of modeling within the U.S. air quality management system. Specific EPA approved, or preferred, air quality models are listed in Appendix A of the *Guideline*. These guidelines are periodically revised through rulemaking following the EPA's ADP to ensure that quality information supports all new model developments or regulatory recommendations and/or requirements that are incorporated into the *Guideline*.

The *Guideline* is used by EPA; SLT air agencies; and industry to prepare and review new source permits and SIP/TIP revisions. The *Guideline* is intended to ensure consistent air quality analyses for activities regulated at 40 CFR 51.112, 51.117, 51.150, 51.160, 51.166, and 52.21. OAQPS originally published the *Guideline* in April 1978 and it was incorporated by reference in the regulations for the PSD of Air Quality in June 1978. OAQPS revised the *Guideline* in 1986, and updated it with supplement A in 1987, supplement B in July 1993, and supplement C in August 1995. OAQPS published the *Guideline* as appendix W to 40 CFR part 51 when OAQPS issued supplement B. On April 21, 2000 OAQPS issued a Notice of Proposed Rulemaking (NPR) in the Federal Register (65 FR 21506), which was the original proposal for the promulgation of the AERMOD modeling system, the EPA's preferred dispersion model for near-field modeling applications.

Most recently, the model formulation of the AERMOD modeling system was updated through regulatory revisions to the *Guideline* in January 2017. In accordance with the *Guideline*, after a one-year grandfathering period, it was fully promulgated as of January 17, 2018 as the preferred dispersion model for near-field modeling under NSR and PSD programs as well as other CAA programs as specified in the *Guideline* (e.g., Transportation conformity). Through adherence to the ADP, as described in section 2.6.7.1, this regulatory action was based on the supporting information contained in the docket that reflects peer review and was developed in adherence

with EPA's QA policy and procedures and also reflected public comments gained through the notice and comment rulemaking process. However, the state-of-the-science for modeling atmospheric deposition continues to evolve, the best techniques are currently being assessed, and their results are being compared with observations. To facilitate the continual improvement in EPA approved dispersion models, the Agency convenes a *Conference on Air Quality Modeling* as required by Section 320 of the CAA to be held every 3 years. The purposes of these conferences are to provide an overview of the latest features of the new air quality models and to provide a forum for public review and comment on potential revisions to the way the Agency determines and applies the appropriate air quality models in the future. These comments on the *Guideline* and associated revisions assist the Agency in introducing improved modeling techniques into the regulatory process.

For periodic maintenance updates to the AERMOD modeling system, an AERMOD Release QAPP will be developed based on AQMG's AERMOD Development and Update report to ensure adherence to EPA's QA system in the process of these periodic model updates.

2.6.7 Rule Writing

2.6.7.1 Action Development Process

The ADP is a comprehensive framework for producing quality actions, and OAQPS uses the ADP as its template/model for developing its rules. The process ensures that OAQPS uses quality information to support its rules and ensures that scientific, economic, and policy issues are adequately addressed at the right stages in the rule development. The details of the ADP are documented in *EPA's Action Development Process – Guidance for EPA Staff on Developing Quality Actions* (March 2018), and contains four key elements and five major stages, as outlined in the linked document.

2.6.7.1.1 ADP Key Elements

1) Includes steps for planning sound scientific and economic analyses to support the action, including peer review, when necessary.
2) Includes steps for developing and selecting regulatory and nonregulatory options based on relevant scientific, economic and policy analyses.
3) Ensures early, active and appropriate cross-agency participation by both managers and staff from program and Regional offices.
4) Encourages appropriate and meaningful consultation with external stakeholders in the process through substantive consultative procedures.

2.6.7.1.2 ADP Major Stages

1) Tiering the Action and Obtaining Commencement Approval;
2) Developing the Proposed Rule or Draft Action;
3) Requesting OMB Review (if necessary) for Proposed (and Final) Actions;
4) Requesting Signature, Publishing an Action in the Federal Register, and Soliciting and Accepting Public Comment; and

5) Developing the Final Action and Ensuring Congressional Review.

2.7 Scientific Integrity Policy

Science is integral to EPA's decision-making, and the Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies. In 2012, EPA established a Scientific Integrity Policy to ensure that sound science drives Agency decision making. In this document, "science" and "scientific" are expansive terms that refer to the full spectrum of scientific endeavors, e.g., basic science, applied science, engineering, technology, economics, social sciences, and statistics. The term "scientist" refers to anyone who collects, generates, uses, or evaluates scientific data, analyses, or products.

This policy provides a framework intended to ensure scientific integrity throughout EPA and promote scientific and ethical standards, including quality standards; communications with the public; the use of peer review and advisory committees; and professional development. It also describes the scope and role of a standing committee of Agency-wide scientific integrity officials to implement this policy.

OAQPS follows the applicability and implementation requirements outlined in the policy.

2.7.1 Scientific Integrity Committee

The Agency has appointed Francesca T. Grifo as the Scientific Integrity Official to champion scientific integrity throughout the Agency. The Scientific Integrity Official chairs a standing committee of Deputy Scientific Integrity Officials representing each EPA Program Office and Region. These senior- level employees provide oversight for the implementation of the Scientific Integrity Policy at EPA, act as liaisons for their respective Programs and Regions, and are available to address any questions or concerns regarding this policy.

The Agency's Scientific Integrity Committee is charged with implementing, reviewing, and revising, as needed, policy governing the four specific areas of scientific integrity described in more detail in the Policy. These areas are a) the culture of scientific integrity at the EPA, b) public communications, c) the use of peer review and Federal Advisory Committees, and d) professional development of government scientists.

OAR's Deputy Scientific Integrity Official, Betsy Shaw, provides representation on this Committee. OAQPS' Scientific Integrity Liaison communicates Scientific Integrity issues directly to OAR's Scientific Integrity Official.

2.8 Field Operations Group (FOG) Operational Guidelines for Field Activities

A National Field Operations Group (FOG) exists under EPA's Regional Science and Technology (RS&T) Organization and is charged with promoting national consistency among the Agency's field activities. Examples of field operations include, but are not limited to sampling, monitoring, field measurements, investigations, inspections, surveys, some enforcement activities as well as emergency and remediation cleanup activities.

The Procedure applies to all EPA organizations including Headquarters Offices, Program Offices, Regions, National Research Laboratories and Centers, and their sub-organizations whose EPA employees conduct field activities.

While OAQPS does not frequently engage in field operations, when field operations occur the FOG Guidelines will be used in conjunction with the OAQPS QMP for project planning and implementation. When used together, the FOG Guidelines and the OAQPS QMP provide a means for defensible field data collection from initiation to repository and, ultimately, decision-making. The CIO 2105-P-02.0 *EPA QA Field Activities Procedure* was approved by the CIO September 23, 2014 and reviewed on September 23, 2017.

3 Personnel Qualifications and Training

A critical function of the mandatory Agency-wide QS (CIO 2105.0) is identifying, developing, and implementing QA training programs. All OAQPS personnel involved with environmental data operations are required to have the appropriate QA training as outlined in the following sections. Additionally, it is the supervisor's responsibility to ensure that the individuals in their organizations meet the minimum QA training requirements for their assigned activities.

The staff members of OAQPS are expected to have met the educational, work experience, and training requirements for their positions, as outlined by the Office of Personnel Management in their position descriptions. OAQPS requires appropriate training for its employees, supporting contractors, and grantees. Such training may consist of classroom lectures, workshops, teleconferences and on-the-job training. Courses may be mandatory, such as QA, safety, CBI, and contract and grant management; or non-mandatory, such as leadership, teamwork, ambient and stationary source data collection, and the development of QAPPs and DQOs for data collection and analyses.

At the end of each fiscal year, a summary of the QA training offered in OAQPS will be summarized in the QAARWP. The summary will include the courses offered and the number of attendees for both EPA and non-EPA training offerings.

3.1 QA Training

The Environmental Quality Management Division (EQMD), within the Office of Enterprise Information Programs (OEIP) develops a variety of traditional training materials on QA activities and the EPA QS. These materials are posted on epa.gov and are periodically updated. The EQMD courses are generic in nature, therefore OAQPS tailors them with program-specific activities or information to provide context, emphasis and relevance to OAQPS programs.

The EQMD is responsible for coordinating the implementation of the Agency Quality System, developing Agency policies and procedures on quality, and providing training on quality issues. The EQMD accomplishes these activities by developing Agency guidance and policy; providing training and training aids for quality assurance procedures; reviewing Agency QMPs and recommending Agency approval; assessing implementation of established QMPs; facilitating communication among members of EPA's QA community; and providing general outreach and consulting services to the EPA QA community.

The OEIP helps ensure the proper collect, use, release, and management of EPA information. OEIP leads the Agency's Paperwork Reduction Act (PRA), dockets, records and Section 508 of the Rehabilitation Act programs. The Office also houses the Agency's Electronic Discovery (eDiscovery) Program, the EPA Quality Program, the Agency's National Library Network, Controlled Unclassified Information Program, and FOIAonline Program, which supports certain federal agencies' management of their Freedom of Information Act (FOIA) requests.

3.1.1 QA Personnel

The OAQPS QAM, and DQAOs because they will be responsible for review and approval of QAPPs and QARFs, are required to take three courses:

1. Introduction to EPA Quality System Requirements;

   This course is intended to introduce the concepts of quality management and includes an overview of the Agency's QS; an overview of basic QA concepts; and a description of the application of these concepts to environmental programs involving the collection or use of environmental data. Topics covered include QA terms and nomenclature; roles and responsibilities; and principal QA activities. The course will be tailored with program specific information to provide context and relevance to the target audience.

2. Introduction to Data Quality Objectives

   This course teaches participants the Agency's QS; basic elements of the Data Quality Objectives (DQO) Process; how the process applies to a regulatory program at EPA; and how to interpret the consequences of potential decision errors.

3. Introduction to Quality Assurance Project Plans

   This one-day course provides an overview of QAPP development which stresses the need for systematic planning, includes EPA's graded approach to project plan development and describes in detail the twenty-four elements of a QAPP. The review and approval of the OAQPS QARF is also included in this course. Participants are expected to have some basic experience in quality assurance. *Introduction to EPA Quality System Requirements* is a prerequisite for this course. The course will be tailored with program specific information to provide context and relevance to the target audience.

3.1.2 Management and Staff

The Core QA Training Course, *Overview of the EPA Quality System*, provides an overview of the mandatory Agency-wide QS based upon QA requirements outlined in regulations, EPA Orders and other pertinent standards. This course is an abbreviated version of the *Introduction to the EPA Quality System Requirements* course discussed above that focuses on the policies and specifications of the EPA QS. This course describes the EPA QS and the specific elements that managers and project personnel must address to comply with EPA policy.

The course directs the class participants to the QA tools developed to implement the QA/QC requirements in OAQPS, and provides updates on continuing, new, and/or changing QA/QC requirements. Elements of the Core QA Training Course may be expanded as necessary to address findings from internal or external QS audits/reviews and/or to incorporate new QA regulations, requirements and standards.

All OAQPS management and staff involved with environmental data operations (i.e., funding, managing, creating, handling, interpreting, or reporting environmental data) are required to take the Core QA Training course. EPA personnel must attend the Core QA Training every two years; this course cannot be substituted with another QA training course.

The QA Program will maintain a tracking system of attendees to its training sessions. Employees must ensure his/her attendance is recorded in the QA Program Tracking System.

3.2 Delegated QA Approval Training

The DQAO is a valued and important part of OAQPS's QS, who has been delegated project-level QA document approval authority by the OAQPS QAM. Delegation depends, in part, on completion of special training. The training requirements established for DQAOs are designed to provide a foundation for new Approving Officers and to keep existing Approving Officers current and abreast of new innovations.

3.2.1 Training requirements for New Approving Officers

To be eligible for delegation, candidate Approving Officers must have the approval of their supervisor and complete the Introduction to Delegated QA Approving Officer Training for Project-level QA Documents. This training is currently undergoing revision and will be located on the OAQPS QA SharePoint site.

3.2.2 Annual Refresher Training Requirements

DQAOs must maintain their Approving Officer status by attending annual (±6 months) DQAO Refresher Training. The annual training will review the functional elements of an Approving Officer's duties. Additionally, each annual training course may include a special training unit, which has been tailored to address specific areas for enrichment as demonstrated from QSAs and/or other assessment instruments.

3.2.3 Periodic updates from the OAQPS QAM

Throughout the year, DQAOs and their managers may receive updates from the OAQPS QAM. These updates, which are pertinent to their project-level QA document approval duties, may include notice of any new EPA Orders, guidance or review requirements; approval status updates for Contract-level QA documents (e.g., QMPs, QAPPs, etc.); or similar information. Dissemination of this information will typically be via email through the OAQPS QA Team. DQAOs are expected to immediately incorporate the information and/or new practices into their reviews/approvals. DQAOs should contact the OAQPS QAM with any questions about implementation of the update.

3.2.4 OAQPS QAM Consultation

At any time, OAQPS DQAOs, managers, and staff may contact the OAQPS QAM to obtain consultation on how to conduct project-level QA document reviews or clarity regarding any other QA concerns. If an assessment reveals that an DQAO's supporting documentation is deficient, then the OAQPS QAM will request a meeting with the DQAO for coaching or consultation in coordination with their supervisor.

3.2.5 Existing Data Training

OAQPS staff whose functions involve the oversight and approval of projects that generate, use, or report environmental data must complete data quality assessment training. The course will be tailored with program specific information to provide context and relevance to the target audience. Attendance is required every two years.

3.2.6 Training Documentation

The OAQPS QAM (or designee) will maintain a record of all formal training sessions (i.e., training sign-in sheets) offered by the QA Program for DQAOs. Training records will include the training agenda, name of all attendees, the date and title of each course offering. This information will be tracked electronically to ensure all staff are up to date on required training.

4 Procurement of Items and Services

OAQPS must ensure the items and services it acquires are procured within EPA regulations, delivered in a timely fashion, and are within the required specifications. The following sections will provide general guidance on OAQPS procurement procedures.

4.1 Procurement of Items

The Office of Acquisition Solutions (OAS) follows the guidelines developed in the Federal Acquisition Regulations (FAR) Sections 8 and 13, which establish Government-wide Policies and procedures governing the acquisition process. EPA's Office of Acquisition Management (OAM) has developed and maintains supplemental regulations and guidance, foremost amongst which are the EPA Acquisition Regulations (EPAAR), the EPA Acquisition Guide (EPAAG). EPA attempts to purchase through FAR-mandatory sources (i.e., GSA). Therefore, items on the FAR source list that meet the minimum specifications must be purchased through a FAR source. Note that procurements of computer hardware and software (information technology or IT) are subject to additional internal review and approval by the OAQPS Information Resource Manager (IRM) and the OAR Information Management Official (IMO).

In EPA, only Contracting Officers (COs) and Government bankcard holders are authorized to procure items and services, unless it is an imprest-fund transaction approved by the CO prior to the originator's purchase of the item. The Federal Government is not bound by any commitments made by anyone other than authorized personnel.

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

All procurements are documented using the OAQPS QARF which is consistent with the requirements of EPAAG Chapter 46.2.1 Appendices A-D. Instructions are included with the form. The form and instructions are posted on the OAQPS QA SharePoint. A Contracting Officer will inform the originator of the item that most closely matches his or her request that is available from the FAR mandatory sources. A Contracting Officer may "compete" a purchase on "brand name or equal" specifications. Manufacturer names and model numbers help make a description complete. This does not mean that the brand name will be ordered. If the item available from the mandatory source does not meet specifications, and no substitute is adequate, a Contracting Officer will help the originator process a Waiver Request. However, if the item's total price is less than $10,000, and the type of item is not available through mandatory sources, purchasing may buy from the suggested source (Block 13 on the EPA Form 1900-8).

PRs are entered into EPA's Acquisition System (EAS) by a Contracting Officer's Representative (COR), typically either a Task Order Contracting Officer Representative (TOCOR) or a Contract-Level Contracting Officer Representative. Each PR is then routed through the financial interface to a Funds Control Officer (FCO) who reviews the PR for completeness and accuracy

and enters the appropriate accounting information. The FCO then routes the draft PR to the appropriate Division management for concurrence; for all IT procurements there is the additional step of IRM/IMO approval. Following this review and approval process, the FCO certifies funds as available, assigns a document control number (DCN), and routes the PR through the financial interface where the funds are committed. The PR is then routed via EAS to the Office of Acquisition Solutions (OAS) where the funds are obligated by a CO.

Government bankcard purchases are not routed through the OAS; each bankcard holder is issued a warrant as a CO up to the micro-purchase limit. Unauthorized purchases will not be reimbursed without submittal of a "Ratification of Unauthorized Commitment Form." This process is very time consuming and costly and requires approval of OAS.

4.2 Procurement of Services

Two types of mechanisms are primarily used to procure services: contracts and assistance agreements (grants, cooperative agreements, and interagency agreements or IAs). As mentioned in Section 4.1, COs are the only individuals who can obligate funds for contracts, whereas the authority to obligate funds on an assistance agreement resides with the Grant or IA Award Official.

Procedures for procuring services via contract are essentially the same as for the procurement of items. There are certain activities that are of a Policy- and decision-making nature that must remain the sole authority of EPA. The OAS should be consulted during the initial planning of a PR to discuss specific requirements for the procurement.

The Contract-Level Contracting Officer Representative defines the service that will be delivered, assesses the quality of the service provided, and determines the degree to which that service was acceptable. When a level-of-effort contract is used in procuring services, the COR provides the technical expertise for the work assignment and assumes responsibility for the QA requirements assigned to the COR. The OAS issues the contracts and enforces all associated provisions. The COR has overall responsibility to see that the service is provided but works through the CO's authority. The COR is appointed by the CO and is formally designated a technical representative of the CO in the contract. WACORs and TOCORs must be certified as CORs; Chapter 7 of the CMM specifies the required training, experience, and workload limitations for COR certification.

Two requisite documents are vital to ensure that adequate service is provided: a well-defined statement of work (SOW), and a QAPP that includes provisions for audits. The COR is responsible for ensuring that the QAPP is developed, provided to the OAQPS QAM or DQAO for review and comment, that those comments are appropriately incorporated, and that the final QAPP is approved by the OAQPS QAM or DQAO before and EDO begins. The COR is also responsible for the implementation of the QAPP.

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

4.2.1 Contracts

Contracts are used when the Government derives sole benefit from a particular product or service. Contracts can be specific and can require a degree of lead time for development. Depending upon the scope of the service, QA attributes can be developed that must be adhered to under the terms and agreements of the contract. There is a requisite QARF (discussed and linked in Section 4.1) that the COR must use to determine whether an EDO exists. The COR submits the completed form to the OAQPS QAM or DQAO for review and approval/signature prior to proceeding with further contract actions.

Whenever the Government enters into a contract, it is entitled to receive quality products and services. In order to define and measure this quality, the COR must develop a SOW or PWS that will accurately define the minimum acceptable requirements for the products and/or services. This is the first step in the procurement process that helps to ensure that services produce results or products of acceptable quality. The COR must succinctly state his or her expectations of the product or service and must be able to communicate this to the supplier. Good communication between the COR and the supplier of a product or service is essential to a mutual understanding of the expectations and how quality will be defined. 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. Supplement 2 to the Office of Management and Budget (OMB) circular A-76, *A Guide for Writing and Administering Performance Statements of Work for Service Contracts*, provides guidance for writing PWS (or SOWs) and on implementing QA surveillance plans. Another important source of information is the Environmental Protection Agency Acquisition Guide (EPAAG) (formerly the EPA Contracts Management Manual) which specifies all required documents for developing contracts.

Part of the procurement process of large and/or complex requirement acquisitions includes the use of a three plus member technical evaluation panel (TEP). When a significant percent of the cost (> 25 percent) includes EDO, the TEP must include a QA representative, typically the OAQPS QAM, as QA documents under review are at the contract level. Part of the TEP responsibilities will include rating each potential contractor against a well-defined set of criteria. A portion of these criteria can include various assessments such as on-site audits and the analysis of performance evaluation materials.

Depending upon the type of contract used to acquire a service, different types of QA methods for determining the quality of product or output may be used. However, in all cases, thorough documentation, a key responsibility of each COR, is essential.

4.2.1.1 Contracting QA Clause

The FAR clause at 52.246-11, and its tailoring, will be included in all applicable solicitations and contracts. This clause will be incorporated into applicable solicitations and contracts by the EPA Contracting Officer, after consultation with QA personnel, based on the prescriptions at FAR 42.202-4 and FAR 46.311.

FAR 52.246-11 Higher-level Contract Quality Requirement (Feb 1999)

The Contractor shall comply with the higher-level quality standard selected below. [If more than one standard is listed, the offeror shall indicate its selection by checking the appropriate block.]

	Title	Numbering	Date	Tailoring
	Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs	ANSI/ASQC E4-2014	2/4/2014	See below.

[Contracting Officer insert the title, number (if any), date, and tailoring (if any) of any additional higher-level quality standards.]

As authorized by FAR 52.246-11, the higher-level quality standard ANSI/ASQC E4 is tailored as follows:

The solicitation and contract require that the offeror/contractor demonstrate conformance to ANSI/ASQC E4 by submitting the following documents pre-award and/or post-award as described below:

[The Contracting Officer is to select one of the following three options in consultation with technical and quality assurance personnel and include the appropriate option and provisions in the solicitation and contract. Note: Option 1 or 2 only applies if the contract consists of a single project; Option 3 applies to contracts consisting of multiple projects.]

Option 1. This option contains two separate steps (A and B):

A. Solicitation (Pre-Award): The offeror must submit a Quality Management Plan (or equivalent) that describes the offeror's QS for its organization as a separate and identifiable part of its technical proposal. The Plan should be prepared in accordance with the specifications provided in EPA Requirements for Quality Management Plans (QA/R-2), or equivalent specifications defined by EPA.

B. Contract (Post-Award): The following shall be incorporated into the contract's statement of work:

   1. The Contractor shall submit ____ copies of a Quality Assurance Project Plan (or equivalent) to the Contracting Officer's Representative within ____ calendar days after the award of the contract. This Plan will describe the quality assurance and quality control practices for the contract and will be prepared in accordance with the specifications given in EPA Requirements for Quality Assurance Project Plans (QA/R-5), or equivalent specifications defined by EPA.

   2. The Government will review and return the draft Quality Assurance Project Plan indicating approval or disapproval, and comments, if necessary, within _____ calendar days of receipt. If necessary, the Contractor shall deliver the Final project documentation within _____ calendar days after the receipt of comments from the government.

3. The Contractor shall not commence work involving environmental data generation or use until the Government has approved the project quality documentation.

Option 2.

Solicitation (Pre-Award): The offeror must submit a joint QMP and QAPP that describes both the offeror's QS for its organization and the necessary quality assurance and quality control practices for the specific application described in the contract statement of work as a separate and identifiable part of its technical proposal. This joint plan shall be prepared in accordance with the specifications defined in the solicitation.

Option 3. This option contains two separate steps (A and B):

A. Solicitation (Pre-Award): The offeror must submit a Quality Management Plan (or equivalent) that describes the offeror's QS for its organization as a separate and identifiable part of its technical proposal. The Plan should be prepared in accordance with the specifications provided in EPA Requirements for Quality Management Plans (QA/R-2), or equivalent specifications defined by EPA.

B. Contract (post-Award): The following shall be incorporated into each applicable project's statement of work for all work involving the production and use of environmental data in environmental programs:

   1. The Contractor shall submit ____ copies of a Quality Assurance Project Plan (or equivalent) to the Contracting Officer's Representative within ____ calendar days after the effective date of the project's task order, delivery order, work assignment, tasking document, etc. This Plan will describe the quality assurance and quality control practices for the project and will be prepared in accordance with the specifications given in EPA Requirements for Quality Assurance Project Plans (QA/R-5), or equivalent specifications defined by EPA.

   2. The Government will review and return the draft Quality Assurance Project Plan indicating approval or disapproval, and comments, if necessary, within _____ calendar days of receipt. If necessary, the Contractor shall deliver the Final project documentation within _____ calendar days after the receipt of comments from the Government.

   3. The Contractor shall not commence work involving environmental data generation or use until the Government has approved the project quality documentation.

4.2.2 Assistance Agreements

Assistance agreements are used when EPA is funding a recipient to support or stimulate activities that are not principally for the direct benefit or use of the Federal Government. Typically, both parties (EPA and the assistance recipient) derive benefit out of the relationship. This usually occurs with grants or cooperative agreements where universities or states derive benefits from participating in EDOs. QA requirements are developed for all assistance agreements that include EDOs. OAQPS follows guidelines developed in the EPA Assistance Administration Manual (EPA-5700).

Assistance agreements (SOWs/PWSs) are usually developed jointly. However, once the SOW/PWS is completed, the parties must also agree on the quality standards for assuring the product or service. It is the responsibility of the COR to be knowledgeable of the EPA QA policy and to represent these standards during the development of the project's SOW/PWS.

Special conditions are usually included in assistance agreements. The COR will list the conditions to which project participants must adhere. One of these conditions relates to QAPPs. Any assistance agreement that includes EDOs must include the following QA Term and Condition:

Acceptable Quality Assurance Documentation must be submitted to the EPA Project Officer within [Enter number of days] days of the acceptance of this agreement. No work involving 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 shall be initiated under this project until the EPA Project Officer, in concert with the EPA Quality Assurance Manager, has approved the quality assurance documentation. (See 40 CFR 30.54 OR 31.45 as appropriate).

4.3 Inherently Governmental Functions

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

This section outlines inherently governmental functions and provides guidance and examples. If after reading this section questions remain, please contact the CORE AAG or the OAQPS QAM for assistance in determining if quality management tasks necessary to comply with the EPA Procedure - CIO 2105-P-01.0 may be performed by non-Government personnel under appropriate management controls.

4.3.1 FAR Guidance on Inherently Governmental Functions

Contracts shall not be used for the performance of inherently governmental functions. Subpart 2 of the FAR defines an inherently governmental function as:

> *…a function so intimately related to the public interest as to mandate performance by Government employees. This definition is a policy determination, not a legal determination. An inherently governmental function includes activities that require either the exercise of discretion in applying Government authority, or the making of value judgments in making decisions for the Government. Governmental functions normally fall*

into two categories: the act of governing, i.e., the discretionary exercise of Government authority, and monetary transactions and entitlements.

FAR Part 7 Subpart 7.5 Section 7.503 provides additional guidance and examples.

4.3.2 CIO 2105-P-01-0: Quality Management Functions

Refer to the EPA Quality Manual for Environmental Programs Section 2.2 *Implementation of Quality System Functions* for specific guidance on quality management tasks that may be performed by non-government personnel under appropriate management controls. Two types of quality management functions are discussed:

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

Note that EPA cannot use cooperative agreements or grants to provide quality management activities such as QA and QC services for EPA because it is an inappropriate use of financial assistance (Office of General Counsel memorandum, August 2, 1994).

4.4 Policies for Field and Laboratory Competency and Accreditation

EPA's Forum on Environmental Measurements (FEM) is a standing committee of senior managers established to develop policies to guide the Agency's measurement community in:

- Validating and disseminating methods for sample collection and analysis;
- Ensuring that monitoring studies are scientifically rigorous, statistically sound, and yield representative measurements; and
- Employing a QSs approach that ensures that the data gathered and used by the Agency is of known and documented quality.

The FEM is engaged in several activities to implement its mission and reports to the Agency's Science Policy and Technology Council (SPTC). In recent years, the SPTC has issued three policies developed by the FEM related to field and laboratory competency requirements. These are:

- Agency Policy Directive on *Assuring the Competency of Environmental Protection Agency Laboratories*, approved on February 23, 2004 and reaffirmed on November 20
    - Establishes the policy and program requirements for a documented QS that extends to Agency to assure the quality of data generated by all the laboratories operated by EPA, including Agency owned, contractor operated facilities
- Agency Policy Directive Number FEM-2011-01: *Policy to Assure Competency of Organizations Generating Environmental Measurement Data Under Agency-Funded Acquisitions*, approved February 22, 2011 and reissued with updates to references for five years from November 14, 2016

    - Requires organizations that generate environmental data through measurement (e.g., laboratory and/or field activities) to submit documentation of their competency to do so
- Agency Policy Directive Number FEM-2012-02: *Policy to Assure the Competency of Organizations Generating Environmental Data Under Agency-Funded Assistance Agreements*, approved: March 13, 2013 and updated December 21, 2016
    - Requires organizations that generate environmental data through measurement (e.g., laboratory and/or field activities) to submit documentation of their competency to do so

These and other policy documents can be found on EPA's Environmental Measurements and Modeling site under Ensuring Measurement Competency.

4.4.1 Policy Applicability

These policies apply to all EPA programs (e.g., Programs Offices, Laboratories) and personnel responsible for evaluating, issuing, and/or managing Agency acquisitions such as purchases, contracts and contract work assignments/statements of work/task orders/etc. The scope of the policy encompasses all acquisitions that either originate in OAQPS or for which QA oversight of the contract is delegated to OAQPS, regardless of contract dollar amount, and that generate environmental data under:

- Agency acquisition requests for proposals (RFPs) or solicitations; and
- Purchases, contracts, contract work assignments/statements of work/task orders, etc.

4.4.1.1 Policy Implementation in OAQPS

Oversight of these policies is the responsibility of the OAQPS QAM. The successful implementation of these policies by OAQPS contract officers (COs), project officers (POs), and contract officer's representatives (CORs) will be evaluated by the QAM through periodic QSAs (Refer to Section 9 for more information). In addition, the OAQPS QAM is currently developing a tracking system to monitor information about competency of contract organizations that are generating environmental data.

Given that accreditation and certification does not exist for all fields of sampling and analysis, and that the cost of accreditation or certification may be prohibitive for some organizations, the FEM provides other tools that can be considered when evaluating competency.

5 Documentation and Records Management

Federal agencies are required to create and preserve federal reports containing adequate and proper documentation of the organization, functions, policies, decisions, procedures and essential transactions of the agency, and all reports necessary to protect the legal and financial rights of the Government and of persons directly affected by the Agency's activities (44 U.S.C. 3101).

Organizations that perform EDOs and management activities must establish and maintain procedures for the timely preparation, review, approval, issuance, use, control, revision and maintenance of documents and reports. A document is any volume that contains information which describes, defines, specifies, reports, certifies, or provides data or results pertaining to environmental programs. As defined in 44 U.S.C. 3501, reports 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...." The terms documents and reports are often used interchangeably. This section will define OAQPS document and reports management procedures.

5.1 Elements of the System

All Agency employees, in the course of conducting Government business that acquires or creates reports, shall be responsible for following the Agency guidelines for the retention and disposition of reports and other project documents. Detailed information about EPA records policies and regulations that govern federal records management are posted on the EPA National Records Management Program website. EPA's records are managed with records schedules in final status, that is records schedules approved by the National Archives and Records Administration (NARA).

OAQPS staff are responsible for preparing many different types of QA documentation, which include.

- QMPs
- QAPPs
- SOPs
- Work plans and SOWs/PWSs
- QA Reports and/or DQAs
- QARFs for Contracts and Task Orders
- Guidance Documents
- QA Team Reports
- Audit and Corrective Action Reports

Currently, these documents are maintained in project files at project level and/or contract level. OAQPS will work towards creating and implementing a documents repository on SharePoint so

they can be tracked more readily. Although it is ultimately the responsibility of the project lead to file all pertinent documents and reports, a formal process that allows for an inventory of expected documentation is very advantageous. A list of expected deliverables will be developed by the project lead. This list will serve as the basis for generating unique file numbers for the documents and will serve as the basis for development of a checklist to ensure that all deliverables are available.

5.2 Document Preparation, Review, and Approval

Document preparation, review, and approval depends upon the type of document being produced. For example, an internal document will have different preparation, review, and approval requirements from an external document. The process befitting each document will be determined by the task lead and his/her immediate supervisor. The approval process for some QA documentation is discussed in Section 2. The peer review process is discussed in detail in Section 11.

6 Computer Hardware and Software

6.1 OAQPS Information Management System

The Resource Planning and Management Group (RPMG), located in CORE, is responsible for directing and managing office-wide information resources planning and budgeting and for assuring that the information systems and information technology acquisitions within OAQPS comply with Federal and EPA Policies and regulations. The Information Resource Manager (IRM), located in RPMG, has the functional responsibility for the acquisition, management, and operation of information systems resources including: 1) acquisition management of hardware; 2) acquisition of general purpose, non-application specific software such as operating systems, database management systems, etc.; and 3) approval of system-oriented proprietary software.

OAQPS operates six major data management systems:

- AQS which stores ambient air quality data;
- Emissions Inventory System (EIS) that stores facility and emissions data;
- Compliance and Emissions Data Reporting Interface (CEDRI) interface used to submit emissions data required by Part 60 and 63 to EPA;
- Web Factor and Information Retrieval (WebFIRE) which stores and searches for emissions factors and other emissions reports;
- State Planning Electronic Collaboration System (SPeCS) which enables state air agencies to officially submit SIPs; and
- AirNow which reports the Air Quality Index (AQI)

The IRM is also responsible for directing and managing office-wide information resources planning and budgeting and for assuring that the information systems and information technology acquisitions within OAQPS comply with Federal and EPA Policies and regulations.

6.1.1 Air Quality System (AQS)

AQS contains ambient air quality data collected primarily by SLT air pollution control agencies from thousands of monitoring stations. About 5,000 monitors currently report air quality data to AQS. Though most data in AQS are from the past 20 years, some data date back to the 1950's. AQS also contains descriptive information about each monitoring site and each monitor (e.g., method) and data QA/QC information. AQS data are used in many regulatory applications (e.g., the determination of nonattainment areas).

The backbone of any information system is the quality of the information it contains. AQS has comprehensive quality steps built into the loading, storing, and analysis functions of the software. Essentially all data in AQS are collected and reported by SLT personnel. They operate the monitors, report the data, then certify that the data in the system are correct. There is no CBI and only a limited set of personal identifying information (PII) received into the system.

The first step in ensuring that AQS contains data of high quality and accuracy is a set of regulatory standards for how the data are to be collected. The location of the monitors that collect pollutant concentrations must meet siting criteria. The responsible agencies must follow prescribed operating procedures, including having a QAPP. The monitors must use scientifically

proven sampling methods and must be regularly tested for precision and accuracy for the data to be considered valid. All these procedures are subject to periodic EPA audits and performance reviews.

Once the quality assured data are collected, it is reported to the system itself. AQS uses security protocols to assure that the data submitted are valid and authorized. Then the data must pass through three levels of QA checks: individual data element checks, relationship checks, and statistical checks. The first type of check is to make sure there are numbers in numeric fields (and that these numbers are physically realistic), characters in character fields, and the like. The second set of checks is to verify that each reported value fits into the database: was it taken from a valid monitor, was that monitor quality assured, was that monitor still operating at the time the sample was taken, etc.? The final checks are an attempt to make sure the data aligns with statistical parameters: is the value an outlier, does it represent a new minimum or maximum pollutant concentration, etc. Once all these checks are passed, the data are entered into the AQS database and are available for public release.

The data in AQS are also reviewed by OAQPS for timeliness and completeness. Summary reports are prepared by OAQPS staff and sent to the state and local agencies including an identification of those agencies that have not submitted complete or timely data along with a request for them to do so.

6.1.2 Emissions Inventory System (EIS)

EIS contains facility descriptive information and emissions estimates collected from EPA, SLT air pollution control agencies. The emissions estimates are reported for Point, NonPoint, onroad, and nonroad sources, and wildfires. Every three years state air pollution control agencies are required to submit a complete emissions inventory. In the intervening years, they are required to submit an emissions inventory for just major Point sources.

EIS stores criteria air pollutants (CAPs), HAPs, and greenhouse gases (GHGs). The reporting of CAPs is required while the reporting of HAPs and GHGs is voluntary. There is no CBI and only a limited set of personal identifying information (PII) received into the system.

EIS has quality checks built into every step of the process. As the data file is being submitted, it is subjected to screening and will not pass to the system unless it is a valid data file. Once received by EIS, the data are validated against over 1,000 QA checks. Data that pass the checks are loaded into the system.

The first step in ensuring that EIS contains data of high quality and accuracy is the availability of the QA environment. This is a function of the system that allows users to submit their data for validation without the data being permanently stored in the system. The data file itself is checked to ensure its conformance with requirements, then the data are checked for codes, data value ranges, and cardinality. Feedback is provided to the user with the results of the validation. When the user is certain that their data are of the highest quality, they can submit them to the Production environment. Here, only the data that pass validation are stored in the system.

The data in EIS are also reviewed by OAQPS for timeliness and completeness. Summary reports are prepared by OAQPS staff and sent to the SLT agencies including an identification of those agencies that have not submitted complete or timely data along with a request for them to do so.

6.1.3 Compliance and Emissions Data Reporting Interface (CEDRI)

CEDRI is an application on EPA's Central Data Exchange for submitting various reports required under 40 CFR Parts 60, 62 and 63. CEDRI will allow for the submittal of performance test reports, performance evaluation reports, air emissions data reports and notifications of compliance status reports. It is designed to support improved data quality and review of reports. Data submitted using CEDRI will be accessed by stakeholders through the Web Factor and Information Retrieval System (WebFIRE).

6.1.4 Web Factor and Information Retrieval System (WebFIRE)

WebFIRE is the EPA's online database that contains emissions factors for criteria and HAP for industrial and non-industrial processes and reports submitted to the EPA in response to regulatory requirements under Parts 60, 62, and 63 of Title 40 of the U.S. Code of Federal Regulations (CFR). These emissions factors are primarily used in preparing regional and national emissions inventories when valid site-specific information is not available.

In addition, the EPA has been in the process of enhancing the WebFIRE system to develop new and improved emissions factors. A key feature of this new approach is to utilize performance test report data that has been submitted electronically via the CEDRI node on the CDX to WebFIRE to develop new or revised emissions factors. Another key feature is the ability to automatically determine the impact of the new data on the existing emissions factor. This will help to streamline the emissions factors development process to develop new or revise existing emissions factors in a timelier manner and result in higher quality emissions factors that are more representative of the population.

6.1.5 State Planning Electronic Collaboration System (SPeCS)

SPeCS is a web-based system that enables state air agencies to officially submit SIPs and associated information electronically for review and approval to meet their Clean Air Act obligations related to attaining and maintaining the NAAQS and improving and protecting long-range visibility.

6.1.6 AirNow

The U.S. EPA, National Oceanic and Atmospheric Administration, National Park Service, SLT agencies developed the AirNow system to provide the public with easy access to national air quality information. State and local agencies report the AQI for cities across the US and parts of Canada and Mexico.

Map and forecast data are collected using federal reference or equivalent monitoring techniques or techniques approved by the SLT monitoring agencies. To maintain "real-time" maps, the data are displayed after the end of each hour. Although preliminary data quality assessments are performed, the data in AirNow are not fully verified and validated through the QA procedures monitoring organizations used to officially submit and certify data on the EPA AQS.

This data sharing and centralization creates a one-stop source for real-time and forecast air quality data. The benefits include quality control, national reporting consistency, access to automated mapping methods, and data distribution to the public and other data systems.

AirNow data are used only to report the AQI, not to formulate or support regulation, guidance or any other EPA decision or position, which is why it does not require the same level of verification/validation.

6.2 Hardware and Software Requirements

AQS, EIS, CEDRI/WebFIRE operate at EPA's National Computer Center (NCC), which is managed by the Office of Environmental Information (OEI). These systems meet all Agency hardware, software, and security requirements of the NCC. Major software enhancements to AQS, EIS, CEDRI/WebFIRE must be reviewed and approved by the NCC via the Application Deployment Checklist (ADC) process before any revised software can be deployed at the NCC. A security assessment and review of the system security plan is conducted on an annual basis.

AQS is a web-based Oracle application with an Oracle back-end database. Users submit files to AQS through the Agency's Central Data Exchange (CDX) node on the National Environmental Information Exchange Network (NEIEN) and access the system through a web-accessible interface. The AQS data elements that SLT agencies must report, the frequency with which they must be reported, QA criteria and calculations, and statistical analysis measures are codified in 40 CFR Part 58.

EIS is a web-based Java application with an Oracle back-end database. Users submit files to EIS through the Agency's Central Data Exchange (CDX) node on the National Environmental Information Exchange Network and access the system through the EIS Gateway, a web-accessible interface. The EIS data elements that SLT agencies must report, the frequency with which they must be reported, and QA criteria are codified in 40 CFR Part 51 and in the NEI-EIS Implementation Plan.

CEDRI/WebFIRE is a web-based Java application with an Oracle back-end database (WebFIRE). Users submit files to WebFIRE through the Agency's Central Data Exchange (CDX) node on the National Environmental Information Exchange Network and access the system through the CEDRI Gateway, a web-accessible interface. The CEDRI/WebFIRE data elements that facilities must report, the frequency with which they must be reported, and QA criteria are codified in 40 CFR Part 60 and 63.

AirNow is a public website, supported by a contractor-managed Data Management Center (DMC). AirNow partner agencies submit files to AirNow's DMC, located at our contractor's facility in Petaluma, CA. AirNow relies upon the AQS data elements that SLT agencies must report, the frequency with which they must be reported, QA criteria and calculations, and statistical analysis measures as codified in 40 CFR Part 58.

SPeCS for SIPs utilizes the Central Data Exchange interface with a Drupal database.

6.3 Data Standards

Chapter 5 of the IRM Policy Manual provides the Agency principles on data standards and assigns organizational responsibilities for implementing and administering common data standards. Request for waiver or deferment to the use of Agency data standards as outlined in the IRM Policy Manual, Chapter 5, must be submitted by the IMO to THE Office of Information Resources Management for approval.

- AQS meets all applicable Agency data standards.
- EIS meets all applicable Agency data standards.
- CEDRI and WebFIRE meet all applicable Agency data standards.
- AirNow data standards piggy-back on the AQS and monitoring network data standards. AirNow accepts data from the same monitoring networks and rely upon the existing monitoring QAPPs. There are no additional requirements imposed by AirNow
- SPeCS is web-based system that enables state air agencies to submit and track SIPs for attaining the national ambient air quality standards, meeting long-range visibility protection goals, and related information, electronically to U.S. EPA for review and approval. There are no additional requirements imposed on SPeCS.

6.4 Data Acquisition, Management, and Transfer

The process of capturing the data is known as acquisition. The organization of the data is known as management. The process of providing the data to EPA is known as Transfer. The process of EPA disseminating the data is known as Sharing. Data systems must be effectively managed using a set of guidelines and principles by which adherence will ensure data integrity. This OAQPS QMP defines six data management principles:

1) DATA: The system must provide a method of assuring the integrity of all entered data. Communication, transfer, manipulation, and the storage/recall process all offer potential for data corruption. The demonstration of control necessitates the collection of evidence to prove that the system provides reasonable protection against data corruption.
2) FORMULAE: The formulas and decision algorithms employed by the system must be accurate and appropriate. Users cannot assume that the test or decision criteria are correct; those formulas must be inspected and verified.
3) AUDIT: An audit trail that tracks data entry and modification to the responsible individual is a critical element in the control process. The trail generally utilizes a password system or equivalent to identify the person or persons entering a data point, and generates a protected file logging all unusual events.
4) CHANGE: A consistent and appropriate change control procedure capable of tracking the system operation and application software is a critical element in the control process. All software changes should follow carefully planned procedures, including a pre-install test protocol and appropriate documentation update.
5) SOPs: Control of even the most carefully designed and implemented systems will be thwarted if appropriate procedures are not followed. The principle implies the development of clear directions and SOPs; the training of all users; and the availability of appropriate user support documentation.

6) DISASTER: Consistent control of a system requires the development of alternative plans for system failure, disaster recovery, and unauthorized access. The control principle must extend to planning for reasonable unusual events and system stresses.

This section provides guidance in these areas, including identification of advanced equipment and procedures that are recommended for implementation. The recommended procedures rely on digital communication by the data acquisition system to collect a wider variety of information from the analyzers, to control instrument calibrations, and to allow for more routine, automated, and thorough data quality efforts. The following subsections will discuss:

1) Data acquisition- collecting the raw data, storing it for an appropriate interval, aggregating or reducing the data, and transferring this data to final storage in a local data base
2) Data management- ensuring the integrity of the data collection systems
3) Data transfer- preparing and moving data to EPA data systems such as AIRNOW, AQS, CEDRI, and WebFIRE
4) Data sharing – EPA providing access to the data through various mechanisms

What is most important in any data acquisition process is that the raw data values are transferred to other media in a manner that does not affect data integrity. This means the reported value is the value that should be in the final set of data.

6.4.1 Data Acquisition

Data acquisition and handling system (DAHS) is a term that describes any system that collects, stores, summarizes, reports, prints, calculates, or transfers data. The transfer is usually from an analog or digital format to a digital medium. In addition, this section will discuss limitations with data collected with DAHS. Uncertainty of data will be discussed and how to ascertain the quality of the data.

Other means of data acquisition, used primarily for emissions inventories, include EPA-approved models and Title V permit reports. SLT agencies acquire data from the regulated point sources in their jurisdictions based on the Title V permit process. For other emission sources, such as on-road and nonroad sources, and wildfires, these agencies rely on EPA-approved models. Activity data and emission factors are used by the models to estimate the emissions.

6.4.2 Data Management

The following sections provide guidance when managing the data.

6.4.2.1 Security

Data management systems need to be safeguarded against accidental or deliberate:

1) Modification or destruction of data - This relates to maintaining the integrity of the data, which includes developing Policy/procedures for computer use (password protection and authorization), data entry (i.e., double entry, verification checks, etc.), editing, and transfer;

2) Unavailability of data or services - Ensuring that data do not get lost (i.e., data backup policies and storage on more than one media or system) or that services are not interrupted (maintenance of hardware, surge protection, backup systems); and
3) Unwanted disclosure of data - This relates to confidentiality and ensuring that secured or confidential data cannot accidentally or deliberately be disclosed.

6.4.2.2 Standard Operating Procedures

SOPs are protocols for routine activities involved in a data collection activity that generally involve repetitious operations performed in a consistent manner. SOPs should be established for:

- Maintaining system security;
- Defining raw data (distinction between raw and processed data);
- Entry of data;
- Verification of manually or electronically input data;
- Interpretation of error codes/flags and corrective action;
- Changing data;
- Data analysis, processing, transfer, storage, and retrieval;
- Backup and recovery; and
- Electronic reporting (if applicable).

6.4.2.3 Software

Software, either developed internally or "off-the-shelf", must accurately perform its intended function. Tests of the software prior to implementation should occur and be documented. Algorithms should be checked, and source code reviewed as part of the process. Source code, including processing comments, should be archived. Procedures for reporting software problems and corrective action should be in place.

6.4.2.4 Data Entry and Formatting

Electronic DAHS can report, average, and compile the monitoring data in a variety of reporting formats. If the monitoring organization transfers data to an external data system (i.e., AIRNOW, AQS etc.), the personnel responsible for the DAHS should assure that the reported data are in the formats required for such reporting to data systems.

In many cases, monitored data are reported as hourly average values. However, it is suggested that monitoring organizations consider reporting and archiving data with shorter time resolution (e.g., as five-minute averages). Such data can be used to compute averages over longer time periods and are valuable for diverse data analyses. For example, short time period data can be used to assess the variability and uncertainty in hourly or longer time period data, to evaluate temporal trends or source impacts and be used in special research projects. The availability of high time resolution data is valuable to the data-user community and is likely to foster analyses of air quality that could not be attempted with hourly or longer data periods.

Data generated by models and permit reports are provided in the time increment specified by the appropriate regulation.

6.4.2.5 Data Review

The review of collected data is the most important means to assure data quality in ambient monitoring. The review process has multiple stages, beginning with observations in the field, continuing through the analysis of electronic data, and ending with the reporting of final data. Data review should be the subject of a SOP that defines the criteria an agency will apply in processing and reporting the monitoring data.

Data review in the field should involve the observations and reports of site operators on topics such as the operational status of analyzers, the need for maintenance or repair, the occurrence of unexpected or unexplained readings, the existence of difficult or unusual meteorological conditions, and the observation of ambient data outside the normal range for the site. At a minimum, such observations must be reported in a station/instrument logbook or other document. Preferably, such observations should be reported by electronic word processor. These reports should be associated with the ambient data through the data acquisition system. Data review in the field is the first step in flagging suspect data for subsequent review.

Data review is a key component of the data analysis process. Electronic data acquisition systems allow automatic flagging of data based on the status (i.e., alarms, internal diagnostics, and calibration results) of the analyzer, or based on other criteria such as expected data ranges. However, review of the data by experienced personnel is still necessary. This review should be carried out promptly after data collection and should consider any field observations such as those noted above. The aim of this review is to identify and remove suspect data, and to identify and retain valid data based on the variety of information reported. Software associated with an electronic data acquisition system can be used to automatically compare various types of data to flag or confirm the validity of the ambient measurements.

The final step of data review is conducted to ensure that data is appropriately reduced (aggregated, averaged etc.) and formatted for reporting. The usefulness of publicly accessible data repositories is dependent on the consistency and accuracy of the processed data submitted to the repositories. Careful review of the data must take place to assure complete and correct submission of formatted data sets.

6.4.3 Data Transfer

Data are transferred to the Agency in different ways and in different formats, depending on the program for which the data are being supplied. For AQS, the data are transferred in either a flat file or XML file, which can be zipped or unzipped. Regardless of the file format, the data are transferred to through the Agency's CDX node on the National Environmental Information Exchange Network. Select data can also be provided through the AQS application.

For EIS, all data must be formatted in XML, and be zipped prior to transfer. The only exclusion to this are inputs to the mobile source models, which are formatted in flat files and data tables. Like AQS, data files can only be transferred to EIS through the Agency's CDX node on the National Environmental Information Exchange Network. Select data can also be provided through the EIS application.

For CEDRI, all data must be formatted in the provided spreadsheet template, XML schema, .PDF, or a submission file that contains a database file and an XML. The files can only be transferred to WebFIRE through the Agency's CDX node on the National Environmental Information Exchange Network.

6.4.4 Data Sharing

The data collected by and stored in EPA data systems are relied upon by several other agency mechanisms in order to provide it to various user communities. The following is a list of other ways the data are distributed.

AirData: This agency website provides access to air pollution data for the entire United States. AirData produces reports and maps of air pollution data based on specific criteria. The site provides access to yearly summaries of United States air pollution data, taken from AQS. AirData has annual summary data only and does not include detailed hourly or daily measurements of air pollution.

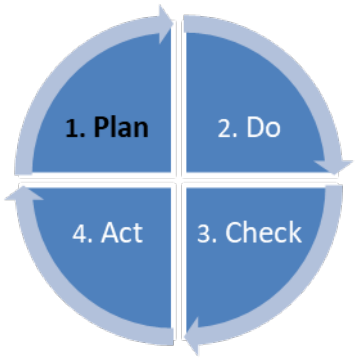
AirNow: EPA, NOAA, NPS, SLT agencies developed the AIRNow website to provide the public easy access to national air quality information for $PM_{2.5}$ and ozone. The website offers daily AQI forecasts, as well as real-time AQI conditions for over 500 cities across the U.S. and provides links to state and local air quality websites

AQS DataMart: Users of the AQS Data Mart are air quality data analysts in the regulatory, academic, and health research communities who need to download large volumes of detailed air quality data for analysis. The AQS Data Mart is not a web front-end nor does it provide interactive analytical tools. Anyone can get access to the DataMart and instructions on the AQS Data Mart website.

EIS Web Site: Users of emissions inventory data have access to the latest version and historic versions of the National Emissions Inventory. The data are available in a query format or in static data sets that can be downloaded from the Air Emissions Inventories website.

CHIEF Web Site: Users of the data submitted to WebFIRE via CEDRI can access the submitted data using the WebFIRE database. CEDRI can be accessed by the submitter of the data and the SLT. WebFIRE provides public access to the submitted data. The available data includes locate emissions factors, performance test reports, and other types of air emission reports.

7 Quality Planning



A key component of OAQPS's QS and the Plan, Do, Check, Act (PDCA) quality model is to promote an effective plan for the collection, analysis, evaluation and processing of environmental data, and all other EDOs. Quality planning must occur at three levels to ensure that such data meets programmatic and quality goals. Planning should occur at the Office-wide, Program-specific and Project levels.

OAQPS participates in Agency-wide planning through its contribution to the OAR operating plan.

7.1 Office-wide Planning

Careful annual planning is necessary to the success of the OAQPS QS. For management to budget adequate resources to implement the QS for an organization, estimates of the QS workload are needed. Moreover, management must give priority to QS resource needs with respect to other mission requirements; this planning may come in several forms, including installation of the OAQPS QMP. Office-wide planning activities occur both internally and with our extramural partners and contractors

The OAQPS operating plan, developed by OAQPS and its Divisions' planning staff, is the foundation upon which all programmatic activities and corresponding EDOs are based. Annual program plans, tied to the budget process, identify the types of EDOs that should occur.

OAQPS provides input into the Office of Air and Radiation (OAR) information resources management (IRM) strategic plan. The IRM plan reflects the Office-wide goals outlined in the OAQPS operating plan. The plan identifies the automated data processing hardware, software, full time employees, and type and quality of data needed to meet the OAQPS QA objective. The plan also identifies annual program priorities.

OAQPS will outline planned operational activities in those areas where the organization will focus its quality management efforts for the upcoming year. OAQPS determines those areas on which it will focus its efforts by reviewing activities from the previous year. Based on this review and on the available budget, OAQPS will include plans to correct any deficiencies in its QA activities.

OAQPS must increasingly coordinate the collection and use of environmental data and related activities across many EPA, federal, SLT, academic, and private organizations. This close coordination is essential to ensure that data are of known type and quality and can be shared where DQOs are similar.

7.2 Program-specific Planning

Programs are functional areas of work authorized by statutory reference (e.g., Air Toxics Program) or by Executive or Agency direction. All OAQPS environmental data operations conducted in support of these programs are covered by this QMP, though not all require the same level of QA. The program is responsible for establishing, and updating when necessary (e.g., initiation of a new program, incorporating major statutory changes) the minimum QA required to achieve program compliance.

The OAQPS programs covered by this QMP include the following:

- Implementation of National Ambient Air Quality Standards;
- Implementation of the national visibility protection and improvement program (Regional Haze Program);
- Regulation of HAPs;
- Permit programs, including New Source Review and Title V;
- Information transfer; and
- Technical support.

7.2.1 QA Program Annual Planning

Annual systematic planning for the OAQPS QA Program ensures that resources are used efficiently to accomplish OAQPS's QA activities. Planning is undertaken at two levels: QA Program Work Plan and annual planning goals will be included in QAEMS.

The OAQPS QAM provides monthly updates to the Director of CORE on QA Program work plan accomplishments and briefs senior managers about QA Program work plan activities and status twice annually (e.g., mid-year and end-of-year timeframes).

The OAQPS QAARWP is prepared by the OAQPS QAM as part of the annual planning process and contains descriptions of OAQPS QA activities. It also includes information about the range of activities completed, the significant fiscal year QA accomplishments, proposed work for the new fiscal year and may be used to provide limited updates to the approved OAQPS QMP. Prior to its submission, the OAQPS QAM briefs the CORE Director about the QAARWP, incorporating any input and/or refinement provided by senior management. The QAARWP is submitted by OAQPS under the signature of the OAQPS QAM to the Director of the Quality Staff in the Office of Environmental Information.

7.3 Project-level Planning

Planning at the project level is paramount for all projects and tasks involving environmental data operations that are conducted by or for OAQPS. Refer to OAQPS's Project Life Cycle diagram (Figure 7-1, below) to visualize the role planning has in the overall project life. There are four components to the Project Life Cycle:

1. Project Planning;
2. QAPP Development;
3. Implementation and Assessment; and
4. Assessment and Decision-making.

The colored bands in the life cycle roughly represent the relative time spent for each of the four stages. As seen, time spent in Project Planning can be as much (or more) than time spent during Implementation.

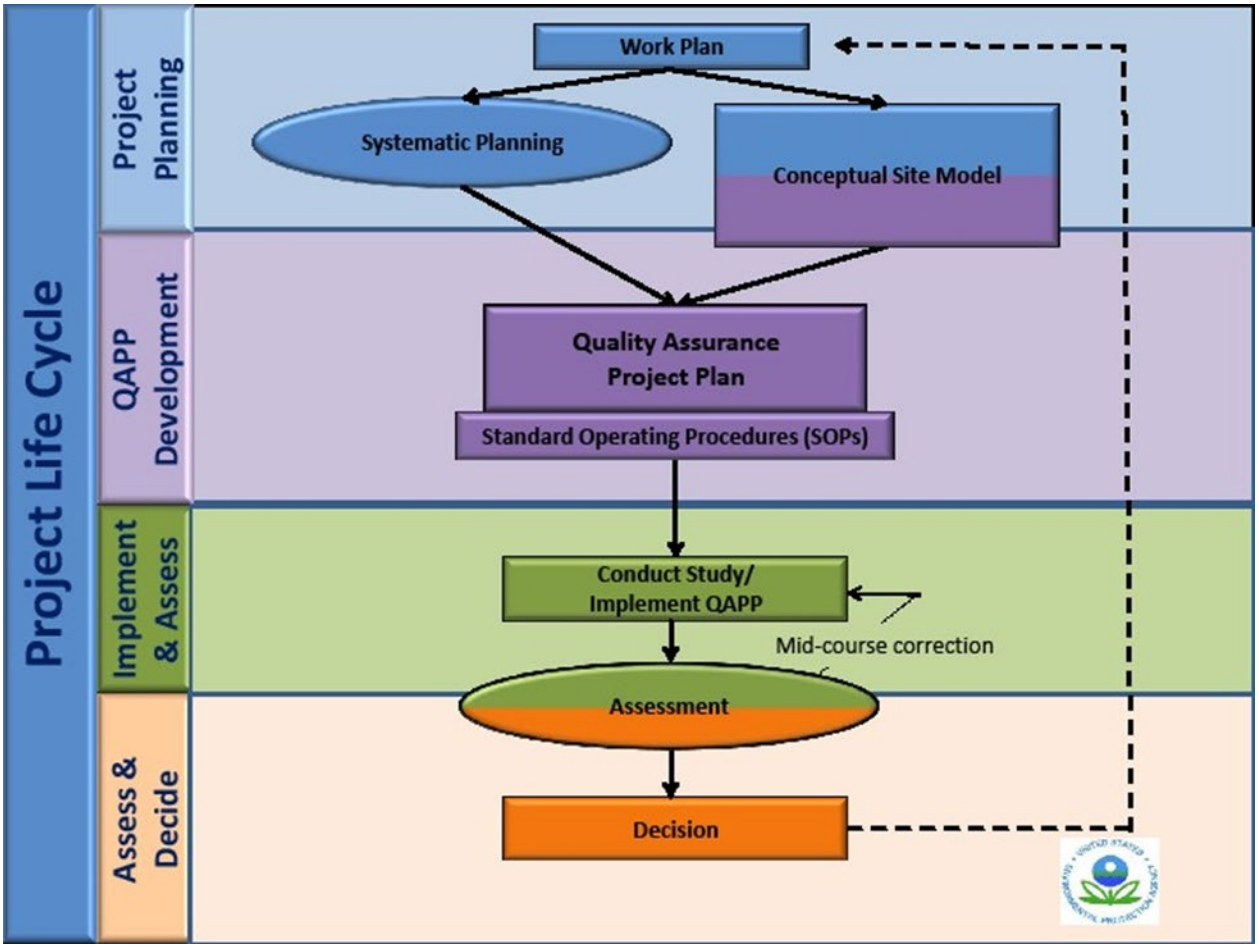


Figure 7-1. Project Life Cycle

Each project must employ a systematic planning process which results in the development of a conceptual model, a sampling network design, generation of appropriate data quality indicators, selection of measurement and analytical methodologies, standard operating procedures, qualification and use of secondary data, records management, assessment activities, data validation and assessment approaches, etc. sufficient in detail to support defensible decision-making. EPA Order 2105.0 requires that the results of the systematic planning process be documented in a QAPP and approved by the OAQPS QAM or DQAO prior to implementation.

The only exception to this requirement shall be for environmental data operations that require immediate action to protect human health and the environment or operation conducted under police powers. In these cases, the required documentation must follow shortly after the action or operation (See Section 2 for information on conditional QAPP approvals).

7.4 QA Documents in Planning

EPA recognizes two key documents for use in planning QA activities: QMPs and QAPPs. Other QA documents that may be associated with QAPPs include Sampling and Analysis Plans (SAPs) or Field Sampling Plans (FSPs). These QA documents are described in further detail in the next sections. Also, refer to Figure 7-2, QA Document Types.

- The **Quality Management Plan (QMP)** describes processes and procedures at the organizational level, management and staff functional responsibilities and line of authority. Include all QMP elements (QA/R-2).
- The **Quality Assurance Project Plan (QAPP)** is the document that details the who, what, when, where, why and how of the project objectives (data quality objectives). Include all QAPP elements (QA/R-5 and QA/G-5).
- The **Field Sampling Plan** (**FSP**) provides the field sampling details for the sampling event(s).
- The **Sampling and Analyses Plan** (**SAP**) provides the field and analytical details for the sampling event(s).
- **Standard Operating Procedures** (**SOPs**) describe specific procedures (e.g., sampling techniques or field analytical methodologies) used. These are attached to the approved QA Document(s).

Note:

- FSPs, SAPs, and SOPs are subsets of a QAPP
- FSPs and SAPs may be addendums to a previously approved QAPP
  or
  a standalone document, if all QAPP elements are included (QA/R-5 and QA/G-5)

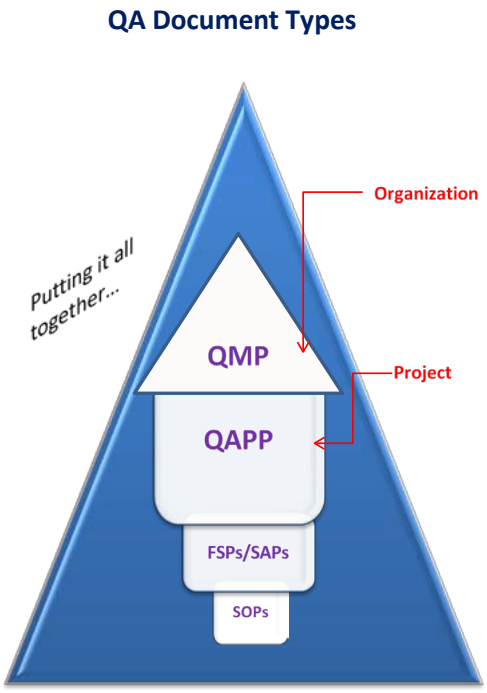


Figure 7-2. QA Document Types

7.5 Quality Management Plans (QMPs)

QMPs describe the broad view of an organization's QS, including management/staff responsibilities, organization structure, and lines of authority. An approvable QMP must address all the required QMP elements. Guidance for preparing QMPs is found in EPA QA/R-2 (2000), *EPA Requirements for Quality Management Plans*, reissued May 2006. Additional EPA Guidance documents are available at the EPA QA Program website.

A Program-level or project-level QMP may be appropriate for projects that are complex in nature (e.g., multiple projects of similar construct, emergency response activities, several operable units under investigation at the same time, etc.) to establish standard programmatic QA/QC requirements. The appropriateness of installation of a Program-level or project-level QMP is determined on a case-by-case basis by the PM in coordination with the QAM. Any OAQPS Program QMPs must be reviewed and approved by the OAQPS QAM and must align with the OAQPS QS described herein.

QMPs are approved for a period of no longer than 5 years. Prior to its expiration, a QMP must be revised and/or reissued to OAQPS for review and QAM approval. All QMPs considered by OAQPS shall be reviewed and documented using the OAQPS QMP checklist which is based on the required elements in QA/R-2 (linked above).

7.5.1 Annual QMP Reviews

All QMPs shall be reviewed annually by the authoring organization and the review shall be documented. The OAQPS QMP checklist should be used to document the review. If minor revisions are necessary, the QMP's author shall document those in the annual report, which is submitted to the OAQPS QAM or DQAO and placed in the project file. Major revisions in QSs or organizational structure require that the QMP be revised and resubmitted by the author for review and approval by the OAQPS QAM. The completed checklist must accompany the approved QMP. These companion documents must be maintained by the Project Manager in the project file. The Project Manager is responsible for ensuring all versions of QMPs are controlled and distributed, their versions tracked, and older versions are removed from circulation.

7.6 Quality Assurance Project Plans (QAPPs)

The results of the systematic planning process (Section 7) must be documented in a QAPP (or in an equivalent QA planning document). Equivalent documentation is determined on a case-by-case basis in consultation with the OAQPS QAM and is based upon the project quality objectives and the intended use of the data. Approved QAPPs are required for all environmental data operations. Project Managers are responsible for ensuring that QAPPs are developed and approved prior to project initiation for all projects under their authority. Guidance for preparing QAPPs is found in EPA QA/R-5 (2001), *EPA Requirements for Quality Assurance Project Plans*, reissued May 2006.

QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

EPA Order 2105.0 (6.a.7).

To be approvable, the QAPP must address all the required QAPP elements outlined in QA/R-5. If a QAPP element does not apply to the project, the element must be included, and an explanation provided for why it does not apply. A QAPP is sometimes referred as a FSP or SAP, which is acceptable if the QA document contains all the required QAPP elements. On occasion, a SAP or FSP may not include all the required QAPP elements; however, in this case the SAP or FSP must be appended to a previously approved companion QAPP. In these cases, the DQOs within the companion QA documents must remain consistent.

7.6.1 QAPP Approval Authority

All environmental data operations conducted by EPA or funded by EPA must have an approved QAPP in place prior to the initiation of data collection. The only exception to this requirement is for environmental projects that require immediate action to protect human health and the environment or operations conducted under police powers. The OAQPS QAM has the authority and responsibility to approve all extramural and intramural environmental data operation QAPPs, unless delegated as described in this QMP.

7.6.2 Implementing and Revising QAPPs

Approved QAPPs must be implemented as documented; however, a QAPP may be modified and amended at any time. Minor modifications may be necessary to address changing site/project conditions and to ensure project objectives are met. Such changes must be documented and approved by the Project Manager prior to implementation. Significant modifications (e.g., changes in DQOs or decision criteria, etc.) must be documented in either an amendment or revised QAPP, as appropriate, and undergo a review and approval process like that of the original QAPP prior to implementation of the changes.

It is essential that project QAPPs and any companion documents to the QAPP such as SOPs, SAPs or FSPs be kept current and that all personnel involved in the work have easy access to a current version of the QAPP. It is the Project Manager's responsibility to ensure this. The Project Manager is responsible for ensuring all versions of the QAPP are controlled and distributed, the versions tracked, and older versions are removed from circulation. The OAQPS QAM reserves the right to expire a QAPP, SAP, FSP or similar document that is not reviewed and updated annually.

7.6.3 Annual QAPP Reviews

All QAPPs shall be reviewed annually by the Project Manager and/or authoring organization, and the EPA project DQAO for programs or projects of duration exceeding 1 year. The review must be documented. All QAPPs or equivalent QA documents considered by OAQPS shall be reviewed using the OAQPS QAPP checklist, which is based on the required elements in QA/R-5 and QA/G-5. The completed checklist must accompany the approved QAPP. These companion documents must be maintained by the Project Manager in the project. For more information about annual reviews, see Section 9.

7.7 Standard Operating Procedures (SOPs)

Standard operating procedures (SOPs) are a mechanism to assure comparability across programs and individual environmental data operations and are a means of ensuring that routine or

repetitive activities, processes or procedures are performed consistently and with acceptable quality. SOPs are discussed in detail in Section 2.8.5.

7.8 Definition and Use of Existing Data

Existing (secondary) data are not collected through direct measurement (primary) but are obtained from any secondary source, which may be internal or external to EPA. A large existing source is data generated during previous EPA investigations as well as obtained from other government agencies, industries, geographical information systems (GIS), databases, surveys, literature searches, etc.

Existing (secondary) data typically make up most data used in OAQPS decision-making and/or designing new data collection efforts. Because of the key role existing data has in decision-making or in new study design at EPA, the quality of the existing data needed for its use must be documented in a QAPP, just as is required for collection of primary data. Data quality assessments of existing data must be performed prior to use.

7.8.1 Use of Existing Data Requires a QAPP

As described in Quality Assurance Project Plan Requirements for Secondary Data Research Projects:

> A secondary data research project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes.

Prior to its use, existing (secondary) data shall be evaluated to ensure a level of quality that is adequate for its intended use. The process for obtaining, evaluating and using the existing data must be documented in a project-level QAPP which shall:

- Identify the types of data needed for project implementation or decision-making;
- Describe the intended use of the data;
- Define the acceptance criteria for use of the data;
- Specify any limitation on the use of the data; and
- Identify the individual(s) responsible for evaluating and qualifying the data.

For those projects which involve the compilation and use of existing (secondary) data exclusively (i.e., there will be no direct environmental data generation performed to accomplish the project), a project-level QAPP is required. The level of detail for this QAPP will differ from that for a direct environmental data generation project. Chapter 3 of the *Guidance for Quality Assurance Project Plans (G-5)* identifies elements to consider when planning projects that use existing data. Assistance with determining the appropriate elements for a QAPP for projects involving existing data sources may be provided by the OAQPS QAM, upon request. Resources for Planning Projects that Use Existing Data contains links to additional guidance, including guidance on assessing existing data, and a checklist for quality concerns related to existing data.

The Project Manager is responsible for ensuring a QAPP is prepared for projects involving use of existing (secondary) data.

7.9 Systematic Planning Using Data Quality Objectives

The hallmark of all successful projects, studies and investigations is a planned data collection process that is conducted following the specifications given by an organization's QS. EPA Order CIO 2105.0 requires that before information or data are generated or used for Agency-funded or regulated environmental programs and projects, a systematic planning process must occur during which performance or acceptance criteria are developed for the collection, evaluation, or use of these data. For this reason, systematic planning is a key component of EPA's QS.

Systematic planning is a process based on the widely accepted "scientific method" and includes concepts such as objectivity of approach and acceptability of results. The process uses a common-sense approach to ensure that the level of documentation and rigor of effort in planning is commensurate with the intended use of the information and the available resources. The systematic planning approach includes well-established management and scientific elements that result in a project's logical development, efficient use of scarce resources, transparency of intent and direction, soundness of project conclusions, and proper documentation to allow determination of appropriate level of peer review.

EPA's approach to systematic planning is the DQOs process, which is outlined in the guidance document EPA QA/G-4 *Systematic Planning Using the Data Quality Objectives Process*. The DQO Process is a stepwise approach that guides managers or staff to a resource-effective plan for the acquisition of environmental data. It is both flexible and iterative, and applies to both decision-making (e.g., compliance/non-compliance with a standard) and estimation (e.g., ascertaining the mean concentration level of a contaminant). The DQO Process is used to establish performance and acceptance criteria, which serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the goals of the study. Use of the DQO Process leads to efficient and effective expenditure of resources; consensus on the type, quality, and quantity of data needed to meet the project goal and/or decision; and the full documentation of actions taken during the development of the project.

The Project Manager is responsible for ensuring that

1. The DQO Process (or a functionally equivalent systematic planning process) is used and documented; and
2. All organizations and/or parties who contribute to the quality of the environmental project or use the results are identified and participates in the planning process.

7.9.1 Conceptual Models

As part of the DQO process, it is important to concisely describe all information related to the project and to provide a conceptual model that summarizes information that is currently known and how this relates to the project's goal. A concise summary of the underlying scientific or engineering theory should be appended to the information that describes the project's goal to help facilitate any necessary peer review.

An example of a conceptual model is a diagram that portrays the environmental conditions at your site and depicts known or potential:

- Sources of contamination;
- Contaminants of concern;
- Movement of contamination through the environment;
- Media that are contaminated or may become contaminated; and
- Exposure scenarios and human health or ecological receptors.

The planning team will typically begin by developing a conceptual model of the problem, which summarizes the key environmental release, transport, dispersion, transformation, deposition, uptake, and behavioral aspects of the exposure scenario which underlies the problem.

Additionally, the CSM may also present or be used to develop potential benchmarks or action levels for the program or project. The conceptual model is an important tool for organizing information about the current state of knowledge and understanding of the problem, as well as for documenting key theoretical assumptions underlying an exposure assessment.

It is important to identify theories and assumptions underlying the conceptual model to ensure adequate transparency. If the problem is complex, the team may consider breaking it into more manageable pieces, which might be addressed by separate studies. Priorities may be assigned to individual segments of the problem and the relationship between the segments examined. Errors in the development of the conceptual model will be perpetuated throughout the other steps of the DQO Process and are likely to result in developing a QAPP or study that may not achieve the data required to address the relevant issues.

The Project Manager is responsible for ensuring that the DQO Process (or functionally equivalent systematic planning process), including development of a conceptual model, is applied and documented whenever environmental data are collected or used.

7.9.2 Team Approach

OAQPS encourages the team approach for those projects for which expertise is not available within the Program managing the project. Each PM is encouraged to involve as many professionals on his/her site team as relevant to site or project issues. The PM retains the primary responsibility to ensure the environmental data under his/her auspices meet the objectives of the project/program.

7.9.3 Involving Data Users in the Planning Process

Project Managers are strongly encouraged to include data users (including, but not limited to: states, tribes, PRPs, toxicologists, hydrologists, GIS specialists, modelers, enforcement personnel, permit writers, community groups or the general public) in the development of DQOs, QAPPs and other QA planning documents.

7.10 Policy for Geospatial Data

Geospatial data provide EPA with the capacity to spatially locate, identify, and assess aspects of the environment critical to program operations. The National Geospatial Data Policy, CIO 2131 establishes principles, responsibilities, and requirements for collecting and managing geospatial

data used by federal environmental programs and projects within the jurisdiction of the EPA. This policy applies to all EPA organizations, grantees, agents working on behalf of EPA, tribes, localities and partner states of EPA who directly or indirectly design, develop, compile, operate, or maintain EPA information collections developed for environmental program support. By reference, the National Geospatial Data Policy includes within it the commitment to implement the requirements specified by the National Spatial Data Infrastructure and to abide by the guidelines and data standards of the Federal Geographic Data Committee.

There are several different types of projects that utilize geospatial information. Some projects involve the development of new techniques and/or new underlying spatial data to answer specific questions. Others utilize GIS to manage existing data, while still others utilize GIS to manage newly collected data or a combination of both old and new data. GIS is a collection of computer hardware, software, and geographic data designed to capture, store, update, manipulate, analyze, and display geographically referenced data.

In general, most projects require an approved QAPP prior to generation or use of geospatial data. Examples of this are projects that involve in-field data collection of new spatial data (e.g., Global Positioning System [GPS] points or real-time mobile mapper) or development of new procedures to support environmental decisions (i.e., GPS coordinates during a site survey). One example where a QAPP is not required prior to using existing geospatial data is previously obtained GPS coordinates that have been collected using established procedures and documented under a previously approved QAPP (i.e., GPS coordinates used to locate an emission point during a follow-up inspection).

All QAPPs that include or require geospatial or GIS data generation or use shall conform to the following policies and guidance and shall be reviewed by the OAQPS GIS Coordinator (or designee) prior to the QAPP approval by the OAQPS QAM (or DQAO):

- CIO 2131-P-01-0, Procedure for Geospatial Metadata Management;
- OMB Circular A-16, Coordination of Geographic Information, and Related Spatial Data Activities;
- OMB Circular A-130, Management of Federal Information Resources;
- Latitude/Longitude Data Standard;
- National Geospatial Data Policy;
- Interim Guidance for Developing Global Positioning System Data Collection Standard Operating Procedures and Quality Assurance Project Plans; and
- Guidance for Geospatial Data Quality Assurance Project Plans.

The Project Manager is responsible for ensuring that generation and use of geospatial data meets the policy requirements described herein.

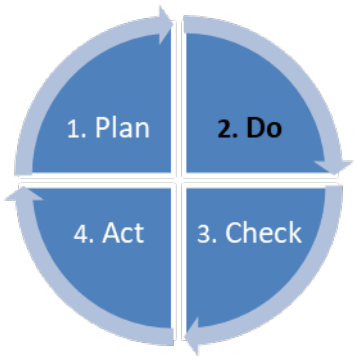
7.11 Peer Review in Project Planning

Peer review is discussed in Section 11.

7.12 Information Quality Guidelines and Pre-Dissemination Reviews in Project Planning

Information Quality Guidelines are discussed in Section 11.

8 Implementation (Do)



The implementation phase or Do component of the PDCA quality model is certainly the most visible and active portion of the Project Life Cycle and may represent about one quarter of the total time spent on the project. Successful execution of the project is paramount to ensuring generation and use of defensible data.

8.1 Implementation of Work Processes

Complete application of the Planning Process (Section 7) paves the way to successful and efficient implementation of environmental data operations. Implementation occurs at all three levels: Office-wide, Program and project-level. Thus, assurance that work processes are implemented in accord with EPA Order 2105.0 requires OAQPS managers and staff to implement the planning, review and approval, assessment, and reporting activities outlined throughout the QMP.

OAQPS has a centralized QS, authorized by the Administrator, who has delegated QA responsibilities and authority to the OAQPS QAM through the Assistant Administrator for the OAQPS Office of Technical and Management Services (TMS).

8.2 Guidance and Standard Operating Procedures Implementation

OAQPS-specific QS guidance can be found in the applicable sections of this QMP. Quality guidance is shared with OAQPS staff, contractors, and grantees for their use in developing and authoring quality documentation to support their projects. The QAM is responsible for ensuring the updated guidance is provided in the QMP.

Quality documentation for projects (e.g., QAPPs and supporting SOPs) is submitted to the QAM or DQAO for review and approval. If changes are required, the QAM or DQAO provides comments to the author (via the COR or PO for extramural mechanisms) and files a copy of the requested changes or weaknesses that need to be addressed. When the revised documentation is resubmitted for approval, the QAM or DQAO verifies that the changes or weaknesses have been addressed. SOPS are required for routine operations to ensure consistency in the execution of a procedure. The SOPs could take many forms, such as work instructions, analytical methods, traceability instructions, process documents, or quality system procedures. Staff are encouraged to identify operations needing written SOPs. For extramural agreements, any member of the project team is responsible for identify the need for an SOP.

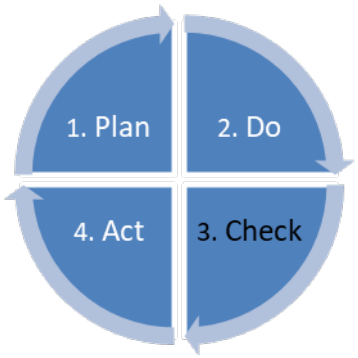
During use, it could be determined that an SOP requires revision. Users are required to verify that they are using the latest version of an SOP. For extramural agreements, the document control process identified in the applicable QMP and QAPP is followed.

8.3 Project Implementation

It is OAQPS policy that all decisions and work involving the use of environmental data are supported by an approved QAPP or equivalent document such as an SAP or FSP. The QAPP describes the QA, QC, and technical activities that must be implemented to ensure that the results obtained are of the type and quality needed and expected. For multi-year projects, the QAPP must be reviewed and re-approved every 12 months. The COR or PO for extramural mechanisms or the Project Manager for internal programs ensures that the tasks are carried out according to the plan by providing copies of the planning documentation to relevant parties. The COR, PO, or Project Manager is also responsible for ensuring that personnel understand their roles and responsibilities. To ensure that tasks are being performed according to the QAPP, the COR, PO, or Project Manager has regular communication with the project personnel. Communication could include meetings, teleconferences, project status reports, and site visits to observe data operations. The COR, PO, or Project Manager also has the responsibility to ensure that the final records accurately represent the completed work; if not, the records shall be revised and reissued.

Group Leaders are responsible to oversee the work products of their staff and are responsible for ensuring data and information products are reviewed prior to their dissemination.

9 Evaluation and Assessment



EPA Order CIO 2105.0 requires all Agency employees involved in environmental data activities and any extramural organization or individual conducting environmental activities in support of EPA activities (e.g., grantees, contractors, etc.) to comply with the Agency's QS requirements. To implement and maintain the QS, the EPA Orders require an annual assessment of the effectiveness of the OAQPS QS and implementation of corrective actions based on the assessment results. Evaluation and assessments are the Check component of the PDCA quality model. Corrective actions taken as a result of the assessments are governed under the Act portion of the PDCA quality model (Section 10).

This section describes how technical assessments of OAQPS activities are planned, conducted, and evaluated. OAQPS uses assessments to evaluate and improve the quality of environmental data collection activities; the assessments help to ensure the integrity of the data. A quality management system requires periodic assessments to determine if the system is effective, operating as designed, and to identify areas for continuous improvement. Different types of assessments are used to verify that the management and measurement systems are operating properly, to assess whether data quality is adequately documented, and to evaluate the management of quality assurance programs. Oversight is tailored to the nature of the activity and the associated QMPs and QAPPs. The assessment activities are outlined in the project's QAPP.

Quality issues that are Office-wide, pertain to the OAQPS quality management system, or overlap Divisions are elevated to the QAM to facilitate resolution. Quality issues that could recur or affect other Divisions or programs are elevated for resolution by the affected Divisions and the QA Team. Quality issues that impact other parts of the EPA follow the CIO Notification Process (CIO 2105-P-03.0), outlined in Section 9.9.

Results of the assessments are documented and archived and included in the QAARWP.

9.1 Assessments

An assessment is an all-inclusive term used to describe an evaluation process used to measure the performance or effectiveness of a system and its elements. Some examples of assessments include audits, inspections, management systems reviews, peer reviews, performance evaluations, QSAs, technical audits, and surveillance, among others.

Any assessment for environmental data activity must outline how and at what frequency the assessment will be conducted. Each planning document must describe: the process for implementing and documenting the required assessments; the required assessor qualifications; the process for monitoring and documenting the corrective actions; and the requirements for reporting results to management.

Personnel conducting an assessment must be independent of work being assessed. Assessors must have enough experience and training to conduct an assessment. Assessment personnel must be granted enough authority, access to programs and personnel (staff and manager), access to documents and records, and organizational freedom to conduct the assessment.

9.2 Self-Assessment

The emphasis in OAQPS's quality program is on self-assessment. In addition to following detailed quality assurance guidance in SOPs, individuals performing environmental measurements or working with secondary data and databases monitor the quality of their own efforts. Teamwork is stressed, and teams are expected to monitor their work and resolve quality issues. Work groups perform internal assessments on data, projects, and equipment. OAQPS's quality assurance program is assessed each year in the preparation of the QAARWP. The QAM is responsible for the consolidation, analysis, and submission of the QAARWP to EQMD. Opportunities for improvement are identified during the year as a result of reviews and observations. Self-assessment activities and their schedules are discussed in project QAPPs and reported in progress reports, typically monthly, to the COR. Contractors monitor their own quality control data and resolve any problems that are identified. CORs of contracts and POs for grants, cooperative agreements and interagency agreements are responsible for monitoring their contractor or grantee through discussions and review of progress reports and audits. CORs and POs are responsible for resolving or facilitating a resolution of problems elevated to them. The QAM participates in resolution of quality issues when required.

9.3 Technical System Audits

A technical system audit (TSA) is a qualitative audit of personnel, equipment, facilities, procedures, and quality control and assurance activities and are discussed in detail in Section 2 of this QMP. This audit can be performed prior to the data collection activity, in order to verify the existence, and to evaluate the adequacy of equipment, facilities, supplies, personnel, and procedures that have been documented in the QAPP. TSAs are also employed during the data collection activity in order to verify and evaluate the project results.

TSAs of randomly selected programs may be conducted as resources permit; or if a program is of high visibility, regulatory or compliance driven; a new activity for the Office; uses new equipment, and at the request from management. As resources permit, the QAM conducts audits of at least two programs of this nature each year. Additional non-routine audits and follow-up audits to verify the effectiveness of corrections or corrective actions also may be performed.

9.4 Performance Evaluation or Inter-laboratory Comparisons

A Performance Evaluation (PE) is a type of audit in which the quantitative data generated in a measurement system are obtained independently and are compared with routinely obtained data,

to evaluate the proficiency of an analyst or laboratory. Details of PE programs conducted and managed by OAQPS can be found in Sections 2 and 4 of this QMP. PE samples are also used, as appropriate and when available, to evaluate the competency of testing laboratories.

9.5 Data Quality Assessments

Data quality assessments are quantitative audits in which data are reviewed and evaluated following collection to determine the quality and usability of the data. DQAs are discussed in detail in Section 2.75 of this QMP. In addition to DQAs conducted at the program level, DQAs may be performed by the QAM as determined by the uniqueness of the project, or as requested by management.

9.6 Quality System Assessments

A quality system assessment (QSA) is an assessment of an organization's ability to implement and manage an effective quality assurance program; it establishes whether the quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. It is used to determine the effectiveness of, and adherence to, the quality program and the adequacy of resources and personnel provided to achieve and ensure quality in all activities.

Internal assessments of the OAQPS QS will be conducted annually. Internal assessments may focus on a selected Division or program to serve as a sample representative of OAQPS's quality system. The internal assessments place priority on programs that are regulatory, or compliance driven, have new test procedures or equipment, or as determined by observation. A more frequent internal review cycle may be required if serious deficiencies exist.

QSAs are discussed in detail in Section 2.5.1 of this QMP.

9.7 Assessment Process

9.7.1 Audit Team

Personnel performing audits must be trained in the basics of auditing and must have excellent communication skills, good problem-solving and analytical skills, strong sense of ethics and professional conduct, good people-interaction skills, and a technical knowledge of the subject matter. To maintain their skill level, audit personnel must participate in at least one assessment or participate in at least 8 hours of relevant training every 24 months. Audit personnel shall have no real or perceived conflict of interest in the area or entity being assessed. The selection of auditors shall ensure objectivity and impartiality of the audit process. The audit team has the authority and organizational freedom to perform the audits. This authority includes access to personnel, programs, documents, and records to support the audit process. The performance of the audit may be contracted.

9.7.2 Planning

Audit planning is necessary to conduct effective audits. The audit plan should include scope of the audit; audit type (described in Section 9.1 – 9.6); date; audit criteria; checklists of items and documents to be reviewed; organization, personnel, activities and locations to be audited; and proposed audit team. The audit plan also includes schedule for when the audit will be conducted,

presentation of initial findings, delivery of draft report, response to draft report, issue of final report, submission of corrective action plans, and completion of corrective actions. The audit plan is made available to the organization or program being audited, with adequate lead time to ensure appropriate personnel are available for the audit.

9.7.3 Execution

The audit or assessment is performed per the audit plan.

9.7.4 Reporting

At the completion of the audit or assessment, the lead auditor will compile the results and incorporate them into a report. The draft report shall be provided in a timely manner such that corrective actions can be implemented while the draft report is undergoing review and approval. The report will include the audit plan; a list of personnel interviewed; documents and activities reviewed; and a summary of the results and audit conclusions. The report can also have noteworthy practices to share, opportunities for improvement, deficiencies (minor instances of nonconformance), and findings (significant or widespread violations).

A draft report is provided to the audited organization for their review and comment prior to the distribution of the final report. The review should address accuracy of the content, such as agreement on the description of the finding, opportunity for improvement, or noteworthy practice. If there is not agreement on finding, the response to the draft report should include the reason(s) for the disagreement. The audit team leader and the audited organization should attempt to resolve any differences of opinion.

The audit reports provide information for the QAARWP.

9.7.5 Corrective Actions

The audit reports will be discussed with the audited organizations and Corrective Action Requests will be provided to the audited activities. Corrections and Corrective Action(s) necessary to mitigate the findings will be developed to ensure timely and effective resolution to findings. Management and staff will be asked to assist in problem resolution, as necessary. For each audit finding, a response detailing the corrective action is required.

9.7.6 Audit Close-out

Part of the close-out process of an audit is to evaluate and document the implementation of the Corrective Action(s). The finding, corrective action, and evaluation are documented. Supporting documentation or a follow-up audit may be required to verify the implementation and effectiveness of a corrective action. The Corrective Action Request is maintained by the QAM for audits or assessment performed on OAQPS. Otherwise, the documentation is maintained by the Program Manager and the DQAO associated with the program.

9.8 Notification of Environmental Data Quality Issues

The *CIO Notification Procedure for Environmental Data Quality Issues (CIO 2015-P-03.0)* describes the due diligence process for evaluating environmental data quality issues that have a potentially adverse effect on more than one EPA organization and describes the procedure for

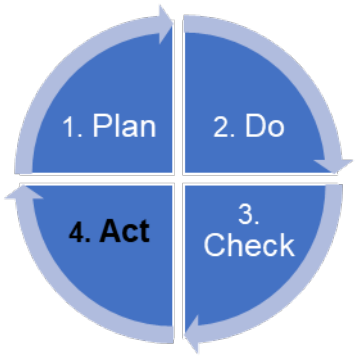
notifying potentially affected EPA organizations. The data quality issues could arise from work supported by a contract, grant, or other extramural agreement.

If a data quality issue is suspected or identified, the staff member notifies their Associate Division Director and the QAM. A work group is convened to conduct an evaluation of the data quality issue. The evaluation process is to:

1. Describe the data quality issue or suspected issue; including
    a. Name of the entity that produced the environmental data
    b. Timeframe in which the environmental data was produced
2. Determine the potential impacts of the data quality issue; including
    a. Severity (magnitude and likelihood) of data quality issue
    b. List of potentially affected organizations
        i. If the data quality issue affects other EPA organizations, the notification process described in CIO 2105-P-03.0, Section 6.2 of the Procedure is followed
        ii. If the data quality issue only affects OAQPS, then the data users are notified
3. Conduct root cause analysis to identify potential corrective actions
4. Implement selected corrective action(s) to mitigate the identified root cause a. Corrective actions may require updates to quality system documentation
5. Evaluation of implemented corrective action(s)

Management is kept apprised of the status of the evaluation process. Reports of data quality issues and the associated evaluation process are included in the QAARWP.

10. Quality Improvement



10.1 Quality Improvement

The OAQPS QA Program is committed to continual improvement of the OAQPS QS. Quality improvement is a process that proactively addresses vulnerabilities and enhances efficiency. The OAQPS QA Program meets regularly to discuss cross-cutting issues and to look at ways of improving the organizational implementation of QA. Quality improvement is incorporated as a core organizational element of OAQPS's quality culture and philosophy and looks to correct systemic problems, improve consistency, and streamline QA processes, as necessary. The OAQPS QA staff also provides a perspective on the continuous improvement process and provides advice and recommendations to program office managers on ways to improve the quality processes within OAQPS. If identified, the QA Program will address areas where a general policy needs to be established or changed.

The QA Program supports continuous training for staff in QA, as well as technical subjects related to their area of expertise and to new areas of interest or of emerging importance to the Agency and to OAQPS Programs.

OAQPS QA Program staff and management develop an annual list of Internal Assessments to be conducted that year, based on their experience during the past year, external reports, etc. This is further discussed in EPA Guidance on Technical Audits and Related Assessments for Environmental Data Operations, QA/G-7.

It is OAPQS's policy that the QA staff and all others associated with environmental data generation, use and reporting strive for continuing improvement in the products and services they provide, and in their performance in doing so. Managers should encourage innovation and improvement and should include it as tangible elements in staff performance reviews and awards. The OAQPS QAM and the other managers and supervisors should seek and implement processes designed to foster an atmosphere of improvement in the OAQPS QA community.

10.2 Corrective Actions

OAQPS's Quality Improvement Policy encourages corrective actions to be made at any time and by anyone; these actions may be formal or informal. Formal corrective actions, in response to assessment findings, must be taken promptly by the designated responsible organization,

Program and/or Office representative. This person is also responsible for tracking the response, confirming the implementation, assessing the effectiveness of any corrective action, and reporting the response status to the OAQPS QAM.

OAQPS managers are responsible for including formal corrective actions and/or corrective action plans into their fiscal work planning activities—for EPA activities as well as those of our partners (e.g., states, tribes, etc.) This approach ensures application of adequate resources and establishment of a timely response/conclusion schedule. OAQPS managers are responsible for reporting corrective action plans and completion status to the OAQPS QAM on a quarterly basis. Documentation includes reporting the original finding, the corrective action to be taken, the status of that action and the schedule for completion.

For findings that rise to a higher level of concern, OAQPS applies the obligations outlined in the Federal Manager's Financial Integrity Act (FMFIA) as a tool to identify and elevate emerging vulnerabilities to senior managers. OAQPS managers are responsible for identifying and communicating findings that may emerge as FMFIA vulnerabilities.

10.3 Dispute Resolution

When issues regarding QA are in dispute, resolution will be sought at the lowest management level possible. Such disputes may occur in situations involving technical issues (e.g., audits, data quality assessments) and management issues (e.g., QMP reviews, QAPP reviews, and quality system assessments).

All parties will make every effort to resolve disputes through discussion and negotiation. Disagreements will be resolved at the lowest administrative level possible. Should agreement not be reached at this level, the issue will be resolved by senior management as described in Section 1.

11 Information Quality Guidelines

OAQPS is dedicated to the collection, generation and dissemination of high-quality information. EPA's Information Quality Guidelines (IQGs) describe EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates. Thus, the IQGs are integral to the OAQPS Quality Management Plan for ensuring the quality of EPA's data products and information. This QMP incorporates by reference all definitions, principles, policies and procedures found in EPA's IQGs: *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*.

11.1 Existing Policies and Procedures to Ensure and Maximize Information Quality

The term "scientific information" or "information" means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page but does not include the provision of hyperlinks on a web page to information that others disseminate. The term includes "preliminary" information that EPA has endorsed or adopted as well as conclusions or facts drawn from or based upon other existing information. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered.

Definition of Dissemination

For the purposes of the OMB Information Quality Guidelines and Peer Review Bulletin, "dissemination" means Agency initiated or sponsored distribution of information to the public. EPA disseminates information when EPA initiates or sponsors the distribution of information to the public. See the OMB guidelines, linked above, for more information and examples.

EPA has developed and implemented numerous programs to ensure the quality of data and information being disseminated by the Agency. OAQPS will adhere to these programs in the development of technical information. Examples of such programs include the following.

11.1.1 Quality System

The EPA Agency-wide Quality System helps ensure that EPA organizations maximize the quality of environmental information, including information disseminated by the Agency. This quality system and OAQP's adherence to its requirements are discussed throughout this document.

11.1.2 Peer Review Policy

In addition to the Quality System, EPA's Peer Review Policy provides that major scientifically and technically based work products (including scientific, engineering, economic, or statistical documents) related to Agency decisions should be peer-reviewed. Agency managers within

Headquarters, Regions, laboratories, and field offices determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made consistent with program goals and priorities, resource constraints, and statutory or court-ordered deadlines.

For those work products that are intended to support the most important decisions or that have special importance, external peer review is the procedure of choice. For other work products, internal peer review is an acceptable alternative to external peer review. Peer review is not restricted to the final version of work products; in fact, peer review at the planning stage can often be extremely beneficial. The basis for EPA peer review policy is articulated in *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency*, which was first issued in 1993 and was most recently updated in 2006. In addition to the policy, EPA has published a Peer Review Handbook which provides detailed guidance for implementing the policy.

11.1.3 Action Development Process

The Agency's Action Development Process also serves to ensure and maximize the quality of EPA disseminated information and is discussed in detail in Section 2.8.7.1 of this document.

11.1.4 Integrated Error Correction Process

The Agency's Integrated Error Correction Process (IECP) is a process by which members of the public can notify EPA of a potential data error in information EPA distributes or disseminates. This process builds on existing data processes through which discrete, numerical errors in our data systems are reported to EPA. The IECP has made these tools more prominent and easier to use. Individuals who identify potential data errors on the EPA web site can contact us through the IECP by using the "Report Error" button or error correction hypertext found on major data bases throughout EPA's web site. EPA reviews the error notification and assists in bringing the notification to resolution with those who are responsible for the data within or outside the Agency, as appropriate. The IECP tracks this entire process from notification through final resolution.

11.1.5 Information Quality Guidelines

The Guidelines for Ensuring and Maximizing the Quality, Integrity, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (or EPA's Information Quality Guidelines [IQG]) contain the Agency's policy and procedural guidance for ensuring and maximizing the quality of information disseminated, and complements the quality management system for assuring the quality of our products and information. "Information" generally includes any communication or representation of knowledge, position or policy such as facts or data, in any medium or form. This includes preliminary information that EPA has endorsed or adopted, and conclusions or facts drawn from or based up on existing information (secondary use of information). Frequently asked questions about when the IQG applies can be found on the IQG intranet page.

Additional information and tools to support implementation of the IQG are available in the IQG Intranet site. This site contains example disclaimers for use by OAQPS staff.

11.1.6 Risk Characterization Policy and Handbook

The EPA Risk Characterization Policy and Handbook provides guidance for risk characterization that is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk. The Policy calls for a transparent process and products that are clear, consistent and reasonable. The Handbook is designed to provide risk assessors, risk managers, and other decision-makers an understanding of the goals and principles of risk characterization.

11.2 Selecting and Conducting an Appropriate Review Process

Whenever possible, existing review procedures will be used for the pre-dissemination review of information subject to the IQGs. The following describes various review processes, roles, and responsibilities for staff and management to implement IQG PDR. One or more types of review may be appropriate, depending upon the nature and importance of the information product.

Authors and supervisors who are developing an information product subject to IQG should use best judgment in determining which of the review procedures listed below are most appropriate. Criteria that management and staff consider when selecting the appropriate review mechanism include:

- Policy implications
- Scientific/technical content
- Precedent setting, innovative, or emerging issues
- Level of controversy or public/political interest
- Interagency implications
- Level of investment of Agency resources
- Crossing multiple jurisdictions

11.2.1 OAQPS Publication Review Process

The overarching purpose of the OAQPS publication review (OPR) process is to ensure that all OAQPS-authored publications are high-quality documents that support and advance the programmatic responsibilities of OAQPS.[1] The OPR process described here provide for timely, transparent, focused, and constructive collaborations across authors[2], reviewers, and managers within OAQPS to ensure the above purpose. As described below, the process consists of two broad stages.

[1] The internal publication review process discussed in this document only covers OAQPS-authored manuscripts submitted for external peer-reviewed scientific journals. OAQPS documents written for other purposes are expected to have their own review procedures.

[2] The OAQPS publication review process is intended both for papers with an OAQPS lead author or where the OAQPS participant is a co-author.

Stage 1: Preapproval and notification (expected timing: 2 weeks)

This stage of the OPR process ensures that OAQPS management approves a planned publication prior to employee(s) drafting it. It also ensures that OAQPS management is aware of ***all*** OAQPS-authored publications and status of Office review/clearance.

The preapproval starts with authors submitting an "abstract" of the planned publication for review and approval. This abstract provides a summary of the planned publication by answering the following questions:

- What is the working title of the proposed manuscript?
- Is the envisioned authorship complete and appropriate? Please explain briefly.
- What questions do you intend to address?
- What methodology do you intend to use to address the questions (e.g., data, models, etc.)?
- What are the anticipated limitations and uncertainties associated with the proposed work?
- Outside of OAQPS, with whom do you plan to collaborate as authors/co-authors?
- Who is the audience? And what key messages do you anticipate communicating to audience?
- How would the proposed paper support or advance the OAQPS programmatic responsibilities? Please point to specific OAQPS actions (past, present, future) where this publication could have tangible benefits.

The preapproval steps are:

- Before initiating any potential publication, the primary OAQPS author or coauthor provides the above information to their group leader (GL) for notification and approval.[3]
- The GL will review the answers and will either: a) disapprove the abstract, b) recommend improvements to the planned paper, or c) forward the abstract to their division director (DD).
- The DD - and, as necessary, the Senior Management Team - then makes the final decision on whether to approve or disapprove the abstract. If approved, the abstract goes into the OAQPS publication review tracking and notification system,

[3] For potential papers that involve multiple OAQPS authors across multiple groups or divisions, the author team will identify a single point of contact that will be responsible for abstract development. Approval will occur within the group/division of the point of contract, informed by conversations with other group leaders or division directors, as appropriate.

which is described in more detail below.

- Also, the OAQPS IO (i.e., OAQPS Science Advisor (SA)) is kept aware of all preapproved abstracts on a monthly basis as described in the notification component below. This provides them a timely opportunity to identify and further discuss any preapproved abstract with the DD. Based on this discussion, the IO may decide to recommend improvements to a prior-approved abstract or disapprove it.

Stage 2: Publication review and approval (expected timing: 4 - 8 weeks)

This stage of the OPR incorporates multiple reviews of preapproved, submission-ready manuscripts.[4]

The publication review and approval steps are:

- The primary OAQPS author or coauthor submits a submission-ready manuscript to their GL and notes any changes in the previously declared authorship.
- The GL will review the manuscript and will either: a) recommend improvements, or b) forward it to their DD or DD's designee.
- The DD or designee will recommend improvements as needed and coordinate any additional reviews by other groups in OAQPS or other EPA organizations (e.g., ORD) as appropriate. They will pass all comments to the primary author.
- The primary author will ensure all comments are addressed, and then will return a clean manuscript to the DD or designee, who will send it to the OAQPS SA for IO review.
- The SA will review and then return the manuscript to the DD or designee, clearing it with or without comments. In rare cases, the SA may involve the Deputy Office Director (DOD) in reviewing the manuscript.
- After all comments from the SA and/or DOD are addressed, the manuscript can be sent out for publication.

The progress of this stage is noted in a tracking system maintained by the SA and assessed in bi-weekly huddles of the publication review team.

[4] This will accommodate GL, DD, SA reviews and author(s) addressing comments. In some cases, the time for clearance may take longer if additional reviews are needed.

11.2.1.1 OAQPS publication review tracking and notification system

An electronic tracking system[5] is used by the SA to maintain a record of preapproved abstracts and publications (under review or published). This system has the capability to provide monthly reports noting the following information generated each month:

- Pre-approved abstracts
- Papers undergoing internal review
- Papers undergoing external review
- Papers published[6]

The SA emails the monthly report to the Senior Management Team.

11.3 Process for Approval of Information Prior to Dissemination

Types of Review Processes:

11.3.1 Author's Review

The primary author has the main responsibility to ensure that the information content of a product is scientifically sound, meets the project's objectives, and fulfills the objectivity, utility, and integrity criteria of the IQGs.

In some cases, the primary author may have had others (*i.e.*, chemists, toxicologists, GIS staff, etc.) prepare all or part of the material required to generate an information product. The technical support staff also has a role to ensure that the method and assumptions used in the analysis are appropriate to meet the primary author's stated purpose, that the data sources used are as defined in the project plan, and that the output produced has provided a reliable rendering of the analysis. The supervisor of technical support staff is responsible for the quality of their work.

11.3.2 Supervisor and/or Management Review

The direct supervisor of the author is responsible for the quality of the information subject to the IQGs disseminated by his/her Group/Program. The supervisor is also responsible for conformance of information products to applicable EPA policy. The supervisor's review of disseminated information includes the responsibility to ensure that the information quality is adequate for its intended use, and has the characteristics of objectivity, utility, and integrity as defined in the IQGs.

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[5] The team will develop and maintain an electronic tracking system to monitor the progress of abstracts and publications through the system (using the proxy card concept), as well as keeping a record of approvals. Until that is established, the team will continue to maintain the flow board on the 4th floor.

[6] Authors have the responsibility to ensure that their publication meets all OAR requirements for EPA-authored publication, including upload to PubMed and ensuring data availability.

11.3.3 Informal External Reviews

The OAQPS periodically solicits reviews of draft documents and information products from qualified individuals who are external to the OAQPS. The focus of an external review should be to ensure that the document or product is scientifically sound. Examples of external reviewers include experts from:

- Other EPA offices
- Other federal agencies
- FACA committees (e.g., SAB, CASAC)
- States/tribes
- Academia

OAQPS personnel have the responsibility to ensure that external reviewers are aware of any specific issues that should be a focus of attention and that reviewers understand their overall responsibilities. Products that are reviewed for quality by external reviewers should also be reviewed by qualified EPA personnel.

11.3.4 Formal Peer Review

Formal peer reviews are conducted and documented in accordance with the Agency's Peer Review Handbook. Formal peer review is generally considered to be the highest level of technical quality review. Supervisors are responsible to inform their respective Office Director and the Peer Review Coordinator about any information products that are likely to be subject to formal peer review. Any scientific and technical products that are peer reviewed must also be reviewed by qualified EPA OAQPS personnel to verify that IQG requirements are fully met.

11.4 Records Management Process for Pre-Dissemination Review

OAQPS requires that all IQG reviews be documented by the author and carried through the review process. When reviews are completed, reviewers sign/acknowledge the review and the author documents the review with the IQG Officer. The IQG Officer will sign off to acknowledge the pre-dissemination review is complete and the product may be processed.

11.5 OAQPS Peer Review

To be most effective and efficient, peer review of a scientific or technical work product must be incorporated into the up-front planning of any decision or action that will be made or taken based on the work product. The planning for peer review activities should occur at the time of overall project planning and includes obtaining the proper resource commitments and establishing realistic schedules to accommodate the peer review process. Peer review is not restricted to the nearly final version of a report or similar work product. In fact, peer review of the planning documents such as QAPPs, study designs or research plans can often be extremely beneficial to avoid fundamental and costly errors in the study design. Proper advance planning by the project or program manager is essential to ensuring a positive and seamless peer review experience.

11.5.1 Policy Overview

The Agency's 2006 Peer Review Memorandum, *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency* states:

"Peer review is encouraged and expected for all scientific and technical information that is intended to inform or support Agency decisions.

Influential scientific information (ISI) and highly influential scientific assessments (HISA) should be peer reviewed according to the *EPA Peer Review Handbook, 4th edition* (2015). See the Handbook for definitions of ISI and HISA. All Agency managers are accountable for ensuring that Agency policy and guidance are appropriately applied in determining if their work products are influential or highly influential, and for determining the nature, scope and timing of their peer review. For HISAs external review is the expected procedure. For influential scientific information intended to support important decisions, external peer review is the approach of choice. Peer review is not restricted to the nearly final version of work products, in fact, peer review at the planning stage can often be extremely beneficial."

The peer review requirements differ somewhat depending on the nature of the work product and/or relevant statutory requirements.

Appendix A OAQPS Groups by Division

A1 Central Operations and Resources Groups

A1.1 Acquisitions and Accountability Group

The Acquisitions and Accountability Group (AAG)

- Manages OAQPS contracts, grants, and other extramural resource management processes, and
- Ensures that adequate fiscal controls are maintained.

A1.2 Resource Planning and Management Group

The Resource Planning and Management Group (RPMG) manages

- Budget formulation and execution for OAQPS portions of Headquarters and Regional resources and state grants; and
- OAQPS computer and information resources and support services, including
    - Local area network support;
    - information system security;
    - capital planning and investment control, and
    - IT cost accounting.

A2 Air Quality Assessment Division

A2.1 Ambient Air Monitoring Group

The Ambient Air Monitoring Group (AAMG) provides leadership in partnership with SLT air monitoring agencies and EPA Regional Offices in the planning and operation of the nation's ambient air quality networks, supporting key objectives including providing air pollution data to the general public in a timely manner, supporting compliance with ambient air quality standards and emissions strategy development, and supporting air pollution research studies. The Group's principal responsibilities include:

- Providing technical leadership for key monitoring networks supporting measurement of criteria pollutants monitored in the SLAMS network, $PM_{2.5}$ speciation (CSN/IMPROVE), ozone precursors (NCore/PAMS), and NATTS;
- Proposing and promulgating regulations to support ambient monitoring activities including specific requirements for network design, probe and siting requirements, QA, and data reporting and certification;
- Collaborating with the ORD and other partners on the evaluation of new methods for measuring criteria pollutants, air toxics, precursors, and meteorology;
- Developing data quality objectives, quality control procedures, guidance documents, and national audit programs (NPAP/PEP) for assuring the quality of ambient air data collected from the National Networks;

- Coordinating the validation and reporting of data to key national databases including the Air Quality System and AIRNOW;
- Assessing concentration and QA data to assure support for monitoring objectives;
- Conducting training and outreach activities including development of training videos and classes, maintenance of AMTIC, and support for the biennial National Ambient Air Monitoring Conference and Air Toxics Workshop;
- Providing grant guidance and coordinates STAG funding for supporting monitoring activities and special programs including the Community Scale Air Toxics Grants;
- Collaborating with other OAQPS groups, OAR offices, EPA Regional Offices, SLT air agencies, multijurisdictional and regional planning organizations, academia, NGOs, and instrument manufacturers to advance and coordinate ambient air monitoring activities; and
- Collaborating with the State Department, World Bank, and foreign country environmental programs in support of international monitoring objectives.

A2.2 Air Quality Analysis Group

The Air Quality Analysis Group (AQAG) is responsible for assessing ambient pollutant levels across the United States through comprehensive and innovative analyses to inform the public of the current status and trends of the nation's air quality, and to support policy and regulatory decisions in the OAQPS, the Office of Air and Radiation (OAR), and the Agency generally. The AQAG leads or performs the following principal functions:

- Assessing air quality data for OAQPS policy and program development, evaluation, and accountability (including the calculation of criteria pollutant design values for assessing current air quality);
- Analyzing complex air quality databases to identify patterns, understand cause-and-effect relationships, and otherwise characterize the nation's air quality to support the development and analytical basis of air pollution regulations and policies;
- Informing the public about the current status and trends of the nation's air quality through the publication of air quality databases, map services, peer-reviewed journal articles, and comprehensive reports;
- Producing state-of-the art analytic and visualization tools, mapping applications, and story-maps to support NAAQS implementation decisions, inform the public of major rulemakings and increase accessibility to air quality data;
- Providing air quality analysis and expertise to inform decisions on highly sensitive policy issues (such as the adjustment of air quality data to account for the influences of changing meteorological conditions);

- Incorporating emerging air quality datasets (such as the Village Green Project), air quality modeling data and novel analytical approaches to supplement and enhance analyses from the existing monitoring network;
- Developing and applying air quality assessment methods and indicators within an accountability framework to assess the progress of air quality management programs (such as those of the EPA, regions, states and others) to ascertain the achievement of their environmental goals and to determine the need/opportunity for mid-course corrections to these programs; and
- Coordinating the analysis and development of air quality information with other OAQPS groups, OAR offices, EPA Regional Offices, Office of Environmental Information, SLT air pollution control agencies, and private sector and academic experts to advance and direct the effective use of EPA's base of relevant scientific information.

A2.3 Air Quality Modeling Group

The Air Quality Modeling Group (AQMG) is responsible for understanding and applying physical and chemical atmospheric processes with numerical simulation models to support policy and regulatory decisions in the Office of Air and Radiation (OAR) and provides leadership and direction on the full range of meteorological and air quality models, and other mathematical simulation techniques used in assessing control strategies and source impacts on national, region, and local air quality levels. The AQMG leads or performs the following principal functions:

- Providing leadership and expertise in understanding physical and chemical atmospheric processes related to characterizing criteria and toxic pollutant ambient concentrations and deposition;
- Providing leadership and expertise in applying photochemical, dispersion and other mathematical simulation models and techniques that are integral to policy and regulatory decisions by the Agency for multiple pollutants, sources, and spatial scales (e.g., global, national, regional, and local or neighborhood);
- Providing leadership and direction through technical guidance on the selection, use, and evaluation of models to meet Clean Air Act and related federal requirements for assessments of source impacts and control strategies by the EPA as well as other federal agencies; multi-state organizations; SLT agencies; research institutions; and stakeholder organizations;
- Collaborating with the ORD and the atmospheric research community to promote the development and evaluation of new models, techniques, and atmospheric research studies that meet policy and regulatory needs (e.g., NAAQS reviews and implementation, risk and exposure analyses, cost-benefit analyses, future projections of air quality levels, etc.);
- Collaborating across modeling community on modeling studies to assess future air quality and the sensitivity of control programs and policies under alternative climate

regimes and conducts global to regional-scale modeling to identify and evaluate linkages of regional air quality and climate; and

- Collaborating with the EPA's ORD, National Oceanic and Atmospheric Administration (NOAA), National Aeronautics and Space Administration (NASA), and other scientific and stakeholder organizations to ensure best practices for the development and use of meteorological and atmospheric chemistry models for use in general and Air Quality Management in particular.

A2.4 Emissions Inventory and Analysis Group

The Emissions Inventory and Analysis Group (EIAG) is responsible for creating and using air emissions inventories, methods, and tools to support policy and regulatory decisions in the Office of Air and Radiation (OAR). EIAG provides leadership and direction on the full range of emissions inventory technical and policy issues for characterizing national, regional, and local air quality. The EIAG is responsible for the following principal functions:

- Developing and maintaining a complete, credible, representative, timely, and transparent National Emissions Inventory (NEI) of criteria pollutants and precursors, hazardous air pollutants, and greenhouse gases;
- Creating emissions data and future year projections for air quality models to support regulatory development, cost/benefit analyses, and risk assessments, while ensuring high quality and timely delivery;
- Creating and providing emissions trends, summaries, quality reviews, and other analyses to inform the public, respond to inquiries, and support air quality analysis, Clean Air Act implementation, international emissions reporting, and risk management decisions;
- Developing, sharing, and supporting state-of-the-science software tools and associated data to improve the NEI, manage emissions data, project emissions to the future, and to create finer spatial, temporal, and species resolution of emissions needed for air quality modeling.
- Coordinating and hosting the International Emissions Inventory Conference, providing training for the emissions community on emissions processes and tools, and consistently striving to keep others informed about our efforts;
- Developing guidance and contributing to regulatory requirements for emissions aspects of implementing the NAAQS, including development of SIPs;
- Working with SLT agencies as key data partners, and with other EPA offices, other federal agencies, and multi-state organizations to enhance all the group's activities; and
- Continually improving the collection, scientific basis, data quality, delivery, and availability of air emissions products.

A2.5 Measurement Technology Group

The MTG is responsible for development and advancement of effective and reliable emission measurement methods, procedures, and technology for measurement of criteria pollutants, air toxics, and greenhouse gases to underpin emission standards and implementation of national regulatory programs. The MTG leads or performs the following principal functions:

- Developing and specifying critical measurement and monitoring procedures for the assessment of source and near source emissions to inform Information Collection Requests and standards setting, development of emission factors and inventories, and other national air quality management decisions;
- Proposing and promulgating federal reference test methods and emission monitoring performance specifications including QA procedures to be used in determining compliance with federal emissions standards (New Source Performance Standards (NSPS) and National Emissions Standards for Hazardous Air Pollutants (NESHAP)), SIPs, and PSD, NSR, and Title V permits;
- Implementing the EPA Administrator's delegated authority to review and approve/disapprove requests for alternative test methods for application under 40 CFR Parts 59, 60, 61, 63, and 65 and publishes broadly applicable alternatives in the Federal Register and on the EPA website;
- Evaluating and demonstrating emerging measurement technologies through lab and field studies assessing performance in collaboration with other EPA offices, federal agencies, industry, and technology vendors focusing on more continuous, cost-effective characterization of more pollutants and emissions from both ducted and non-ducted fugitive sources;
- Bridging the gap between traditional source and ambient air quality measurement through development of methods to assess facility emissions near-source and at the facility fence line;
- Providing technical expertise to EPA Regional Offices, state/local agencies, regulated industry, testing consultants as well as the international community regarding consistent application of emission test methods and monitoring procedures and interpretation of data;
- Disseminating technical guidance and other informational documents, test methods and monitoring procedures, and related tools through the EPA website, workshops for regulators, and conference presentations; and
- Coordinating with other EPA media programs on the Forum on Environmental Measurement and other cross agency groups regarding shared measurement issues and advancement of innovative measurement technologies.

A3 Air Quality Policy Division

A3.1 Geographic Strategies Group

The Geographic Strategies Group (GSG) develops and implements air quality management regulations, policies and strategies to address regional, national, and multi-national scale

pollution problems. This includes pollution transported across state borders and international borders with Canada and Mexico, and transcontinental pollution transported from the Far East and Africa. Additionally, GSG:

- Develops regulations, technical guidance and other support to assist EPA Regional Offices and state and local air agencies in implementing the programs that address these problems;
- Provides necessary technical assistance to federal, SLT agencies to implement the regulations, policies and strategies that it develops;
- Coordinates its product development with other EPA offices and federal agencies, and works closely with SLT agencies and other key interested stakeholders in developing policies;
- Provides direct support to assist Regional Offices in the review and approval or disapproval process of state-submitted revisions to SIPs that involve its programs (e.g., regional haze, interstate and international pollution transport);
- Works with Regional Offices to coordinate Clean Air Act program implementation efforts, evaluate strategic directions, and align program priorities; and
- Works closely with other OAQPS Divisions to ensure that OAQPS policies incorporate and encourage cross-program integration of implementation strategies (including co-control of hazardous and criteria air pollutants), the use of innovative regulatory strategies and pollution prevention strategies, and consideration of environmental justice issues.

GSG's principal substantive areas of responsibility include:

- Designating areas as attainment or nonattainment for new or revised national ambient air quality standards;
- Interstate pollution transport programs;
- Provisions governing international pollution transport;
- Class I area visibility protection program (a/k/a regional haze program);
- Integrated multi-pollutant national and regional pollution reduction strategies; and
- Exceptional event provisions.

A3.2 New Source Review Group

The New Source Review Group (NSRG) manages the development and implementation of requirements under the NSR programs which include the nonattainment new source review (NNSR) and PSD provisions of the Clean Air Act. It serves as national program manager guiding federal, SLT agency efforts related to pre-construction permitting. Additionally, NSRG:

- Determines and develops regulations, technical guidance and other support to assist EPA Regional Offices and state and local air agencies in implementing the national program at their level;
- Provides direct support to assist Regional Offices in the review and approval/disapproval process of state-submitted revisions to pre-construction programs;
- Promotes integration of NSR, operating permits, hazardous air pollutants, and related programs, and coordinates the identification and resolution of cross-program implementation issues; and
- Works with Regional Offices to coordinate Clean Air Act program implementation efforts, evaluate strategic direction, and align program priorities.

The Group's principal substantive areas of responsibility include:

- NSR program framework;
- NSR program regulations and policies;
- Federal NSR regulations for Indian country;
- PSD increment assessment;
- Implementation of NSR across EPA including issuance of permits, where applicable; and
- Oversight, evaluation, and improvement of NSR programs.

A3.3 Operating Permits Group

The Operating Permits Group (OPG) is responsible for developing national regulations and guidance as required under the Clean Air Act Title V operating permits program (CFR Parts 70 and 71). It serves as national program manager guiding federal, SLT agency efforts related to issuing and renewing operating permits. Additionally, OPG:

- Determines and develops regulations, technical guidance and other support to assist EPA Regional Offices and state and local air agencies in implementing the national program at their level;
- Establishes and maintains cooperative working relationships with Regional Offices, state and local agencies, other EPA programs, and interested parties outside the Government on regulatory and policy issues related to the operating permits program and the applicability of industrial sector regulations;
- Provides direct support to assist Regional Offices in the review and approval/disapproval process of state-submitted revisions to operating permit programs. It also assists Regional Offices in ongoing oversight of state programs;
- Coordinates resolution of selected technical support issues with national implications with Regional Offices and state and local agencies;

- Establishes national operating permit program information requirements and other performance measures for use in evaluating the program; and
- Works with Regional Offices to coordinate Clean Air Act program implementation efforts, evaluate strategic direction, and align program priorities.

OPG's principal substantive areas of responsibility include:

- Title V permit program implementation issues;
- Parts 70 & 71 rule revisions;
- Title V permit program implementation in Indian country;
- Title V permit program fees;
- Title V permit issuance tracking;
- Resolution of Title V citizen petitions;
- Oversight, evaluation, and improvement of Title V permit programs; and
- Applicability determinations for NSPS and NESHAP.

A3.4 State and Local Programs Group

The State and Local Programs Group (SLPG) develops and implements air quality management policies, regulations, and other strategic measures for attainment and maintenance of national ambient air quality standards (NAAQS) for criteria pollutants. It serves as national program manager guiding federal, SLT agency efforts for attainment and maintenance of the NAAQS. Additionally, SLPG:

- Provides national oversight and coordination of SIP development and review with regional offices, SLTs, and other appropriate federal agencies;
- Determines and develops regulations, technical guidance and other support to assist EPA regional offices and state and local air agencies in implementing the national program at their level;
- Coordinates policy development with other EPA offices and federal agencies, and works closely with SLT agencies and other key interested stakeholders in developing policies;
- Develops locally targeted strategies and policies where an air quality problem is not suited to a uniform national or regional program;
- Works with Regional Offices to coordinate Clean Air Act program implementation efforts, evaluate strategic direction, and align program priorities; and
- Works closely with other OAQPS Divisions to ensure that OAQPS policies incorporate and encourage cross-program integration of implementation strategies (including co-control of hazardous and criteria air pollutants), the use of innovative regulatory

strategies and pollution prevention strategies, and consideration of other program priorities such as environmental justice.

SLPG's principal substantive areas of responsibility include:

- SIPs for attainment and maintenance of NAAQS;
- Nonattainment area attainment determinations for NAAQS;
- Nonattainment area reclassifications and redesignations for NAAQS;
- NAAQS implementation rules and guidance;
- Reasonably Available Control Technology/Reasonable Available Control Measures (RACT/RACM) issues;
- General conformity program; and
- Incentives for voluntary pollution control programs for criteria pollutants.

A4 Health and Environmental Impacts Division

A4.1 Air Economics Group

The Air Economics Group (AEG) assess the cost and economic impacts of air pollution programs. Specifically, AEG:

- Provides scientifically defensible and transparent economic assessments to EPA and other stakeholders in a policy relevant timeframe;
- Develops methodologies, models and applied tools for economic analyses;
- Conducts analyses of costs and economic impacts of air quality management strategies, programs, and regulations developed throughout EPA;
- Participates in Agency-wide assessments of the cost and economic impact of environmental programs and development of policies, methodologies and models for this purpose;
- Performs and documents a wide range of economic analyses to address social cost economic impacts, regulatory flexibility (e.g., impacts on small business and Tribes), environmental justice, and information collection requests;
- Collaborates with researchers throughout the Agency as well as in academic, research institutes, and other government organizations to improve the science of applied environmental economics;
- Provides technical support and expertise on cost and economic impact models to regional, SLT agencies, international agencies, and the public;
- Serves as coordinator for Regulatory Impacts Analyses (RIAs) for OAQPS; and
- Provides expertise to assist the public and others in the understanding of cost and economic impact of environmental regulations and policies.

A4.2 Ambient Standards Group

The Ambient Standards Group (ASG) leads the review and revisions, as appropriate, of existing primary and secondary NAAQS and/or the establishment of new NAAQS. The ASG:

- Manages the interoffice NAAQS review process, including coordination with intra-agency workgroups;
- Coordinates and collaborates with ORD in preparing Integrated Review Plans and in ORD's development of Integrated Science Assessments;
- Coordinates and collaborates with other groups within HEID in their development of risk and exposure assessments and on issues related to ecosystem services, air quality and climate change, and regulatory impact analyses;
- Coordinates and collaborates with other groups within OAR on NAAQS review-related activities, including ambient air monitoring, air quality data analysis and evaluation of health evidence related to the NAAQS reviews;
- Prepares NAAQS Policy Assessments that integrate science and exposure/risk information to identify policy options for the Administrator's consideration;
- Prepares proposed and final NAAQS rules;
- Obtains peer review of Integrated Review Plans and Policy Assessments through the Clean Air Scientific Advisory Committee;
- Provides support to the Office of General Counsel and the Department of Justice in litigation related to NAAQS decisions;
- Develops and provides communication materials related to NAAQS reviews for use in communicating with SLT agencies, stakeholder groups, the scientific community, and the public;
- Holds public hearings and responds to public comments that come in on the documents and proposed rules;
- Collaborates with researchers throughout the Agency as well as in academic and research institutes and other government organizations to expand and improve the scientific information on health and welfare effects associated with criteria pollutants for use in supporting NAAQS reviews;
- Reviews and revises the AQI, as appropriate, and supports effective public communication of information related to health effects of criteria pollutants; and
- Coordinates and collaborates with other federal and state agencies and public health, medical, and environmental organizations on issues related to public health and environmental indicators, public health and environmental tracking, and health and welfare effects communication.

A4.3 Air Toxics Assessment Group

The Air Toxics Assessment Group (ATAG) works closely with relevant OAQPS divisions to perform quantitative exposure and risk assessments for national air toxics program regulations, including quantitative assessments of human and environmental exposures and risks due to air toxics emitted from sources which have been identified under the residual risk program or other similar mandate. Specifically, ATAG:

- Collaborates with researchers throughout the Agency as well as academic, research institutes, and other government organizations, striving to improve the implementation of state-of-the-art scientific developments in EPA exposure and risk modeling methodologies;
- Manages and conducts the NATA and works to improve the modeling methods and databases on which the NATA assessments are based, including efforts to integrate with the National Air Pollution Assessment results;
- Uses NATA results to inform air toxics monitoring strategies and initiatives such as the School Air Toxics program;
- Works with the Air Quality Analysis Group to analyze and characterize the public health and risk implications of the monitoring data generated by monitoring initiatives;
- Develops risk communication language interpreting the estimated and potential health effects of all hazardous air pollutants to support rulemaking efforts, NATA data releases, SAT data and analysis releases, emergency response activities, fact sheets, and communications support materials for other parts of OAQPS and OAR; and
- Serves as the HEID Environmental Justice Policy Lead, coordinating across OAQPS the development of expertise in analyzing and interpreting health and risk data with respect to environmental justice concerns and implications, and ensuring that the methods used are scientifically defensible and that the interpretations of the results are accurate and useful to policy-makers.

A4.4 Climate, International and Multimedia Group

The Climate, International and Multimedia Group (CIMG):

- Works in close coordination with other OAQPS Divisions, OAR and EPA Offices, State Department and other external organizations to develop, implement and lead international initiatives, assessments, strategies, programs and projects to address air pollution ofof relevance to U.S. air quality.
    - Leads and coordinates EPA participation in United Nations' Convention on Long Range Transboundary Air Pollution and US/Canada Air Quality Agreement;
    - Leads and coordinates OAQPS participation in bilateral and multilateral cooperation on air quality management with key countries (especially, Mexico), regions and organizations;

  - Provides national and local policy makers in other countries with a framework for developing and implementing comprehensive action plans to address air quality and improve public health in urban centers;
  - Manages, coordinates and addresses requests directed to OAQPS for international policy development and review, strategy development, international travel and technical support;
  - Manages web area on air quality management for international audiences and addresses requests for visitors, technical exchange, trainings and information originating from other countries and international organizations; and
  - Oversees international efforts on the hemispheric transport of air pollution and its relative contribution to the United States as well as the contribution of air pollution from the U.S. to other countries. This includes ozone and its precursors, particulate matter and its precursors, heavy metals such as mercury, and persistent organic pollutants (POPs).
- Leads and coordinates participation in multi-pollutant and multimedia initiatives in OAQPS.
  - Leads, participates in, and keep abreast of assessments related to cross-border or global emissions and their impacts on ecosystems and human health in the United States via multi-media exposure pathways, including mercury and nitrogen;
  - Engages as OAQPS liaison on ecosystem protection and multimedia program activities that extend beyond NAAQS and residual risk programs, including issues related to multimedia effects of reactive nitrogen, binational strategies for chemicals under the Great Lakes Water Quality Agreement, and international agreements (e.g., Minamata Convention for mercury); and
  - Builds capacity to use and advance the foundation of data and techniques that exist to support multi-pollutant assessments for criteria pollutants, air toxics, and greenhouse gases.
- Serves as EPA and OAQPS subject matter experts on international air quality management, including linkages with climate change, and international multimedia and multipollutant issues.
  - Promotes data-driven and evidence-based approaches for reducing air pollution;
  - Participates in and provides expertise on international health risk communication, international air quality indices, and the role of emerging technologies in air quality health assessment such as low-cost sensors and satellite-based remote sensing;
  - Responds to requests for information from EPA management, EPA communications staff, other federal agencies, international organizations, the scientific community, and the public;

- Participates in expert panels and conferences focused on related subject matter;
- Provides technical guidance to air quality management initiatives run by other federal agencies (e.g., State Department's embassy monitoring program, air quality management training for foreign service officers); and
- Promotes an integrated approach for air quality management to achieve multiple benefits, including human health, climate change mitigation, agriculture, and ecological systems. Manages and provides expert input on the co-benefits of addressing climate change and air quality together, with a focus on short-lived climate pollutants, in particular, black carbon, tropospheric ozone, and ozone precursors..

A4.5 Risk and Benefits Group

The Risk and Benefits Group (RBG):

- Conducts risk and exposure assessments for the criteria pollutants as part of the reviews of the National Ambient Air Quality Standards, including assessments related to both public health and public welfare;
- Conducts health impact and economic benefit assessments for inclusion in Regulatory Impact Analyses prepared in support of major rulemakings;
- Conducts ecological and welfare benefits assessments for inclusion in Regulatory Impact Analysis prepared in support of major rulemakings, including direct exposure to ambient concentrations of air pollution and exposures due to deposition or other transformations of ambient air pollution;
- Works with ORD and academia to develop methods to conduct exposure, risk, health impact, and benefits analyses and to develop and improve exposure and risk models for multimedia, multi-pollutant assessments;
- Assesses health and ecological benefits associated with changes in air quality resulting from policies to decrease emissions of greenhouse gases or short-lived climate forcers such as black carbon or ozone;
- Works with Air Toxics Assessment Group to address environmental justice concerns by assessing exposures, risks, and benefits among different socio-demographic groups and susceptible/vulnerable populations;
- Provides technical support and expertise on risk, benefit, and impact models to regional, SLT agencies, international agencies, and the public on the benefits and costs of improving air quality;
- Provides support for enforcement cases for the Office of Enforcement and Compliance Assurance and Department of Justice in terms of information on the health impacts of emissions from sources, or health impacts from decreases in emissions resulting from enforcement actions; and

- Serves as focal point for communication materials related to risk analysis and benefits characterization for use in communicating within EPA and externally with other federal agencies, SLT officials, the scientific community, and the public.

A5 Outreach and Information Division

A5.1 Community and Tribal Programs Group

The Community and Tribal Programs Group (CTPG) provides technical expertise and assistance to Tribal Nations, small businesses, environmental justice communities, and state and local environmental organizations as they seek to better understand and implement the provisions of the Clean Air Act (CAA). Specifically, the group:

- Builds tribal, community, and small business capacity by providing targeted training on CAA topics;
- Provides technical support for tribal, small business, and community programs as they seek to reduce criteria pollutants and toxics;
- Prepares tribes, small businesses, and communities to help them meaningfully participate in the rulemaking process;
- Facilitates government-to-government consultation and meaningful engagement with tribal leaders;
- Serves as the OAQPS lead for environmental justice and community outreach; and
- Serves as the OAQPS point of contact for small business issues and outreach.

A5.2 Information Transfer Group

The Information Transfer Group (ITG) serves as a bridge between OAQPS programs and information technology. By maintaining much of OAQPS' web content, building small to medium applications, operating information systems like AirNow, and providing expertise in technology, ITG puts OAQPS information into the hands of the public. Millions of people rely on the real-time air quality information available through AirNow to make public health decisions for themselves and their families, especially during wildfires. Specifically, ITG:

- Operates the Agency's real-time and forecast air quality system, AIRNow;
- Coordinates air quality forecast efforts between EPA, state, and local air agencies, and the National Weather Service;
- Manages the operation and maintenance for various OAR and OAQPS websites;
- Leads Section 508 training and compliance related activities for OAQPS. Section 508 of the Rehabilitation Act of 1973, requiring all federal agencies to make electronic systems and content accessible to people with disabilities;
- Provides leadership in the planning and execution of the bi-annual National Air Quality Conference, which brings hundreds of air quality professionals together to discuss the

latest information on the air quality index, AIRNow, air quality forecasting and mapping, air quality's impacts on health, and innovative outreach programs;

- Administers the Air Quality Flag Program, which is designed to inform the public of daily air quality conditions, health effects, and simple actions they can take to reduce exposure to air pollution;
- Manages the Targeted Airshed Grant program, which is a competitive program designed to provide funds to the most polluted nonattainment areas in the US so they can reduce particulate matter and ozone emissions; and
- Plans and conducts an annual Air Quality Workshop for Educators for K-12 teachers in North Carolina. The workshop is a hands-on event that supports NC teachers in learning more about EPA's air quality programs, with the goal of encouraging environmental education and stewardship in schools.

A5.3 Innovative Programs and Outreach Group

The Innovative Programs and Outreach Group (IPOG) partners with multi-jurisdictional organizations to meet the training needs of environmental professionals across the country. SLT environmental professionals depend on CAA training to help them implement OAQPS regulations fairly and accurately. The National Training Program, which is managed by IPOG, provides hundreds of comprehensive training courses on air pollution topics using self-instructed lessons, video modules, and classroom education. Specifically, IPOG:

- Manages the Agency's Air Pollution Training Institute. This involves developing training for SLT air agencies on air pollution control, OAQPS policies, guidance, and regulations;
- Works with OAQPS partners to educate the public on burning the right wood, the right way, in the right appliance through the Burn Wise Program; and
- Administers the Agency's woodstove changeout program.

A5.4 National Air Data Group

The National Air Data Group (NADG) is responsible for designing, operating, maintaining, and continually improving the large-scale information systems that house data used to develop and implement EPA's national air programs. Two of NADG's systems, the AQS and the Emissions Inventory System (EIS), are included among the agency's number one mission essential functions. Specifically, NADG:

- Designs, operates, maintains, and enhances large-scale information systems through in-house software development;
- Continually assesses current information system technologies and uses IT best practices to operate and maintain the information systems;
- Works closely with customers and stakeholders to define and develop tools and strategies that help them meet their regulatory responsibilities;

- Offers its considerable IT expertise to other information system teams throughout OAQPS; and
- Provides tribal leaders with the information they need to make decisions about consultation requests on OAQPS programs and to strengthen government-to-government relations.

A6 Sector Policies and Programs Division

A6.1 Energy Strategies Group

The Energy Strategies Group (ESG) is responsible for investigating and developing flexible, innovative and cost-effective regulatory alternatives, including non-combustion alternative energy processes; for stationary combustion sources; reviewing, evaluating, and adopting new and innovative technologies and energy strategies to reduce the nation's dependence on foreign oil imports; and providing expertise to increase overall energy system efficiency, fuel diversity and stability for the nation's green energy economy future. Specifically, the ESG is responsible for:

- Completing appropriate ongoing regulatory efforts under the Clean Air Act for Maximum Achievable Control Technology, area sources, residual risk, and new source performance standards relative to stationary combustion turbines and steam electric generating units;
- Coordinating the above activities across SPPD for reciprocating internal combustion engines (RICE) in developing a sector-based approach for these sources;
- Working collaboratively with SLT, regional, national, and international regulatory organizations to ensure relevant stationary source regulations promote flexible technology and process alternatives, energy efficiency and fuel diversity;
- Implementing an industrial boiler strategy that incorporates achieving emission reductions from industrial boilers within a sector framework;
- Ensuring that OAQPS is a recognized leader in emerging technologies and processes for energy production, including those which transcend current combustion technologies, and strategies for reducing criteria pollutants, hazardous air pollutants and greenhouse gas emissions;
- Providing programmatic support to encourage energy efficiency and air pollutant emission reductions across all commercial and industrial sectors, including emerging alternative power generation; and
- Managing the RACT/BACT/LAER Clearinghouse, including merging the ORD GHG Mitigation Database into this framework.

A6.2 Fuels and Incineration Group

The Fuels and Incineration Group (FIG) is responsible for developing and implementing regulatory and non-regulatory actions for the production of fuels, including coal, oil, and natural gas; alternative fuel sources such as biofuels; and solid waste management including municipal

waste combustion. The FIG develops and implements innovative strategies to reduce toxic, criteria, and non-criteria air pollutant emissions, including the use of market-based mechanisms, alternative technologies, processes, and compliance options, as well as regulatory and economic incentives to achieve environmental goals of the air program. The FIG is also responsible for:

- Completing appropriate ongoing regulatory efforts for these sectors under the Clean Air Act for air toxics (developing and reviewing technology standards and residual risk reviews), criteria pollutants (new source performance standards and control techniques guidelines), and non-criteria pollutants (new source performance standards and emission guidelines);
- Conducting comprehensive analyses of the fuels production sector and waste management to identify opportunities for multi-pollutant emission reductions and cost-effective control strategies and process alternatives to support national air program objectives;
- Seeking innovative strategies to promote the production and use of alternative fuels and the use of waste as a fuel, while reducing emissions of toxic, criteria, and non-criteria pollutants and improving air quality;
- Reviewing and assessing existing regulatory requirements for these sectors to reduce conflicts and redundancies among the various requirements while achieving equivalent or better environmental outcomes;
- Developing and maintaining technical and policy expertise to solve air pollution problems related to the fuels production sector and waste management on a regional, national and international scale; and
- Working collaboratively with SLT, regional, national, and international regulatory organizations to ensure relevant stationary source regulations promote flexible technology and process alternatives, energy efficiency and fuel diversity.

A6.3 Measurement Policy Group

The Measurement Policy Group (MPG) is responsible for directing a national program that improves emissions quantifications. The MPG is also responsible for the following functions:

- Standardizing and streamlining the emissions data collection and reporting process for emissions factors, including establishing procedures for defining data uncertainty in reporting and for using emissions factors in inventory and non-inventory applications;
- Establishing an outreach program to improve the understanding and applications of emissions factors and other emissions quantification tools;
- Integrating improved emissions monitoring and control demonstrations into multi-pollutant strategies and policies;
- Strengthening scientific and technical capacity to assess risk and track progress through the application of improved emissions monitoring technology;

- Supporting the development of national performance-oriented control strategies including development of technology-neutral standards and market-based approaches through the deployment of improved emissions monitoring techniques, including continuous emissions monitoring systems (CEMS), and through the development of effective measurement-based emission factors and estimation techniques;
- Tracking and assessing control strategy performance, including measuring benefits associated with new and innovative technologies through improved measurement and estimation of source emissions;
- Strategically directing improved monitoring in regulations and control strategies to emphasize the pollutant or pollutants associated with the greatest health and environmental risk;
- Characterizing, making transparent, and reducing uncertainties associated with monitoring technologies and process operations; and
- Designing strategies to accommodate flexibility in monitoring selection and advancements in technology with appropriate incentives.

A6.4 Metals and Inorganic Chemicals Group

The Metals and Inorganic Chemicals Group (MIG) is responsible for developing and implementing effective control strategies and associated regulatory actions for the metals (e.g. iron and steel, lead smelting) and inorganic chemical (e.g. nitric acid manufacture) sectors. The MIG develops and implements innovative strategies to reduce toxic, criteria, and non-criteria air pollutant emissions, including the use of market-based mechanisms, alternative technologies, processes, and compliance options, as well as regulatory and economic incentives to achieve environmental goals of the air program. The MIG is also responsible for:

- Completing appropriate ongoing regulatory efforts for these sectors under the Clean Air Act for air toxics (developing and reviewing technology standards and residual risk reviews), criteria pollutants (new source performance standards and control techniques guidelines), and non-criteria pollutants (new source performance standards and emission guidelines);
- Conducting comprehensive analyses of the metal and inorganic chemical sectors to identify opportunities for multi-pollutant emission reductions and cost-effective control strategies and process alternatives to support national air program objectives;
- Reviewing and assessing existing regulatory requirements for these sectors to reduce conflicts and redundancies among the various requirements while achieving equivalent or better environmental outcomes;
- Developing and maintaining technical and policy expertise to solve air pollution problems related to the metals and inorganic chemicals sectors on a regional, national and international scale; and

- Working collaboratively with SLT, regional, national, and international regulatory organizations to ensure relevant stationary source regulations promote flexible technology and process alternatives, energy efficiency and fuel diversity.

A6.5 Minerals and Manufacturing Group

The Minerals and Manufacturing Group (MMG) is responsible for developing and implementing effective control strategies and associated regulatory actions for the mineral processing (e.g. cement manufacture, brick and structural clay manufacture) and manufacturing sectors (e.g. appliance and electronics manufacturing), including the commercial services and products sectors. The MMG develops and implements innovative strategies to reduce greenhouse gas, air toxics, and criteria air pollutant emissions, including the use of market-based mechanisms, alternative technologies, processes, and compliance options, as well as regulatory and economic incentives to achieve environmental goals of the air program. The MMG is also responsible for:

- Completing appropriate ongoing regulatory efforts for these sectors under the Clean Air Act for air toxics (developing and reviewing technology standards and residual risk reviews), criteria pollutants (new source performance standards and control techniques guidelines), and non-criteria pollutants (new source performance standards and emission guidelines);
- Conducting comprehensive analyses of the mineral processing and manufacturing industry sectors to identify opportunities for multi-pollutant emission reductions and cost-effective control strategies and process alternatives to support national air program objectives;
- Reviewing and assessing existing regulatory requirements for these sectors to reduce conflicts and redundancies among the various requirements while achieving equivalent or better environmental outcomes;
- Developing and maintaining technical and policy expertise to solve air pollution problems related to the mineral processing and manufacturing sectors on a regional, national and international scale; and
- Working collaboratively with SLT, regional, national, and international regulatory organizations to ensure relevant stationary source regulations promote flexible technology and process alternatives, energy efficiency and fuel diversity.

A6.6 Natural Resources Group

The Natural Resources Group (NRG) is responsible for developing emission reduction strategies and associated regulatory actions for the forest products (e.g. pulp and paper) and agriculture sectors. The NRG builds on current understanding of emissions reductions, costs, control opportunities and alternative processes associated with the affected sectors and industries to reduce emissions of toxic, criteria, and non-criteria (e.g., greenhouse gases) pollutants. The NRG is also responsible for:

- Completing appropriate ongoing regulatory efforts for these sectors under the Clean Air Act for air toxics (developing and reviewing technology standards and residual risk reviews), criteria pollutants (new source performance standards and control techniques guidelines), and non-criteria pollutants (new source performance standards and emission guidelines);
- Conducting comprehensive analyses of the forest products and agricultural sectors to identify opportunities multi-pollutant emission reduction opportunities that satisfies multiple control requirements while also providing flexible, innovative, and cost-effective regulatory and non-regulatory alternatives;
- Reviewing and assessing existing regulatory requirements for these sectors to reduce conflicts and redundancies among the various requirements while achieving at least equivalent environmental outcomes;
- Developing and maintaining technical and policy expertise to solve air pollution problems related to the forest products and agricultural sectors on a regional, national, and international scale; and
- Working collaboratively with SLT, regional, national, and international regulatory organizations to ensure relevant stationary source regulations promote flexible technology and process alternatives, energy efficiency and fuel diversity.

A6.7 Policy Strategies Group

The Policy and Strategies Group (PSG) is responsible for designing regulatory and non-regulatory mechanisms to implement regulatory and non-regulatory strategies based on comprehensive information and understanding of key industrial sectors, their operations, economic profiles and capital planning cycles, as well as policy decisions and a broad array of opportunities for the incorporation of market-based mechanisms. The PSG is also responsible for the following functions:

- Responsible for the program design, implementation and coordination of the development of Residual Risk and Technology Review (RTR) standards required under Section 112(f) of the CAA;
- Responsible for the program design, implementation and coordination of the development of New Source Performance Standards (NSPS) regulations under Section 111(d) of the CAA;
- Management and oversight of the development of risk modeling files used in the development of air toxics standards under section 112(d) of the CAA;
- Development of cross-cutting regulatory policies with regards start-up, shutdown, and malfunction, major source to area source policies, alternative means of emission limitations, and other policies designed to implement air toxics requirements of the CAA;

- Implement and coordinate the process for the listing and delisting of pollutants on the CAA Section 112(b)(1) list of HAPs as well as the process for the listing and delisting of source categories on the CAA section 112(c)(1) list of source categories;
- Ensure that stationary source air pollutant regulations are consistent in their implementation and air pollutant reduction strategies by directing the process for consistency review of regulations developed within SPPD;
- Manage and update the General Provisions for Parts 59, 60, 61, 62, and 63 of the CFR; and
- Provides leadership and support for SPPD information sharing activities, this includes leading requests for information from EPA management, development of guidance and templates for information collection request activities and helps with information acquisition and collection activities.

A6.8 Refining and Chemicals Group

The Refining and Chemicals Group (RCG) is responsible for developing and directing emission reduction strategies and associated regulatory actions for the petroleum refining and chemical production sectors, including the development of uniform standards to be used in all the sector rules and a consolidated rule for the chemical sectors. The RCG works collaboratively with stakeholders to identify opportunities for cost effective strategies to reduce emissions of toxic, criteria, and non-criteria pollutants. The RCG is also responsible for:

- Completing appropriate ongoing regulatory efforts for these sectors under the Clean Air Act for air toxics (developing and reviewing technology standards and residual risk reviews), criteria pollutants (new source performance standards and control techniques guidelines), and non-criteria pollutants (new source performance standards and emission guidelines);
- Conducting comprehensive analyses of the petroleum refining and chemical production sectors to identify opportunities for cost effective multi-pollutant emission reductions and control technologies and alternative processes to support national air programs;
- Reviewing and assessing existing regulatory requirements for these sectors to reduce conflicts and redundancies among the various requirements while achieving at least equivalent environmental outcomes; and
- Developing and maintaining technical and policy expertise to solve air pollution problems related to the petroleum refining and chemical production sectors on a regional, national, and international scale.

Appendix B OAQPS Data Collection Activities

B1 Ambient Air Data

The EPA's ambient air quality monitoring program is implemented by SLT agencies under grants awarded by EPA Regions in coordination with OAQPS staff. Most of the ambient air monitoring networks supporting air quality management are designed and operated by SLT's. Figure B-1, below, provides an overview of the ambient air quality monitoring process and how the data generated in the various monitoring networks supports programs across OAQPS.

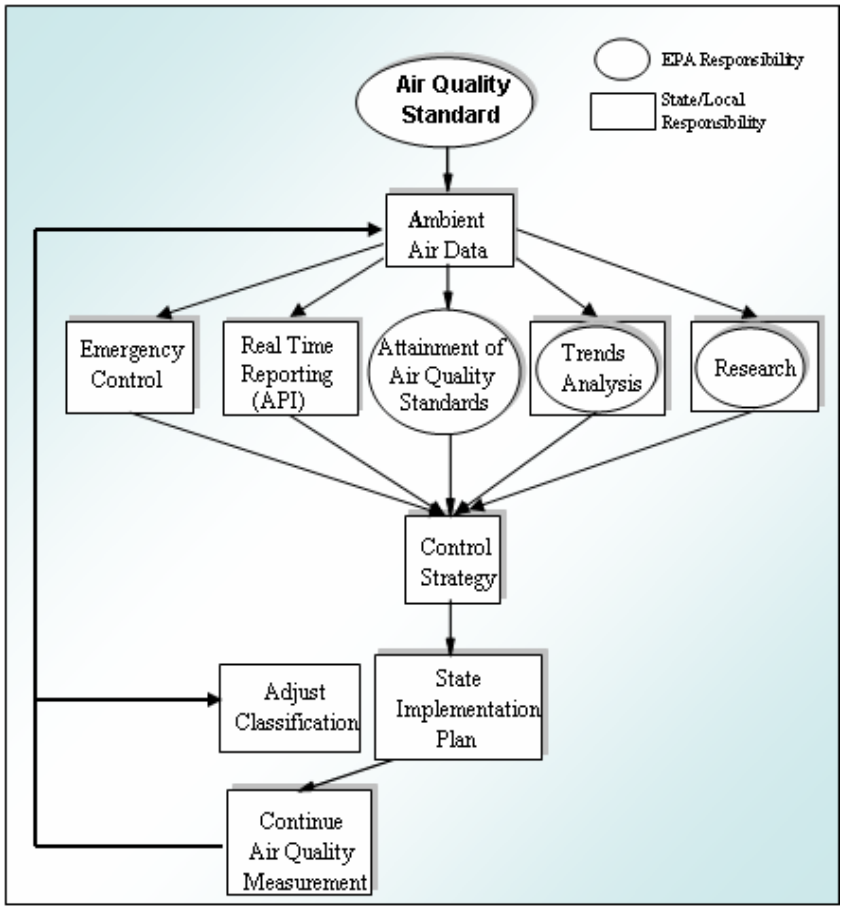

Figure B-1. Ambient Air Quality Monitoring Process

The monitoring networks include those for criteria pollutants particulate matter with an aerodynamic diameter of ≤ 10 µm (PM_{10}), particulate matter with an aerodynamic diameter of ≤ 2.5 µm ($PM_{2.5}$), sulfur dioxide (SO_2), carbon monoxide (CO), nitrogen dioxide (NO_2), ozone (O_3), and lead (Pb); hazardous air pollutants (HAPs) also known as toxic air pollutants or air toxics; and O_3 precursors (approximately 60 volatile hydrocarbons and carbonyl).

EPA develops requirements and guidance for various aspects of these networks which it publishes in the Code of Federal Regulations (CFR). The requirements for network design and operation are in the CFR under Title 40. Requirements related to network monitoring methods

are in the appendices to CFR Part 50 and in CFR Part 53. Network requirements are in CFR Part 58 – Ambient Air Quality Surveillance.

Ambient air monitoring is an integral part of an effective air quality management system. The AAMG is responsible for the ambient air quality monitoring program which collects air quality samples to:

- Assess the extent of pollution; compliance with and/or progress made toward meeting ambient air quality standards;
- Activate emergency control procedures that prevent or alleviate air pollution episodes;
- Observe pollution trends throughout a region, including non-urban areas;
- Provide a database for research evaluation of effects: urban, land-use, and transportation planning development and evaluation of abatement strategies; and development and validation of diffusion models;
- Evaluate potential alternative forms of the NAAQS;
- Manage the PM Performance Evaluation Program (PEP);
- Provide air pollution data to the general public in a timely manner;
- Support implementation of air quality goals or standards;
- Evaluate the effectiveness of emissions control strategies;
- Provide information on air quality trends;
- Provide data for the evaluation of air quality models; and
- Support research (e.g., long-term studies of the health effects of air pollution).

B2 Emissions Data

Collecting emissions data involves a variety of OAQPS programs, including source characterization. AQAD/MTG and SPPD/MPG are responsible assisting OAQPS in the following data-gathering activities:

B2.1 Source Characterization

- Field testing to
    - Validate the performance test methods and source monitoring procedures;
    - Evaluate formal requests to allow the use of alternative methods;
    - Investigate the feasibility of new or modified performance test methods or source monitoring procedures;
    - Support the development of New Source Performance Standards, National Emission Standards for Hazardous Air Pollutants, and emission standards under SIPs;
    - Perform emission screening studies to assess regulatory needs;
    - Generate emission factors; and
    - Perform pollutant assessment projects.
- Evaluation of industry, state and local generated emission measurement data and information used for purposes of supporting rule, method, or monitoring system development by the Agency.

- Such activity encompasses the determination of data quality in relation to anticipated defense of supporting program data quality objectives.

B2.2 In-house Source Emission Measurement Projects

In-house data evaluation and quality assessments and testing are usually limited to projects in Categories II and III. The project leader for this work is responsible for developing a project plan and data quality objectives, in concert with the requesting supporting program Project Leader, and for obtaining Group Leader approval for the work to be done. This project plan must include a Quality Assurance Project Plan (QAPP) to ensure that defensible data of known quality and integrity are generated. The MTG's project leader is also responsible for preparing or referencing standard operating procedures (SOPs), when applicable. The Group's Delegated QA Approving Officer (DQAO) reviews and approves the QAPP and also seeks concurrence from the QA Division Representative of the requesting support Division.

B2.3 Extramural Source Emission Measurement Projects

Most field test projects in Categories I, II and III are conducted through either GSA managed contracts, cost-plus-award-fee level-of-effort contracts or through agreement with the private sector. The agreements with the private sector are those that OAQPS agrees to accept and consider for use environmental data collected, documented and paid for voluntarily by a private sector party. The private sector parties are requested to submit a QAPP. OAQPS is under no obligation to use these data unless they are determined to be adequate and sufficient for their intended use.

For the contracts used for this work, technical proposals must include detailed discussions of the company's QA program and organization of QA activities. These discussions include development of QAPPs, responsibilities of the contractor's Quality Assurance Official (QAO), periodic QA activity updates, and corrective action plans for adverse QA findings. Only contractors with high quality QA programs are selected for final awards, and consideration is enhanced where the contractor's QAO can function independently of the testing program.

For specific work assignments, individual work plans and test reports are reviewed, emission test procedures are observed, as resources permit, and performance evaluation audit samples are administered by the appropriate COR/COR to ensure high quality emission data. Examples of high-quality work plans and test reports are available to the COR as minimum acceptable criteria.

B3 Air Quality Modeling

Air quality models use mathematical and numerical techniques to simulate the physical and chemical processes that affect air pollutants as they disperse and react in the atmosphere. Based on inputs of meteorological data and source information like emission rates and stack height, these models are designed to characterize primary pollutants that are emitted directly into the atmosphere and, in some cases, secondary pollutants that are formed as a result of complex chemical reactions within the atmosphere. These models are important to our air quality management system because they are widely used by agencies tasked with controlling air pollution to both identify source contributions to air quality problems and assist in the design of

effective strategies to reduce harmful air pollutants. For example, air quality models can be used during the permitting process to verify that a new source will not exceed ambient air quality standards or, if necessary, determine appropriate additional control requirements. In addition, air quality models can also be used to predict future pollutant concentrations from multiple sources after the implementation of a new regulatory program, in order to estimate the effectiveness of the program in reducing harmful exposures to humans and the environment.

The most commonly used air quality models include the following:

- Dispersion Models - use mathematical formulations to characterize the atmospheric processes that disperse a pollutant emitted by a source. Based on emissions and meteorological inputs, a dispersion model can be used to predict concentrations at selected downwind receptor locations. These air quality models are used to determine compliance with the NAAQS, and other regulatory requirements such as New Source Review (NSR) and Prevention of Significant Deterioration (PSD) regulations.
- Photochemical Models – simulate the changes of pollutant concentrations in the atmosphere at regional, national and global scales using a set of mathematical equations characterizing the chemical and physical processes in the atmosphere. These models have become widely recognized and routinely utilized tools EPA and SLT air agencies for regulatory analysis and attainment demonstrations by assessing the effectiveness of control strategies.

EPA's OAQPS determines the air quality models and techniques to be used to inform regulatory programs under the Clean Air Act through its *Guideline on Air Quality Models* (also published as Appendix W of 40 CFR Part 51). The *Guideline* was originally published in April 1978 to provide consistency and equity in the use of modeling within the U.S. air quality management system. Specific EPA approved air quality models are addressed in Appendix A of the Guideline. These guidelines are periodically revised through rulemaking following the EPA's Action Development Process to ensure that new model developments or regulatory recommendations and/or requirements are incorporated.

OAQPS provides leadership and direction on a full range of regulatory air quality models and other mathematical techniques to assess and control emission sources and to support policy/regulatory decisions. The AQMG within OAQPS conducts air quality modeling and related analyses integral to policy and regulatory decisions within the Office of Air and Radiation for multiple pollutants, sources and spatial scales (e.g., international, national, regional, and local, etc.); conducts evaluation studies on air quality models and simulation techniques for use by the air quality modeling community and makes revisions to the *Guideline* or technical guidance to improve model applications in regulatory analysis and decisions; and collaborates with the research community within EPA and externally to promote policy relevant improvements in the atmospheric models to better inform regulatory and policy decisions.

B4 National Emissions Inventory

The National Emissions Inventory (NEI) was created to provide the EPA, federal, SLT decision makers, and the national and international public the best and most complete estimates of criteria air pollutant and precursor (CAP) and HAP emissions. While the EPA is not directly obligated to

create the NEI, the Clean Air Act authorizes the EPA Administrator to implement data collection efforts needed to properly administer the NAAQS program. Therefore, OAQPS maintains the NEI program in support of the NAAQS. Furthermore, the Clean Air Act requires states (or their delegates) to submit emissions to the EPA as part of their SIPs that describe how they will attain the NAAQS. The NEI is used as a starting point for many SIP inventory development efforts and for states to obtain emissions from other states needed for their modeled attainment demonstrations.

While the NAAQS program is the basis on which the EPA collects CAP emissions from the SLT air agencies, it does not require collection of HAP emissions. For this reason, the HAP reporting requirements are voluntary. Nevertheless, the HAP emissions are an essential part of the NEI program. These emissions estimates allow EPA to assess progress in meeting HAP reduction goals described in the Clean Air Act amendments of 1990. These goals seek to lessen the negative impacts to people of HAP emissions in the environment, and the NEI allows the EPA to assess how much emissions have been reduced since 1990.

To create the NEI, the EPA takes many steps that result in a triennial release of the NEI every three years, with both updates to the triennial inventories and interim-year inventories created as needed to support EPA projects. Each of these steps is listed below along with identification of oversight needs and points of internal coordination for QA and QC activities.

B4.1 Collection of emissions data and inputs from external data partners

For this step, a process exists to collect data from SLT air agencies as well as from the Bureau of Ocean Energy Management (BOEM). State and local agencies are required to submit CAP data in accordance with the Air Emissions Reporting Rule (AERR); 40 CFR 51 Subpart A. Tribes can voluntarily submit the data unless they have been delegated the authority for their territory by the state, in which case the same requirements apply. States may also delegate to local air agencies. The rule requires that some emissions sources be reported as point sources (individual facilities), other sources be reported as nonpoint emissions (county totals), and mobile data be reported as model inputs for all states except California, which is required to submit mobile emissions because they use a customized EPA-approved mobile source model. All SLT air agencies can voluntarily submit HAPs and greenhouse gas (GHG) emissions. In addition, SLT air agencies and forestry agencies can provide data regarding the timing, location, and activity levels for prescribed burning and wildfires, which the EPA uses to create an “events” inventory of the emissions from these fires. In the case of offshore oil and gas platforms, the BOEM computes emissions from these sources and sends data to EPA.

The format and required data fields for submission are specified by the AERR. In most cases, the Emissions Inventory System (EIS) is the required mechanism for submitting the data to the EPA. In some cases (e.g., fires activity, nonpoint input data, new tools), collection of data is managed through other techniques including email and SharePoint. The collection step includes EPA staff communication of changes to SLTs about the required or voluntary aspects of reporting. In addition, EPA staff review data and communicate with the SLT agencies as needed to ensure complete collection.

B4.2 Collection of emissions data from other federal programs (point, nonpoint, mobile, events)

To help achieve completeness in the NEI, the NEI team staff and contractors collect and use other federal data sources to augment where the SLT data may be incomplete for point sources. In addition, EPA staff and contractors collect and use a variety of data sources at the state and/or county levels as a starting point for estimating county-level activities for the nonpoint and mobile data categories. Coordination is needed between EPA staff and contractors who assist with some of these activities.

B4.3 Development of emissions calculation methods (nonpoint and commercial marine vessels for ports and county totals)

For all nonpoint categories and commercial marine vessels, NEI team staff lead the development, QA, and publishing of emissions methods, models and tools for use in the NEI. These methods, models and tools can include custom software, Microsoft Access databases, and Microsoft Excel spreadsheets. For some specific nonpoint sectors (e.g., fertilizer ammonia, biogenic vegetation and soils, and agricultural burning), the EPA ORD has active research improving emissions estimation methods on which the NEI team staff rely to estimate emissions. In many cases, SLT air agencies choose to use these EPA-developed methods as a means of meeting their AERR reporting requirements for those sectors. Coordination is needed among EPA staff, contractors, and SLT agency staff.

B4.4 Development of augmentation factors to calculating one pollutant from another pollutant (point, nonpoint, events)

EPA staff uses various data sources to create pollutant ratios for the purpose of computing emissions of one pollutant (e.g., a HAP volatile pollutant) from another pollutant for which data are available from a SLT agency (e.g., volatile organic compounds). This step is needed when SLT agency data are incomplete (as is the case for PM components), when SLT agencies provide a summed pollutant but pollutant components are needed for NEI (e.g., SLT can report total chromium but NEI publishes trivalent chromium and hexavalent chromium), or to augment for unreported HAPs scaling from reported criteria air pollutants. These ratios can be based on a variety of internal and external data sources, including the SPECIATE database, emission factors from WebFIRE, non-EPA emission factors, source test data, emissions reported from other similar sources, and from the peer-reviewed literature.

B4.5 Development of inputs to tools and models (mobile, nonpoint, events)

EPA staff and EPA contactors create inputs for the models and tools used to estimate emissions for mobile sources, nonpoint sources, and events. This task involves data processing and manipulation of other data sources to convert the information into the formats and resolution needed by the models and tools. Coordination is needed between EPA staff and contractors.

B4.6 Using models and tools to create emissions (point airports, point rail yards, point ports, mobile, events, nonpoint)

EPA staff, EPA collaborators, and contractors use models and tools that take input data and create emissions estimates. For aircraft and support equipment at airports, the EPA uses a Federal Aviation Administration (FAA) model. For rail yards, the EPA relies on a system developed by the Eastern Research Technical Advisory Committee (ERTAC) whose members also gather the input data and run the tools for use in the NEI. For point source ports, the EPA relies on programs that process satellite-based tracking data for commercial marine vessels. For on-road mobile sources and nonroad equipment, the Office of Transportation and Air Quality (OTAQ) publishes the Motor Vehicle Emissions Simulator (MOVES), which OAQPS uses to estimate emissions for the NEI. For events (prescribed burning and wildfires), the EPA adapts a series of models developed by the US Forest Service, known collectively as BlueSky/SMARTFIRE. For nonpoint sources, OAQPS uses tools that EPA staff and contractors develop as described above. Coordination is needed between EPA staff and EPA collaborators or between EPA staff and contractors who run these tools and models and deliver the output data for evaluation and use by EPA staff.

B4.7 Compilation of inventory data into a data release

EPA staff use the EIS to compile the emissions inventory data into a data release, which involves selecting the best available data from all the individual datasets loaded into EIS. EPA staff make sure that any data not submitted to EIS directly are loaded into the EIS. EPA staff design a "selection" that specifies the priority order of available datasets for each pollutant and emissions process. EPA staff run the EIS to create a "selection" of data, and then they evaluate it to ensure that the intended data outcomes have been achieved. NEI team staff must coordinate during the selection process among themselves and with the EIS system owners. Depending on QA findings after the data selection, multiple selections may be run.

As part of this step, once the data have been selected and QA'd, the results are provided to the Emissions Modeling Team (EMT) in OAQPS for calculating the PM model species (organic carbon (OC), elemental carbon (EC), sulfate (SO_4^{2-}), nitrate (NO_3^-), and crustal/other) using speciation profiles and cross-references. The resulting data are then loaded into the EIS, and NEI team staff use EIS to make a final selection. Coordination is needed among the NEI team staff and with the EMT staff.

B4.8 Public release of data (summaries, website, and posting data outside EIS firewall)

NEI team staff use the EIS to create emissions summaries and provide data electronically outside of the EIS firewall. Summaries and other data releases must be checked for consistency with the raw NEI data, with one another, and to ensure that each of the summaries or data tables provided externally match the formats and content required for the individual distribution mechanisms that they support. Examples of distribution mechanisms include the Air Emissions Inventory website, the Qlik NEI Report, the Air Emissions Modeling website, Envirofacts, and the Facility Registry Service (FRS).

B5 Air Quality Analysis

The AQAG of AQAD is responsible for:

- Tracking and analyzing air quality data for policy and program development, program evaluation and accountability, and informing the public about the status of the nation's air quality, including the analysis of temporal and spatial air quality trends, and the distribution of program-critical information on progress in air quality;
- Developing and applying air quality assessment methods and indicators within an accountability framework to assess the progress of air quality management programs (those of the EPA, regions, states and others) in order to ascertain the achievement of their environmental goals, as well as to determine the need and opportunity for mid-course corrections to these programs;
- Providing air quality analysis and expertise to inform decisions on highly sensitive policy issues (e.g., analysis of speciated fine particle data to characterize the regional and local sources contributing to fine particles, statistically adjusting air quality data to account for the influences of changing meteorological conditions);
- Analyzing complex air quality data to identify patterns, understand cause-and-effect relationships, and otherwise characterize air quality to support the development and analytical bases of air pollution control programs and Policies;
- Assessing and interpreting the status and trends in the nation's air quality and publicizing these results through the EPA web site and periodic trends publications; and
- Developing, maintaining, and reporting findings from regulatory, ambient air quality data systems (i.e., criteria pollutant design values) for attainment/nonattainment decision-making and program evaluation.

Appendix C OAQPS QMP Review Checklist

QUALITY MANAGEMENT PLAN
REVIEW CHECKLIST

ORGANIZATION: _____ **Reviewer:**_____**Review Date:**_____

This checklist will be used to review the Quality Management Plans (QMPs) that are submitted to the Office of Air Quality Planning and Standards (OAQPS) for Agency review under CIO 2105.0[i]. Items from this checklist are discussed in detail in Chapter 3 of CIO 2105-P-01-0[ii] and in *EPA Requirements for Quality Management Plans (QA/R-2)*. Consult these resources for more information on the items below.

Note that all items below are required to be included or addressed in the QMP. If an item is not relevant, please provide an explanation about why this is not relevant in the comments column. Also note that a process may either be described or referenced in the QMP; however, all references should be readily accessible within the organization and available to OAQPS with the QMP.

An electronic version of this checklist is also available on the OAQPS QA SharePoint site.

Element	Section & Pages(s)	Comments	Recommended Change
Management and Organization [Reference CIO 2105-P-01-0 §3.3.2; EPA QA/R-2 §3.2]			
1) QMP Approved by senior manager (signed if hard copy or approved by separate cover memo if electronic QMP copy)?*			
Items with * marking may be verified on submission of provisionally approved QMP (OAQPS pre-approval prior to organizational management signature).			
2) Signed and dated by senior line management (for subordinate			

Element	Section & Pages(s)	Comments	Recommended Change
offices) as applicable (signed if hard copy or approved by separate cover memo if electronic QMP copy)?*			
3) Signed and dated by QA manager (signed if hard copy or approved by separate cover memo if electronic QMP copy)?*			
4) Includes statement of the organization's QA policy?			
a) QA policy statement includes general objectives/goals?			
b) QA policy includes general discussion of management and staff responsibilities?			
5) Includes organizational chart?			
a) Organizational chart identifies all components of organization?			
b) Organizational Chart identifies position of QA manager?			
c) Organizational Chart identifies lines of reporting of the QA manager?			
d) Organization Chart identifies any other QA staff?			
6) Includes discussion of roles, responsibilities, and authorities of the QA manager and QA staff (QA			

Element	Section & Pages(s)	Comments	Recommended Change
Officers, Coordinators, etc.), as applicable?			
7) Documents the organizational independence of the QA manager?			
8) Describes procedures to ensure QA staff has access to appropriate levels of management?			
9) Discusses technical activities or programs that require application of quality management practices?			
10) Discusses where oversight of delegated (i.e., States, Tribes) and/or extramural programs is needed?			
11) Identifies where internal coordination of QA and QC activities among organizations (e.g., divisions, offices, branches) is needed?			
12) Discusses how management assures understanding and implementation of quality practices in all programs and activities?			
13) Describes process for resolving disputes relating to quality issues?			
Quality System Components [Reference CIO 2105-P-01-0 §3.3.3; EPA QA/R-2 §3.3]			
14) Includes description of the quality system as it pertains to the organization's mission?			

Element	Section & Pages(s)	Comments	Recommended Change
15) Addresses and describes principal quality system components and tools developed by the organization, including how they are implemented and by whom? (Note: list specific tools, such as SOPs, guidance, training, etc., in Column 3.)			
a) Planning work			
b) Implementing work.			
c) Assessing work performed.			
16) Identifies internal organizations (e.g., subordinate offices, divisions) that develop QMPs?			
17) Identifies review and approval procedures for these internal QMPs?			
18) Includes assurance that QA responsibility is incorporated into performance standards for QA Managers/Directors of Quality Assurance?			
Personnel Qualifications and Training [Reference CIO 2105-P-01-0 §3.3.4; EPA QA/R-2 §3.4]			
19) States policy regarding QA training for management and staff?			

Element	Section & Pages(s)	Comments	Recommended Change
20) Describes minimum training for personnel necessary to implement the QMP?			
21) Describes process for identifying, ensuring, and documenting that personnel have necessary quality-related competencies?			
22) Describes process for ensuring personnel maintain quality-related competencies, including continuing education or refresher training?			
23) Describes roles, responsibilities, and authorities managers and staff relative to training planning and implementation?			
Procurement of Items and Services [Reference CIO 2105-P-01-0 §3.3.5; EPA QA/R-2 §3.5]			
24) Describes process for reviewing and approving all extramural agreements (grants, cooperative agreements and contracts), including use of the QA Review Form[iii]?			
a) Review process ensures documents are complete and accurate?			
b) Review process ensures agreement clearly describes the item or service needed?			

Element	Section & Pages(s)	Comments	Recommended Change
c) Review process ensures agreement describes the associated technical and quality requirements?			
d) Review process ensures agreement describes the quality system elements for which the supplier is responsible?			
e) Review process ensures that the supplier's conformance to requirements will be verified?			
25) Describes process for reviewing and approving applicable responses to solicitations and requests to ensure that they satisfy all technical and quality requirements?			
a) Review process includes the review of evidence of the supplier's capability to satisfy EPA quality requirements?			
b) Review process provides for ensuring that procured items and services are acceptable?			
26) Describes process for review and approval of suppliers' quality-related documentation (e.g., QA Project Plans and QMPs)?			
27) Includes discussion of any policy and criteria for delegations of review of QA Project Plans and			

Element	Section & Pages(s)	Comments	Recommended Change
QMPs?			
28) Describes process to ensure EPA extramural agreement policies, including quality, are satisfied?			
29) Describes roles, responsibilities, and authorities managers and staff relative to extramural agreement planning and implementation?			
Documents and Records [Reference CIO 2105-P-01-0 §3.3.6; EPA QA/R-2 §3.6]			
30) Describes process for identifying quality-related documents and records (including electronic) requiring control (e.g., guidance, SOPs)?			
31) Describes process for preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records?			
32) Describes process for ensuring that records and documents accurately reflect completed work?			
33) Describes process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?			
34) Describes process for establishing and implementing appropriate chain of custody and confidentiality			

Element	Section & Pages(s)	Comments	Recommended Change
procedures for evidentiary records?			
35) Records on environmental data and information comply with applicable EPA policies (e.g., locational data for samples, Agency records management)?			
36) Describes roles, responsibilities, and authorities managers and staff relative to documents and records?			
Computer Hardware and Software [Reference CIO 2105-P-01-0 §3.3.7; EPA QA/R-2 §3.7][iv]			
37) Describes process for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware (e.g., computers, servers) and software, including software products like models, data bases, and programs?			
38) Describes process for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance?			
39) Describes process for evaluating purchased hardware and software?			
40) Describes process for ensuring that data and information produced from or collected by computers meet applicable EPA Orders, requirements, and standards?			

Element	Section & Pages(s)	Comments	Recommended Change
41) Describes roles, responsibilities, and authorities managers and staff relative to computer hardware, software, and information management?			
Planning [Reference CIO 2105-P-01-0 §3.3.8; EPA QA/R-2 §3.8]			
42) Includes a description of the systematic planning process for environmental information/data acquisition (e.g., direct measurement, compilation from other sources) and use?			
a) Does this process include identification and involvement of relevant customers and suppliers?			
b) Does this process include description of the project goal, objectives, and questions and issues to be addressed?			
c) Does this process include identification of project schedule, resources, milestones, and any applicable requirements?			
d) Does this process include identification of the type and quantity of information/data needed and how the data will			

Element	Section & Pages(s)	Comments	Recommended Change
be used to support the project's objectives?			
e) Does this process include specification of performance criteria for measuring quality?			
f) Does this process include specification of needed QA and QC activities to assess the quality performance criteria?			
g) Does this process include description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection?			
h) Does this process include description of how the acquired data will be analyzed, evaluated, and assessed against its intended use and the quality performance criteria?			
43) Describes process for developing, reviewing, approving, implementing, and revising QA Project Plans?			
44) Describes process for evaluating and qualifying information acquired from other sources (e.g., States, other Federal Agencies)?			

Element	Section & Pages(s)	Comments	Recommended Change
45) Describes roles, responsibilities, and authorities managers and staff relative to planning?			
Implementation of Work Processes [Reference CIO 2105-P-01-0 §3.3.9; EPA QA/R-2 §3.9]			
46) Describes process for ensuring that work is performed according to planning and technical documents (e.g., SOPs, approved methods and protocols)?			
47) Describes process for identifying operations needing procedures (e.g., SOPs)?			
48) Describes process for preparation, review, approval, revision, and withdrawal of these procedures?			
49) Describes policy for use of these procedures?			
50) Describes process for controlling and documenting the release, change, and use of planned procedures?			
a) Process includes description of necessary approvals?			
b) Process includes removal of obsolete documentation from work areas?			
c) Process includes verification that the changes are made as			

Element	Section & Pages(s)	Comments	Recommended Change
prescribed?			
51) Describes roles, responsibilities, and authorities managers and staff relative to implementing work processes.			
Assessment and Response [Reference CIO 2105-P-01-0 §3.3.10; EPA QA/R-2 §3.10]			
52) Describes the process for assessing the adequacy of the quality management system at least annually?			
53) Describes the process for planning assessments?			
a) Process includes selecting an assessment tool, the expected frequency, and the roles and responsibilities of assessors?			
b) Process includes determining the competence of assessment personnel?			
c) Process includes ensuring that personnel have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?			
d) Process includes ensuring that personnel conducting assessments have sufficient authority, access to programs			

Element	Section & Pages(s)	Comments	Recommended Change
and managers, access to documents and records, and organizational freedom?			
54) Describes the process for implementing and documenting assessments and reporting results to management?			
a) Describes the process for completing assessment reports in a timely manner, including appropriate levels of review and approval?			
55) Describes process for management's review of, and response to, findings?			
56) Describes process for identifying how and when corrective actions are to be taken in response to the findings of the assessment?			
a) Process includes ensuring corrective actions are made promptly?			
b) Process includes confirming the implementation and effectiveness of any corrective action?			
c) Process includes documenting effectiveness of the corrective actions implemented?			

Element	Section & Pages(s)	Comments	Recommended Change
57) Describes process for addressing disputes encountered as a result of assessments?			
58) Describes roles, responsibilities, and authorities managers and staff relative to planning and implementing assessments and responses to assessments?			
Quality Improvement [Reference CIO 2105-P-01-0 §3.3.11; EPA QA/R-2 §3.11]			
59) Describes process for ensuring that conditions adverse to quality are prevented, identified promptly, corrected promptly and that actions are taken toward prevention, documented and actions tracked to closure?			
60) Describes process for encouraging staff to establish communications between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems?			
61) Describes roles, responsibilities, and authorities managers and staff relative to quality improvement?			
Other Review Criteria			
62) Are regulatory or other citations in the QMP current and accurate?			

Element	Section & Pages(s)	Comments	Recommended Change
63) Are there any inconsistencies in the text?			
64) Is the writing clear?			
65) Are organizational units identified consistent with the most recent reorganization?			
66) Are activities described in the QMP consistent with QA Annual Report and Work Plans?[v]			
67) Are tasks proposed for other organizations not covered solely by this QMP documented elsewhere (e.g., in another organization's QMP)?			
Information Quality Guidelines[vi]			
68) Does the QMP identify criteria for information products that are subject to Information Quality Guidelines?			
69) Is the process for pre-dissemination review discussed?			
70) Does the pre-dissemination process description include protocols for clearance review, requirements for clear disclaimer language; identify roles and responsibilities of management and staff?			

Appendix D OAQPS QAPP Review Checklist

OAQPS QA PROJECT PLAN REVIEW CHECKLIST

This checklist is based on the elements in *EPA Requirements for QA Project Plans (QA/R-5)* (EPA, 2001a) and can be used to either write or review a QA Project Plan, especially those involving field sampling and laboratory analyses. If an element is not relevant, please provide an explanation about why this is not relevant in the comments column. Also note that a process may either be described or referenced in the QAPP; however, all references should be readily accessible within the organization and available to OAQPS with the QAPP.

An electronic version of this checklist is also posted on the OAQPS QA SharePoint site.

PROJECT TITLE	
Preparer	
Date Submitted	
Reviewer	
Date of Review	

Element	**Acceptable (Yes/No)**	**Page/ Section**	**Comments**
A1. Title and Approval Sheet			
Contains project title			
Indicates revision number, if applicable			
Indicates organization's name			
Date signature of organization's project manager			
Dated signature of organization's QA manager present			
Other signatures, as needed			
A2. Table of Contents			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	Lists QA Project Plan information sections			
	Document control information indicated			
A3.	**Distribution List**			
	Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization			
A4.	**Project/Task Organization**			
	Identifies key individuals involved in all major aspects of the project, including contractors			
	Discusses their responsibilities			
	Project QA Manager position indicates independence from unit generating data			
	Identifies individual responsible for maintaining the official, approved QA Project Plan			
	Organizational chart shows lines of authority and reporting responsibilities			
A5.	**Problem Definition/Background**			
	States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained			
	Clearly explains the reason (site background or historical context) for initiating this project			
	Identifies regulatory information, applicable criteria, action limits, etc. necessary to the project			
A6.	**Project/Task Description**			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	Summarizes work to be performed, for example, measurements to be made, data files to be obtained, etc., that support the project's goals			
	Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as sampling, analysis, data or file reviews, and assessments			
	Details geographical locations to be studied, including maps where possible			
	Discusses resource and time constraints, if applicable			
A7.	**Quality Objectives and Criteria**			
	Identifies performance/measurement criteria for all information to be collected and acceptance criteria for information obtained from previous studies, including project action limits and laboratory detection limits and range of anticipated concentrations of each parameter of interest			
	Discusses precision			
	Addresses bias			
	Discusses representativeness			
	Identifies the need for completeness			
	Describes the need for comparability			
	Discusses desired method sensitivity			
A8.	**Special Training/Certifications**			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	Identifies any project personnel specialized training or certifications			
	Discusses how this training will be provided			
	Indicates personnel responsible for assuring these are satisfied			
	Identifies where this information is documented			
A.9.	**Documentation and Records**			
	Identifies report format and summarizes all data report package information			
	Lists all other project documents, records, and electronic files that will be produced			
	Identifies where project information should be kept and for how long			
	Discusses back up plans for records stored electronically			
	States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individual responsible for this			
B1.	**Sampling Process Design (Experimental Design)**			
	Describes and justifies design strategy, indicating size of the area, volume, or time period to be represented by a sample			
	Details the type and total number of sample types/matrix or test runs/trials expected and needed			
	Indicates where samples should be taken, how sites will be identified/located			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	Discusses what to do if sampling sites become inaccessible			
	Identifies project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc.			
	Specifies what information is critical and what is for informational purposes only			
	Identifies sources of variability and how this variability should be reconciled with project information			
B2.	**Sampling Methods**			
	Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken			
	Indicates how each sample/matrix type should be collected			
	If in situ monitoring, indicates how instruments should be deployed and operated to avoid contamination and ensure maintenance of proper data			
	If continuous monitoring, indicates averaging time and how instruments should store and maintain raw data, or data averages			
	Indicates how samples are to be homogenized, composited, split, or filtered, if needed			
	Indicates what sample containers and sample volumes should be used			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	Identifies whether samples should be preserved and indicates methods that should be followed			
	Indicates whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of			
	Identifies any equipment and support facilities needed			
	Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented			
B3.	**Sample Handling and Custody**			
	States maximum holding times allowed from sample collection to extraction and/or analysis for each sample type and, for in-situ or continuous monitoring, the maximum time before retrieval of information			
	Identifies how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt)			
	Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible			
	Discusses system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the plan			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	Identifies chain-of-custody procedures and includes form to track custody			
B4.	**Analytical Methods**			
	Identifies all analytical SOPs (field, laboratory and/or office) that should be followed by number, date, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures			
	Identifies equipment or instrumentation needed			
	Specifies any specific method performance criteria			
	Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation			
	Identifies sample disposal procedures			
	Specifies laboratory turnaround times needed			
	Provides method validation information and SOPs for nonstandard methods			
B5.	**Quality Control**			
	For each type of sampling, analysis, or measurement technique, identifies QC activities which should be used, for example, blanks, spikes, duplicates, etc., and at what frequency			
	Details what should be done when control limits are exceeded, and how effectiveness of control			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	actions will be determined and documented			
	Identifies procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data			
B6.	**Instrument/Equipment Testing, Inspection, and Maintenance**			
	Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this			
	Identifies testing criteria			
	Notes availability and location of spare parts			
	Indicates procedures in place for inspecting equipment before usage			
	Identifies individual(s) responsible for testing, inspection and maintenance			
	Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented			
B7.	**Instrument/Equipment Calibration and Frequency**			
	Identifies equipment, tools, and instruments that should be calibrated and the frequency for this calibration			
	Describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment			
	Identifies how deficiencies should be resolved and documented			
B8.	**Inspection/Acceptance for Supplies and Consumables**			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	Identifies critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials			
	Identifies the individual(s) responsible for this			
B9.	**Non-direct Measurements**			
	Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used			
	Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project			
	Indicates the acceptance criteria for these data sources and/or models			
	Identifies key resources/support facilities needed			
	Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing			
B10.	**Data Management**			
	Describes data management scheme from field to final use and storage			
	Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs			
	Identifies data handling equipment/procedures that should be used to process, compile,			

Element		Acceptable (Yes/No)	Page/ Section	Comments
	analyze, and transmit data reliably and accurately			
	Identifies individual(s) responsible for this			
	Describes the process for data archival and retrieval			
	Describes procedures to demonstrate acceptability of hardware and software configurations			
	Attaches checklists and forms that should be used			
C1.	**Assessments and Response Actions**			
	Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates			
	Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process			
	Describes how and to whom assessment information should be reported			
	Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented			
C2.	**Reports to Management**			
	Identifies what project QA status reports are needed and how frequently			
	Identifies who should write these reports and who should receive this information			

Element		Acceptable (Yes/No)	Page/ Section	Comments
D1.	**Data Review, Verification, and Validation**			
	Describes criteria that should be used for accepting, rejecting, or qualifying project data			
D2.	**Verification and Validation Methods**			
	Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any			
	Identifies who is responsible for verifying and validating different components of the project data/information, for example, chain-of-custody forms, receipt logs, calibration information, etc.			
	Identifies issue resolution process, and method and individual responsible for conveying these results to data users			
	Attaches checklists, forms, and calculations			
D3.	**Reconciliation with User Requirements**			
	Describes procedures to evaluate the uncertainty of the validated data			
	Describes how limitations on data use should be reported to the data users			

[i] Formerly EPA Order 5360.1 A2
[ii] Formerly EPA Order 5360.1 A2
[iii] Quality Assurance Review Form (QA Review Form) is required for EPA Organizations.
[iv] This may be a statement of compliance with Agency standards and practices if no specialized hardware or software are purchased or used by the organization.
[v] Quality Assurance Annual Report and Work Plans are for EPA Organizations.
[vi] Information Quality Guidelines apply to EPA Organizations and are optional