



Forsyth County Office of Environmental Assistance and Protection

Quality Management Plan

2017

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List of Acronyms

APA	Air Planning Agreement
CAP	Corrective Action Plan
CFR	Code of Federal Regulations
DAO	Designated Approving Official
DAQ	North Carolina Division of Air Quality
DQA	Data Quality Act
DQO	Data Quality Objectives
EIS	Emissions Inventory System
EPA	US Environmental Protection Agency
FCEAP	Forsyth County Office of Environmental Assistance and Protection
FOIA	Freedom of Information Act
GIS	Geographic Information System
ICIS	Integrated Compliance Information System
IAG	Interagency Agreement
MIS	Forsyth County's Management Information Systems Department
NATA	National Air Toxics Assessment
NCDEQ	North Carolina Department of Environmental Quality
NEPA	National Environmental Policy Act
PQAO	Primary Quality Assurance Organization
QA	Quality Assurance
QC	Quality Control
QS	Quality System
PE	Performance Evaluation
PM	Program Manager
PO	Project Officer

QA	Quality Assurance
QC	Quality Control
QAPP	Quality Assurance Project Plan
QMP	Quality Management Plan
SCC	Source Classification Code
SOP	Standard Operating Procedure

Quality Management Plan Contact List

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Plan Coverage: This management plan documents the quality system used in the Forsyth County Office of Environmental Assistance and Protection and is required by EPA Order 5360.1 A2, "*Policy and Program Requirements for the Mandatory Agency-Wide Quality System.*" The plan covers quality assurance policies, roles and responsibilities for environmental data collection activities. This includes the collection, evaluation, and use of environmental data produced in all programs and data generated through grants, contracts, interagency and cooperative agreements.

Approval Signature Page

Approval for Implementation

 12/1/2017

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 12/1/2017

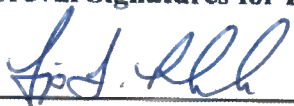
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1.0 Introduction

The Forsyth County Office of Environmental Assistance and Protection (FCEAP) has developed this Quality Management Plan (QMP) for data to achieve the following objectives\goals:

- Provide office support and context for programmatic quality assurance activities
- Create an avenue for interdivisional communication on quality assurance issues
- Create a primary source of information for data quality assurance at FCEAP
- Comply with Environmental Protection Agency (EPA) requirements

This QMP documents FCEAP's policy and procedures to ensure the environmental data we collect and report is of high quality and defensible.

1.1 Mission Statement

The mission of FCEAP is as follows:

The goals of the Office of Environmental Assistance and Protection and the Environmental Assistance and Protection Advisory Board are to encourage the wise and beneficial use of the natural environment of Forsyth County, to minimize the adverse impact of environmental contaminants on human health and welfare, and to foster public awareness of environmental considerations.

In keeping with this mission, FCEAP also follows the State of North Carolina's policy statement on Quality Assurance:

All FCEAP programs will employ a quality system for the generation and use of environmental data. These quality systems provide a reasonable assurance that all environmental data generated and processed will be scientifically valid, of known precision and accuracy, complete, representative, comparable and, where appropriate, legally defensible. FCEAP is committed to the principle that the measure of that data quality shall be used as an important factor in all decisions arising from that data. FCEAP is further committed to ensuring that a system is in place for continuing improvement in data quality at all levels throughout this Office.

1.2 Importance of Environmental Data

Environmental data are a critical input to FCEAP's decisions to protect human health and the environment. Most of the decisions which are made in the region concerning the management of the environment and the reduction of risk ultimately require the use of environmental data which are generated by EPA, or by state, tribal, local government, and/or private sector organizations and regulated facilities. Therefore, it is critically important that decision makers know the origin and quality of the environmental data used in these decisions. The quality of environmental data is known when all

components associated with their derivation (precision, bias, completeness, comparability, sensitivity, representativeness, and usability) are documented. In cases where data (e.g. emissions data) are generated by regulated facilities, reproducibility of calculated data through qualified and accepted engineering practices is verified by FCEAP prior to its acceptance for distribution to state, federal, or public users.

1.3 Essential Definitions

1.3.1 Quality System (QS) - A structured and documented management system describing the quality assurance policies, practices, protocols, and procedures for

- (1) ensuring that environmental data are of known and documented quality; and
- (2) that environmental technology is designed, constructed and operated in a manner to produce the desired environmental results; and
- (3) includes the organizational arrangements, documents, and processes described in this Quality Management Plan (QMP).

1.3.2 Environmental Data - Information collected directly from measurements or indirectly from regulated facilities, produced from models, or compiled from other sources such as data bases or literature, which are used for decision making or compliance purposes. This data/information may include secondary data.

1.3.3 Internal Data - Data generated by or for FCEAP programs where FCEAP staff have primary responsibility for project or task decision making. FCEAP's quality assurance system requirements apply to these data. Contractors that produce environmental data for FCEAP programs (air, including asbestos management) also fall into this category.

1.3.4 Extramural Data - Data generated by organizations other than FCEAP that are funded by EPA through grants, cooperative agreements, contracts and/or interagency agreements. Overall EPA quality assurance requirements for financial assistance agreements, covered in 40 CFR 30.54 and 31.45, apply to these data. Extramural data is also referred to as external data.

1.3.5 Secondary Data - Historical data or information produced during previous environmental investigations or studies, etc. Secondary data includes internal data produced by the agency or a contractor for FCEAP, and extramural data produced outside FCEAP. This includes information or data that were collected for other purposes or obtained from other document information systems. (See Chapter 3, Projects Using Existing Data, Guidance for Quality Assurance Project Plans, EPA/240/R-02/009, EPA QA/G-5, December 2002, for additional clarification.)

1.3.6 Environmental Technology - Pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies that are used to remove contaminants from the environment or prevent contaminants from entering the environment.

1.3.7 Quality Assurance (QA) - An integrated system of activities including planning, verification, implementation and assessment to ensure that environmental data are of known

and documented quality, and that environmental technology produces acceptable and defensible results.

1.3.8 Quality Control (QC) - The overall system of technical activities that measure the performance of a process or item against defined standards to ensure that the process or item meets the pre-defined standards of the customer. Quality control measures also apply to engineering controls for construction and design activities.

1.3.9 Quality Assurance Project Plan (QAPP) - A critical planning document for a project, study or task, describing how data collection activities are planned, implemented, and assessed.

1.3.10 Data Quality Objectives (DQOs) - A systematic planning system designed to produce qualitative and quantitative statements that clarify project objectives, define the appropriate type of environmental data, delineate the decision rules, and specify tolerable levels of decision error.

2.0 Management and Organization

2.1 Department Organization Structure

FCEAP is a local air quality program that has been certified by the North Carolina Environmental Management Commission. Our organization consists of the following Divisions: Analysis and Monitoring, Compliance Assistance and Permitting, Community Hygiene, and Logistic and Support Services. See **Appendix A** for a complete organizational chart.

A team of representatives from the programs identified above developed this QMP. This team worked under the guidance of the Director of FCEAP. The Director and each Program Manager are responsible for all environmental data that is reported by this Department. All environmental data collected by FCEAP is collected by the different divisions under the management and review of the Program Managers. Through various plans, meetings, and reports between the Director and the Program Managers, the quality of both the collected and reported environmental data is assured. The organization and responsibilities within each division, including delegation of environmental data quality assurance to senior level staff, is described in the following Section.

2.2 Management and Organization

The Director of FCEAP has the overall responsibility for the development, implementation, and continued operation of the FCEAP Quality Management Plan (QMP). Due to small staff size, there are no internal staff members who have full-time, exclusive assignments to QA. Each Program Manager within the Department ensures compliance with the FCEAP QMP for their division's activities. QA Project Managers are assigned by the PMs for the projects within their supervision. QA Project Managers are allowed to operate independently to assure non-biased QA assessments. The Program Managers report to the Director who reports to the Assistant County Manager and Forsyth County Manager. Contacts are as follows:

- Director, FCEAP, (336) 703-2441

- Program Manager, Community Hygiene, (336) 703-2443
- Program Manager, Compliance Assistance and Permitting, (336) 703-2430
- Program Manager, Logistic and Support Services, (336) 703-2442
- Program Manager, Analysis and Monitoring, (336) 703-2448

FCEAP has two QA Project Managers as outlined in associated QAPPs for Air Monitoring and Emissions Inventory (EI). Contacts are as follows:

- Air Monitoring QA Project Manager - Analysis and Monitoring Division, (336)703-2451
- Emissions Inventory QA Project Manager - Logistics and Support Services, (336)703-2444

Note: The EI QA Project Manager also has the responsibility to QC data submitted to the Integrated Compliance Information System (ICIS). QA of ICIS data is inherent in engineering reviews of submitted data and validation of actions prior to submitting for entry to ICIS.

The following sections detail the responsibilities of FCEAPs staff with regards to its Quality System (QS).

2.2.1 Director

The Director is ultimately responsible for ensuring that data-related activities are conducted in accordance with this document. The Director assures that the applicable elements of the quality system (QS) are understood and implemented throughout all program areas through the development and implementation of: 1) standard operating procedures; 2) internal training seminars; 3) staff meetings; and/or, 4) other appropriate procedures/processes. Daily QA management is delegated to the appropriate Program Managers and/or QA Project Managers. Program Managers are accountable for procedures within their areas of responsibility to ensure the acceptability of data generated. Key responsibilities of the Director are:

- Establish planning policies to ensure that QA matters are reflected in program budgets, program plans, and operating plans;
- Provide concurrence with QAPP and QMP content by signature of QAPP and QMP cover pages;
- Review and evaluate internal/external monitoring QA implementation and progress.
- Participate in and/or approve outputs from internal systematic planning process for data related activities;
- Approve corrective action as required by QA assessments or reviews;

- Oversee the Program/Project Manager's QA activities;
- Assure that data quality problems are addressed and properly reported

2.2.2 Program Managers (PM)

Each Program Manager is responsible for their specific internal environmental data-related programs/projects and are accountable for the management of their extramural assistance agreements. Therefore, the PM has the principal responsibility for ensuring that the systematic planning process outputs are met (Data Quality Objectives (DQOs), or other applicable outputs). Key responsibilities of the PM are:

- Prepare and/or direct the preparation of QAPPs for each project and/or program and submit to EPA for review and approval prior to implementation.
- Prepare or approve DQOs, or other systematic planning output, specifications, and acceptance criteria for the programs/projects.
- Oversee the quality of data generated from extramural projects funded through financial assistance agreements as required.
- Evaluate the quality of data generated by the monitoring programs or data collection projects (e.g. Emissions Inventory, stack test data, etc.)
- Participate in conducting assessments of programs/projects as requested by the Director.
- Coordinate review of all QAPPs and SOPs
- Coordinate QA activities within the Division and provide updates to the Director.
- Assign a QA Project Manager for QAPP related data projects and assures this staff member operates autonomously within the Division. Where resources and adequate training exist, third party QA assistance will be sought outside of the Division performing the data collection activities.
- Respond to quality control (QC) issues/problems and respond to requests for guidance or technical direction within his/her Division.
- Assist the Division's staff in developing and maintaining an effective QA program.
- Respond to requests for input or decisions related to the systematic planning process or other quality-related issues in the relevant area of programmatic responsibility.
- Attend QA training provided by the Department and assure Division staff is provided adequate training for all QA and technical work associated with data collection.

- Serve as an official Division contact and lead quality assurance staff for QA matters pertinent to the data-related program activities of that Division or other Division where possible.

2.2.3 QA Project Manager

Due to the small size of this agency (< 20 FTE devoted to the Air Program) and the training involved, a QA Project Manager resides within each Division where the duties are performed and has direct access to the PM and the Director. Duties of the QA Project Manager revolve around system and technical audits and data verification. Key responsibilities include the following:

- Evaluate the quality of data generated by the monitoring programs and/or data collection projects
- Report data quality problems to staff when remedy of the problem can be expedited or to the PM when the problem is more complex
- Flag data found suspect and address any data issues in consultation with the Program Manager and technical staff prior to submission to EPA's Air Quality System or to the EIS
- Initiate corrective action that may be required as a result of assessment findings
- Take corrective action that may be required as a result of assessment findings or consult with Program Manager where corrective action is extensive and/or involves equipment maintenance requiring the loss of data or, in the case of external data, requires resubmission of data by the external party.

2.2.4 FCEAP Technical Staff

Technical staff must support the QS by providing technical assistance in their area of expertise as requested by the Program Manager. This support enhances the QA program's capability within the Department. The specific duties assigned to the technical staff are as follows:

- Assist the PM with technical aspects of QA as related to their area of expertise (e.g., air, engineering, field operations, and data operations).
- Identify QA needs, resolve problems, and answer requests for guidance or assistance in area of expertise.
- Conduct and/or participate in on-site field assessments.
- Inform the PM of the need for new, modified, or improved methods.
- Participate in technical assistance and training, as resources permit.

- Train in QA procedures in order to assist or back-up QA Project Manager in his/her absence.

2.2.5 Contracts and Cooperative Agreements

Due to the small size of this local program, contractors are rarely hired to perform data collection or other technical services. In the event that contractors are required, FCEAP will provide general oversight including a scope of services that must be approved prior to contractor acceptance and/or initiation of work. Depending on the program, each contractor will be required to use procedures outlined in FCEAP's standard operating procedures (SOPs) or must have an approved project plan and/or work plan. As part of the field data collection efforts some activities may be observed by FCEAP personnel. Final reports generated by the contractor will undergo review by FCEAP personnel. Quality Assurance staff may participate in any of these activities as requested by the Director or Program Manager. All contracts issued by FCEAP must be processed through Forsyth County's Contract Control System. Standard terms and conditions associated with dispute resolution and addressing problems identified during audits will be included in the Contract agreements. More details are provided in Section 5 (Procurement Policy) and *Appendix B*.

3.0 Quality System Components

3.1 Quality System Components

FCEAP was established as the Primary Quality Assurance Organization (PQAO) for all of its data collection activities in March 2015. This provides a quality system (QS) specific to the equipment, resources, and needs of FCEAP.

The agency implements a QS designed to ensure that environmental programs produce the type and quality of data needed and expected. Environmental data are critical to decision-making related to the protection of the public and the environment from adverse effects of pollutants from natural and manmade sources. These data are key to decisions and actions pertaining to environmental protection efforts. Quality assurance and quality control practices need to ensure that data involving environmental efforts such as pollution detection, characterization or abatement (e.g. asbestos), cleanup, public health protection, and environmental technology, successfully perform their intended purpose.

FCEAP's quality system includes the organizational arrangements, documents, and processes described in this Quality Management Plan (QMP). This plan documents the approach used to assure the quality of work conducted by FCEAP, lines of reporting and communication, and coordination mechanisms. The quality system includes both organizational and project controls. Organizational controls refer to activities that support common functions or functions that encompass several projects and programs. Project controls are specific to work programs and activities.

Environmental programs are administered and performed by qualified personnel using appropriate technologies and techniques. Staff is responsible for planning, executing, documenting, and reviewing work performed to ensure that it conforms to the Data Quality Objectives (DQO), or similar systematic planning process. Detailed guidance for developing project or study-specific DQOs is provided in the document: *Guidance on Systematic Planning using the Data Quality Objectives Process (QA/G-4)*, EPA/240/B-06/001, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

The FCEAP quality system encourages staff to resolve problems in a timely manner. Program Managers assist staff to ensure all facets of a problem are considered and the best options used. The Program Manager is responsible for approving quality-related procedures incorporated for use by Department staff. When applicable, the quality-related activities of contractors/consultants are delineated in the respective contracts and QAPPs.

The process for implementing QS activities within FCEAP (as delineated in FCEAP quality documents) begins with training. Personnel receive training in the responsibilities/duties and associated program elements, codes, standards, and procedures of the quality system. The training may include formal instruction, seminars, on-the-job training, participation in technical conferences, and other activities determined to be appropriate. (See also Section 4)

Documentation is critical to ensure work is done correctly and available for review, as needed. Proper documentation saves resources by enabling staff to review proposed work, minimize errors and omissions, and permits future work to build smoothly upon work already completed. Documentation becomes particularly important as staff are reassigned or moved to other positions. New staff must be able to review past work to ensure ongoing project consistency and quality.

The major programs of FCEAP that require application of quality management practices and the responsible divisions are:

- Ambient Air Monitoring for Criteria Pollutants - Analysis and Monitoring Division
- Stationary Source Enforcement - Compliance Assistance and Permitting Division
- Emissions Inventory - Compliance Assistance and Permitting and the Logistics and Support Divisions (data management and transfer)
- NESHAP - Asbestos Permitting and Inspections - Community Hygiene Division

3.1.1 Procurement of Items and Services

See Section 5 and Appendix B

3.1.2 Documents and Records

FCEAP follows the Forsyth County Records and Retention Policy as well as policies established by the State of North Carolina. Records and correspondence, particularly those related to sources of air pollution, are kept in a secured central location. Monitoring data, monthly data reviews, and data summary reports are stored electronically and backed up daily. Each staff member of the Analysis and Monitoring Division, the QA Project Manager, and Program Manager are all responsible for ensuring these data are available and complete. Quality assurance for records is further described in the various standard operating procedures as well as Section 6 of this document.

Examples of quality assurance documents include:

- FCEAP Quality Management Plan (QMP)
- Quality Assurance Program/Project Plans (QAPP)
- Standard Operating Procedures (SOPs)
- Field Training Manuals and Logs
- Work Plans
- Databases and Spreadsheets documenting activities and storing collected data □
Technical Assessment documentation and guidance

3.1.3 Computer Hardware and Software

See Section 7.

3.1.4 Planning

Plans to ensure that data collected directly by FCEAP is of the expected quality are described in the quality assurance documents and standard operating procedures. FCEAP also depends on a significant amount of data measured or generated by regulated sources. FCEAP provides various forms, spreadsheets, and instructions to industry to assist these groups. This material, along with links to reference documents, is available for download at our website: www.forsyth.cc/EAP. Website availability facilitates rapid dissemination of updated materials to ensure that industry is using the latest assumptions and emission factors. Additional information on planning is contained in the approved QAPPs and Section 8 of this document.

3.1.5 Implementation of Work Processes

Implementation of work processes is described in the quality assurance documents and standard operating procedures. Additional guidance documents are provided to the permitting staff by the

Compliance Assistance and Permitting PM. In addition, reports of quality assurance activities are made by the Program Managers to EPA as part of the grant commitments and reporting requirements.

3.1.6 Assessment and Response

FCEAP QA staff conducts routine performance and technical audits of the monitoring equipment and accumulated data in accordance with the associated QAPP and SOPs. Audits are conducted monthly, quarterly, and annually utilizing existing staff. External audits are conducted by other agencies, including DAQ and EPA, as feasible by those agencies. All audits are recorded in electronic logbooks and site spreadsheets and uploaded to the central computer system for long-term storage. Corrective actions are documented on these forms as well as in the monthly data report packages before data is uploaded. External data, such as emissions inventory surveys from permitted facilities, follow the QA procedures as set forth in the relevant QAPP including review by FCEAP Staff, QA analysis of the staff's review by the Program Manager, and then an additional QA review by the Logistics and Support Services staff to assure technical and data format protocols are in place for final submission to the EIS system.

See Section 10 for a more extensive discussion of Assessment and Response.

3.1.7 Quality Improvement

The monitoring QA Manager is responsible for documenting the routine audit results and communicating these results to management. The Program Manager works closely with third party audits (e.g. EPA's TSA) to assure recommended corrections are achieved and QA documents changed to assure these improvements are formalized into FCEAP's QS. As part of the continual assessment process described above, ongoing improvements in quality management occur through experience and training. FCEAP staff attends regional and national meetings, workshops, and courses where topics are covered which can lead to further improvement in quality management. There are also meetings with stakeholder groups and individual citizens that can result in similar changes in quality management. Where data is collected indirectly from third party sources (e.g. emissions inventories, etc.), FCEAP continually seeks ways to improve data quality through changes in data forms/surveys, updating reference material, and providing updated database user interfaces that assure consistency and accuracy.

See Section 11 for a more extensive discussion of Quality Improvement

3.2 Quality System Tools

3.2.1 Quality Management Plan (QMP)

This Quality Management Plan documents FCEAP's strategy for building quality into its environmental programs. The quality system includes planning, implementing, and assessing the quality assurance and quality control operations as they are applied to the FCEAP environmental data programs. The FCEAP

QMP and its revisions are developed by the FCEAP Program Managers with general oversight by the Director. When approved, the QMP is located on a shared drive identified and assessable to all FCEAP staff.

3.2.2 Quality Assurance Program/Project Plan (QAPP)

The Quality Assurance Program/Project Plan (QAPP) is the fundamental FCEAP quality assurance document for environmental data related activities. When fully implemented across the Department, Programs and Projects funded by EPA and involving environmental data used for decision-making shall have a QAPP approved by EPA. A QAPP specifies the data quality objectives or other systematic planning output (See Section 8), minimum project management requirements regarding data measurement, acquisition, assessment, oversight, validation, and usability. The QAPP includes the main elements listed in the document *EPA Requirements for Quality Assurance Project Plans (QA/R-5), EPA/240/B-1/003*. Additional guidance for developing QAPPs may be found in the document, *Guidance for Quality Assurance Project Plans (QA/G-5), EPA/240/R-02/009*. FCEAP staff performing specific tasks associated with environmental measurements or assessments are supplied with or provided access to QAPPs. Those QAPPs are maintained by each program and are available upon request by outside parties. All QAPPs and SOPs are developed in accordance with EPA guidance documents and describe procedures associated with data verification, review, and validation. All QAPPs are approved by EPA and identify personnel responsible for adhering to requirements for data collection, review, and analyses. The Department's QAPPs also include data qualifier flags and definitions assigned to noncompliant data. Specific elements contained in these documents and roles and responsibilities of pertinent staff are discussed in greater detail in Section 10.

3.2.3 Standard Operating Procedures

Standard Operating Procedures are documented protocols for performing certain routine repetitive tasks. These tasks frequently involve such operations as sample collection, chain of custody, analysis methods, instrument or method calibrations, preventive and corrective maintenance, quality control, and data reduction. The purpose of an SOP is to assure that random errors produced as a result of differences in performance of the task are minimized.

FCEAP Standard Operating Procedures (SOPs) are developed using the EPA document, *Guidance for Preparing Standard Operating Procedures (SOPs) (QAIG-6), EPA600/B-07/001* as a guide. All Departmental monitoring activities and data collection procedures are documented in SOP format. The SOPs help ensure work standardization by documenting processes that are consistently, effectively, and regularly performed including sampling and analytical procedures. FCEAP staff and contractors performing specific tasks associated with environmental measurements or assessments are supplied with or provided access to SOPs. References to applicable SOPs are included in the associated QAPPs. SOPs are developed and maintained by each program and are available upon request.

3.2.4 Data Management Review

3.2.4.1 Integrated Compliance Information System (ICIS)

FCEAP enters inspection, reporting, stack tests, and enforcement data for permitted stationary sources as actions into the EPA's Integrated Compliance Information System (ICIS). All actions go through a chain-of-command review beginning with the case manager. The PM performs the final QA review before initiating enforcement actions that include violations and civil penalties. All ICIS Plant Action Data are discussed in monthly enforcement group conference calls that includes the Assistant Program Manager of the Compliance Assistance and Permitting Division and EPA. This meeting assures that the action taken by the Department is catalogued in accordance with ICIS requirements. Once enforcement activity is quality assured within the conference call by the Compliance Assistance and Permitting Assistant Program Manager, actions entered into ICIS by the Logistics and Support Services Senior Environmental Specialist who acts as the QC coordinator for ICIS data. Quality Control is ensured through end of year reports that are generated by EPA and reviewed for accuracy by comparing these ad hoc reports with reports from FCEAP's in-house databases. Where discrepancies or omissions are found, FCEAP submits corrections with consultation and assistance from EPA staff when needed.

The Senior Environmental Specialist of LASS is responsible for documenting the facility parameters and communicating these results to management. As part of the continual assessment process described above, ongoing improvements in quality management occur. FCEAP staff attends regional and national meetings, workshops, and courses where topics are covered which can lead to further improvement in quality management. There are also meetings with stakeholder groups and individual citizens that can result in similar changes in quality management.

3.2.4.2 Emissions Inventory System (EIS)

FCEAP follows all QA/QC procedures and chain of command review in accordance with its EPA approved Emissions Inventory QAPP for all emissions data collected from Forsyth County permitted facilities. In addition to QAPP procedures, 3-year data review for inclusion of Forsyth County data into the NATA database provides a coordinated review between EPA and FCEAP to validate and/or verify outliers where emissions appear unusual for a specific SCC or industry group. Amendments are made, if necessary, to assure NATA data is complete and accurate.

3.2.5 EPA Grant Reporting Requirements

EPA grant reports provide a framework tool for certain QA activity and data inclusion. (e.g. including HAPs in Emission Inventory surveys).

FCEAP currently maintains two EPA funding grants, the Section 105 Air Quality Program Grant and the Section 103 PM_{2.5} Special Purpose Grant. FCEAP maintains comprehensive records of all activities funded by the Section 105 as agreed upon in the annual Air Planning Agreement (APA), an inter-agency agreement negotiated between FCEAP and EPA. The APA outlines reportable QA activities that are reported to EPA in a timely manner. The Section 103 grant reporting requirements center around the annual network plan, including QA activities, submitted by FCEAP in conjunction with the end of each grant cycle (April 30th). All reports are backed by verifiable and auditable records. Federal Financial Reports are submitted at the end of each project period and undergo strict financial review by both FCEAP staff and Forsyth County's Finance Department. The Forsyth County

Finance Department executes periodic Financial audits of FCEAP to assure all financial interactions and purchase acquisitions meet high fiscal standards.

4.0 Personnel Qualifications and Training

4.1 General

FCEAP personnel are provided access to the FCEAP QMP and other related quality documents via shared electronic filing systems. FCEAP staff performing the tasks are required to understand and apply the procedures to ensure the work performed is consistent with the policy and procedural documents. Initial and ongoing personnel qualifications and training needs shall be identified. Access to appropriate training opportunities shall be provided as resources allow, and the acquisition of needed knowledge and skills should be verified through on-site evaluations performed by program technical staff. Adherence to quality system requirements is verified by confirming compliance with program QAPPs and SOPs. On-site evaluations and training (if required) are performed by FCEAP program technical staff. Training requirements are addressed in Section 4.4 and 4.5.

4.2 Position Descriptions

The Forsyth County Human Resources Department administers and maintains a Job Classification Plan to which all positions within FCEAP are allocated. Each position within the Office is described in a Job Classification that lists the job duties, decision-making responsibilities, equipment regularly used, commonly used written work-guideline documents, financial responsibilities, and any required licenses, registrations or certifications necessary. Percentages of time devoted to different programs are assigned by the Program Manager and Director during the annual budgetary process as needs change. Job Classification forms with the associated Americans with Disabilities Act (ADA) Physical Efforts Checklist are maintained by the Forsyth County Human Resources Staff.

4.3 Personnel Qualification

Personnel that are hired by FCEAP must meet the specific requirements of the job classification. Each classification has minimum quality-related criteria including educational requirements, technical and nontechnical knowledge and skills, certifications, professional experience, and other requirements for entry-level and advanced positions within a series of related jobs (e.g., Program Managers, Environmental Specialists, Senior Environmental Specialists, etc.). The Forsyth County Human Resources Department and the Director of FCEAP are responsible for establishing the qualifying criteria.

4.4 Employee Training Needs

It is the responsibility of each PM to ensure that all personnel performing tasks and functions related to data quality have the necessary education, training, and experience. Training needs, including QA Training, are determined on an individual basis by PMs in consultation with employees. Training determinations are based on statutory requirements, management directives, audit findings, and

midyear/annual employee performance appraisals. The quality-related training needs are not static, but are a dynamic function of program requirements and are addressed on an as-needed basis by the PMs and the Director. The PM may, in consultation with the Director, require staff to participate in specific QA related training as a result of an internal audit, significant modification to program procedures, or other quality-related issue. In addition, staff are encouraged to communicate training needs to their PM or to the Director.

4.5 Training Programs

Providing internal training is a priority to ensure that FCEAP staff retain and enhance their technical competence, and perform their jobs efficiently. Notwithstanding funding limitations, FCEAP remains committed to continual training of staff. Currently, the responsibility for coordination of FCEAP training lies within the individual Divisions and programs. The responsibility for developing, planning, and conducting training is shared among supervisors and staff. Management and staff receive quality systems training which helps ensure that programs produce and use quality data during the decision making process. Staff enhance their quality system skills both in-house and externally, as resources allow, through classes, seminars, and conferences to learn both fundamental concepts and new procedures. Training may be formal or informal, mandatory or voluntary. Quality-related training may be obtained from : 1) an external vendor (if available and Departmental resources permit); 2) EPA; or 3) from other available sources. The effectiveness of any QA related training may be determined through course evaluations, testing, review of subsequent audits, and/or management reviews. EPA Region 4 funded training classes provide important opportunities for Departmental staff to develop skills consistent with other air agencies and EPA. Employees and supervisors also determine whether training programs and courses offered outside of FCEAP and EPA by educational institutions, professional associations, and other providers are useful for enhancing job performance or professional development. These programs and courses may include such activities as instructional courses, seminars, professional meetings, and workshops.

Examples of training opportunities include:

- Air Pollution Control Orientation
- Air Pollution Source Inspection
- Computer Applications
- Computer Modeling Applications & Training
- Web-based EPA-sponsored Training Seminars
- EPA Region 4 Air Monitoring Workshops
- EPA Emissions Inventory Conference
- National Air Monitoring Conferences
- National Air Quality Conferences
- EPA Annual Quality Assurance Conferences

- EPA Air Quality Systems (AQS) Training/Workshop
- National Association of Clean Air Agencies (NACAA) Conference
- NESHAP - Asbestos Certification Training

4.6 Training Records

Supervisors maintain individual training records for their staff members.

5.0 Procurement Policy

5.1 Overview

The Forsyth County Office of Environmental Assistance and Protection (FCEAP) follows purchasing procedures as outlined in Chapter 143 of the North Carolina General Statutes. In addition, FCEAP complies with Federal Regulation 40CFR Part 33 (utilizing woman and minority owned businesses) whenever possible. Specific purchasing procedures from Forsyth County Finance Department are attached (*Appendix B and Appendix C*).

All purchases relating to the collection and reporting of air quality monitoring data must be preapproved by the Analysis and Monitoring Program Manager and the FCEAP Director. Purchases are initiated by the Analysis and Monitoring Program Manager who ensures that any technical or QA\QC specifications required are included in the procurement document. When equipment meeting comparable technical and quality requirements is available from multiple vendors, bids are obtained to leverage the best value and warranty agreements. Once received, the equipment is tested to assure that the technical and QA\QC specifications are met. If the equipment fails to meet specifications after testing (this includes working with the Vendor where their assistance is needed), the equipment is returned to the Vendor for refund or replacement with equipment that meets the specifications expected. In cases where this process is delayed, older but functional equipment may be returned to service until appropriate replacement equipment can be purchased and tested.

5.2. Direct Purchases

FCEAP is allowed by the County's Finance Department to directly purchase goods and services up to \$5,000. Where multiple vendors exist, at least three estimates are obtained to assure fiscal controls, including costs and preventing the potential for appearance of preferential treatment toward specific vendors. If a department prefers to use Performance Purchasing (see section 5.2.1), it can still initiate an online purchase requisition for an order less than \$5000 to be processed by City/County Purchasing. The intention of the procedure is not to require departments to purchase supplies directly from vendors when the order is less than \$5000, but to provide the option to departments to facilitate the timely acquisition of goods and materials necessary to meet departmental objectives.

These purchases are reviewed and processed by the Department's Fiscal Technician to ensure all

County Finance requirements are met, and signed by an authorized Program Manager, or FCEAP Director, then submitted to Finance for final review and authorization by the Forsyth County Fiscal Supervisor or the Director of the Finance Department/Finance Officer.

5.3 Purchase Orders and Service Contracts

5.2.1 Purchase Orders for Goods and associated contracts

Purchases of \$5,000 or more for goods must be submitted as a Purchase Order through the Performance Purchasing System. Where multiple vendors exist, at least three estimates are recorded to assure fiscal controls, including costs and preventing any appearance of preferential treatment toward specific vendors. Purchase Orders are approved by FCEAP's Logistics and Support Services Program Manager and the FCEAP Director. Once approved by FCEAP management, representatives of the City/County Purchasing Department and the County Finance Department review and give final approval for the purchase.

Service Contracts over \$5000.00 must also go through the Contract Control process. Each contract is assigned a control number by the County Manager's Office, and then forwarded to Finance. Insurance requirements are confirmed. Funds availability is verified and the contract is encumbered, pre-audited and signed by the Finance Officer. It is then forwarded to the County Attorney. After the Attorney approves the contract, it is returned to the Manager's office for Board/Manager approval and execution. Requests for Payment may be processed once the contract is executed by all parties.

5.2.2 Purchase of Services

Purchase of Services under \$5,000 are submitted through Forsyth County's *Contract Limited (CL)* system. Where multiple vendors exist, at least three estimates are recorded to assure fiscal controls, including costs and avoidance of potential preferential treatment toward specific vendors. The CL system provides a more streamlined contract control system. Contracts are more standardized to assure County liability issues are covered in accordance with the requirements set forth by the County's Risk Manager. Once requirements are met, the contract limited purchase can be approved through the Finance Department without the extensive review of the Budget Department, the Attorney's Office, or the County Manager.

5.4 Financial Audit

To assure fiscal integrity, the Forsyth County Internal Audit Department performs value-added, risk-based audits, designed to independently review, test, and evaluate the financial, electronic, and operational controls of FCEAP as well as all other Departments. Audits not only evaluate fiscal operations but compliance with all aspects of the Department's operations. The Audit Department's functions include examination and assessment of:

- Compliance with policies, procedures, laws, and regulations
- Safeguarding and use of County assets

- Accuracy, reliability, and integrity of County records and reports
- Development and implementation of methods, systems, and procedures
- Suspected fraud, waste, abuse, etc.
- Adequacy of internal controls

Where deficiencies are identified, the Department submits a work plan and makes the necessary adjustments in procedures and/or recordkeeping. These changes are followed up by the auditors until the issue is resolved.

6.0 Documents and Records

6.1 General

Documents that specify requirements and instructions affecting the quality of environmental programs shall be adequate for the intended purpose and shall be controlled as required by federal or state programs. Documents are controlled by the use of information such as title, date, version, etc. Quality assurance records should be produced, controlled, and maintained so as to reflect the achievement of the required quality for completed work and to fulfill statutory, regulatory, and contractual requirements. The most current version of controlled documents shall be made readily available to staff and posted online. All FCEAP programs follow a policy and procedure for access/inspection and storage of records based on North Carolina state law. FCEAP staff receive training on their duties and the requirements for records and retention that are based on North Carolina's Public Records Law, N.C.G.S. 132, and Forsyth County policy. Records relating to personnel issues are confidential and may not be subject to public inspection. Documents identified to be older versions or obsolete will be archived according to each program's document retention schedule. The process for maintaining chain-of-custody and confidentiality is a component of QAPPs and SOPs. As such, they are addressed in these documents, including identifying the individuals responsible for maintaining and protecting this information.

6.2 Identification of Quality-Related Documents

Quality-related documents and records that are outlined in the records retention policy, federal/state regulations or identified by PMs are controlled. The quality-related documents listed below currently require control:

- FCEAP Quality Management Plan (QMP)
- Quality Assurance Project Plans (QAPPs)
- Standard Operating Procedures (SOPs)
- Field Sampling Plans/Study Plans

- Environmental Data Program Guidance Documents

Any of the following may be controlled as required by the applicable QAPP:

- QA/QC Records
- Audit Records
- Calibration Records
- Maintenance Records

QAPPs and SOPs are prepared, reviewed, approved, issued, distributed, maintained, and revised per the policy located within the Office's Criteria Pollutant QAPP, Section 1.9. This section follows the requirements and guidance set by EPA. Field Sampling Plans/Study Plans specify quality-related requirements/instructions or record quality-related information (per approved QAPPs and SOPs) and are drafted by the appropriate managers and staff. Each document undergoes a peer and chain-of-command review process.

Quality Management Plans, QAPPs, and SOPs are prepared, reviewed, approved, issued, distributed, maintained, and revised according to procedures described in Division specific SOPs. Field Sampling Plans/Plans of Study are prepared, reviewed, and approved according to the same procedures as QAPPs. These documents specify quality-related requirements/instructions or record quality-related information and are drafted by the appropriate managers and staff. Each document undergoes a peer and chain-of-command review process.

Quality documents valid for more than one year generally undergo an annual review process to ensure applicability and are revised as needed using the same peer and chain-of-command review process. As per SOPs regarding development of QAPPs and SOPs, critical revisions to QAPPs, SOPs, and Sampling Plans are tracked in the Change Tracking table located in each document. Program/Project Managers are responsible for distributing QAPPs/Study Plans with critical revisions to each person listed in the QAPP Distribution List. Critical SOP revisions, as well as new SOPs are listed in either program specific or Department-wide emails distributed to appropriate Departmental staff when the documents are posted to the FCEAP shared drive location.

The PM is responsible for ensuring the appropriate use of quality-related documents by program/project staff and that these documents and records accurately reflect the completed work. The methods used to accomplish these activities are determined by the individual program/project managers. The PMs are responsible for documenting that those implementing the SOPs have documented that they have read and understand the new SOP or the revisions to an existing SOP. This documentation is maintained by their supervisor.

The Analysis and Monitoring PM coordinates development of Department-wide QMP, the Air Monitoring QAPP, and its related SOPs. The Logistics and Support Services PM coordinates development of the Emissions Inventory QAPP with the Compliance Assistance and Permitting PM.

At a minimum, each PM maintains procedures for review, approval, distribution, revision, and control of: the Departmental QMP • Departmental QAPPs • Departmental SOPs.

6.2.1 Availability

The current versions of the QMP, QAPPs, and signed SOPs are maintained on FCEAP's shared drive in a location to facilitate availability to all FCEAP staff. Documents may be opened and printed or saved to individual staff computers. The most current versions are maintained on the shared drive in a known location for use by Departmental staff. Previous versions are archived as described below.

6.2.2 Archival

Electronic versions of available historical quality-related documents are maintained on the FCEAP shared drive. The PM responsible for each QAPP or the QMP is responsible for ensuring archival of these documents. Maintenance and archival of SOPs, program/project QAPPs/study plans, and quality related records is the responsibility of each PM.

7.0 Computer Hardware and Software

7.1 General

Information technology is critical to the performance of the mission of the Department. Computer systems are used to gather, store, analyze, retrieve, visualize, archive, and publish data for use by FCEAP staff, interested parties, and the general public. Computer software and hardware used to calculate or develop data for environmental programs included in the Quality Management System are managed to ensure that data are of acceptable precision and accuracy and that data are not corrupted or lost. Equipment and systems covered under this section include

- Desktop hardware and software used by FCEAP staff
- Server hardware and software used to store and access environmental data and documents
- Communications hardware and software used to interconnect desktop and server equipment including local area networks (LANs), the Internet, and other remote networks.

7.2 Roles and Responsibilities

7.2.1 Management Information Services (MIS)

The Forsyth County Management and Information Services Department (MIS) is responsible for managing computer hardware, software, and data telecommunication infrastructure for the Department.

Specific processes, procedures, and individuals responsible for determining the quality of environmental data residing in FCEAP databases and information systems are available in program area QAPPs and SOPs. Some programs utilize computer models to perform environmental data analysis. The individuals and their responsibilities regarding quality related activities are identified in the QAPPs.

FCEAP data quality is frequently assessed, and various policies and procedures have been implemented to assure computer software and hardware purchases conform to a standard that ensures environmental data integrity.

MIS is responsible for the following technical services:

- The planning and procurement of the Department's LAN infrastructure (firewalls, routers, switches, hubs, etc.).
- Installation, operation and maintenance of the LAN infrastructure including oversight of any contracted services that ensure infrastructure meets the goals and needs of Forsyth County.
- Installation, maintenance, and operation of servers used by FCEAP up to the operation system layer. This includes database servers, file and print servers, system management servers, endpoint security servers, geographic information servers (GIS), and web servers.
- PC hardware and software maintenance, printer maintenance, and other IT hardware and software maintenance including VOIP phone systems and wireless routers for building web access. FCEAP staff request software and hardware maintenance by use of the MIS Help Desk available through email or by telephone.
- Assist FCEAP with mission-critical interfaces in relation to data retrieval from monitoring sites to the County's data servers.
- Website development and maintenance, including interfaces that provide FCEAP easy access to the development team for website changes and updates.

7.2.2 FCEAP Management and Technical Staff

FCEAP management is responsible for budgeting and procurement of hardware and software for staff in compliance with the policies and guidelines set forth by the MIS Department and County administration.

FCEAP technical staff is responsible for development and maintenance of mission-critical database applications. The staff predominantly uses MS Access[®] and MS Excel[®] for the development and maintenance of environmental data. Financial, personnel, and the Emissions Inventory data systems are managed by the Logistics and Support Services PM. Monitoring data collection, maintenance, and data submittal are managed under the oversight of the Analysis and Monitoring Division PM. Data systems involving registered facilities (Dry Cleaners and Stage I Vapor Recovery systems) as well as NESHAP asbestos inspection and compliance data are managed by the Community Hygiene PM.

FCEAP does maintain an internal license agreement with 3rd-party vendors for environmental data acquisition software. This software has been approved by MIS for installation and daily operation. The management of the agreement is coordinated through this Department and maintained within FCEAP. When necessary, MIS is consulted before testing any new software or hardware to determine its compatibility with the existing infrastructure.

7.3 Evaluating Purchased Hardware and Software

The MIS staff is responsible for specifying, procuring, installing, and maintaining computer hardware and software so that they meet the needs of FCEAP's programs and are consistent with the policies set forth by the Forsyth County Manager and the Board of County Commissioners. PCs, laptops, and other mobile devices are procured via a county-wide contract led by MIS and utilized by departments throughout the County as a block purchase. Specifications are updated at least annually to reflect the state of current technology. Operating system (Microsoft Windows) and office productivity software (Microsoft Office Professional suite) is obtained via an Enterprise Agreement led by MIS. The Enterprise Agreement entitles the Department to all current versions as well as updates. Standardized disk images that encompass the operating system, office productivity software, and endpoint security software are created for each client hardware platform and tested for proper operation and configuration. Once operationally stable configurations are achieved, images are released for subsequent installations to a particular hardware platform. Images are periodically updated to incorporate critical software updates. System images are accessible only to authorized MIS staff responsible for deployment and maintenance. All operating system and application software is installed from Forsyth County's network where it is secured against unauthorized use or access.

The acceptability of hardware/software configuration standards for FCEAP staff is evaluated by the Director of FCEAP and the PMs. Information about concerns or problems is transmitted to MIS staff.

7.4 Data and Information Requirements & Standards

Responsibility for the quality of data produced from or collected by computers, computer systems, and/or databases lies with the related program staff. Depending on the age and design of the database, the system may have fields within the data records documenting the conduct of applicable data review and validation processes. Guidance documents (QAPPs, SOPs and other operational documents) set forth the procedures and means of managing data to ensure their quality during their useful life. In the case of Emissions and Compliance Data (data related to the Permitting Program), data accuracy and completeness responsibilities lie with the EI QA Project Manager. Facility data is reviewed on a routine basis and reports are sent to the Program Manager when data is inaccurate or incomplete. Quarterly reviews are performed on data submitted to EPA's ICIS database to assure data was transmitted accurately and completely to ICIS by FCEAP. In the case of our Particulate Matter 2.5 Data (data related to the Monitoring Program), data accuracy and completeness responsibilities lie with the site operator, QA specialist, and A&M Program Manager. PM 2.5 data is reviewed on a monthly

basis and the QA specialist and Program Manager are notified when data is inaccurate or incomplete. Quarterly reviews are performed on data submitted to EPA's AQS database to assure data was transmitted accurately and completely to AQS by FCEAP.

7.5 System Safeguards

Systems and data are protected against malicious and unintended loss and corruptions through measures designed to restrict access, detect threats, and reduce the probability of loss.

7.5.1 System Access

Access to systems is administered through the MIS department in consultation with FCEAP's Director and the PMs. Users are set up to access only the systems they need to do their work. Access is controlled by user id/password authentication both at the desktop level and program application level. Individual database systems may have additional safeguards to provide access to sensitive levels of data for management purposes.

7.5.2 Endpoint Security

Computer malware poses a significant threat to computer systems and the data stored on them. MIS maintains an endpoint security server that pushes antivirus software updates to all client systems connected to the Forsyth County LAN. The updates are obtained daily or more frequently if necessary, from the operating system or antivirus software vendor.

7.5.3 Backup and Recovery

Server backup and recovery are the responsibility of MIS. Server operating configurations, software, and data are backed up on a daily basis. Multiple generations of media are maintained to support rollback to prior versions. Backups are scheduled, tested and media stored according to standardized procedures and validated in the Continuity of Operations plans. Users are directed to store all nonvolatile data on servers that are covered by the backup plan or to create and maintain a system with equivalent safeguards. Only temporary copies of data are to be stored on hard drives not covered by a backup plan.

8.0 Planning

8.1 General

Environmental data-generating programs shall be planned in accordance with Local, State, and federal laws and rules, Departmental guidelines, and contractual requirements. Environmental programs and projects are planned through the development of the Departmental program plans/strategies and budgets, grant work plans, QAPPs, this QMP, and contracts/cooperative agreements executed by

FCEAP and external organizations. These documents translate requirements and expectations into measurable specifications, commitments, and performance criteria.

8.2 Program Planning

Planning is an integral part of each FCEAP program; however, the frequency and mode of the planning process varies between Divisions and programs. Many Division programs conduct planning as part of the annual grant continuation/commitment process or conduct ongoing program planning/strategy development sessions as part of their routine activities. Programs that require adherence to the QMP are a key component of FCEAP's strategic plan. Execution of this QMP and achieving the Data Quality Objectives (DQOs) will help ensure that the goals identified in the strategic plan are met. Periodic reviews are conducted to evaluate goals and resources to determine if adjustments are needed.

8.3 Systematic Project Planning

Projects involving the generation, acquisition, and use of environmental data should be planned using a systematic process. A systematic planning process such as the one outlined in the document, *Guidance on Systematic Planning using the Data Quality Objectives Process, EPA QA/G-4*, or other comparable process, may be used for FCEAP programs or projects. DQOs are qualitative and quantitative statements of the quality of data needed to support specific decisions or regulatory actions. Each FCEAP Program/Project Manager (PM) is responsible for initiating a systematic planning process, as appropriate. During the early phases of planning the PM clearly establishes the intended use of the data needed. The process requires interaction between the PM and technical staff with significant expertise in the type of activities planned for the program/project. These Planning activities are conducted to:

- Ensure that data collected are of the type and quality appropriate to their intended use, and therefore support decision-making, by defining the project goal(s) and objective(s);
- Generate the sampling design to include the type and quantity of data needed, a project schedule, resource requirements and availability, milestones, and any applicable requirements (e.g., what, how many, when, where, and how to collect samples);
- Determine what and if any existing data could be used to support decision-making; and
 - Optimize the data collection efforts by ongoing evaluation of the program needs, data collection activities that support these program needs, and technology advancements available for generating data; and by promoting communication among all involved parties before, during, and after project completion. This method is also used to assess the effectiveness of the systematic planning process.

If expertise in sampling, statistics, risk assessment (both human health and ecological), laboratory analytical services, engineering, or other services are not internally available, external expertise may be

sought. Contractors are only utilized when sufficient resources are available in accordance with Forsyth County's Procurement Policy. The outputs of the systematic planning process are used for the detailed design of the program/project and preparation of the associated QAPP(s). QAPP documents shall be developed following the procedures outlined in current EPA guidance. The QAPP is peer reviewed and compared to the QAPP Requirements Checklist. Upon concurrence, the QAPP prepared for FCEAP environmental data collection operations/programs funded through EPA cooperative agreements, etc., must be approved by EPA.

9.0 Implementation of Work Processes

9.1 General

Environmental programs shall be performed so as to ensure that customer needs and requirements are met and products and results are produced in a timely manner. Environmental programs conducted by FCEAP should be implemented in accordance with approved plans. Exceptions, deviations, and changes to these plans must be documented.

9.2 Planning

The Department ensures environmental work is performed according to plan through the following:

- implementation of a quality assurance program;
- program and project planning;
- staff development and training; and,
- ongoing oversight of performance.

The quality system implemented by FCEAP is described in Sections 2 (Management and Organization) and 3 (Quality System Components) and elsewhere in this QMP. Program and project planning inputs, processes, and results are described in Sections 6 (Documents and Records) and 8 (Planning) of the QMP. Staff development and training activities are described in Section 4 (Qualifications and Training) of the QMP. Assessment and response (oversight) programs implemented by DENR are described in Sections 10 (Assessment & Response) and 11 (Quality Improvement) of the QMP.

9.3 Implementation of QA Program/Project Plans

At FCEAP, QAPPs are "data-focused" plans that are designed to ensure that data gathered or generated to support Department decisions are scientifically sound. The implementation of these plans is the responsibility of the PM and generally includes a meeting of all project managers and staff to discuss the technical and QA/QC requirements specified in the QAPP. The approved QAPPs are placed on the FCEAP shared drive to allow continued easy access by all Department staff to the most current version.

Program/Project managers are responsible for assuring that their respective QAPPs are implemented properly and conducted within the specified timeframes. Additionally, they are responsible for documenting any significant departures from the QAPP requirements. The latter may also be documented as part of a Management Self-Assessment or during any associated technical audits.

In general, QAPPs are reviewed annually, and whenever any modifications are made to an existing QAPP, these changes are transmitted to all staff included on the QAPP distribution list. Any new SOPs or modifications to existing SOPs required to correctly document procedures used in a QAPP are prepared/modified and approved. Current SOPs and guidelines are maintained on the Department's shared drive.

10 Assessment and Response

10.1 General

An assessment and response program designed to monitor conformance to and assess the effectiveness of the Department's quality system continues to be developed and implemented as resources allow. Program development information is available in EPA Quality Documents such as Guidance on Assessing Quality Systems (EPA QA/G-3).

An assessment is designed to provide objective feedback about the quality system. It evaluates and documents the management policies and procedures that are used to plan, implement, assess, and correct the technical activities for environmental programs. It may include a quality system document review, file review, and discussions with managers and staff responsible for environmental data operations.

Assessments can be conducted for specific FCEAP environmental programs or can apply to the entire Department. Some assessments are regularly scheduled (e.g. Select Internal Audits, Quarterly Air Monitoring Performance audits) or may be specifically scheduled as the result of a trend noted during a data validation procedure. Assessments generally follow a prepared checklist. The assessment results are documented in formal reports and provided to appropriate management personnel for review, response as necessary, and follow-up corrective actions as appropriate. Various assessments may be used by the Department, as appropriate, to assist in determining the status of measurement systems, the adequacy of the data collection systems, the completeness of data collection activity documentation, and the abilities of program management to meet mandated data collection and data quality objectives.

10.2 Assessment Tools:

The following tools may be used by the Department to assess its quality system.

10.2.1 Quality System Assessments

System assessments (i.e., audits) are typically conducted as part of a corrective action or when a significant problem is identified or suspected. Program practices and procedures may be assessed by management through a routine random performance evaluation when the quarterly data evaluations indicate that certain program objectives are not being met. Additional information is available in the EPA document *Guidance on Assessing Quality Systems* (EPA QA/G-3).

10.2.2 Management Assessment

Management Assessments engage the program/project manager or coordinator and appropriate senior staff to determine if objectives are being met. Internal programmatic meetings take place on a monthly basis to facilitate communication between management and program staff, address quality concerns and recommend corrective actions.

10.2.3 EPA Program Audits

EPA sponsored programs may be subject to review or audit by EPA. Scope and timing of audits may vary depending on the program. Formal assessment of performance by EPA may occur as part of a comprehensive review and evaluation of Departmental programs. The process is governed by EPA's Policy on Oversight of Delegated Programs, which states evaluations should focus on overall program performance.

10.2.4 Technical Audits and Assessments

A technical audit or assessment is a systematic and objective examination of a program or project to determine whether environmental data collection activities and related results comply with the program/project's QAPP and other planning documents (such as SOPs), are implemented effectively, and are suitable to achieve its data quality goals. Additional information is available in the EPA document *Guidance on Technical Audits and Related Assessments for Data Operations* (EPA QA/G-7). Technical audits are qualitative assessments of personnel, equipment, facilities, procedures, and QA activities. FCEAP data generation activities are audited by Division staff as resources permit or when evidence of an inadequate performance or data quality concern arises for a particular activity, or according to the schedules outlined in the applicable QAPPs.

10.2.4.1 Technical Audits

Technical System Audits (TSAs) are thorough, on-site, independent quantitative and qualitative evaluations of the "total measurement" and QA system of a project or program for the purposes of determining (a) the capability of the measurement system to generate data of the required quality and

(b) the extent of compliance of an operational system with its applicable QAPP. TSAs may incorporate qualitative reviews of facilities, equipment, training, procedures, recordkeeping, data validation, data management and reporting, as well as quantitative analyses (i.e., performance-based determinations) of measurement system accuracy. The quantitative portion may involve challenging the sampling and/or analytical systems with audit standards, audit equipment, and where possible, personnel who are different from those routinely involved in the operation of the program or project. TSAs are typically conducted on the Air Monitoring Program on a three year cycle. Results are reported to the Director and PM.

10.2.4.2 EPA Field Audits

EPA Field Audits may be conducted for specific individual programs. External field audits also include participation in the National Performance Audit Program (NPAP) and Performance Evaluation Program (PEP) as prescribed by regulatory requirements.

Data Management Reviews

Data Management Reviews may be conducted by FCEAP staff on regular intervals to evaluate the effectiveness of data quality assurance procedures. These include auditing of field staff data entry into various databases as a means of verifying and evaluating data entry accuracy and completeness quality measures. In the case of EIS or ICIS, this includes data comparisons with consultations/negotiations with EPA technical staff regarding data validity, accuracy, and identifying outliers, etc..

10.3 Frequency of Assessments

The FCEAP QMP is reviewed at least once during its five year review cycle. Program QAPPs are submitted for approval every five years. In addition, the Department relies on several tools or processes to assist with the review of its Quality System.

- The PM and Quality Assurance Project Manager conduct periodic evaluations of various quality system components to ensure continued application and expansion of quality system principles.
- PMs conduct ongoing assessment of the quality of work product. Significant problems with work products trigger a re-evaluation of any associated quality system tools. In such instances, the Department does not intend that program areas await scheduled assessments and corrective actions, but instead recommends the immediate correction of problems discovered during real time surveillance.

Any EPA Region 4 assessments, such as a program review, serve as a highly-valued critique of the Department's quality system. The EPA Region 4 staff review, provide comments, and approve Departmental program/project QAPPs.

Table 1 - Audit and Assessment Commitments

Assessment Type	Assessment Agency	Frequency
Technical System Audit	EPA Region 4	Every 3 years
Network Review	EPA Region 4 FCEAP	Annually
Data Qualifiers/Flags Review	FCEAP	Monthly
Standard Operating Procedures Review	FCEAP	Annually
Data Quality Assessment	FCEAP	Monthly
PM2.5 Performance Evaluation Program	EPA designated Contractor	25% of sites per year/4 times per year
National Performance Audit Program	EPA designated Contractor	As Scheduled
Data Management Review - ICIS	FCEAP and EPA cooperative	Annually
Data Management Review EIS\NATA	Annual EIS - FCEAP 3 Year NATA - FCEAP and EPA	Annually/3 years

10.4 Selection of Assessment Personnel

All Department program areas have substantial workloads associated with: 1) the core program work functions; 2) ongoing development of SOPs and other quality system tools; and 3) self-assessment within the program areas. Program areas designate unbiased, experienced staff to participate in quality assessment efforts. Current financial resources are not sufficient to allow independent assessors/auditors. However, each program strives to assign quality assurance personnel that have minimum perceived conflict of interest. Each QAPP approved by EPA defines the roles of such assessors/auditors and any major issues are resolved prior to approval of the plans.

10.5 Assessment Planning

The Department does not have a specific established assessment plan in place. Section 10.2 demonstrates that the Department has a reliable inventory of assessment tools available for use. As demonstrated in Section 10.3 and Table 1, the Department also has a basic schedule under which assessments are carried out. The A&M division communicates assessment/audit findings during weekly meetings and in some cases through email. Findings are discussed openly as a group to better train and inform other site operators and maximize cross-training opportunities. Corrective actions are also discussed as a plan for implementation may involve more than one person.

10.6 Response

Responses to the findings of an audit or assessment are anticipated at several levels. The program/project manager has the responsibility to review the assessment findings and take the necessary corrective action(s) if any deficiencies are found during an audit.

10.6.1 Corrective Actions

Corrective actions address findings identified during an audit or assessment or as a result of informal management reviews. Written responses to the formal assessment finding should be prepared and the effective dates of all corrective actions noted. Formal corrective actions are documented and tracked through completion by QA/QC staff. Follow-up review of all corrective actions should be conducted to confirm that the prescribed action was adequate to address any deficiencies noted in the audit report. Some corrective actions are initiated and completed immediately by the PM or supervisory staff. Significant problems with work products trigger re-evaluation of any associated quality system tools. In such instances, the Department does not intend that program areas await scheduled assessments and corrective actions, but instead recommends the immediate correction of problems discovered during real-time surveillance. Corrective actions written and presented to FCEAP by EPA Region 4 QA Managers (such as the Technical Systems Audit) are always a priority for senior Management. Either the Department implements the EPA-recommended corrective actions through direct involvement at the Department-wide level, or program managers implement the EPA -recommended quality system corrections with senior staff input and recommendations.

10.6.2 Dispute Resolution

Any disagreement by program managers or staff with respect to a corrective action recommended by the QA Project Manager or EPA Region 4 that cannot be resolved through the chain of command are mediated by the Director. The Director takes the lead in resolving any resource or policy issues that inhibit pursuit of corrective action measures by any Department program area. Similarly, the Director could modify the assessment recommendation.

11 Quality Improvement

11.1 General

Quality system deficiencies shall be prevented wherever possible. Identified deficiencies shall be documented and corrected in a timely manner as resources allow. Corrective actions should be verified to ensure timely and effective implementation. Efforts are made to continuously improve the Department's quality system. Systems, documents, and tools described in preceding sections summarize the approach taken by FCEAP to plan, organize, implement, monitor, and assess quality systems for environmental programs. All personnel working on environmental programs are encouraged to identify, plan, implement, and evaluate quality improvement activities for their areas of responsibility. Examples of communication may include: coordination meetings, conference calls, electronic (email, fax), letters and memos, etc. Personnel should prevent quality problems wherever possible and report opportunities for improvement as well as quality problems as they are identified.

11.2 Quality System Implementation

The Director of FCEAP has the overall responsibility for the development, implementation, and continued operation of the FCEAP Quality Management System. Each Program Manager (PM) has responsibility for the development, implementation, and continued operation of the QMS within their program area. The FCEAP Quality Assurance Project Manager has the responsibility for evaluating the Department's air monitoring data for completeness and accuracy. In addition, FCEAP PMs have the responsibility for continual monitoring of the effectiveness of their individual program's quality system.

11.3 Process(es) for Continuous Improvement

Internal reviews per schedule in Section 10.3 provide a cycle of continuous improvement. Ongoing interaction with EPA Region 4 managers, along with annual EPA reporting requirements and periodic program reviews and audits performed at FCEAP by EPA also enable the Department to continue steady, long term improvement of its quality system. Additionally, quality system issues detected during the real-time surveillance further ensures steady improvement of the Department's quality system development, implementation, assessment, and improvement cycle.

11.4 Process(es) for Preventing or Improving Conditions Adverse to Quality

11.4.1 Preventing Conditions Adverse to Quality

The Department's use of standard procedures/guidelines serve to ensure quality work products and also help guarantee the effectiveness of existing and new quality system tools. Various internal and external quality training activities are used by the Department in preventing conditions adverse to quality.

11.4.2 Identification of Conditions Adverse to Quality

The chain of command for review and approval serves to detect problems with the quality system. Any perceived decline in the quality of work products triggers a review of quality system tools and methodologies. For example, if a work product does not meet established standards it could be an indicator that management and staff should revisit and perhaps revise one or more of the written SOPs. The tools to ensure quality work products - the QMP, QAPPs, and SOPs- are systematically put into place at FCEAP as a result of the Department's commitment to expanding the quality system. These tools lead to standardization and help put widely accepted business practices into common use. Various assessments conducted by QA staff also keep quality system development on track and help to identify problems or gaps in the Department's quality system.

11.4.3 Correction of Conditions Adverse to Quality

The Department intends that any quality system problems flagged for review and approval by staff, the QA Project Manager, or by EPA Region 4 audits will be addressed in a timely manner. Corrective actions should be implemented by the affected program and tracked by the appropriate quality staff to ensure the effectiveness of quality system tools (i.e., SOPs and QAPPs) is addressed within a reasonable time after problems are detected and reported.

11.4.3.1 Deficiencies and Non-conformances (Informal Corrective Actions)

Significant deficiencies and non-conformances to QAPPs, SOPs, or Department requirements observed outside of a formal audit or assessment process are reported by Department staff to supervisors. Each PM has the authority to suspend or stop work upon detection and identification of an immediate adverse condition affecting quality or health and safety. The deficiency or non-conformance should be documented by the PM who should inform the Director. A formal Corrective Action Plan (CAP) may be required, and if so, tracked until closure. Any documentation should be included in the project or program file(s) to ensure that future individuals involved with the project or activity are able to trace the evolution of procedural or policy change (including what was done, by whom, and why).

11.4.3.2 Formal Corrective Actions

When significant deficiencies and non-conformances to QAPPs, SOPs, or Department requirements are observed during a formal audit or assessment process a corrective action system should be employed. Corrective actions may be immediate or long term. Immediate corrective actions form part of normal

operating procedures such as to correct data or repair nonconforming equipment. Long-term corrective actions may be required to eliminate the cause(s) of nonconformance through training, or development of, or revision to, an SOP. In either case, the occurrence of the problem, the corrective action employed, and the verification that the problem has been eliminated should be documented. In the event quality problems are identified, the quality staff, in consultation with the PM, determine whether attainment of acceptable quality requires either immediate or long-term actions, or both.

The Steps comprising a closed-loop corrective action system typically include:

- Define the problem and any programmatic impact;
- Assign the responsibility for investigating the problem;
- Document the means by which corrective action completion is documented and verified;
- Investigate and determine the cause(s) of the problem;
- Determine a corrective action to eliminate the problem including action(s) needed to prevent recurrence;
- Estimate a timetable;
- Assign and accept responsibility for implementing corrective action;
- Establish effectiveness of the corrective action and implement the correction; and,
- Verify that the corrective action has eliminated the problem.

12. Competency of Data Generated Under EPA Assistance Agreements

This section addresses the US Environmental Protection Agency's Policy to Assure the Competency of Organizations Generating Environmental Measurement Data Under Agency-Funded Assistance Agreements (FEM-2012-02). The policy requires organizations performing activities involving the use or generation of environmental data under covered assistance agreements shall provide the Agency with:

- Quality documentation such as a quality management plan (QMP), and/or other documentation that demonstrates conformance to U.S. EPA quality program requirements; and

- Demonstration of competency in the field(s) of expertise.

The EPA policy directive (FEM-2012-02) states that demonstration of competency may include (but not be limited to):

- Current participation in accreditation or certification programs that are applicable to the environmental data generated under the Agency-funded assistance;
- Ongoing participation by the organization in proficiency testing (PT) or round robin programs conducted by external organizations;
- Ongoing U.S. EPA accepted demonstrations and audits/assessments of proficiency; and
- Other pertinent documentation that demonstrates competency (e.g., past performance to similar statement of work [SOW]).

Competency is achieved through implementing the quality system components for those FCEAP programs that generate data under EPA assistance agreements. Quality system components include Quality Assurance Program Plans (QAPPs) and Standard Operating Procedures (SOPs) or other quality system components that are described for each Division in the appendix.

13. References

EPA. 2000, as amended/re-issued. *Guidance on technical Audits and Related Assessments for Data Operations (QA/G-7)*, EPA/600/R-99/080, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

EPA. 2001, as amended/re-issued. *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*, EPA/240/B-1/003, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

EPA. 2001, as amended/re-issued. *EPA Requirements for Quality Management Plan (QAIR-2)*, EPA/240/B-01/002, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

EPA 2002, as amended/re-issued. *Guidance for Quality Assurance Project Plans (QA/G-5)*, EPA/240/R-02/009, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

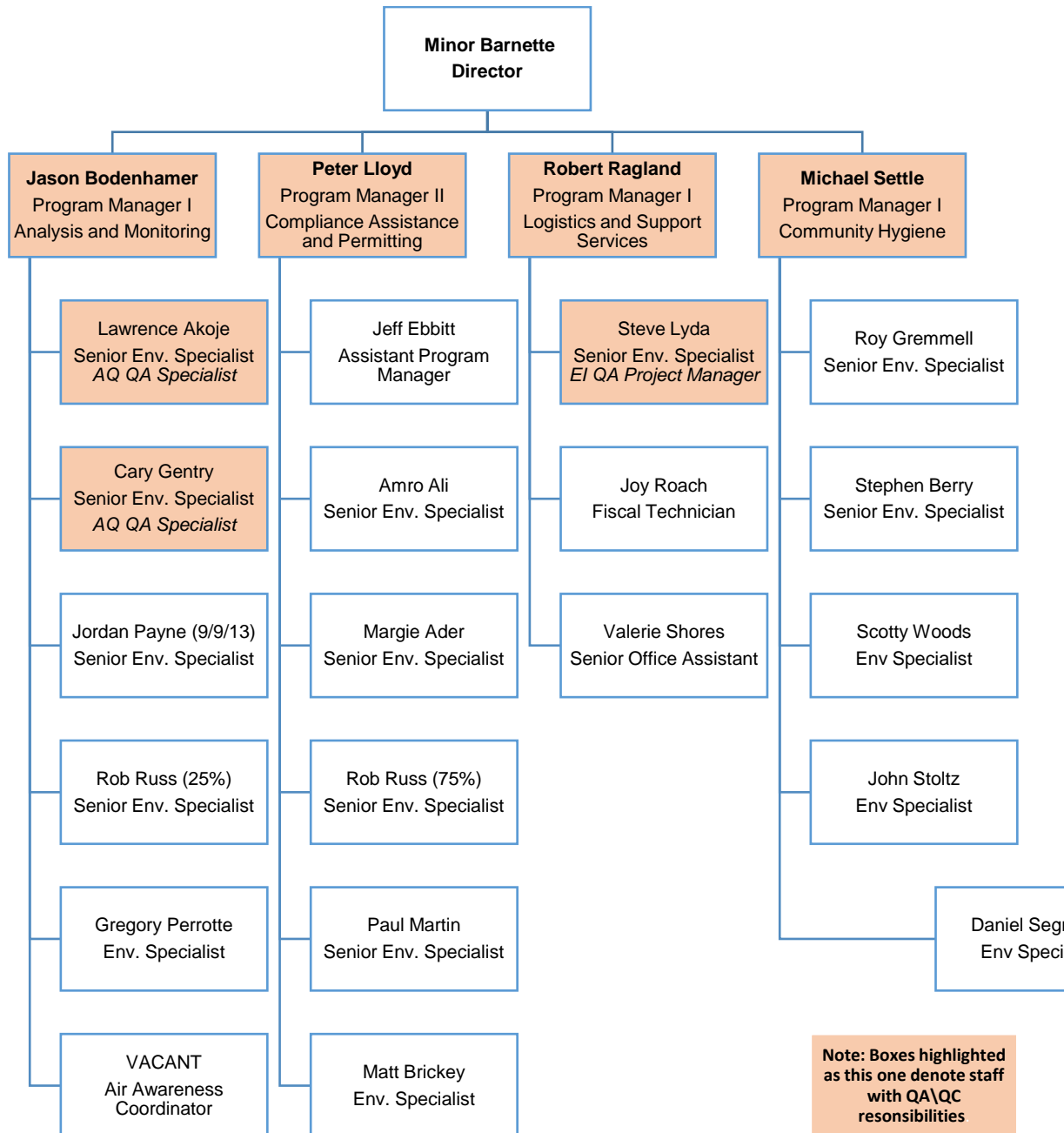
EPA 2003, as amended/re-issued. *Guidance on Assessing Quality Systems (QA/G-3)*, EPA/240/R-03/002, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

EPA 2006, as amended/re-issued. *Data Quality Assessments: A Reviewers Guide (QA/G-9R)*, EPA/240/B-06/002, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

EPA 2006, as amended/re-issued. *Guidance on Systematic Planning using the Data Quality Objectives Process (QA/G-4)*, EPA/240/B-06/001, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

EPA 2007, as amended/re-issued. *Guidance for Preparing Standard Operating Procedures (SOPs) (QAIG-6)*, EPA600/B-07/001, Office of Environmental Information, United States Environmental Protection Agency (EPA), Washington, DC.

Appendix A - Forsyth County FCEAP- Organizational Chart



Appendix B - QMP Review Checklist

QUALITY MANAGEMENT PLAN

REVIEW CHECKLIST

ORGANIZATION: Forsyth County Office of Environmental Assistance and Protection (FCEAP)

This checklist will be used to review the Quality Management Plans (QMPs) that are submitted to the Quality Staff of the Office of Environmental Information (OEI) for Agency review under CIO 2105.0^a. Items from this checklist are discussed in detail in Chapter 3 of CIO 2105-P-01-0^b 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 provided to the Quality Staff with the QMP.

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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)?*			
2) Signed and dated by senior line management (for subordinate 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			
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Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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 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?			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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?			
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?			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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?			
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 ^c ?			
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 (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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 QMPs?			
28) Describes process to ensure EPA extramural agreement policies, including quality, are satisfied?			
29) Describes roles, responsibilities, and			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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 procedures for evidentiary records?			
35) Records on environmental data and information comply with applicable EPA policies (e.g., location 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]^d			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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?			
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			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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 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,			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
and revising QA Project Plans?			
44) Describes process for evaluating and qualifying information acquired from other sources (e.g., States, other Federal Agencies)?			

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 prescribed?			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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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 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			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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?			
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,			

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
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?			
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? ^e			
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^f			
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			
Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by Quality Staff)
protocols for clearance review, requirements for clear disclaimer language; identify roles and responsibilities of management and staff?			

^a Formerly EPA Order 5360.1 A2 ^b Formerly EPA Order 5360.1 A2 ^c Quality Assurance Review Form (QA Review Form) is required for EPA Organizations. ^d 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. ^e Quality Assurance Annual Report and Work Plans are for EPA Organizations. ^f Information Quality Guidelines apply to EPA Organizations and are optional element.