

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION III 1650 Arch Street

Philadelphia, Pennsylvania 19103-2029

DATE: August 31, 2021

SUBJECT: West Virginia Department of Environmental Protection – Quality Management

Plan

FROM: Kia Long, Region 3 Quality Assurance Manager

Applied Science & Quality Assurance Branch (3LS10)

TO: Christina L. Richmond

West Virginia Department of Environmental Protection – Business Operations

Thank you for submitting the revised *West Virginia Department of Environmental Protection*- *Quality Management Plan* (EPA QA # 210162) for approval. The QMP satisfies the minimum criteria contained in EPA QA/R-2, Requirements for Quality Management Plans, 3/2001 and is hereby approved for five years (valid until August 31, 2026).

In accordance to EPA's QA policy, this QMP shall be reviewed annually by WVDEP to reconfirm the suitability and effectiveness of the approved quality management practices. WVDEP shall submit a revised QMP to EPA for approval for any material changes made to the quality system.

The QMP has been digitally signed by the EPA Region 3 Quality Assurance Manager. Should you have any questions, please feel free to contact me at (215) 814-2111 or long.kia@epa.gov

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QUALITY MANAGEMENT PLAN

FOR THE

WEST VIRGINIA DEPARTMENT OF ENVIRONMENTAL PROTECTION

2021

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	CHAPTER 2: DEP ORGANIZATION/MANAGEMENT AND QMP IMPLEMENTATION CHAPTER 3: DEP'S QUALITY MANAGEMENT SYSTEM

List of Key Acronyms

BMP Best Management Practice

CBP Chesapeake Bay Program

CEDS Comprehensive Environmental Data System

DQA Data Quality Assessment

DQI Data Quality Indicators, such as PARCCS

DQO Data Quality Objective

NPS Nonpoint Source

PARCCS Precision, Accuracy, Representativeness, Completeness, Comparability, and Sensitivity

QA Quality Assurance

QAM Quality Assurance Manager

QAPP Quality Assurance Project Plan

QAPrP Quality Assurance Program Plan

QC Quality Control

QMP Quality Management Plan

QMS Quality Management System

SAP Sampling and Analysis Plan, or equivalent document (e.g., Site Assessment Work Plan)

SOP Standard Operating Procedure

TSA Technical System Audit

EPA United States Environmental Protection Agency

DEP Department of Environmental Protection

DWWM – Division of Water and Waste Management

DLR – Division of Land Restoration

DAQ-Division of Air Quality

DMR- Division of Mining and Reclamation

CHAPTER 1: POLICY, SCOPE AND OBJECTIVES OF DEP'S QUALITY MANAGEMENT PLAN

DEP QUALITY ASSURANCE POLICY

Background and Purpose

The Quality Management Plan (QMP) describes the processes the Department of Environmental Protection (DEP) uses to maintain a Quality Management System (QMS) consistent with the Environmental Protection Agency (EPA) requirements. The Quality Management System supporting DEP programs involving environmental data or technology shall be covered by this QMP. The QMP is an "umbrella" document which describes policies and, procedures, and management systems within the organization that govern quality control activities of environmental information collection and use with the DEP. Implementation of this plan within the DEP programs ensures that decisions made by the agency are based upon sound professional principles and environmental data of known and acceptable quality. The QMP is intended to provide overarching structure and guidance to DEP's EPA funded programs.

Environmental data are defined as information or measurements resulting from field data collection activities, laboratory analyses, or models involving the assessment of chemical, physical, or biological factors relating to the environment. Programs and activities that generate such data and are funded by the EPA are required to comply with the requirements of this QMP.

Policy Statement

The DEP is committed to implementing a Quality Management System that will ensure that data and decisions made are technically correct and defensible. This document links the management policies, objectives, and principles of the program with the procedures described in associated Quality Assurance Program Plans (QAPP), Quality Assurance Project Plans (QAPPs) and Standard Operating Procedures (SOPs), which are designed to produce data of known quality.

The DEP is committed to continuously evaluating and improving Quality Management Systems described in this QMP. The QMP establishes the foundation for implementing an effective Quality System and applies to all DEP program activities, grants, contracts, and interagency agreements that collect, evaluate, or use environmental data and information governed by EPA.

General Goals and Objectives of the Quality Management System

The DEP's Quality Management System is designed to reduce the possibility that environmental data collected do not meet the quality requirements established by law;

or are suspect or unusable. The primary goal is to ensure that all environmentally related data collection and processing activities result in data that have documented quality at an acceptable level for the intended use. The data should support specific decisions or actions with a high degree of certainty to help ensure that the final product is correct. This includes actions or decisions made by monitoring or measurement activities supported through EPA grants, other state and federal grants, or interagency agreements. This goal is achieved by ensuring that adequate resources are made available and proper procedures are followed throughout the process of planning, collection, analyzing and interpreting environmental data.

Specifically, the following items are considered priorities:

- Ensure that all environmental data generated by or for the agency are scientifically valid, defensible, and of documented and adequate quality
- Maintain communication on QA issues and activities among management and staff
- Accomplish the QA process in the most cost-effective manner without compromising data quality
- Encourage the use of QA/QC in the management of environmental projects
- Assure the quality objectives for generating new environmental data will be determined prior to collection activities. This predetermination ensures that appropriate resources and QA/QC methods can be applied to generate a level of data quality that meets the intended use.
- Programs that create or support externally generated environmental data through contracts, subgrants, or interagency agreements will ensure that data collection complies with DEP policy. Contracts, subgrants, or agreements must require the external parties to develop and follow acceptable Quality Management practices.
- There will be an ongoing system of evaluation for QA efforts to ensure that the Quality Management System is meeting the needs and expectations of data users as well as QA requirements.
- Programs or activities that accept externally generated environmental data used in decision making are to ensure that the supplying entity has followed acceptable Quality Management practices.

Resources for the Quality Assurance System

Quality Assurance (QA) is viewed as an integral part of any program and activity within the agency that deals with environmental measurements, monitoring and data generation. The level of QA resources needed for any given program or project is determined by the relevant Division Director, Program or Project Manager.

The Agency Quality Assurance Manager (QAM) is responsible for ensuring quality data is produced in the WVDEP. The QAM position resides within the Business Office and is

independent from the other offices and divisions in the DEP. The Quality Assurance Manager is provided with resources to help develop and implement associated program activities and work with Programs, where necessary. The DEP QAM operates independently from programs that generate data and works directly with Managers to ensure that QA responsibilities are conducted without conflict of interest and any necessary corrective actions are completed.

CHAPTER 2: DEP ORGANIZATION/MANAGEMENT AND QMP IMPLEMENTATION

ORGANIZATIONAL STRUCTURE

The DEP is the primary state agency in West Virginia with regulatory authority and responsibility for air and water pollution control programs, regulation of mining and reclamation as well as oil and gas extraction, solid and hazardous waste management programs, and environmental remediation. Currently the agency employs a decentralized approach to QA management, whereby each division or office is responsible for deciding how it will specifically implement the general policies and procedures of the QMP.

While the day-to-day oversight of QA management falls to the individual divisions and offices, the Agency has an appointed Quality Assurance Manager to assist with a centralized oversight of Agency Quality Systems.

The DEP secretary has delegated the day-to-day responsibility of overseeing the QMP to the Agency Quality Assurance Manager (QAM). The Agency Quality Assurance Manager works to address quality issues through regular interaction with programs as well as through workgroups formed when needed to address specific issues and provide recommendations for solutions. Each Division and major office shall ensure adequate resources are available to successfully implement QA requirements for their environmental programs and data.

ROLES AND RESPONSIBILITIES

All employees within the DEP are covered by the QMP when directly or indirectly involved with environmental data collection or with ensuring data quality.

Through the formation of the enterprise model, employees at all levels of the agency are providing input and reviewing quality concerns within the agency. These groups also work together to make recommendations to ensure that quality issues are recorded and addressed, as priorities or when immediate needs arise.

DEP Cabinet Secretary:

The Cabinet Secretary has overall responsibility for the DEP QA Program as outlined in EPA Order 5360.1 A2. More specifically, the Cabinet Secretary is responsible for ensuring that QA is an identifiable activity that has adequate resources allocated to accomplish the agency's mission and goals. These goals include providing the resources for the collection of the correct type, quantity, and quality of data for all in-house and external projects.

Division Directors:

The Division Directors have the overall responsibility for managing the QA program within their assigned oversight in accordance with the QMP and EPA approved program QAPrPs, where applicable. Each Director has the authority to ensure that adequate resources are provided to support necessary QA Program responsibilities.

Program Managers:

The Program Managers coordinate staff to ensure implementation of the Quality Management System where environmental measurements are to occur. The Program Managers

- Ensure Program-specific QA-related training needs are identified.
- Confirm that all individuals working with environmental data and information have the appropriate QA training commensurate with those responsibilities.
- Ensure environmental data collection activities are covered by appropriate planning and documentation including Data Quality Objectives (DQO), QAPPs, QAPrPs, SOPs, etc.
- Ensure QAPPs are written, signed, and effectively implemented for projects that
 generate environmental data. (QAPPs may be developed by contractors or other
 responsible parties outside the agency. QAPP components may be incorporated into
 a Sampling and Analysis Plan (SAP) or equivalent work plan document. Final
 approval, must come from authorized personnel. Authorized personnel can include
 EPA or DEP, whichever authority is required for program oversight.
- Ensure effective implementation for projects that generate environmental data by overseeing approval of DEP site-specific QAPPs, written by program personnel, contractors, or other responsible parties by appropriate program personnel.
- Ensure an adequate degree of data auditing is performed to determine and achieve compliance with QA requirements.
- Cooperate with QA assessments and audits, and implement appropriate corrective actions recommended, if there are program findings.
- Address deficiencies identified in audits and ensure any quality issues are corrected expeditiously.
- Work with their program to ensure that QA requirements, data quality issues, and disputes are addressed, and request the appropriate resources needed from management.

Agency QA Manager:

• Ensures the QMP is developed, updated, and effectively implemented;

- Encourages a culture of quality within the DEP.
- Leads and facilitates communication between and among staff across the Agency and disseminates QA guidance documents, policies and procedures as needed.
- Ensures members from program offices who are designated to assist with QA implementation are reporting information back to all employees of the program.
- Helps develop training related to QA and works with HR to maintain training records for staff.
- Coordinates review of DEP's QA procedures and documentation in the QMP at least annually or per the prescribed schedule

Project Managers and Program Staff

- Ensure environmental data collection activities are covered by appropriate planning and documentation including Data Quality Objectives (DQO), QAPPs, QAPrPs, SAPs, SOPs, etc.
- Ensure QAPPs and QAPrPs are written, signed, and effectively implemented for all projects that generate environmental data. (QAPPs and QAPrPs may be developed by contractors or others outside the agency. QAPP components may be incorporated into a SAP. Final approval, however, must come from authorized personnel in the DEP or EPA.)
- Ensure an adequate degree of data auditing is performed to determine and achieve compliance with QA requirements.
- Address deficiencies highlighted in audits and ensure any quality issues are corrected expeditiously.
- Ensure project-specific QA-related training needs are identified and provided.

Program QA leads (where appointed):

- Assist in maintaining and updating the QMP.
- Distribute QA documents, policies, and procedures to all employees who need the information.
- Routinely review the QA procedures and keep Division Directors and senior managers apprised of issues.
- Conduct reviews and assessments of QA and QC activities and prepare recommendations as needed.
- Assess training needs and report such needs to the Division Directors and senior managers.
- Assist in the provision and implementation of QA training to staff within their respective program.
- Actively participate in QMS and other quality activities within the agency and regularly disseminate information to other employees in their respective offices/divisions.

DISPUTE RESOLUTION

In order to resolve disputes related to QA activities, the DEP will first utilize informal procedures by elevation through the management chain. The QAM, Division Directors and appropriate Senior Management will be notified of any Quality System related disputes that cannot be resolved at the program level and the QAM will document the resolution. If a resolution cannot be obtained at the program level, the dispute will be taken to the Division Director and Executive Staff for resolution. At all levels of dispute resolution, the Division Directors and the program staff will be kept advised of the progress of the dispute resolution. If a dispute cannot be resolved at the Executive level DEP can contract with outside mediators to provide assistance and help the Agency overcome the dispute and reach an agreement.

COMMUNCATIONS

Formal lines of communication regarding the QA program status and needs are essential to ensure that an effective QA program is implemented within the DEP. Lines of communication among the Quality Assurance Manager, directors and others will keep all persons informed of new developments, policies, and other QA procedures. The Agency Quality Assurance Manager or designee will have direct access to the DEP Executive Staff on QA matters. The DEP will also provide appropriate training on an on-going basis in order to ensure that the DEP personnel responsible for QA functions understand the QA requirements and practices related to their responsibilities.

The QMP will be accessible to all employees through the Agency Intranet and through the Electronic Document Management System. SOPs are numbered and stored in the document management system or maintained in a consolidated location on the shared network drive.

Quality Assurance Training

Core QA training, as needed, will be offered on an ongoing basis to ensure that persons responsible for QA functions will understand requirements and practices related to their responsibilities. The Quality Assurance Manager, Program Managers and Division Directors will be responsible for ensuring that adequate training is provided and that staff members who need to receive the training will be given the time to do so. Staff involved in activities covered by this QMP will receive training to ensure that all aspects of the QMP are followed. The agency can request and rely upon training by qualified personnel including EPA personnel.

IMPLEMENTATION

The procedures outlined in the QMP will be implemented by each division within a reasonable period of time upon approval of the document by the EPA. Staff are encouraged by supervisors to draw upon their educational background, experience, technical training, and on-the-job training to enhance their understanding and performance of QA-related procedures. Data collection activities will be associated with specific QAPPs developed and implemented in accordance with the EPA-approved QMP.

Organizational Quality Components at the WV DEP

Divisions and Offices that perform QA-related activities through their management of environmental data and information shall develop and maintain QA documentation (e.g., SOPs,QAPPs, QAPrPs, program guidance).

The organization's QA requirements may be more, but not less, stringent than those presented in this QMP. However, no additional requirements, procedures or practices not otherwise required by specific federal rules and guidelines are created in this document. DEP's QA documentation shall be approved by appropriate authorities and documented as detailed in Appendix 1.

PRINCIPAL COMPONENTS OF THE SYSTEM

The DEP's Quality Management System consists of staff, defined functions, tools, and QA procedures. These components are used to ensure that environmental data generated by the DEP are of an appropriate quality for their intended purpose.

PRINCIPAL TOOLS AND PRACTICES

Successful implementation of a Quality Management System requires a consistent approach for QA practices, commensurate with the intended uses of the data and degree of confidence needed in the results. A variety of tools and procedures are employed for planning, implementing, and evaluating the Quality Management System. Managers and staff members are informed of the availability and use of these tools through training and interaction of all persons involved with the Quality Management System.

Primary QA planning and implementation tools include QMPs, establishment of DQOs, QAPPs, QAPrPs and SOPs. Agency QMPs, QAPrPs and QAPPs are valid for up to 5 years.

Primary QA evaluation and assessment tools include Management System Review (MSRs), Technical Systems Audit (TSAs), Performance Audits, and DQAs. Most of these activities are arranged and performed by the QA members or other designated personnel.

Quality Management Plan

This QMP describes the policies, procedures, and systems governing DEP data collection activities.

Future revisions and updates of this QMP will be drafted by the QMP Workgroup with assistance from other staff and will be reviewed by the Division Directors, assistant directors and the Cabinet Secretary of the DEP. After all appropriate levels of DEP management have approved the revisions; the revised portions of the QMP will be submitted to EPA Region III's regional QA officer for comments and approval. The QMP Workgroup is responsible for responding to EPA's comments. The response to comments and the revised QMP will then be reviewed by appropriate levels of DEP management and resubmitted to EPA for approval.

QMP Updates

In accordance with the requirements set forth in EPA document QA/R2-EPA Requirements for Quality Management Plans, EPA approval of the QMP is valid for 5 years. The QMP shall be reviewed at least annually to reconfirm the suitability and

effectiveness of the approved quality management practices. More frequent revisions may be necessary if substantive modifications occur. The last approved version of a QMP shall remain in effect (i.e., shall not expire) until a revised version has been approved by the DEP and EPA, as appropriate. However, if significant changes have been made to the Quality Management System that affect the performance of work for the agency, the QMP shall be submitted to EPA for re-approval.

Data Quality Objectives (DQO)

Data Quality Objectives (DQOs) are statements of the quality of environmental data required to support program decisions or actions. DQOs establish the level of risk or uncertainty that a program is willing to accept in the environmental data in order to make a defensible decision. The DQOs are updated as needed to reflect changes in environmental policies as defined by management. DQOs are intended to accomplish the following: 1) clarify the project objectives, 2) define the most appropriate types of data to collect, 3) determine the most appropriate conditions under which to collect the data, and 4) specify the level of uncertainty that is acceptable as the basis for establishing the quantity and quality of data needed. DQOs may establish the minimum data validation requirements and Data Quality Indicators (DQIs), such as Precision, Accuracy, Representativeness, Completeness, Comparability, and Sensitivity (aka PARCCS).

Quality Assurance Project Plan (QAPP)

If a program is required by EPA, QAPPs may be developed as specified in EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, or other applicable EPA QAPP quidance documents.

The QAPP shall ensure that:

- a) The level of data quality needed is determined and stated prior to data collection;
- b) All environmental data generated and processed will reflect the quality and integrity established by the QAPP.

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

Grant recipients, IA participants, and contractors conducting projects that involve environmental data operations should submit a QMP documenting their Quality System, as appropriate, and/or a QAPP for each project. The terms and conditions may require submittal of the QMP and QAPP within a specified timeframe. Environmental data operations funded by EPA programs may not commence until the QMP, QAPP and other

equivalent QA documents have been approved by EPA Region 3. A copy of approved documents shall be stored in the Agency Document Management System.

QAPP Preparation

Program Managers should ensure QAPPs are developed and approved for data-related projects under their purview for projects within or funded by their programs. QAPPs shall be prepared in accordance with a "graded approach" as defined in Section 2.4.2 of *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5.* The level of detail found in the QAPP should be commensurate with the nature of the work being performed and intended use of the data.

Quality Assurance Program Plan (QAPrP)

Work under a regulatory program funded by EPA that involves the acquisition of environmental data generated through direct measurements, collected from or submitted by other sources, or compiled from computerized data bases and information systems should be implemented in accordance with an approved programmatic QAPrP. The QAPrP establishes policies that define and document the methods and procedures for collecting, analyzing, and assessing data to support program decisions. Data generated as part of a standalone project that is funded by EPA should be gathered using an approved project QAPP or Sampling and Analysis Plan (SAP). EPA's Quality System requires extramural organizations, conducting environmental data operations and receiving financial assistance from EPA to submit a QMP, QAPrPs, QAPPs, FSPs or other appropriate QA documentation for EPA R3's approval. A QAPrP should describe the guidance, requirements, and approval procedures that have been established for internally generated project QAPPs.

A QAPrP should be developed, wherever possible and appropriate, based on a graded approach. No work covered by this requirement shall be implemented without a QAPrP being approved prior to the start of the work except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

Each QAPrP is to be reviewed and approved by authorized WVDEP employees to ensure that it contains the appropriate content and level of detail. Authorized reviewers are the Program Managers and Quality Assurance Managers, who review the document from a program perspective. Each QAPrP must be reviewed and approved by the USEPA before it can be implemented. Project Managers will ensure that individual project QAPPs are reviewed and approved prior to sampling or data collection, and signed by the appropriate personnel.

A QAPrP and/or SOP will be developed for activities that are conducted continuously or routinely throughout the project; therefore, a site-specific QAPP will be prepared only for sampling events not classified as continuous or routine. QAPrPs will be revised as needed in response to audits conducted by the DEP or as a result of input from management or staff responsible for implementing the QAPrP. QAPrPs will be reviewed annually by the Program Managers and/or Quality Assurance Managers and updated as necessary or on a timeline specified within the QAPrP itself.

QAPrPs will use a document control format that provides a version number and effective date. These documents will be stored in a central location using the Agency Electronic Document Management System.

Updated QAPrP guidance will be implemented as it becomes available.

QA Reports

Where necessary, a QAPrP, QAPP or SAP will include information on the frequency, content, and format of any required QA reports. Any QA reports required by a QAPrP, QAPP or SAP will be placed in the project file and will be used to help track project progress. Each report should address, at a minimum, the following elements:

- Changes that occurred in program activities (sampling, QC control measures, analytical methods).
- A summary of performance and system audits, as they apply.
- Any corrective actions taken.
- Any organizational changes.
- Reports of the assessment of DQIs (PARCCS)

For some programs, rules or policies supersede these QA reports. The policies or rules establish requirements similar to status reports and can function as an alternative. The alternative should be referenced in the plan, and may, if necessary, discuss elements in addition to those listed above.

Standard Operating Procedures (SOPs)

The use of Standard Operating Procedures (SOPs) serves as a mechanism to ensure comparability across individual environmental data collection projects. SOPs are incorporated in full or by reference in the QMP and relevant QAPrP or QAPP. SOPs will be maintained and developed by the unit or section managers as needed. SOPs detail the work processes conducted or followed within the program. The SOPs document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. SOPs are intended to be specific to the program whose activities are described and assist the program to maintain its QA/QC processes.

SOPs developed by DEP are peer reviewed and approved by the Division Directors or their designees, and may also be approved by EPA. SOPs and templates are available for reference and are centrally stored in the DEP Electronic Document Management System or maintained in a consolidated location on the shared network.

Technical Systems Audits (TSAs)

A TSA assesses the sampling and analytical quality control procedures used to generate environmental data. Programs will use TSAs to evaluate the procedures used by field monitoring staff and laboratory contractors. TSAs may entail a comprehensive on-site evaluation of field equipment and laboratory instrument calibration; record keeping procedures; and data validation, data management, and reporting, or may be a focused evaluation depending upon the needs of the project.

Corrective Actions

In the normal case, if deficiencies are identified during a review or audit, corrective actions will be developed. However, there can be cases when deficiencies are identified during regular work routines that are not part of a review or audit. In these situations, a corrective action memo or appropriate documentation is generated to document and communicate the deficiency. The documentation, at a minimum, should explain the problem and document procedural changes and actions to correct the problem and minimize the chance for repeat problems and deficiencies. In some situations, no corrective action is required; however, it is necessary to document the occurrence. For these situations, the corrective actions can be referred to as non-conformances.

CHAPTER 4: PERSONNEL QUALIFICATIONS AND TRAINING

POLICY FOR QUALITY ASSURANCE-RELATED TRAINING

All DEP employees who generate data covered by the QMP must have adequate knowledge and skills in their technical specialties and applicable QA practices to ensure quality data are generated. DEP utilizes class and compensation specifications for employees to confirm they meet minimum experience and educational requirements for job postings and candidate selection.

A written position description and register for each job is utilized to hire competent employees. The position descriptions include the knowledge, skills, abilities, and duties required of the position. A performance appraisal is prepared annually for each employee, and their performance is evaluated via one interim and one final evaluation. Training is conducted at the division and group level. Individual performance appraisals can be used to specify appropriate general or specific responsibilities for ensuring QA. Managers and supervisors can be evaluated for their implementation of quality responsibilities if their program requires. It is the responsibility of the supervising manager to ensure QA orientation for new employees.

Responsibilities

Program Managers are responsible for ensuring that each staff member involved with collecting environmental data has the necessary technical, QA, and project management training and certifications or documentation required for his/her assigned tasks and functions. Managers are also responsible for ensuring that technical staff maintains the necessary level of proficiency to effectively meet QA responsibilities. QA training and additional development needs will be identified as part of regular performance discussions.

Maintaining staff proficiency is the joint responsibility of the individuals filling those positions and the managers. Program and/or Project Managers are to have a working knowledge, through appropriate training, of the DEP planning process and the EPA QAPrP/QAPP requirements.

Program Managers should know and understand the components of the EPA Quality Management System and the EPA QMP, QAPrP and QAPP requirements for their area(s) of responsibility. Training, if needed, will be based on resources available from the EPA. Program Managers are responsible for identifying any training needs related directly to implementing the QMP.

Identification of Training Needs

QA-related training needs are assessed by first determining which personnel have QA-related responsibilities, what specific types of QA functions they perform, and with what frequency. These assessments are conveyed by Program Managers to the Division Directors and appropriate training is provided for the personnel.

The QAM, in conjunction with program managers, will identify continuing professional training requirements and address those requirements utilizing external resources for the latest technological advances and evolutions in industry standards. This will ensure that program staff that can benefit from training will have an opportunity to participate and learn from other DEP offices.

New employees involved in an environmental data generation or collection activity will be provided training in QA-related topics to supplement other training determined necessary by each division. Training milestones include training in QA-related topics.

Implementation of Training Requirements

Staff members are encouraged to draw upon their educational background, experience, professional background, and on-the-job training to enhance their understanding and performance of QA-related activities. Appropriate documentation and guidance manuals will be distributed to new employees and adequate time and supervision will be provided or made available to the employees to ensure their complete understanding of the QA material and requirements.

The QAM and the Division Directors will discuss the training needs of QA personnel and provide training, as appropriate, to ensure that environmental data collection requirements are met. QA training can be offered by internal groups within the agency or by third-party vendors to address QA training needs.

Assurance for Grants and Contracts

Program Managers or their designated personnel are responsible for ensuring that grant recipients or contract personnel involved with environmental data generation have the necessary QA training to successfully complete their grant or contract tasks and functions. Minimum QA training should be described in Requests for Proposals (RFPs) and Requests for Bids (RFBs) and in grant applications and/or conditions.

Documentation of Training

Personnel training files can be used to keep a record of QA training taken by staff and managers responsible for environmental data generation.

CHAPTER 5: PROCUREMENT OF ITEMS AND SERVICES

The DEP procures items such as sampling equipment, instrumentation, field equipment, laboratory services, and consulting services. Items and services for environmental data collection and generation may be obtained through the procurement process. The DEP procurement process is guided by the West Virginia Procurement WV Code 148/Rules administrated by the West Virginia Purchasing Division.

When appropriate, it is DEP's policy that procurement involving data collection or generation requires suppliers and/or contractors to have a Quality Management System in accordance with EPA requirements (EPA QA/R-2). Laboratory contracts and other procurement items are covered by this policy. In general, a QMP will be reviewed and approved by the DEP *before* the formal execution of any agreement or related action.

DEP Procurement ensures that purchases and contracts for commodities and services are based on competitive bid whenever possible. Procurement documents will contain technical specifications and evaluation criteria for all deliverables.

Where QA requirements apply, the Project Manager submitting the purchase/bid paperwork will assure that QA terms and conditions are included in contract statements of work. The QA terms and conditions require contractors to document its Quality System in a QMP and submit QAPPs or appropriate planning documents that meet program-specific project goals and objectives.

The PM will assure that the contractor complies with the conditions and deliverables. The QMP shall be reviewed by the DPM as a condition for award of any contract involving environmental data operations. The QMP shall be submitted as part of the contract proposal.

If the QAPP (or QAPrP) is not submitted as part of the contract proposal and DEP decides to award the contract, DEP will include terms and conditions requiring the contractor to submit the QMP, QAPP, or QAPrP within a specified timeframe after award of the contract. The contractor may not begin work involving environmental data operations until the Program Manger has granted approval.

Prior to undertaking any work involving environmental data collection or use, the contractor shall also be required to submit QAPPs, QAPrPs, and/or SOPs to DEP for review and approval by the Project Manager

CONTRACTS

DEP divisions may require the services of commercial analytical laboratories. The primary procurement item covered by this QMP is the award and utilization of these laboratory contracts.

The procurement and contracting procedures involve an evaluation of the QMP of the prospective contract laboratories. Laboratories without state certification or without Quality Management Systems and QAPPs that meet the minimum standards provided by EPA and DEP will not be considered for contract award.

DEP personnel will employ the following steps in procuring laboratory or other contract support involving the generation or compilation of environmental data:

Statement of Work:

Program Managers review statement of work and provide QA tasks where required.

Acquisition Plan:

Division Directors or their designees define QA oversight roles in the acquisition process. This information is included in the Request for Bid or Request for Proposal (RFB or RFP).

RFP/RFB Development:

Project Managers incorporate QA activities into the evaluation as needed, including QA in sample work assignments, QMPs, QAPrPs and QAPPs.

RFP/RFB Evaluation:

The Division Directors or their designees may serve on selection panels to score specified submissions.

Contract Award:

The designated personnel may provide recommendations for contract awards.

STANDARDS FOR REQUISITION

In accordance with 155CSR 1, all procurement activities are governed by regulations promulgated to support W.Va. Code § 12-3-10. These regulations are included as Appendix E. The rule is further augmented by the West Virginia Purchasing Procedures Handbook Quality Assurance Procedures, which include:

- Determination that the commodity was needed
- Determination that the quantity, the quality level, the delivery location and timeframe are specifically addressed in requests for bids

- Requirements for the evaluation process, which are to include documented comparison of the standards established in the specifications for award to the specifications of the received items or services
- Description of procedures for documenting closure of purchase orders
- Procedures for adding reportable fixed property to the West Virginia Fixed Assets System
- Procedures for documenting vendor performance and product quality
- Procedures for complaint resolutions and corrective actions

CHAPTER 6: DOCUMENTATION AND RECORDS MANAGEMENT

Maintaining quality related documents and records is a continuous process for the DEP. This process serves as a vehicle for identifying quality-related documents and records requiring management control. DEP manages records in accordance with WV Code 5A-8-1 Records Management and Preservation of Essential Records Act. Approved record retention polices are developed by individual programs and approved by the Agency Record Retention Manager, the Agency Head and the State Director of Archives and History and State Records Manager. Moreover, this process ensures that QA documents and records are accessible and protected in storage from damage and deterioration. Finally, the process ensures compliance with all statutory, contractual, and assistance requirements for records for environmental programs, while providing adequate preservation of key records necessary to support the mission of the program. QA documents and records are maintained as follows:

ROUTINE QUALITY ASSURANCE OPERATING DOCUMENTS

Project or site-specific QA documents generated as part of the program are used and stored at the DEP headquarters while transitioning the entire agency to an Electronic Document Management System. The DEP has made the decision to utilize ApplicationXtender as the central Electronic Document Storage System and the offices and divisions are in various stages of transition at this time. Project or site-specific QA documents generated as part of the program will be stored in ApplicationXtender or transferred to the system when finalized. Records will be maintained according to each programs record retention policy or program requirements.

Official records and documents associated with a given project are the responsibility of the specific office. Copies may be maintained in duplicate by an office, however official records will be stored in one file location. These records provide support to the validity of the environmental data for making decisions. Projects involving the generation of environmental data will frequently include a QAPP or SAP and final report. These documents should be stored together, allowing a subsequent analyzer or investigator to understand the full context of the data produced and the conclusions reached.

IN-HOUSE QUALITY ASSURANCE GUIDANCE DOCUMENTS

Each Division and Office is responsible for establishing and implementing procedures for ensuring consistency and technical accuracy of its work outputs and products. Senior Leadership has responsibility to ensure that each organization uses established procedures to ensure that disseminated information products are of adequate quality for their intended use. QA guidance documents developed in-house will be reviewed by their Office or Division and the appropriate level of management. However, many

guidance documents will be those generated by the EPA, which will be appropriately disseminated, reviewed, and utilized by program staff.

DISPOSITION OF DOCUMENTS AND RECORDS

The Program Managers ensure that the QA documents for their respective office are current. In the event that a QA document becomes outdated, the Program Manager will determine the status of the document, make recommendations, and initiate appropriate actions.

Final documents will be maintained by responsible staff in accordance with file retention procedures specific to each Division. Following all appropriate actions, those persons with document management responsibilities will take special care to preserve the integrity of the documents such as audit reports, PE reports and environmental data.

CHAPTER 7: COMPUTER HARDWARE AND SOFTWARE

Data management serves a critical function in both preserving information and making that information available. Data management necessarily encompasses a variety of activities related to Permits, Inspections, Violations, Reclamation projects and planning environmental monitoring, collecting samples from different media, laboratory and insitu analysis of samples, organizing and storing resulting data, analyzing and interpreting data, disseminating data, and communicating the monitoring results and knowledge gained.

In order to ensure effective and efficient use of the DEP data management systems, including hardware and software system design, development, implementation, and maintenance, DEP's IT Support complies with all applicable state & federal standards including legislative requirements, regulatory requirements, and audit recommendations of WV IT Security State Law, FISMA pertaining to hardware, software system development, and data. Hardware purchases using federal grant funds are included in the specific grant work-plan or are specifically approved by EPA or the federal agency involved.

In addition, DEP computer systems conform, to the extent possible, to all policies and guidance provided by the Governor's Office of Technology and the Information Agency Council (ITAC), of which the DEP's IT Support CTO is a voting member, as those policies and guidance relate to the procurement and development of information systems for DEP.

Pages 13-15 (in hardcopy format, pages 18-20 in .pdf) of Attachment C describe in detail the mission statement, description and some specific accomplishments of IT Support related to hardware and software within the DEP.

AGENCY STANDARDS

The IT Support group develops DEP minimum standards for hardware and software based on the state standard. The IT Support technical staff establishes and updates these minimum standards as required. A constant evaluation of current and future needs and available products are conducted to meet these needs. A life cycle concept is used to evaluate options based on the life cycle of the hardware and software. The IT Support group works in conjunction with the Steering Committee to prioritize information technology projects within the agency to ensure efficient development of projects.

SOFTWARE DEVELOPMENT

The program office is responsible for developing or procuring software for DEP through the assistance of the IT Support group. The scope of IT Support assistance is to provide uniformity and the benefit of experiences to the purchase process. We are currently guided by the contracting software document and supporting templates. The Agency contracts with vendors for additional contract programming support for projects that have manpower requirements beyond current staffing. The procurement of these services is accomplished through contracts with vendors. These procurement services will also follow established agency, state and federal contracting guidelines. DEP maintains and extends internal client/server technology. DEP maintains and extends internal web applications and content.

PROCUREMENT

Hardware and application software procurement requests are routed through the IT Support staff to ensure compatibility and usability prior to purchase and to ensure the requested hardware or software is appropriate for the intended use. Non-agency standard software and hardware requests are evaluated to ensure compatibility with standards. However, selection and validation of the software remains the responsibility of the user. IT Support, as a rule, does not provide technical support for non-standard hardware and software.

VALIDATION OF DEP STANDARD HARDWARE AND SOFTWARE

All DEP system development, enhancement, and modernization efforts will comply with agency standards. The standards include a systematic and comprehensive dialogue between the data providers, data/system users, and system developers. The majority of the dialogue occurs prior to the design of the system in order to ensure extensive and successful user participation, and a systematic approach to the design. Systems will be designed and built to integrate with core DEP data in such a manner that re-use of code, and its associated cost savings, is maximized.

STANDARD SOFTWARE VALIDATION

Purchased application software is validated prior to purchase through a technical test and evaluation period. After purchase, the user will use the software without prejudice. Non-standard application software is the responsibility of the user in the category "user beware." DEP will utilize data management applications with integrated QA/QC components. Some examples of such trademark applications to be utilized containing built-in QA/QC components are Earthsoft, AIRTRAX, ERIS, and many others.

CHAPTER 8: QUALITY ASSURANCE PLANNING

The major goal of the DEP's Quality Management System is to promote effective planning for the collection, analyses, and processing of environmental data. Quality planning occurs at three levels for data to meet DEP programmatic and quality goals:

- Agency-wide requirements
- Division/program-specific and
- Project level

AGENCY-WIDE PLANNING

Internal Strategic Planning

Work plans developed annually with EPA for each division forms the basis for programmatic priorities and corresponding environmentally related data collection and use activities. Using the projected annual budget, the Executive Committee and other designated staff set priorities for the agency. These priorities are reflected in the DEP grant work plan processes, documenting and establishing goals, directions, resource utilization policies and budget allocations. Yearly plans are developed to describe the work plan and budget process and specify the types of environmentally related data generation activities that are projected. These yearly plans incorporate or involve decisions to be supported by planned environmental data collection activities.

DIVISION/PROGRAM-SPECIFIC PLANNING

DEP divisions/programs are functional areas of work authorized by statutory reference or by agency direction. Any DEP environmental programs that generate environmental data are covered by the QMP though it is acknowledged that not all programs or projects require the same level of QA. Generally, managers are responsible for program-level planning which includes the responsibility to ensure expected data quality.

PROJECT LEVEL PLANNING

Project level planning ensures efficient use of resources and emphasis on quality, objectivity, utility and integrity of data.

Quality Assurance Requirements for External Organizations

External organizations are required to conform to applicable QA requirements: "If the grantee's project involves environmentally related measurements or data generation, the grantee shall develop and implement quality assurance practices consisting of policies, procedures, specifications, standards, and documentation sufficient to produce data of quality adequate to meet project objectives and to minimize loss of data due to out-of-control conditions or malfunctions." External organizations, which conduct

environmental data operations and receive financial assistance from DEP and EPA, shall submit a QMP, QAPP, or other appropriate QA documentation for DEP's internal review and EPA final approval.

CHAPTER 9: IMPLEMENTING OA PROCEDURES

This chapter of the QMP describes the processes used by DEP for facilitating the effective implementation of QA plans and procedures which comprise DEP's Quality Management System. Substantial changes to the QMP will be documented in revisions and will receive Executive Committee-level approval. As with the QA planning described in Chapter 8, implementation of QA procedures takes place at the agency, program, and project levels.

AGENCY-WIDE IMPLEMENTATION

The QA/QC program for each Division or Program may be a centralized or de-centralized function but will be structured so as to ensure that environmental data is of sufficient quality for its intended purpose. This QMP meets the requirements set forth by EPA as outlined in EPA QA/R-2. At a minimum, the QMP workgroup will meet annually to ensure the document is correctly defining what the agency is doing.

DIVISION/PROGRAM-SPECIFIC PLANNING

Any DEP program that generates, or uses, environmental data will document its QA policies and procedures, and will develop and/or use appropriate policy and procedure manuals for its programs. The QAM can provide support and oversight in the generation of such documents. The EPA quality staff issues documents to provide information on satisfying federal regulations. For example, *Guidance for Preparing Standard Operating Procedures, March, 2001 (QA-G6)* is a document that should be referenced by programs when developing procedure manuals for administrative and technical QA operations. Implementation of these procedures will enable program personnel to gain and document procedural knowledge about their operations and will also serve as a training guide for new staff members.

Project Managers, who are qualified technical personnel, will review QA documents for adequacy and appropriateness for each specific project. Exceptions to plans and activities, which are documented by project staff, are jointly implemented and controlled by the division director, the project manager, and project personnel. Project Managers routinely perform oversight and/or audits of field activities to ensure compliance with the approved planning and technical documents.

PROJECT-LEVEL IMPLEMENTATION

QAPP Implementation

Environmental data operations will be implemented in accordance with an approved QAPP. Changes to the approved QAPP will be documented and approved by the program QAMs and/or the EPA as applicable in writing through an amended QAPP.

For contracts involving environmental data generation, the program shall ensure that the applicable assignment includes specific requirements for reports on the QA of products or services to be supplied.

For example, the Watershed Improvement Branch (WIB) within DWWM subgrants federal funding to other state agencies, local governments, nonprofit organizations, colleges, universities, and other groups who carry out educational efforts and water quality improvement projects. WIB requires these subgrantees to prepare QAPPs. QAPPs have been submitted to EPA for review and approval in the past, but WIB is developing (has developed, will have developed) a Standard Operating Procedure for the review of Subgrantee QAPPs. Appendix X contains a list of approved Subgrantee QAPPs

Standard Operating Procedures

The use of Standard Operating Procedures (SOPs) serves as a mechanism to ensure comparability across environmental data collection projects of various programs. A project's SOP may be either standalone document or may be incorporated into the project QAPP. In either case, the SOP is maintained by the Program who developed it. DEP continues to focus on development of SOPs, where needed. A previous Agencywide workgroup has established policies and procedures for SOP development across the agency.

SOPs detail the work processes conducted or followed within the program. The SOP documents the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. The SOP is intended to be specific to the program whose activities are described and assist the program in maintaining its QA/QC processes.

The best written SOPs will fail if not followed. Therefore, the use of SOPs needs to be reviewed and reinforced by appropriate personnel. Copies of current SOPs need to be readily accessible for reference by individuals actually performing the activity, either in hard copy or electronic format.

Managers and staff should review SOPs on an annual basis and determine whether the current version is applicable. Whenever field procedures or analytical requirements are

changed, the SOPs should be updated, reviewed, and re-approved as soon as possible rather than waiting for an annual review. Changes or modifications may be exclusively made to the pertinent section of a SOP, but the process should indicate the modification date and/or revision number in the document control notation.

It is the responsibility of the Program Managers to ensure that policies and procedures are current and that any changes are communicated to the program staff to implement in their environmental data operations.

CHAPTER 10: QUALITY ASSESSMENT AND RESPONSE

Assessments are evaluations intended to measure the success of the program or system being examined, and to provide a basis for improving such programs or systems. This section of the QMP describes how and by whom assessments of environmental programs are planned, conducted, or evaluated. Staff members who perform tasks related to the generation, management, and/or use of environmental data should participate in training related to the generation of such data. Because management is ultimately responsible for the quality of data, supervisors also receive the necessary training to ensure their understanding of the importance of the Quality Management System, their responsibilities as supervisors of data collection activities, and specific Quality Management System policies and procedures. Division Directors are responsible for ensuring that their staff members have the qualifications needed to do their jobs, including those related to the Quality Management System. This section also describes the process by which management determines the assessment activities appropriate for a particular project, which assessment tools may be used and the expected frequency of use.

IMPLEMENTATION SCHEDULE

This section describes how DEP will assess the effectiveness of its Quality Management System (QMS). DEP will use a variety of internal management and technical reviews, PEs, and QA audits to ensure that the procedures in this QMP are implemented successfully. DEP will also utilize, as needed, independent reviews of the systems and procedures described in the agency's QMP by personnel from the EPA Region III Quality Assurance Office.

The QMP workgroup will annually review the QMP and report any changes needed for approval to the QAM, or to the Executive staff, if consensus is not reached at the QAM. Once changes are approved, the QMP will be submitted to the Executive staff for signature and resubmission to EPA Region III. The QMP will need full review and revisions completed once every five years and final approval from EPA Region III.

QAPrPs and QAPPs will be implemented upon approval by the responsible person and the appropriate levels of management or EPA. The division director determines the appropriate levels of management review and approval, and the level of detail required for specific types of QAPrPs and QAPPs. Data collection activities should not be conducted without an approved QAPrP and/or QAPP for that activity with the exception of emergencies, in which case SOPs are to be followed.

DATA QUALITY ASSESSMENTS

Data received by the DEP is assessed based on its intended use. Data may include laboratory or other types of submitted data, such as field data or reports. Each program or office establishes the acceptance criteria needed for data assessment. Submitted data is assessed for quality by qualified technical staff in each program using the QAPrP, QAPP or DQA procedure established by that program, or federal regulations and guidelines. Program Managers are responsible for assuring that data received is checked for completeness and assessed for usability in meeting project objectives.

Data submitted by the regulated community pursuant to a license condition is reviewed and verified by DEP technical staff as part of regular inspections. Each program receiving such data establishes and documents its own assessment standards and procedures. Additionally, review of data should be performed in compliance with the EPA document *Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency Funded Assistance Agreements*.

UNIT/PROGRAM ASSESSMENT AND REVIEW

Management at each level is responsible for assuring that functional units and programs are assessed on a regular basis to ensure that identified objectives, such as those delineated in annual work plans, are being met.

Division Directors may request a program review to assess whether program objectives, policies, methods, documents and procedures are up to date and consistent with legislative and department goals and priorities.

Directors will determine the need for and timing of program reviews not otherwise required by federal rules and guidelines. The QAM may also recommend to senior management that a program be reviewed, based on results of a review or audit.

FORMAL AUDITS

The DEP employs an internal auditor who conducts systematic and objective compliance and performance audits and reviews throughout the agency. The objective of internal audits and reviews is to verify compliance with state rules and regulations as well as the agency's rules, policies, and procedures. The timing and nature of internal audits and reviews are based on identified risk, the annual internal audit work schedule and management concerns. The internal auditor is also responsible for following up with sections for any internal or external audit findings on the agency. External audits include federal audits, state legislative audits, independent financial audits, and other audits or reviews performed on the agency. The objective of internal follow-ups is to ensure corrective actions have been, or are planned to be, established to correct compliance issues.

A Program Manager, according to quality objectives and risk, may schedule audits of outside laboratories, contractors or suppliers. Audits are conducted according to the procedure established by the department plus any additional requirements that may be

established by each office or program. Additional requirements are documented as part of a specific audit plan.

Audits are conducted in a rigorous and systematic manner, using objective evidence to make findings regarding nonconformance to requirements and the need for any corrective action. Audit findings are documented and reported in a timely fashion to management. Proposed corrective actions are evaluated and tracked, and the effective implementation of corrective actions is verified before the audit is closed.

The agency may rely on or require third-party audits, such as laboratory certification or ISO 9001 certification, in lieu of conducting its own audits.

EPA ASSESSMENTS

EPA-sponsored programs are subject to review or audit by EPA. Scope and timing of audits may vary depending on the program and its enabling legislation, rules or authorities. Formal assessment of performance under an EPA Performance Partnership Agreement occurs as part of a comprehensive review and evaluation of department programs. The process is governed by EPA's *Policy on Oversight of Delegated Programs*, which states evaluations should focus on overall program performance.

PERFORMANCE EVALUATIONS (PE)

PEs are conducted to assess the ability of a laboratory or field measurement system to provide reliable data. PE samples will be considered for laboratories providing analytical services directly or indirectly for the DEP. The evaluation consists of providing a reference or "blind" sample to the laboratory for analysis. This PE sample contains a known concentration of chemical constituents of interest and will be in the appropriate media (air, water or soil). The analytical results obtained from the laboratory will be compared to the known concentrations in the PE sample as a means of determining whether the laboratory demonstrated its ability to properly identify and quantify contaminants within established, calculated and acceptable limits.

PEs will be scheduled at a frequency as required by program requirements or on an asneeded basis depending on the specific laboratory or program involved. The results of the PEs provide a means for assessing overall data integrity and may be used to evaluate analytical laboratories or sampling techniques.

DATA QUALITY EVALUATIONS

Data quality requirements and evaluation methods are included in this QMP and as specified in the associated QAPrP and/or QAPP. The QMP describes the methods by which data quality evaluations will be conducted and utilized and how these evaluations relate to the Data Quality Assessments (DQAs).

Data Quality Assessments (DQA)

A DQA refers to the process used to determine whether the quality of a given data set is adequate for its intended use, using appropriate statistical tools. DQAs can be performed on all or a subset of projects involving data collection. The purpose of this type of evaluation is to determine whether the data collected is acceptable to decision-makers or users for their intended use since the data is ultimately only meaningful in this context. A DQA will be performed periodically throughout projects, but at the midpoint and end of the data generation phase of a project at a minimum. The Program Manager or project manager will be responsible for the performance of DQAs, as well as responding to the findings. A DQA involves a comparison of the collected data with the DQOs for the project. The intended use of the data is established by the project's DQOs. This evaluation and comparison will result in the determination that the data is useable for its intended purposes. Results of DQAs will be documented in accordance with guidance contained in programmatic QAPrPs and QAPPs for specific projects. Guidance for this procedure is provided in EPA QA/G-9 Guidance for Data Quality Assessment (July 2000).

Data Quality Audits

A related evaluation tool involving data review and assessment is the Data Quality Audit used to evaluate the documentation of the quality of data generated for a given project. The assessment primarily involves an evaluation of the completeness of the documentation of field and analytical procedures and QC results. The process usually involves tracing the paper trail accompanying the data from sample collection and custody to analytical results and entry into a database, if available.

Results from both data quality assessments and data quality audits can be used in a number of ways. First, they can be used in making recommendations for changes in the design and performance of the data collection efforts and in the use and documentation of QC procedures. Secondly, they can be used as a guide for planning and acquisition of supplemental data for the project and potentially for other related projects. Program Managers and/or Project Managers are responsible for the performance of these assessments and responding to any findings.

CHAPTER 11: CONTINUOUS QUALITY IMPROVEMENT

The QA procedures and processes described in the previous chapters serve to establish a strong foundation for ensuring that acceptable data quality is provided in the program. By simply raising awareness and focusing attention on these procedures and ensuring that the prescribed QA practices are followed, the program will reinforce QA as an important component in its environmental sampling. The quality management system is designed to identify opportunities for improving the measurement process. Improvement can take the form of preventing quality problems from occurring by adjusting current work processes or seeking out better ways to do the work. The goal is to prevent quality problems from occurring or recurring. Every attempt is made to ensure QA problems are identified and resolved quickly by encouraging open communication between personnel.

APPROACH TO IMPROVEMENT

The program QMP is the first step in the process of implementing a comprehensive and effective Quality Management System. The QMP serves as the framework for applying QA and QC procedures to environmental data operations.

Following reapproval of the QMP by the EPA Region III staff, the DEP program staff members will continue their work to improve and maintain the QMP.

Beyond implementation of the QMP, improvements to the Quality Management System will also occur through the evaluation of the various programs described in Chapter 10. These reviews will provide the opportunity to identify areas of weakness and, thus, opportunities for improving the quality of the system.

IMPROVEMENT LEADERS

Program personnel involved with data collection, analyses, or generation have a responsibility for meeting QA requirements. Beyond meeting these obligations, staff and managers have the opportunity to offer suggestions for improving the Quality Management System through the QAM. The program staff and managers have the responsibility to promote and facilitate Quality Improvement by detecting and correcting underlying problems of the system, raise an awareness of the importance of quality, and to encourage staff to offer suggestions for improvements.

DEFICIENCIES AND NON-CONFORMANCES

Significant deficiencies and non-conformances to QAPrPs, QAPPs, SOPs or department requirements observed outside of a formal audit or assessment process are to be reported by department staff to supervisors.

Each division director or Program Manager is to establish who has the authority to suspend or stop work upon detection and identification of an immediate adverse condition affecting quality or health and safety. Supervisors are to ensure that the deficiency or nonconformance is documented, and forward reports to the appropriate project manager and lead QA staff. A formal Corrective Action Plan may be required, and tracked until closure.

CORRECTIVE ACTIONS

Corrective actions generally are developed on a case-by-case basis. Once a problem has been identified, the problem is documented and individuals involved with the project are notified of the problem. Involved parties meet to discuss the problem. When deficiencies or non-conformances have been identified, Project Managers determine and document the information needed for corrective action.

The project manager forwards copies of corrective action plans to supervisory and lead staff involved in monitoring corrective actions.

Managers and supervisors ensure that corrective action plans are effectively implemented in a timely manner, and that activities necessary to carry out such plans are included in annual work plans or other planning documents as appropriate. Division Directors and lead staff monitor the implementation of corrective action plans. If determined necessary, Managers and supervisors can include completion of corrective actions in employees' performance management plans and annual performance reviews.

Non-conformances and corrective actions are documented in the project or program file to ensure that future individuals involved with the project or activity will be able to trace the evolution of procedural or policy change (including what was done, by whom, and why).

LIST OF REFERENCES

CIO 2105.1 Environmental Information Quality Policy, March 2021

CIO 2105-P-01.1 Environmental Information Quality Procedure, March 2021

EPA Requirements for Quality Management Plans, EPA QA/R-2, USEPA, Quality Assurance Management Staff, March 2001 (Reissued May 2006).

U.S. EPA Acquisition Regulations, U.S. EPA Office of Administration and Resources Management.

U.S. EPA Grant Regulations, QA Requirements, 40 CFR Part 30.54 for Universities and Other Non-Profits, and 40 CFR Part 31.45 for states, tribal, and local governments.

Managing Your Financial Assistance Agreement, U.S. EPA Office of Administration and Resources Managements, EPA 202/8-94/001, May 1994.

TERMS AND DEFINITIONS

Acceptable Quality Level – a limit above which quality is considered satisfactory and below which it is not. In sampling inspection, the maximum percentage of defects or failures that can be considered satisfactory as an average.

Activity – an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

Assessment – the evaluation process used to measure the performance or effectiveness of a system and its elements. In this document, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection or surveillance.

Audit – a planned and documented investigative evaluation of an item or process to determine the adequacy and effectiveness, as well as compliance with established procedures, instructions, drawings, quality assurance project plans (QAPPs), quality assurance program plans (QAPrPs). Standard Operating Procedures (SOPs) and other applicable documents.

Characteristic – any property or attribute of a datum, item, process, or service that is distinct, describable, and measurable.

Compliance Monitoring Evaluations – a type of inspection conducted at Interim Status land-disposal facilities to ensure compliance with groundwater monitoring requirements. Groundwater split-samples are collected during these inspections.

Computer Program – a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter or a translator to prepare the program for execution. A computer program may be stored on magnetic media, and be referred to as a "software" or may be stored permanently on computer chips, and be referred to as "firmware." Computer programs covered by this document are those used for design analysis, data acquisition, data reduction, data storage (data bases), operation or control, and data base or document control registers when used as the controlled source of quality information.

Contractor – any organization or individual that contracts to furnish services or items or perform work.

Corrective Action – measures taken to rectify conditions adverse to quality and, where necessary, to preclude their recurrence.

Customer – any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.

Data Quality Assessment (DQA) - a process for performing statistical analysis to determine whether the quality of a data set is adequate for its intended use.

Data Quality Objectives (DQO) – qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations with the data users' needs.

Data Usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Design Review – a documented evaluation by a team, including personnel other than the original designers, the responsible designers, the customer for the work or product being designed, and a QA representative to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Environmental Conditions – the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical or biological characteristics.

Environmental Data – any information or measurements resulting from field data collections activity, laboratory analyses or modeling involving the assessment of chemical, physical or biological factors related to the environment that describe environmental processes or conditions or the performance of engineered environmental systems.

Environmental Data Operations – work performed to obtain, use or report information pertaining to environmental processes and conditions.

Environmental Monitoring – the process of measuring or collecting environmental data.

Environmental Processes – manufactured or natural processes that produce discharges to or impact the ambient environment.

Environmental Programs – an all-inclusive term pertaining to any work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of engineered environmental systems; and laboratory operations on environmental samples. In this document, the term also refers to functional areas of work performed by groups or teams of people within the organization.

Environmentally Related Measurements – the data collection or analyses activity or investigation involving the assessment of chemical, physical or biological factors in the environment which affect human health or the quality of life.

Financial Assistance – the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

Graded Approach – the process of basing the level of application of managerial controls applied to an item or work according to the intended use of results and the degree of confidence needed in the quality of the results.

Hazardous Waste – any waste materials that satisfy the definition of "hazardous waste" as given in 40 CFR Part 261, "Identification and Listing of Hazardous Waste."

Inspection – examination or measurement of an item or activity to verify conformance to specific requirements.

Item – an all-inclusive term used in place of the following: appurtenance, facility, sample assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

Management – individuals directly responsible and accountable for planning, implementing and assessing work.

Management System – a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

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

Method – a body of procedures and techniques for performing activities (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

Peer Review – a documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or an organization) who are independent of those who performed the work but are collectively equivalent in technical expertise (i.e., peers). The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports that work. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation (PE) – a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Procedure – a documented set of steps or actions that systematically specifies or describes how an activity is to be performed.

Process – an orderly system of actions that are intended to achieve a desired end or result. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Qualified Data – any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Quality – The sum of features and properties/characteristics of process, item, or service that bears on its ability to meet the stated needs and expectations of the user.

Quality Assurance (QA) – an integrated system of management activities involving planning, implementation, assessment reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

Quality Assurance Program Plan (QAPrP) – a document establishing policies that **define** and document the type and **quality** of data needed for **program** level environmental decisions and to describe the methods required for collecting, analyzing, and assessing data to support those decisions.

Quality Assurance Project Plan (QAPP) – a formal document describing in comprehensive detail the necessary QA, QC, and other managerial and technical activities implemented to ensure that the results of the work performed will satisfy the stated performance (data quality) objectives at the individual project or program level

Quality Control (QC) – the overall system of technical activities that measures attributes and performance of a process, item, or service against defined standards to verify that it meets the stated requirements established by the customer.

Quality Improvement – a management program of improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality Indicators – measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include precision, accuracy, sensitivity, bids, completeness, representativeness, reproducibility, comparability, and statistical confidence.

Quality Management – that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the Quality Management System.

Quality Management Plan (QMP) – a formal document that describes the Quality Management System in terms of the organizational structure, functional responsibilities

of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all QA activities conducted.

Quality Management System – a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The Quality Management System provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC procedures.

Remediation – the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health and the environment.

Service – the category of economic activity that does not produce manufactured items. In environmental data operations or engineering projects, such activities include design, inspection, laboratory and/or field analysis, repair, and installation.

Significant Condition – any state, status, incident, or situation of an environmental process or condition of an engineered environmental system in which the work being performed will be adversely affected in a manner sufficiently serious to require corrective action to satisfy quality objectives or specifications and safety requirements.

Standard Operating Procedure (SOP) – a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

Supplier – any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surveillance – the act of monitoring or observing a process or activity to verify conformance to specified requirements.

Technical Review – a documented critical review of work. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review consists of an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical Systems Audit (TSA) – a thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training procedures, record keeping, data validation, data management, and reporting aspects of a system.

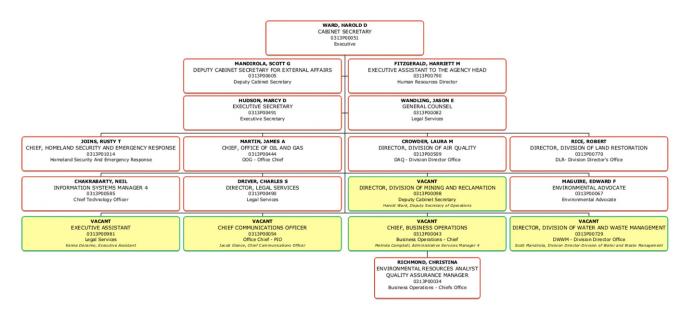
Validation – an activity that demonstrates or confirms that a process, item, data sets, or service satisfies the requirements defined by the user.

Verification – the act of authenticating or formally asserting the truth that a process, item, data set, or service is, in fact, that which is claimed.

Appendix 1 – DEP Quality Organizational Chart



WEST VIRGINIA DEPARTMENT OF ENVIRONMENTAL PROTECTION 8/04/2021



Appendix 2 – DEP Programs Impacted by QMP

This section includes major (not all inclusive) program areas/activities for each organization that may include QA responsibilities.

Division of Air Quality

Ambient Air Monitoring

Laboratory

Division of Water and Waste Management

Watershed Assessment Branch

Permitting

Environmental Enforcement

Watershed Improvement Branch

Laboratory Certification Program

RCRA

Division of Mining and Reclamation

HPU Program

Division of Land Restoration

Brownfields Section

Superfund Section

Appendix 3 – Current QAPPs and SOPs approved by EPA

Quality Assurance Program Plan for the West Virginia Department of Environmental Protection Division of Land Restoration Office of Environmental Remediation, Revision Number 5, Effective Date September 21, 2016. Renewed every 5 years. This QAPrP is for the Voluntary Remediation Program (VRP) and Uniform Environmental Covenants Act – Leaking Underground Storage Tank (UECA-LUST) program. This QAPrP also contains seven SOPs:

SOP OER-0100 General Decontamination Procedures for Non-Disposable Field Sampling Equipment

SOP OER-0101 PID Field Screening

SOP OER-0102 XRF Field Screening

SOP OER-0110 Groundwater Well Sampling Procedures

SOP OER-0120 Soil Sampling

SOP OER-0121 Soil Sampling Using Direct-Push Drilling

SOP OER-0122 Soil Sampling Method 5035

Quality Assurance Program Plan for the West Virginia Department of Environmental Protection Division of Land Restoration Office of Environmental Remediation CERCLA (Superfund) Program, Revision Number 5, Effective Date September 21, 2016. Renewed every 5 years.

Tanks (UST & LUST)

The LUST Program is currently covered under the Quality Assurance Program Plan for West Virginia Department of Environmental Protection Division of Land Restoration Office of Environmental Remediation referenced above.

The UST program has Quality Assurance Program Plan for the WVDEP DWWM Office of Enforcement Underground Storage Tanks. Approved in 2016. Renewed every 5 years.

SOP Underground Storage Tank Inspections

SOP Underground Storage Tank LUST 4 Reporting

Note: we are currently writing a QAPrP for UST & LUST that will be combined now that the programs are back together after the reorganization. We will plan on submitting to EPA in 2nd quarter 2021.

EPA Approved West Virginia Nonpoint Source Program Section 319 grant subrecipient monitoring QAPPs

Coal River Group – Lower Coal River

Eastern Panhandle Conservation District - Elks Run

Friends of Blackwater - North Fork Blackwater River and Beaver Creek

Friends of Deckers Creek – Deckers Creek

Friends of the Hughes River - North Fork of the Hughes River

Piney Creek Watershed Association – Piney Creek

West Virginia Conservation Agency – Knapp Creek

West Virginia Rivers Coalition and Trout Unlimited – Water quality impacts in cold water streams

Watershed Assessment Branch

Watershed Assessment Branch QAPP – May 2019. WAB is currently updating its QAPrP that will cover all aspects of WAB activities. The current and soon to be completed plans reference our SOPs that are updated regularly - last update 2018:

https://dep.wv.gov/WWE/watershed/Pages/WBSOPs.aspx

Division of Air Quality Final QAPPs

PM2.5 Air Monitoring/Laboratory Program - December 5, 2017 EPA Signed/Final Approval

NCore Air Monitoring - February 27, 2020 EPA Signed/Final Approval

Ozone Ambient Air Monitoring -February 25, 2020 EPA Signed/Final Approval

National Air Toxics Trends Station Inductively Coupled Plasma-Mass Spectrometer Laboratory Metals Analysis Program - April 2, 2020 EPA Signed/Final Approval

Sulfur Dioxide Air Monitoring - May 19, 2020 EPA Signed/Final Approval

PM10 Air Monitoring - July 31, 2020 EPA Signed/Final Approval