

# **APPENDIX H**

# WEST VIRGINIA DIVISION OF ENVIRONMENTAL PROTECTION QUALITY MANAGEMENT PLAN

**US EPA ARCHIVE DOCUMENT** 

# QUALITY MANAGEMENT PLAN

(Date)

Prepared for:

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# FORWARD

The West Virginia Division of Environmental Protection (DEP) has developed this manual in general accord with the EPA Guidance Document, "EPA Requirements for Quality Management Plans (EPA QA/R-2)". The DEP has prepared this Quality Management Plan (QMP) to document the policies, procedures, along with roles and responsibilities associated with the DEP's Quality System with respect to environmental measurements gathered by the DEP, or its contractors. This document, together with the various required Quality Assurance Project Plans, Memorandum of Understanding (MOU), and guidance documents, aim to provide the necessary QA/QC documentation to ensure that the data collected by the DEP meets appropriate Data Quality Objectives.

In accordance with EPA Order 5360.1, Policy and Program Requirements to Implement the Mandatory Quality Assurance Program, and EPA Order 5360.1 Change 1 (1998) Policy and Program Requirements for the Mandatory Agency-wide Quality System (Attachment A), the QMP for Region III (September 1996), and relevant guidance, the DEP is providing the USEPA with a QMP for activities involving environmental data collection. EPA QA/R-1, EPA Quality Assurance Requirements for Environmental Programs and Programs and EPA QA/R-2, EPA Requirements for Quality Management Plans, provide details of the contents and organization of a typical QMP. Interim Draft QA/R-2 (July 1993) was the basis for the preparation of this document. Once approved, this document becomes the QMP for all DEP activities resulting in the generation, compilation, and use of environmental data.

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# **TERMS AND DEFINITIONS**

Acceptable Quality Level - a limit above which quality is considered satisfactory and below which 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, polar 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, QAPjPs, 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 (CMEs)** - 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, referred to as "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 (DQOs)** - qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to a crept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent 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 collection activity, laboratory analyses or modeling involving the assessment of chemical, physical or biological factors related to the environment, and 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 or 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, 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".

**Independent Assessment** - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

**Inspection** - examination or measurement of an item or activitiy 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** - those individuals directly responsible and accountable for planning, implementing and assessing work.

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

**Management 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 an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

**Mixed Waste** - hazardous waste material, as defined by 40 CFR Part 261 (RCRA), mixed with radioactive constituents.

**Operation and Maintenance Inspections (O&Ms)** - type of inspection conducted at permitted facilities to ensure compliance with groundwater monitoring requirements contained in facility Hazardous Waste Management Permits requiring.

**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 organization) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. 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 them. 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 a 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 Manager(s) (QAM)** - the designated DEP leaders for oversight of the QA Program who assists with a variety of QA functions, including evaluations for contract laboratory and review of QAPjPs.

**Quality Assurance Project Plan (QAPjP)** - a formal document describing in comprehensive detail the necessary QA, QC, and other managerial and technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance (data quality) objectives.

**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 they meet the stated requirements established by the customer.

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

**Quality Indicators** - measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include, precision, 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 system.

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

**Readiness Review** - a systematic, documented review of the readiness for the startup or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

**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.

**Self-Assessment** - assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

**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 that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the origianl work. The reviews are 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 set, 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.

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

# 1.1 WEST VIRGINIA QUALITY ASSURANCE POLICY

# 1.1.1 Background

The West Virginia Division of Environmental Protection and its predecessor organizations have historically employed the fundamental elements of quality assurance and quality control programs for statemandated and federally delegated environmental management programs involving the generation of environmental data. The Quality Management Plan (QMP) set forth in this document is intended to effect continuing improvements to those DEP activities which have historically employed data quality management processes and to extend the QA/QC process to appropriate activities which may not have previously employed effective quality management.

#### 1.1.2 Importance of QA/QC within West Virginia DEP

Managers and staff at the West Virginia Division of Environmental Protection (DEP) make daily decisions which affect the quality of human health and the environment. Those decisions also have a substantial economic impact upon individual citizens and businesses. The decisions must be based on data that is accurate and representative of actual conditions. Although outside influences such as public opinion and the opinion of the regulated community may factor into decisions, accurate information is the most important factor in making decisions, therefore, the need for a QMP becomes preeminent.

Environmental data is used for measuring compliance with rules and regulations and permits, setting priorities, plotting a strategic direction, identifying and supporting enforcement actions, measuring trends, targeting inspections and making other decisions. The accuracy of data is critical because, among other things, it impacts compliance and enforcement decisions, determines possible cleanup options, and demonstrates to the public the effectiveness of environmental management programs implemented by the DEP.

1.1.3 Policy Statement

The DEP is committed to implementing a Quality System that will ensure that all data and decisions made using that data are technically correct and defensible. Moreover, the agency is committed to continuously evaluating and improving the Quality System described in this Quality Management Plan.

# 1.1.4 General Goals and Objectives of the Quality System

The DEP's Quality System is designed to avoid situations wherein environmental data collected does not meet the quality requirements established by law and otherwise specified by the users of the data. The primary goal is to ensure that all environmentally-related data collection and processing activities performed will result in the production of data that is of known quality and is documented. The data must support specific decisions or actions with a high degree of certainty that the action or decision is correct. This includes actions or decisions made by monitoring or measurement activities supported through EPA Grants, other federal grants, or interagency agreements. This goal is achieved by ensuring that appropriate 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:

- 1 Each activity that generates environmental data will incorporate or rely upon an effective Quality Assurance (QA) program. Staff involved in the generation or specification of environmental data will demonstrate their involvement in a QA program within the framework of a Program, Division or Office Quality Management Plan (QMP) by relying upon QAPPS and SOPs.
- 2 The objectives for generating any new environmental data shall be determined prior to collection activities. In that way, appropriate

resources and quality assurance and control methods can be applied to ensure a level of data quality commensurate with the intended uses for the data.

3 - Each activity that generates environmental data shall incorporate or rely upon the development and implementation of a Quality Assurance Project Plan (QAPP) and/or Standard Operating Procedures (SOPs) which specifies the detailed procedures required to assure production of quality data. These QAPPs are prepared by appropriate agency or contractor personnel and are then reviewed, and approved by the appropriate Quality Assurance Manager (QAM) and the respective DEP Office Chief or Section Manager prior to the start of a data collection effort.

4 - Programs that support externally generated environmental data through contracts or interagency agreements will ensure that acceptable QA requirements are included in the appropriate agreement documents and that these external parties follow acceptable Quality Management Practices as described in the relevant State rules.

- 5 Any programs or activities that accept externally generated environmental data for use in decision making will ensure that the party supplying the data has followed acceptable Quality Management practices.
- 6 Quality Assurance (QA) and Quality Control (QC) procedures will be implemented in the most cost effective manner possible without compromising data quality objectives.
- 7 There will be an ongoing system of evaluation for QA efforts to ensure that the Quality System is meeting the needs and expectations of data users as well as QA requirements.
- 1.1.5 Resources for the QA System

The resources necessary to conduct the various QA and QC activities within the DEP are provided by the program customers who require assistance in order to successfully implement their programs. QA is viewed as an integral part of the programs and activities which QA applies, i.e., any program which deals with environmental measurements and data generation. This includes environmental monitoring activities. The level of QA resources needed for any given program or project is determined by the relevant program, section or project manager.

The DEP's QAM position is currently shared by designated personnel located within each Office of the DEP. The Quality Assurance Manager (QAM) position is actually a group position formed by the Quality Management Team located throughout the DEP. The QAM or Quality Management team is answerable to the Division Director, although coordination of all QA activities with other agency personnel is a routine matter.

# 1.2. SCOPE OF THE QUALITY MANAGEMENT PLAN

This Quality Management Plan applies to any and all DEP Program activities and contracts that generate environmental data which is used to make decisions or support actions. Environmental data is defined as information or measurements resulting from any field data collection activity, laboratory analyses, or models involving the assessment of chemical, physical or biological factors relating to the environment. Therefore, programs or activities-generating environmental data are subject to the requirements of this QMP.

# CHAPTER 2: DEP ORGANIZATION/MANAGEMENT AND QMP IMPLEMENTATION

# 2.1 ORGANIZATIONAL STRUCTURE

The WV DEP is the primary environmental management agency in West Virginia having regulatory authority and responsibilities over air and water pollution control programs, mining and reclamation, oil and gas extraction, solid and hazardous waste management programs and environmental remediation . Appendix C is a copy of the WVDEP 1997-1998 Annual Report and contains the following: mission statements and a general description of the functions and management of Office sections within each Program Office which directly or indirectly generate or compile environmental data.

# 2.2 ROLES AND RESPONSIBILITIES

All persons in the DEP Program Offices covered by the QMP who are directly or indirectly involved with environmental data collection have responsibility for ensuring data quality. This may include staff level personnel, managers, senior managers, and personnel specifically assigned to perform QA functions.

The QAM(s) are assigned the responsibilities for the oversight and implementation of the QMP. With respect to these responsibilities, they report directly to the Division Director. However, the duties of the QAMs may only be part of the overall responsibilities of the person or persons assigned the QAM functions; therefore, reporting for non-QMP duties follows the DEP organizational chart.

The following is an overview of the QA responsibilities of DEP Management and QA personnel:

- 1- The Division Director and the Program Office Chiefs have overall responsibility for managing the QA programs appropriate for each Office Those positions are specifically responsible for ensuring that:
  - The QMP is developed, updated, and effectively implemented;

- Adequate resources are provided to support the QA program responsibilities;

- QAM's for each Program Office are designated to assist with QA implementation;

- Environmental data collection activities are covered by appropriate planning Documentation (DQOs, QAPP, SOP, etc.)

- QAPPs are written, signed, and effectively implemented for all projects which generate environmental data; QAPPs may actually be written by contractors outside the agency, however, the agency is responsible for their approval.

-An adequate degree of auditing is performed to determine and achieve compliance with QA requirements;

-Deficiencies highlighted in audits are corrected expeditiously; and

-Program-specific QA related training needs are identified and provided.

- Maintain and update the QMP;
  - Prepare and submit the annual QA report(s) and work plan(s) to the Director and the appropriate Program Office Chiefs;
  - Review and revise QAPPs, as necessary;
  - Distribute QA documents, policies, and procedures;
  - Routinely review the QA procedures and keep the Director and Chiefs apprised;
  - Conduct reviews and assessments of QA and QC activities and prepare reports on same; and
  - Assess training needs and report such needs to the Division Director and the Chiefs.

# 2.3 COMMUNICATIONS

To be effectively implemented, this QMP must not only be completed, circulated, and updated, but also understood by all persons responsible for collecting environmental data and the decisions made on environmental data. Several means will be used to ensure that this occurs. Lines of communication among the QAMs and the Chiefs and others will keep all persons informed of new developments, policies, and other QA procedures.

2.3.1 QA training, as needed, will be offered on an ongoing basis in order that persons responsible for QA functions will understand QA requirements and practices related to their responsibilities. The Chiefs and the Director will be responsible for ensuring that adequate training is provided. Staff involved in activities covered by this QMP will receive training to ensure that all aspects of the QMP are followed. The DEP shall request and rely upon training by USEPA personnel.

## 2.4 IMPLEMENTATION

The procedures outlined in the QMP will be implemented by each Program Office withn a reasonable period of time upon approval of the document by the EPA. Data collection activities will be associated with specific Quality Assurance Project Plans developed and implemented in accordance with the EPA-approved QMP.

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# CHAPTER 3: DEP'S QUALITY SYSTEM

# 3.1 PRINCIPAL COMPONENTS OF THE SYSTEM

The Division of Environmental Protection's (DEP) Quality Assurance System consists of people, functions, tools, and procedures to ensure that an appropriate quality of environmental data is generated for the need of DEP data users and decision makers.

To achieve an effective QA System, the following elements are required (the location of the information is in parentheses):

- Statements of QA goals and policy (1.1);
- Lists of applicable QA requirements and criteria (1.1.4);
- Programs and activities covered by QA requirements (1.1.4);
- Defined QA organizational structure (1.1.5);
- Resource assessment and accommodation (1.1.5);
- Roles and responsibilities of those involved with QA functions (1.4);
- QA tools and procedures (2.2);
- Communications processes (2.3);
- Training requirements (2.3.1);
- Documentation and record keeping (5.0);
- Review and evaluation procedures (7.0, 9.0);
- Methods for continuous improvement (10.0); and
- Definitions of key QA terms;

Activities covered by the QMP may be centralized within the Division to promote consistent procedures and quality of environmental data. QA training and implementation, however, are not centralized, but occur throughout the agency

or where appropriate, the QA training and implementation may be established within a Program Office.

# 3.2 PRINCIPAL TOOLS AND PRACTICES

Successful implementation of a Quality 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 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 System.

Primary QA planning and implementation tools include Quality Management Plans (QMPs), establishment of Data Quality Objectives (DQOs), Quality Assurance Project Plans (QAPPs), and Standard Operating Procedures (SOPs).

Primary QA evaluation and assessment tools include Management Systems Reviews (MSRs), Technical Systems Audits (TSAs), Performance Audits, and Data Quality Assessments (DQAs). Most of these activities are arranged and performed by the QAM or other designated personnel.

#### 3.2.1 Quality Management Plan

This QMP describes the policies, procedures, and systems governing the QA operations. It was developed in order to establish and maintain a formal QA procedure to ensure that the collected environmental data produces sound environmental decisions. This QMP has been drafted by the QAMs and is designed to meet the needs of the specific activities covered. Staff within each Program Office who are responsible for activities described in Paragraph 1.1.4 have participated in drafting this document. As evidenced by the Approval Form of this document, each Program Office Chief as well as the Division Director have reviewed and approved this QMP.

Future revisions and updates of this QMP will be drafted by the QAMs with assistance from the implementing staff and will be reviewed by the Office Chiefs, Assistant Chiefs and the Director 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 QAMs are 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.

The QAMs will ensure that the final QMP is implemented as approved. All staff members who are responsible for collecting environmental data are equally responsible for following the procedures detailed in the QMP.

# 3.2.2 Data Quality Objectives Process

The Data Quality Objectives (DQO) process will be used when appropriate in the planning phase of environmental data collection activities. *Guidance for the Data Quality Objectives Process* (EPA QA/G-4), will be used for the development of DQOs. DQOs are a required element of any Quality Assurance Project Plan (QAPP) submitted to EPA Region III for review and approval.

# 3.2.3 Quality Assurance Project Plans (QAPP, formerly QAPjP)

The QAPP is the planning document for any environmental data collection operation. It is a blueprint for how the DEP's Quality System as described in this QMP is put into actual use for a specific environmental data collection project. The three phases of such a project or QAPP are planning, implementation, and assessment. DQOs specify the expectations and requirements of the data user. In the implementation phase, the data supplier's testing and QA/QC procedures are described to ensure that the data may be suitable to meet the data users' needs. Finally, the data is evaluated using data validation and Data Quality Assessment processes. All three phases are critical, however, the last phase, the assessment phase, is the point at which the determination is made as to the adequacy of the data. This QAPP is simply an outline filled in with specific details of an individual project that interweaves planning, implementation, and assessment phases for the life cycle of the project to ensure data quality and objectives are met. The QAPP presents the policies and procedures, organization, objectives, QA requirements, and quality control activities designed to achieve the type and quality of environmental data necessary to support project objectives. Changes to an existing QAPP are to be in writing, along with rationale for making the change. Data collection or analyses will occur consistent with the QAPP. QAPPs will be reviewed by the QAM and personnel designated by the Chiefs. Persons conducting reviews will have a working knowledge of the QA Program and DQOs and training in QAPP review. QAPPs are not

reviewed as stand alone documents. QAPPs are reviewed in the context of the broader project by area experts who provide specific project recommendations. The Chiefs will ensure that QAPPs are reviewed and approved prior to sampling or data collection, and signed by the appropriate personnel.

A QAPP or SOP will be developed for activities that are conducted continuously or routinely throughout the Grant year; therefore, a sitespecific QAPP will be prepared only for sampling events not classified as continuous or routine. QAPPs will be revised as needed in response to audits conducted by the QAMs or as a result of input from management or staff responsible for implementing the QAPP. QAPPs will be reviewed regularly by the QAMs and updated as necessary.

QAPPs use a document control format that provides a version number and effective date. EPA Guidance Document EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plan for Environmental Data* Operations is used for preparing QAPPs.

Updated QAPP guidance will be implemented as it is available.

# 3.2.4 QA Status Reports

QAPPs for environmental data collection include a section discussing the frequency, content, and format of the required QA status report. Status reports are submitted to the Director and the Office Chiefs by the QAMs, as needed, and will be used to track the progress of QAPPs. A status report addresses the following elements:

- Status of project;
- Changes in project activities (sampling, QA control measures, analytical methods);
- Results of performance and systems audits;
- Any corrective actions taken;
- Project organization changes; and
- Assessment of data quality indicators precision, accuracy, completeness, representativeness, and comparability.

## Standard Operating Procedures (SOPs)

3.2.5

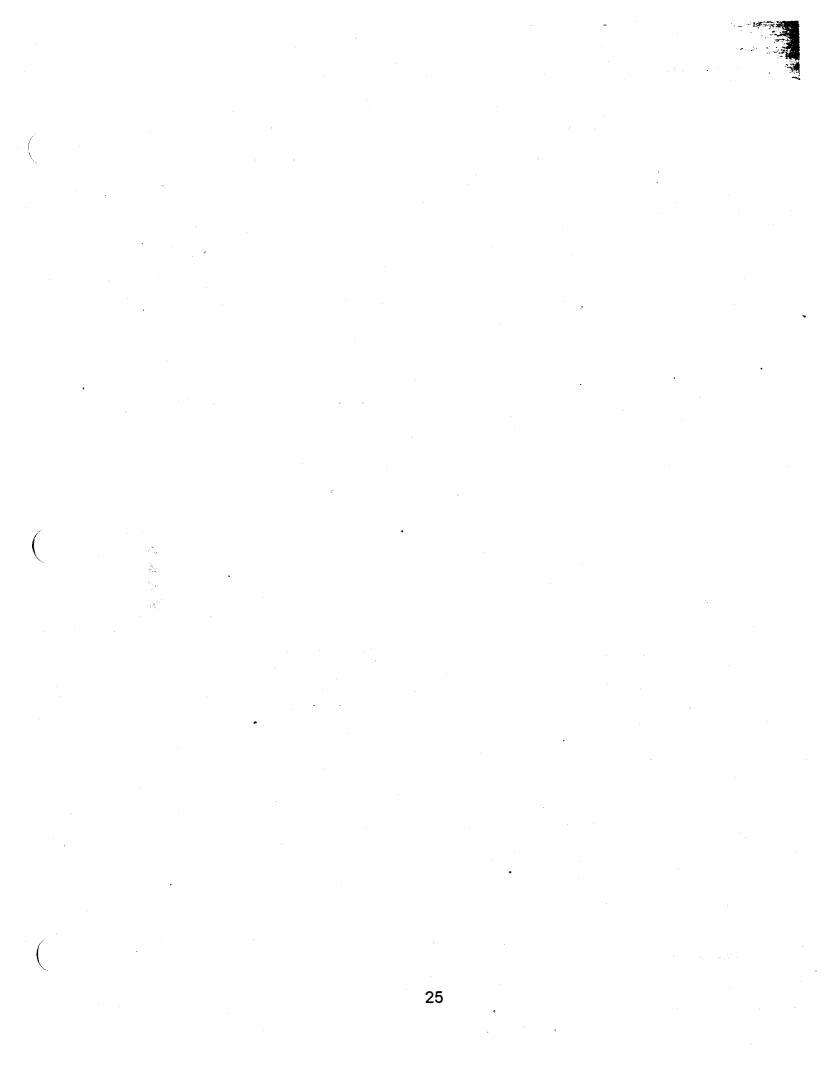
The use of Standard Operating Procedures (SOPs) serves as a mechanism to ensure comparability across individual environmental data collection projects. SOPs are incorporated in full or by reference in the QMP and QAPP. SOPs are maintained by the unit or section manager and provided to the QAMs. SOPs are revised by the individual unit or section managers as needed. SOPs have document numbers and dates.

# 3.2.6 Technical Systems Audits (TSA)

All programs that employ environmental data collection and analyses are subject to a TSA. The TSA involves a thorough review of the equipment, sampling and analysis procedures, documentation, data validation and management, training procedures, and reporting aspects of the technical system for collecting or processing environmental data. TSAs may be routinely planned by the QAMs, specifically requested by a program manager, or result from other audit or review findings. The QAM is responsible for scheduling the TSA, assembling the audit team, and participating in the TSA. Results will be reported to the audited organization in the form of a report.

# 3.2.7 Management System Reviews (MSRs)

Management System Reviews (MSRs) will be performed at least once every three years. The MSR will qualitatively assess the program's organization and data collection procedures to determine whether the quality system in place is adequate to ensure the quality of the program's data. The Division Director or his designee is responsible for assembling the audit team (if necessary) and coordination of audit activities. Results of any MSR conducted will be promptly shared with the Division Director upon completion of the review (but prior to a final written report). The Program Office Chiefs are responsible for taking any necessary corrective actions and determining whether additional audit activities are required.



# CHAPTER 4: PERSONNEL QUALIFICATIONS AND TRAINING

# 4.1 POLICY FOR QA RELATED TRAINING

The purpose of this chapter is to explain the processes used by the Division of Environmental Protection to ensure that staff and managers working in the Program Offices covered by the QMP are trained and qualified to perform their required QA responsibilities as documented in this QMP.

# 4.1.1 Responsibilities

Managers are responsible for ensuring that each staff member involved with collecting environmental data has the necessary technical, quality assurance, and project management training and certifications or documentation required for their assigned tasks and functions. Managers are also responsible for ensuring that technical staff maintain the necessary level of proficiency to effectively meet QA responsibilities. QA training and additional development need 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. The Office Chiefs oversee Program Managers who are responsible for arranging or providing for the training needs so identified.

The QAMs are responsible for identifying any training needs related directly to implementing the QMP.

#### 4.1.2 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 Office Chiefs and appropriate training is provided for the personnel.

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 Program Office. Depending on the number of staff to be trained, this training will generally be conducted in either a classroom setting or as a tutorial. In certain

instances, field training will also occur. Training milestones shall include training in QA related topics.

# 4.1.3 Implementation of Training Requirements

Staff are encouraged by managers to draw upon their educational background, experience, professional background, and on-the-job training to enhance their understanding and performance of QA related activities. All 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 QAMs and the Office Chiefs will discuss the training needs of QA personnel and provide training, as appropriate, to ensure that environmental data collection requirements are met. Much of the required training will be provided by USEPA.

# 4.1.4 Assurance for Grants and Contracts

Project Officers / Managers or their delegated 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 Proposal (RFPs) and Requests for Bids (RFBs) and in grant applications and/or conditions.

4.1.5 Documentation of Training

The Office Chiefs or the QAMs will keep a record of QA training taken by staff and managers responsible for environmental data generation.

# CHAPTER 5: PROCUREMENT OF ITEMS AND SERVICES

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

Procurement documents will contain technical specifications and evaluation criteria for all deliverables.

# 5.1 CONTRACTS

DEP Program Offices require or 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 Quality Management Plan of the prospective contract laboratories. Laboratories without State certification or without quality management systems and quality assurance plans 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:

QAMs review statement of work and provide QA tasks where required.

## Acquisition Plan:

QAMs or the Office Chiefs 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:

QAMs incorporate QA activities into the evaluation as needed, including QA in sample work assignments, Quality Management Plans and Quality Assurance Project Plans.

#### **RFP/RFB** Evaluation:

The QAMs or the Office Chiefs may serve on selection panels to score specified submissions.

#### Contract Award:

The QAMs or designated personnel may provide recommendations for contract awards.

# CHAPTER 6: DOCUMENTATION AND RECORDS MANAGEMENT

Maintaining important QA documents and records is a continuous process for each Program Office. This process serves as a vehicle for identifying quality-related documents and records requiring management control. Moreover, this process serves to ensure 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:

#### 6.1.1 Routine QA Operating Documents

Project or site\_specific QA documents generated as part of the program are used and stored at the DEP Headquarters Office or at the headquarters for each Program Office. Copies of documents are supplied to the appropriate DEP Regional Office for inclusion in the records of those regional offices for review by regional office staff.

Records and documents associated with a given project are the responsibility of the specific office but may, as appropriate, be maintained in duplicate by a Program Office at its headquarters. Hard copies of site or project specific information such as field sampling notes, chain-of-custody records, laboratory notes, and instrument readings will be maintained at the regional office with appropriate copies sent to the Program offices. These records provide support to the validity of the environmental data for making decisions. Projects involving the

generation of environmental data will include a QAPP and final report, as required, which should be stored together, allowing a subsequent analyzer or investigator to understand the full context of the data produced and the conclusions reached.

# 6.1.2 In-House QA Guidance Documents

Quality Assurance guidance documents developed in-house will be reviewed by the QAMs 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.

## 6.1.3 Disposition of Documents and Records

The QAMs ensures that the QMP for their respective Office is current. In the event that a QA document becomes outdated, the QAM will determine the status of the document, make recommendations, and initiate appropriate actions. Quality assurance documents will be filed at the headquarters of the appropriate Program Office. Information will be provided to regional offices as necessary.

Dated copies of all QA documents will be sent to staff involved in the data collecting activities. Updates and revisions will be provided as they are issued by the QAMs. A distribution list will be maintained and all staff on the list will be notified in writing of updates or revisions. To ensure that the correct version of the QA documents are being used, all revisions and replacements pages shall be dated and numbered. QAMs ensure that all superseded pages and documents are removed from circulation.

Final documents will be maintained by responsible staff in accordance with file retention procedures specific to each Office. 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, performance evaluation reports and environmental data.

# CHAPTER 7: COMPUTER HARDWARE AND SOFTWARE

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 Information Technology Office (ITO) complies with all State standards and regulations 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 conforms to the extent possible to all policies and guidance provided by the Governor's Office of Technology and the Information Technology Council, of which the DEP's Information Technology Office (ITO) Manager/CIO is a voting member, as those policies and guidance relate to the procurement and development of information systems for DEP.

Pages 26 and 27 of Attachment C describe in detail the mission statement, description and some specific accomplishments of ITO related to hardware and software within the DEP.

## 7.1 AGENCY STANDARDS

ITO develops DEP minimum standards for hardware and software based on the State standard. The ITO 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.

#### 7.2 SOFTWARE DEVELOPMENT

ITO staff are.primarily responsible for developing or procuring software for DEP. ITO 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 on the State contract. These procurement services will also follow established Agency, State and Federal contracting guidelines. DEP is moving to internal platform client/server technology.

# 7.3 PROCUREMENT

Hardware and application software procurement requests are routed through the ITO staff to ensure compatibility and usability prior to purchase. ITO, to ensure

that the requested hardware or software is appropriate for the intended use, evaluates the request. Non-Agency standard software and hardware requests are evaluated, on their own merits, to ensure compatibility with standards, however, selection and validation of the software remain the responsibility of the user. ITO, as a rule, does not provide technical support for non-standard hardware and software.

#### 7.4 VALIDATION OF DEP STANDARD HARDWARE AND SOFTWARE

To ensure that products meet necessary technical standards and specifications, ITO validates hardware and software. To be used as "standard" DEP tools, hardware may be required to be assembled and tested by ITO prior to being released to the user.

# 7.4.1. 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, AIRS, and ERIS.

# 7.4.2. Hardware Testing and Evaluation

DEP requires hardware to be assembled and acceptance-tested prior to use by staff. ITO also provides support for all Agency standard hardware. Testing and validation is conducted in accordance with manufacturer's specifications and industry standard practices.

# CHAPTER 8: QUALITY ASSURANCE PLANNING

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

- Program-wide and
- Project level.

#### 8.1 PROGRAM-WIDE PLANNING

8.1.1 Internal Planning

Workplans developed annually with EPA for each Program Office forms is the basis for programmatic priorities and corresponding environmentally related data collection and use activities. Using the project annual budget targeted for environmental data collection activities and guidance from EPA Region III and other agencies, the QAMs, the Office Chiefs, Office Program Managers and other designated staff set priorities. These priorities are reflected in the DEP grant Workplan processes, documenting and establishing goals, directions, resource utilization policies and budget allocations. Yearly plans are developed to describe the Workplan 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.

#### 8.1.2 Annual QA Plan

As required by the federal grant, the QAMs will prepare individual QA Reports and Workplans which summarize the past fiscal year accomplishments and outlines the planned QA actions for the upcoming fiscal year. Included in these reports will be a description of the specific audits and evaluations to be performed during the fiscal year. The reports will be submitted to the Division Director, the Office Chiefs and appropriate persons that are involved in environmental data generating activities.

#### 8.3 PROJECT LEVEL PLANNING

A project is an organized set of activities within a program. As previously discussed the Quality Assurance Project Plan (QAPP) is the primary vehicle for

ensuring adequate data quality at the project level. Using a graded approach, QA activities will be described as well-defined components of any project plan involving the collection or use of environmental data. The level of detail of the QA component will be determined by the DEP.

The QAPP will be drafted by the responsible person and reviewed by the relevent QAMs and implementing staff. Written concurrence will be obtained by the implementing staff and their immediate supervisor.

Once the draft QAPP is finalized and all staff level reviewers agree that it is complete and technically accurate, it will be forwarded to the Program QAM for review and approval. The Program Office Chief or his designee will review and approve the draft copy. Changes will be incorporated into the final draft to be submitted to the appropriate level of management for signature.

The cover page to the QAPP will contain all necessary signatures to ensure that all levels of staff and management have been made aware of the requirements.

The responsible person shall distribute all copies of the QAPP and all copies of any revisions to the QAPP.

#### CHAPTER 9: IMPLEMENTING QA PROCEDURES

This chapter of the QMP describes the processes that will be used by each Program Office for ensuring that the QA plans and procedures that comprise the quality system are effectively implemented.

#### 9.1 PROGRAM IMPLEMENTATION

The QA/QC program for each Office 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's QA as outlined in EPA QA/R-2. Any revisions to the QMP is processed in the same manner as the original documents. The QAMs provide oversight of implementation of the QMP.

The QMP contains specific activities that will ensure the generation of quality data by:

- Identifying mission elements and generating or using data for environmental decisions;
- Identifying criteria for collecting or selecting data sufficient to support environmental decisions;
- Describing procedures for the preparation, review, and approval of QAPPs;
- Outlining procedures to ensure that the work described in the QAPP is being performed according to the Plan, including evaluation activities;
- Ensuring that individuals with QA responsibilities have been properly trained; and
- Defining the level of management oversight and inspection to be provided that will be commensurate with the importance of the particular project and the intended use of the project results.

#### 9.2 PROJECT LEVEL IMPLEMENTATION

9.2.1 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 QAMs in writing through an amended QAPP.

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

9.2.2 Standard Operating Procedures (SOPs)

Many repetitive procedures that are routinely used are standardized and documented in writing as standard operating procedures (SOPs). SOPs are prepared for routinely conducted sampling, analytical, and quality control procedures. Once established, the SOPs are cited in QAPPs, contract proposals, and other similar documents.

Tasks or functions that may be effectively addressed within SOPs

include:

- Sampling network design;
- Sampling site selection;
- Sampling and analysis procedures;
- Sample collection methods and devices, containers, preservatives, holding times, handling and transportation methods;
- Documentation and chain-of-custody;
- Calibration and maintenance of instruments and equipment;
- Quality control procedures;
- Data review, reduction, and validation;
- Safety procedures; and
- Inspection and audit procedures.

#### 9.3 IMPLEMENTATION SCHEDULE

The QMP is initially reviewed by EPA Region III. Once the QMP is approved, the QAMs will track the implementation and will ensure that the collection and analyses of environmental samples are accomplished in accordance with the QMP. Decisions from environmental data based on the QMP should meet the guidelines presented herein.

QAPPs will be implemented upon approval by the responsible person and the appropriate levels of management. The Division Director or the Office Chiefs shall determine the appropriate levels of management review and approval, and the level of detail required for specific types of QAPPS. Data collection activities will not be conducted without an approved QAPP for that activity with the exception of emergencies, in which case SOPs shall be followed.

## 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. 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.

#### 10.1 ASSESSMENT TOOLS

The assessment tools for environmental programs include: management systems reviews, surveillances, audits, performance evaluations, audits of data quality, peer reviews and technical reviews, readiness reviews, and data quality assessments. This section addresses the following items pertaining to management assessment of the effectiveness of a program's quality system:

- how the process for the planning, scheduling, and implementation of assessments works, as well as how the organization will respond to needed changes, responsibilities;
- levels of participation, and authorities for all management and staff involved in the assessment process; and

how, when, and by whom actions will be taken in response to the findings of the assessment, and how the effectiveness of the response will be determined.

The DEP will use a variety of internal management and technical reviews, performance evaluations, and audits to ensure that the procedures in the QMP are implemented successfully. Personnel conducting assessmentswill be qualified, based on project-specific requirements, to perform the assigned assessment. This chapter also describes the DEP's commitment to using the results of these evaluations to make any necessary operational adjustments to the DEP's data collection and analytical procedures as well as the Quality System itself.

## 10.2 ANNUAL REVIEW OF THE DEP QUALITY MANAGEMENT PLAN

The QA practices and procedures described in this QMP will be assessed annually and revised or updated as necessary. The Division Director is responsible for coordinating this assessment, arranging for appropriate personnel to assist the QAMs with the review, and for the incorporation of any recommended changes into the document. Minor changes to the QMP will be reported to the Division Director through DEP QA annual reports. Major changes to the QMP may require a formal resubmittal to the EPA Region III. Minor changes to the QMP will be accomplished and all relevent federal agencies will be informed.

10.2.1 Management Systems Reviews (MSRs)

The focus of the MSR is on systems. The assessment seeks to determine that a quality system is established and is operating with the program in a manner such that potential vulnerabilities in environmental data beyond that of inherent error may be detected, prevented, and resolved.

An MSR is an independent assessment of an organization's QA management practices. MSRs address the effectiveness of management controls in achieving and assuring data quality, the adequacy of resources and personnel devoted to QA functions, the effectiveness of training and assessments, and the applicability of data quality requirements. The MSR process uses background documentation, file reviews, case studies, and interviews of managers and staff involved in environmental data operations to assess the effectiveness of the quality system relative to its stated objectives in the QMP. The MSR process is not an audit in the traditional sense in that it seeks to recognize noteworthy accomplishments and to identify needed improvements. Moreover, the MSR process does not judge the quality of any data or the performance of any environmental data collection activities. MSRs identify significant QA concerns and areas of needed improvement, but also point out noteworthy accomplishments.

The DEP's MSRs are initiated and conducted annually by the QAMs, who are outside the office involved with collection of environmental data. If necessary, the QAMs are assisted by the audit team assembled by the Division Director. The MSRs will examine the following elements, as applicable:

- An assessment of the overall effectiveness of the Quality Management System:
- Procedures for developing Data Quality Objectives (DQOs);

- Procedures for developing and approving QAPPs;
- The effectiveness of existing QAPP guidance and QAPPs;
- Procedures for developing and approving SOPs;
- Procedures, criteria, and schedules for conducting audits;
- Tracking systems for assuring that the QA program is operating and that corrective actions disclosed by audits have been taken;
- Responsibilities and authorities of various line managers and QA personnel for implementing the QA program;
- The degree of management; and
- The level of financial and other resources committed to implementing the QA program.

10.2.2 Technical Systems Audits (TSAs)

A Technical Systems Audit is conducted to assess the sampling and analytical quality control procedures used to generate environmental data. The DEP will use TSAs to evaluate office procedures used by DEP and procedures used by contract laboratories. TSAs may include a comprehensive, on-site, evaluation of facilities, equipment calibration, personnel qualifications and training, record keeping procedures, data validations, data management, and reporting of field and laboratory activities. Both office and laboratory TSAs may be performed.

10.2.2.1 Office TSAs

This audit will evaluate the record keeping and documentation involved in an environmental data generating activity. The auditor will review and evaluate all phases of the inspection with respect to data, documents, and records prepared and maintained by the Program Office.

10.2.2.2 Laboratory TSAs

TSAs may be conducted for DEP and contract laboratories that analyze and prepare environmental data for use in DEP programs. The primary goal of these audits will be to review the laboratory organization, operation and capabilities, determine the reliability of data, and note corrective action for any apparent deficiencies. Auditors for TSAs will be selected by the Division Director or his designee based on their technical proficiency in the subject area, and will be responsible for planning and conducting the audit and reporting the findings to the QAMs.

## 10.3 PERFORMANCE EVALUATIONS

Performance Evaluations (PEs) are conducted to assess the ability of a laboratory or field measurement system to obtain reliable data. PEs will normally be conducted at 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 specified by program requirements or on an as-needed basis depending on the specific laboratory or project involved. PEs generally will be performed annually, unless needed more frequently based on a specific need or requirement. The QAMs will determine the frequency of PEs, track, and monitor the PEs and submit the results to the Division Director and the Office Chiefs. The results of the PEs provide a means for assessing overall data integrity and may be used to evaluate analytical laboratories or sampling techniques.

#### 10.4 DATA QUALITY EVALUATIONS

Data quality requirements and evaluation methods are included in this QMP and also specified in the associated QAPP. The QMP describes the methods by which data quality evaluations will be conducted and utilized and how these evaluations relate to the DQOs.

10.4.1 Data Quality Assessments (DQAs)

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A Data Quality Assessment (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. The 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 are acceptable to the decision-maker or user for their intended use since the data are ultimately only meaningful in this context. A DQA involves a comparison of the collected data with the Data Quality Objectives (DQOs) for the project. The intended use of the data is established by the project's DQO. This evaluation and comparison will result in the determination that the data are useable for their intended purposes. Guidance for this procedure is provided in EPA QA/G-9 *Guidance for Data Quality Assessment* (July 1996).

### 10.4.2 Data Quality Audits (DQAs)

A related evaluation tool involving data review and assessment is the data quality audit which is 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 quality control 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 DQAs 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 the planning and acquisition of supplemental data for the project and potentially for other related projects. Problems identified through the DQAs may trigger the need for an MSR to determine management deficiencies or a TSA to identify technical problems.

## CHAPTER 11: CONTINUOUS QUALITY IMPROVEMENT

The Quality Assurance 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 all of its environmental sampling. Before improvements can be made, the basic system components and requirements need to be well established. The program staff realize that this may take several months or longer to accomplish.

#### 11.1 APPROACH TO IMPROVEMENT

The program QMP is the first step in the process of implementing a comprehensive and effective Quality System. The QMP serves as the framework for applying QA and QC procedures to environmental data operations. Because the task of implementing the QMP is significant and resource intensive, the Director does not expect to have all aspects of the QA system in place immediately.

Following approval of the QMP by the EPA Region III staff, the DEP program staff will work to implement, improve, and maintain the QMP.

Beyond development and implementation of the QMP, improvements to the Quality System will also occur through the evaluation of the various QA programs as 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.

#### 11.2 IMPROVEMENT LEADERS

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

## LIST OF REFERENCES

EPA Order 5360, Policy and Program Requirements to Implement the Mandatory Quality Assurance Program, USEPA, April 1984.

*EPA Requirements for Quality Management Plans* (Draft Interim Final), EPA QA/R-2, USEPA, Quality Assurance Management Staff, August 1984.

Standard Operating Procedure for Quality Management Plan Reviews, QAD/96-1, USEPA, Quality Assurance Division, January 1996.

*EPA Information Security Manual* (Craft), USEPA Office of Information and Resources Management, June 1994.

USEPA Acquisition Regulations, USEPA Office of Administration and Resources Management.

*EPA 1900 - Contracts Management Manual*, USEPA Office of Administration, January 1991.

USEPA 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, USEPA Office of Administration and Resources Managements, EPA 202/8-94/001, May 1994.

Region III Order 5361.S, Location Identification Policy and Responsibilities, USEPA Region III, Office of Policy & Management

# SEE ATTACHMENTS

# QUALITY MANAGEMENT PLAN IDENTIFICATION AND APPROVAL FORM

Document title:

**Quality Management Plan** 

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