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EPA Requirements for Quality Management Plans

EPA QA/R-2

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Management Plan as a means of documenting how an organization will plan, implement, and assess the effectiveness of its quality assurance and quality control operations applied to environmental programs. The process of planning, implementing, and assessing these management systems is called *quality management* and the product of this process is called the *Quality System*. The Quality Management Plan is part of the mandatory Agency-wide Quality System that requires all organizations performing work for EPA to develop and operate management processes and structures for assuring that data or information collected are of the needed and expected quality for their desired use.

This document provides the development and content requirements for Quality Management Plans for organizations that conduct environmental data operations for EPA through contracts, assistance agreements, and interagency agreements; however, it may be used by EPA as well. It contains the same requirements as Chapter 3 of the EPA Order 5360 A1 (2000), *EPA Quality Manual for Environmental Programs*, for EPA organizations.

This document is one of the *U.S. Environmental Protection Agency Quality System Series* documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. Questions regarding this document or other *Quality System Series* documents should be directed to the Quality Staff:

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Copies of EPA *Quality System Series* documents may be obtained from the Quality Staff directly or by downloading them from its Home Page:

www.epa.gov/quality

ACKNOWLEDGMENTS

This document reflects the collaborative efforts of many quality management professionals who participate in the challenge for continual improvement in quality systems supporting environmental programs. These individuals, representing the EPA, other Federal agencies, State and local governments, and private industry, reflect a diverse and broad range of needs and experiences in environmental data collection programs. Their contributions and the comprehensive reviews during the development of this document are greatly appreciated.

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

The U.S. Environmental Protection Agency (EPA) annually spends several hundred million dollars in the collection of environmental data for scientific research and regulatory decision making. In addition, non-EPA organizations may spend as much as an order of magnitude more each year to respond to Agency requirements. Furthermore, as EPA is increasingly involved in the use of environmental technology for pollution control and waste clean-up, the use of particular technologies is often specified in permits and regulations. If decision makers are to have the necessary confidence in the quality of environmental data used to support their decisions or that environmental technology successfully performed its intended role, there must be a structured process for quality in place.

A structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications is called a quality system. All organizations conducting environmental programs funded by EPA are required to establish and implement a quality system. EPA organizations are required to document their quality system in a Quality Management Plan through EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System* (EPA 2000). Non-EPA organizations funded by EPA are required to document their quality system in a Quality Management Plan (or equivalent document)[1] through:

- 48 CFR 46, for contractors;
- 40 CFR 30, 31, and 35 for assistance agreement recipients; and
- other mechanisms, such as consent agreements in enforcement actions.

A Quality Management Plan documents how an organization structures its quality system and describes its quality policies and procedures, criteria for and areas of application, and roles, responsibilities, and authorities. It also describes an organization's policies and procedures for implementing and assessing the effectiveness of the quality system. This document describes the elements of a quality system that must be documented in a Quality Management Plan to comply with EPA requirements.

[1]An equivalent document may not be called a Quality Management Plan but still would document an organization's quality system and address the required quality management practices described in this document.

This requirements document presents specifications and instructions for the information that must be contained in a Quality Management Plan for organizations conducting environmental programs funded by EPA. The document also discusses the procedures for review, approval, implementation, and revision of Quality Management Plans. Users of this document should assume that all of the elements described herein are required in a Quality Management Plan unless otherwise directed by EPA.

1.2 QUALITY MANAGEMENT PLANS, THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4-1994

EPA Order 5360.1 A2 and the applicable Federal regulations (defined above) establish a mandatory Quality System that applies to all EPA organizations and organizations that are funded by EPA. Components of this system are illustrated in Figure 1. Organizations must ensure that data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use and that environmental technologies are designed, constructed, and operated according to defined expectations. Quality system documentation (e.g., the Quality Management Plan) is a key component of the EPA Quality System as shown in Figure 1.

EPA policy is based on the national consensus standard, ANSI/ASQC E4-1994, *Specifications and Guidelines for Environmental Data Collection and Environmental Technology Programs*. The ANSI/ASQC E4-1994 standard describes the necessary management and technical elements for developing and implementing a quality system. This standard recommends using a tiered approach to a quality system. The standard recommends first documenting each organization-wide quality system in a Quality Management Plan or Quality Manual (to address requirements of *Part A: Management Systems* of the standard) and then documenting the applicability of the quality system to technical activity-specific efforts in a Quality Assurance Project Plan (QA Project Plan) or similar document (to address the requirements of *Part B: Collection and Evaluation of Environmental Data* of the standard). EPA has adopted this tiered approach for its mandatory Agency-wide Quality System. This document addresses Part A requirements of the standard.

The Quality Management Plan may be viewed as the 'umbrella' document under which individual projects are conducted. The Quality Management Plan is then supported by project-specific QA Project Plans. A QA Project Plan is the 'blueprint' by which individual projects involving environmental data are implemented and assessed and how specific quality assurance (QA) and quality control (QC) activities will be applied during a particular project. EPA requirements for QA Project Plans are defined in *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (EPA 2001). In some cases, a QA Project Plan and a Quality Management Plan may be combined into a single document that contains both organizational and project-specific elements. The QA Manager for the EPA organization sponsoring the work has the authority to determine when a single document is applicable and will define the content requirements of such a document.

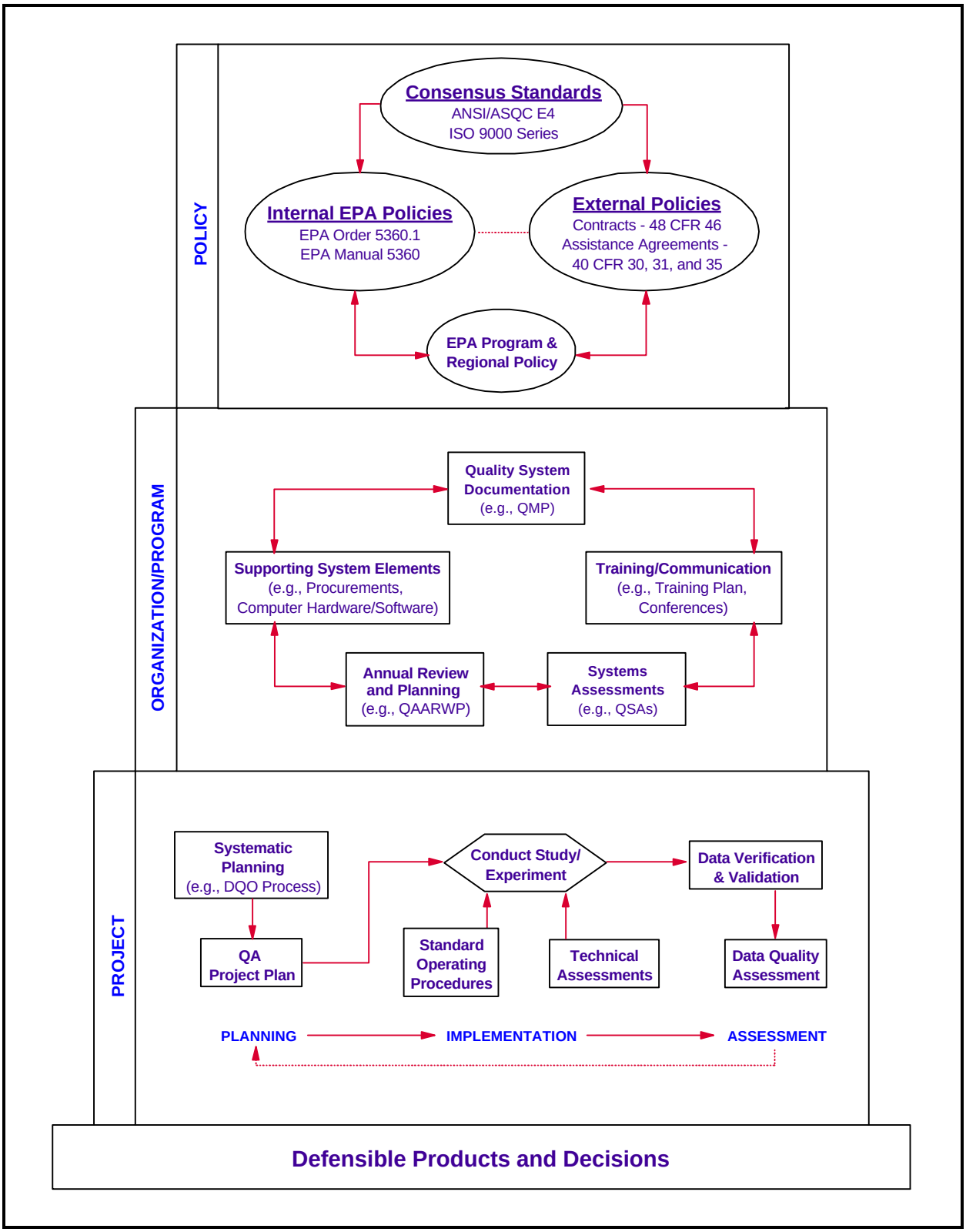

Figure 1. EPA Quality System Components and Tools

1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM

Implementation of the EPA Quality System is based on the principle of graded approach. This principle recognizes that a 'one size fits all' approach to quality requirements will not work in an organization as diverse as EPA so managerial controls are applied according to the scope of the program and/or the intended use of the outputs from a process. For example, the quality expectations of a fundamental research program are different from that of a regulatory compliance program because the purpose or intended use of the data is different. Applying a graded approach means that quality systems for different organizations and programs will vary according to the specific objectives and needs of the organization. The specific application of the graded approach principle to Quality Management Plans is described in Section 2.4.2.

1.4 INTENDED AUDIENCE

This document specifies the requirements for developing a Quality Management Plan for organizations that conduct environmental data operations funded by EPA through contracts, financial assistance agreements, and interagency agreements. EPA organizations may also use this document to develop their Quality Management Plans since this document is clearer and more user-friendly than the equivalent requirements defined in Section 3.3 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs* (an internal policy document). However, the preparation, submission, review, and approval requirements for EPA organizations are still contained in Section 3.2 of EPA Order 5360 A1 as these represent internal EPA policy.

1.5 PERIOD OF APPLICABILITY

This document shall be valid for a period of up to five years from the official date of publication. After five years, it shall either be reissued without change, revised, or withdrawn from the EPA Quality System.

1.6 ADDITIONAL RESOURCES

EPA has issued a checklist for reviewing Quality Management Plans that can be used to verify if the requirements defined in this document are satisfied. This checklist is available on the Quality Staff website, www.epa.gov/quality/tools-org.html#qmp.

1.7 SUPERSESSION

This document replaces QAMS-004/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans* (EPA 1980) in its entirety.

CHAPTER 2

QUALITY MANAGEMENT PLAN REQUIREMENTS

2.1 POLICY

Quality systems supporting environmental programs involving environmental data or technology conducted by EPA organizations or by organizations funded by EPA shall be covered by an Agency-approved Quality Management Plan.

2.2 PURPOSE

A Quality Management Plan is a management tool that documents an organization's quality system for planning, implementing, documenting, and assessing the effectiveness of activities supporting environmental data operations and other environmental programs. The Quality Management Plan is used to demonstrate conformance to Part A requirements of ANSI/ASQC E4-1994.

2.3 APPLICABILITY

These requirements apply to all organizations conducting environmental programs funded by EPA that acquire, generate, compile, or use environmental data and technology. These requirements apply to all work performed through contracts, cooperative agreements, interagency agreements, State-EPA agreements, State, local, and Tribal Financial Assistants/Grants (including Performance Partnership Grants and Agreements), Research Grants, and in response to statutory or regulatory requirements and consent agreements. These requirements shall be negotiated into interagency agreements, including sub-agreements, and, in some cases, included in enforcement consent agreements and orders. Where specific Federal regulations require the application of QA and QC activities (see Section 1.1), Quality Management Plans shall be prepared, reviewed, and approved in accordance with the specifications contained in this document unless explicitly superseded by regulation.

2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS

2.4.1 General Content

The Quality Management Plan documents the quality management practices which are critical to a quality system. Specific Quality Management Plan content requirements are described in Chapter 3. Each organization should evaluate these requirements for applicability to their quality system. Where a particular element is not relevant, an explanation of why it is not relevant must be provided in the Quality Management Plan. Also, if the Quality Management Plan preparer or EPA organization sponsoring the work determines that additional quality management

elements are useful or necessary for an adequate quality system, these elements should be discussed in the Quality Management Plan.

2.4.2 Level of Detail

The Quality Management Plan should describe a Quality System that is designed to support the objectives of the organization. The level of effort expended to develop a Quality Management Plan should be based on the scope of the program. For example, large grants to a State government may require a comprehensive quality system and Quality Management Plan, whereas smaller grants for programs with relatively less significant impacts may require less substantial documentation.

The Quality Management Plan must be sufficiently inclusive, explicit, and readable to enable both management and staff to understand the priority which management places on QA and QC activities, the established quality policies and procedures, and their respective quality-related roles and responsibilities. The Quality Management Plan must be written so that an assessment of the suitability and effectiveness of the organization's quality system can be accomplished. Such assessments will enable management to determine if the quality system meets the needs of the organization. The Quality Management Plan should be focused on the processes and procedures used to plan, implement, and assess the programs to which it is applied, and must include definitions of appropriate authorities and responsibilities for managers and staff.

2.5 QUALITY MANAGEMENT PLAN PREPARATION[2]

An organization's senior manager is responsible for assuring the preparation of a Quality Management Plan to cover all environmental programs supported or undertaken by the organization. Senior management, i.e., the executives and managers who are responsible and accountable for mission accomplishment and overall operations of the organization, is responsible for ensuring that the Quality Management Plan is prepared and that the quality system documented in the Quality Management Plan satisfies all EPA policy requirements and meets all statutory, contractual, and assistance agreement requirements for EPA work.

While senior management is responsible for the preparation of the Quality Management Plan, the actual preparation may be assigned to the organization's staff so long as it is assured that all managers support the effort; for example, the preparation of the Quality Management Plan may be directed by the QA Manager of the organization. However, it is essential that all management levels understand fully the content of the Quality Management Plan and concur with its implementation.

[2]Specific preparation, submission, review, and approval requirements for EPA organizations are contained in Section 3.2 of EPA Order 5360 A1 (EPA 2000) as these represent internal EPA policy.

2.6 QUALITY MANAGEMENT PLAN SUBMISSION AND APPROVAL

The Quality Management Plan must be approved and signed by the senior management of the organization. This will certify that the organization has conducted an internal review of the Quality Management Plan and that management has concurred with its contents.

When a Quality Management Plan is required either by statute, contractual requirement, or assistance agreement condition, the Quality Management Plan must be submitted for review and approval to the EPA official responsible for the work. The EPA official may include the contracting officer's representative (such as the project officer, work assignment manager, or delivery order project office), the award official, and the EPA QA Manager. For example, the review and approval of a State Quality Management Plan that has been submitted as part of a request for an assistance agreement may be performed by the QA Manager of the office awarding the assistance agreement.

EPA approval of a Quality Management Plan will be valid for no more than five years for State, local, and Tribal governments or the length of the extramural agreement for all other extramural agreement holders. The period for which a Quality Management Plan is valid is defined in the Quality Management Plan of the EPA organization sponsoring the work.

2.7 QUALITY MANAGEMENT PLAN REVISIONS

Each organization shall review its Quality Management Plan at least annually to reconfirm the suitability and effectiveness of the approved quality management practices. The process of developing, annually reviewing, and revising (as needed) the Quality Management Plan provides an opportunity for management and staff to clarify roles and responsibilities, address problem areas, and institutionalize improvements. Having an accurate Quality Management Plan at all times is an essential element in every quality system, thus changes in QA policy and procedures shall be documented in the Quality Management Plan in a timely fashion.

In general, a copy of any Quality Management Plan revision(s) made during the year should be submitted to EPA as a report when such changes occur. However, if significant changes have been made to the quality system that affect the performance of work for the Agency, it may be necessary to re-submit the entire Quality Management Plan to EPA for re-approval. Conditions requiring the revision of an approved Quality Management Plan include:

- expiration of the five-year life span of the Quality Management Plan;
- major changes in mission and responsibilities, such as changes in the delegation status of a program;
- re-organization of existing functions that affect programs covered by the Quality Management Plan; and
- assessment findings requiring corrective actions and response.

All appropriate personnel in the organization performing work covered by the scope of the Quality Management Plan shall be notified of changes to the quality system and the Quality Management Plan to keep them informed of the current requirements. This practice should also include active sub-contractors for relevant work.

CHAPTER 3

QUALITY MANAGEMENT PLAN ELEMENTS

3.1 CONTENT REQUIREMENTS

The Quality Management Plan documents management practices, including QA and QC activities, used to ensure that the results of technical work are of the type and quality needed for their intended use. Accordingly, the Quality Management Plan documents:

- the mission and quality policy of the organization;
- the specific roles, authorities, and responsibilities of management and staff with respect to QA and QC activities;
- the means by which effective communications with personnel actually performing the work are assured;
- the processes used to plan, implement, and assess the work performed;
- the process by which measures of effectiveness for QA and QC activities will be established and how frequently effectiveness will be measured; and
- the continual improvement based on lessons learned from previous experience.

The Quality Management Plan reflects the organization's commitment to quality management principles and practices, tailored, when appropriate, by senior management to meet the organization's needs.

The elements to be addressed in a Quality Management Plan include: management and organization; quality system description; personnel qualifications and training; procurement of items and services; documentation and records; computer hardware and software; planning; implementation of work processes; assessment and response; and quality improvement. Specific requirements for each of these elements are described below in Sections 3.2 through 3.11. Items specific to Quality Management Plans developed by EPA organizations under EPA Order 5360.1 A2 (EPA 2000) are noted by "EPA Quality Management Plans." Organizations funded by EPA do not have to address these EPA-specific items.

It is preferable, but not necessary, that the Quality Management Plan address the specifications in the same order as presented below to ensure uniformity and a consistent and complete review. If an existing, approved Quality Management Plan adequately addresses each of these topics, it should not be rewritten simply to conform to the outline provided here.

3.2 MANAGEMENT AND ORGANIZATION

Purpose – To document the overall policy, scope, applicability, and management responsibilities of the organization's quality system.

Specifications – Provide the following:

- an approval page for the signatures of the organization's management and QA manager. The approval page may be part of a title page or a separate sheet following the title page. If EPA approval of the Quality Management Plan is required, the approval page shall include a section for the signature of the EPA official (see Section 2.6). For EPA Quality Management Plans[3], the approval page shall contain the signatures of the organization's senior manager, senior line management (as appropriate), the QA Manager, the Director of the Quality Staff, and the Assistant Administrator of the Office of Environmental Information;

- a statement of the organization's policy on quality assurance, including:

  - the importance of QA and QC activities to the organization and why,
  - the general objectives and goals of the quality system, and
  - the policy for resource allocation for the quality system (EPA Quality Management Plans must discuss personnel, intramural and extramural funding, and travel resources);

- an organization chart that identifies all of the components of the organization and, in particular, the organizational position and lines of reporting for the QA Manager (or similar position such as a Quality Manager) and any QA staff;

- a discussion of the authorities of the QA Manager and any other QA staff that also:

  - documents the organizational independence of the QA Manager from groups generating, compiling, and evaluating environmental data, and
  - indicates how the organization will ensure that QA personnel will have access to the appropriate levels of management in order to plan, assess, and improve the organization's quality system;

- a discussion of the technical activities or programs that are supported by the quality system including:

  - the specific programs that require quality management controls,

[3]Organizations funded by EPA do not have to address these EPA-specific elements.

- where oversight of delegated, contracted, or other extramural programs is needed to assure data quality, and
- where and how internal coordination of QA and QC activities among the group's organizational units needs to occur;

- a discussion of how management will assure that applicable elements of the quality system are understood and implemented in all environmental programs; and

- a discussion of the organization's process for resolving disputes regarding quality system requirements, QA and QC procedures, assessments, or corrective actions (requirement for EPA Quality Management Plans only).

3.3 QUALITY SYSTEM COMPONENTS

Purpose – To document how an organization manages its quality system and defines the primary responsibilities for managing and implementing each component of the system.

Specifications – Provide the following:

- a description of the organization's quality system that includes the principal components of the system and the roles and implementation responsibilities of management and staff with regards to these components. These components include, but are not limited to:

  - quality system documentation
  - annual reviews and planning
  - management assessments
  - training
  - systematic planning of projects
  - project-specific quality documentation
  - project and data assessments;

- a list of the tools for implementing each component of the quality system. These tools include, but are not limited to:

  - Quality Management Plans (quality system documentation),
  - Quality Systems Audits (management assessments),
  - Training Plans (training),
  - QA Project Plan (project-specific quality documentation),
  - Data Verification and Validation (data assessments);

- a list of any components of the organization that develop Quality Management Plans (or equivalent document) in support of the organization's Quality System and the review and approval procedures for such documentation; and

- a discussion of how roles and responsibilities for the principal components of the Quality System are incorporated into performance standards (requirement for EPA Quality Management Plans only).

3.4 PERSONNEL QUALIFICATION AND TRAINING

Purpose – To document the procedures for assuring that all personnel performing work for an organization have the necessary skills to effectively accomplish their work.

Specifications – Provide the following:

- a statement of the policy regarding training for management and staff;

- a description of the process(es), including the roles, responsibilities, and authorities of management and staff, for:

  - identifying, ensuring, and documenting that personnel have and maintain the appropriate knowledge, skill, and statutory, regulatory, professional or other certifications, accreditations, licenses, or other formal qualification necessary, and

  - identifying the need for retraining based on changing requirements.

3.5 PROCUREMENT OF ITEMS AND SERVICES

Purpose – To document the procedures for purchased items and services that directly affect the quality of environmental programs.

Specifications –

Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, pertaining to all appropriate procurement documents or extramural agreements, including grants, cooperative agreements, and contracted and subcontracted activities, involving or affecting environmental programs, for:

- reviewing and approving procurement documents (and any changes to these documents) to ensure that procurement documents are accurate, complete, and clearly describe:

- the item or service needed,
- the associated technical and quality requirements,
- the quality system elements for which the supplier is responsible, and
- how the supplier's conformance to the customer's requirements will be verified;

- review and approval of all applicable responses to solicitations to ensure that these documents:
  - satisfy all technical and quality requirements, and
  - provide evidence of the supplier's capability to satisfy EPA quality system requirements as defined in the extramural agreement or applicable Federal Regulation (requirement for EPA Quality Management Plans only);

- ensuring that procured items and services are of acceptable quality, including the review of objective evidence of quality for applicable items and services furnished by suppliers and subcontractors, source selection, source inspections, supplier audits, and examination of deliverables;

- review and approval procedures for mandatory quality-related documentation (e.g., Quality Management Plans or QA Project Plans) from suppliers (requirement for EPA Quality Management Plans only);

- policies and criteria for delegations of EPA authority to review and approve mandatory quality-related documentation (e.g., Quality Management Plans or QA Project Plans) from suppliers consistent with Chapter 2.2 of EPA Order 5360 A1 (requirement for EPA Quality Management Plans only); and

- ensuring that EPA quality-related contracting policies, as defined by the Federal Acquisition Regulations, Office of Federal Procurement Policy, and the EPA Contracts Management Manual [EPA Order 1900 (EPA 1998)], are satisfied (requirement for EPA Quality Management Plans only).

3.6 DOCUMENTS AND RECORDS

Purpose – To document appropriate controls for quality-related documents and records determined to be important to the mission of the organization.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- identifying quality-related documents and records (both printed and electronic) requiring control;

- preparing, reviewing for conformance to technical and quality system requirements, approving, issuing, using, authenticating, and revising documents and records;

- ensuring that records and documents accurately reflect completed work;

- maintaining documents and records including transmittal, distribution, retention (including retention times), access, preservation (including protection from damage, loss, and deterioration), traceability, retrieval, removal of obsolete documentation, and disposition;

- ensuring compliance with all applicable statutory, regulatory, and EPA requirements for documents and records [EPA Quality Management Plans shall ensure compliance with EPA Order 2160 (EPA 1984) and EPA Directive 2100, Chapter 10 (EPA 1998)]; and

- establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records.

3.7 COMPUTER HARDWARE AND SOFTWARE

Purpose – To document how the organization will ensure that computer hardware and software satisfies the organization's requirements.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- developing, installing, testing (including verification and validation), using, maintaining, controlling, and documenting computer hardware and software used in environmental programs to ensure it meets technical and quality requirements and directives from management [EPA Quality Management Plan specifications must be consistent with EPA Directive 2100 (EPA 1998)];

- assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance;

- evaluating purchased hardware and software to ensure it meets user requirements and complies with applicable contractual requirements and standards;

- ensuring that data and information produced from, or collected by, computers meet applicable information resource management requirements and standards; and

- ensuring that applicable EPA requirements for information resources management are addressed [EPA Directive 2100 (EPA 1998)] including security and privacy requirements (requirement for EPA Quality Management Plans only).

Computer software covered by this requirement includes, but is not limited to, design, data handling, data analysis, modeling of environmental processes and conditions, operations, or process control of environmental technology system (including automated data acquisition and laboratory instrumentation), data bases containing environmental data.

3.8 PLANNING

Purpose – To document how individual data operations will be planned within the organization to ensure that data or information collected are of the needed and expected quality for their desired use.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, for:

- planning environmental data operations using a systematic planning process[4] which includes:
  - the identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers);
  - a description of the project goal, objectives, and questions and issues to be addressed;
  - the identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory and contractual requirements);
  - the identification of the type and quantity of data needed and how the data will be used to support the project's objectives;
  - the specification of performance criteria for measuring quality;

[4]EPA has developed a systematic planning process called the Data Quality Objectives (DQO) Process [See the *EPA Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000)]. While not mandatory, the DQO Process is the recommended planning approach for many EPA data collection activities.

- the specification of needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.);

- a description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection; and

- a description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, verification, validation), and assessed against its intended use and the quality performance criteria;

• developing, reviewing, approving, implementing, and revising a QA Project Plan or equivalent planning document [see *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (EPA 2001)]; and

• evaluating and qualifying data collected for other purposes or from other sources, including the application of any statistical methods, for a new use.

3.9 IMPLEMENTATION OF WORK PROCESSES

Purpose – To document how work processes will be implemented within the organization to ensure that data or information collected are of the needed and expected quality for their desired use.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff for:

• ensuring that work is performed according to approved planning and technical documents;

• identification of operations needing procedures (e.g., standardized, special, or critical operations), preparation (including form, content, and applicability), review, approval, revision, and withdrawal of these procedures; and policy for use; and

• controlling and documenting the release, change, and use of planned procedures, including any necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

3.10 ASSESSMENT AND RESPONSE

Purpose – To document how the organization will determine the suitability and effectiveness of the implemented quality system and the quality performance of the environmental programs to which the quality system applies.

Specifications – Describe or reference the process(es), including the roles, responsibilities, and authorities of management and staff, pertaining to both management and technical assessments for:

- assessing the adequacy of the quality system at least annually;
- planning, implementing, and documenting assessments and reporting assessment results to management including how to select an assessment tool, the expected frequency of their application to environmental programs, and the roles and responsibilities of assessors;
- determining the level of competence, experience, and training necessary to ensure that personnel conducting assessments are technically knowledgeable, have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed;
- ensuring that personnel conducting assessments have sufficient authority, access to programs, managers, documents, and records, and organizational freedom to:
  - identify both quality problems and noteworthy practices,
  - propose recommendations for resolving quality problems, and
  - independently confirm implementation and effectiveness of solutions;
- management's review and response to findings;
- identifying how and when corrective actions are to be taken in response to the findings of the assessment, ensuring corrective actions are made promptly, confirming the implementation and effectiveness of any corrective action, and documenting (including the identification of root causes, the determination of whether the problem is unique or has more generic implications, and recommendation of procedures to prevent recurrence) such actions; and
- addressing any disputes encountered as a result of assessments.

Available assessment tools include quality systems audits, management systems reviews, peer reviews, technical reviews, performance evaluations, data quality assessments, readiness reviews, technical systems audits, and surveillance.

3.11 QUALITY IMPROVEMENT

Purpose – To document how the organization will improve the organization's quality system.

Specifications – Identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities and describe the process to ensure continuous quality improvement, including the roles and responsibilities of management and staff, for:

- ensuring that conditions adverse to quality are:
  - prevented,
  - identified promptly including a determination of the nature and extent of the problem,
  - corrected as soon as practical, including implementing appropriate corrective actions and actions to prevent reoccurrence,
  - documenting all corrective actions, and
  - tracking such actions to closure;

- encouraging staff at all levels to establish communications between customers and suppliers, identify process improvement opportunities, and identify and offer solutions to problems.

REFERENCES

40 CFR 30, Code of Federal Regulations, "Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

40 CFR 31, Code of Federal Regulations, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."

40 CFR 35, Code of Federal Regulations, "State and Local Assistance."

48 CFR 46, Code of Federal Regulations, "Federal Acquisition Regulations."

ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American National Standard, January 1995.

EPA Directive 2100 (1999), *Information Resources Management Policy Manual*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 1900 (February 1998), *Contracts Management Manual*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2160 (July 1984), *Records Management Manual*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 5360 A1 (May 2000), *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 5360.1 A2 (May 2000), *Policy and Program Requirements for the Mandatory Quality Assurance Program*, U.S. Environmental Protection Agency, Washington, DC.

U.S. Environmental Protection Agency, 2001. *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*, EPA/240/B-01/003, Office of Environmental Information.

U.S. Environmental Protection Agency, 2000. *Guidance for the Data Quality Objectives Process (QA/G-4)*, EPA/600/R-96/055, Office of Environmental Information.

U.S. Environmental Protection Agency, 1980. *Interim Guidelines and Specifications for Preparing Quality Assurance Program Plans*, QAMS-004/80, Office of Research and Development.

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APPENDIX A

TERMS AND DEFINITIONS

assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, 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 (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

data quality assessment - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

environmental conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

environmental data - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

environmental data operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

environmental programs - 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 environmental technologies; and laboratory operations on environmental samples.

environmental technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply

to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

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 the results and the degree of confidence needed in the quality of the results.

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 activity to verify conformance to specific requirements.

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 systems review - 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.

objective evidence - any documented statement of fact, other information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

organization - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

peer review - a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A 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.

performance evaluation - 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.

process - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

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

quality assurance project plan - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

quality control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

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 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, documentation, and assessment) pertaining to the quality system.

quality management plan - a 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 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 provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.

readiness review - a systematic, documented review of the readiness for the start-up 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.

record - a completed document that provides objective evidence of an item or process. Records may include photographs, drawings, magnetic tape, and other data recording media.

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

specification - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

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 (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

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 original work. The review is 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 - 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.