October 27, 1998

MEMORANDUM

SUBJECT: Review of External Review Draft Final of *EPA Requirements for Quality Management Plans (QA/R-2)*

FROM: Nancy W. Wentworth, Director /s/
Quality Assurance Division (8724R)

TO: EPA QA Managers
External Reviewers

Attached for your review is the External Review Draft Final, *EPA Requirements for Quality Management Plans (QA/R-2),* dated October 1998. This document formally defines the EPA requirements for Quality Management Plans (QMPs) developed by non-EPA organizations. EPA policy (EPA Order 5360.1 CHG 1, July 1998) requires that all organizations conducting environmental programs by or on behalf of EPA establish and implement effective quality systems to support these programs. Part of this policy is the requirement to document these quality systems in an EPA-approved QMP.

This external review is the last step before this document is finalized and invoked in EPA financial agreements to satisfy the requirements of this policy. Earlier versions of R-2 have been widely circulated inside and outside of the Agency which have yielded many helpful comments. This draft final incorporates revisions necessary to assure conformance with EPA Order 5360.1 CHG 1.

The QMP is a management "blueprint" for applying quality assurance and quality control to environmental programs. The QMP describes an organization's quality system for planning, implementing, and assessing the effectiveness of activities supporting environmental data operations and other environmental programs. The development, review, approval, and implementation of the QMP is required by the mandatory Agency-wide Quality System defined by the Order. This policy requires all organizations performing environmental programs for EPA to

develop and implement procedures and processes to ensure that data collected or compiled for use in Agency decision making are of the type and quality needed and expected for their intended use.

EPA's Agency-wide Quality System 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 defines the requisite management and technical elements necessary to develop and implement a quality system for an organization's environmental programs. The ANSI/ASQC E4 standard requires a QMP or Quality Manual, and the requirements given in this document are consistent with the E4 standard. EPA has invoked ANSI/ASQC E4-1994 through 48 CFR Part 46 for contracts (to be issued shortly) and 40 CFR Part 30 for grants and cooperative agreements to institutions of higher education, hospitals, and other non-profit recipients of financial assistance. The current quality assurance requirements in 40 CFR Part 31, for State, local, and Tribal governments, allows EPA flexibility in defining an acceptable QA program. It is EPA policy that an "acceptable QA program" is one that conforms to the E4 standard. While 40 CFR Part 31 does not currently invoke E4, it is expected to be revised in the future to specifically invoke E4. Compliance with the requirements of this document will be considered consistent with the QMP requirements of E4. In the meantime, the Office of Grants and Debarment will provide standard terms and conditions that address QMP documentation requirements for assistance agreements covered by 40 CFR Part 31.

Please note that this document will not undergo a review through the Federal Register since EPA is invoking this document as a method for complying with the requirements of E4. Also note that the content of this document has undergone an Agency-wide review and has been issued as internal policy as Chapter 4 of EPA Order 5360, *The EPA Quality Manual for Environmental Programs* (July 1998). In addition, this document will be supplemented by the *EPA Guidance for Quality Management Plans (QA/G-2)* (under development) which provides suggestions on preparing, reviewing, and implementing QMPs. Copies of any of these references and additional copies of this review document are available on the world wide web at "es.epa.gov/ncerqa/qa/index.html" or may be obtained directly from EPA's Quality Assurance Division (202/564-6830).

In order to complete a comprehensive peer review of this document, I ask that you carefully review the document to answer the following questions:

- Does R-2 conform to the requirements defined by ASQC/ANSI E4-1994?

- Are there any quality management processes missing from the document?

- Is the text readable and clear in its meaning? If the text is unclear, please provide alternative language to clarify the current text.

Please submit your comments by November 30, 1998 to:

QMP Requirement Comments
Quality Assurance Division (8724R)
U.S. Environmental Protection Agency
401 M. Street, SW
Washington, DC 20460

In addition, comments may be faxed to (202) 565-2441, ATTN: QMP Requirements Comments or e-mailed to ord-qad@epa.gov.

I appreciate your time spent in reviewing this document. Your input is very important. I strongly believe that these requirements will assist both EPA and our extramural agreement holders in ensuring that data collected or complied for EPA are of the type and quality needed to support timely, cost-effective decision making.

Attachment

EPA REQUIREMENTS FOR QUALITY MANAGEMENT PLANS

EPA QA/R-2

United States Environmental Protection Agency
Quality Assurance Division (8724R)
401 M Street, SW
Washington, DC 20460

EXTERNAL REVIEW DRAFT FINAL

OCTOBER 1998

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Management Plan (QMP) as a means of documenting how an organization will plan, implement, and assess the effectiveness of quality assurance (QA) and quality control (QC) 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 development, review, approval, and implementation of the QMP 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. The QMP is an integral part of the fundamental principles of Quality Management which form the foundation of the Agency's Quality System.

This document contains essentially the same requirements as Chapter 3 of the EPA Order 5360 (July 1998), *EPA Quality Manual for Environmental Programs*, for EPA organizations. This document provides the QMP requirements in an external publication primarily for non-EPA organizations that conduct environmental data operations in behalf of EPA through contracts, assistance agreements, and interagency agreements; however, it may be used by EPA as well. A companion document, *EPA Guidance for Quality Management Plans (QA/G-2),* is currently being developed to provide guidance on satisfying the requirements of this document.

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:

U.S. EPA
Quality Assurance Division (8724R)
401 M Street, SW
Washington, DC 20460
Phone: (202) 564-6830
FAX: (202) 565-2441
e-mail: ord-qad@epa.gov

Copies of EPA *Quality System Series* documents may be obtained from the Quality Assurance Division or by downloading them from the QAD Home Page at:

URL Address: http://es.epa.gov/ncerqa/qa/index.html

ACKNOWLEDGMENTS

This document reflects the collaborative efforts of many quality management professionals throughout the Environmental Protection Agency, who are participating in the challenge for continuous improvement in quality systems supporting environmental programs. These individuals, representing the EPA Regional Offices, Program Office organizations, and research and development centers and laboratories, provide a diverse and broad range of needs and experiences in environmental data collection programs. Their contributions and the comprehensive reviews provided by members of the EPA quality community during the development of this document are greatly appreciated.

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

Environmental programs conducted in behalf of the U.S. Environmental Protection Agency (EPA) involve many diverse activities that address complex environmental issues. The EPA annually spends several hundred million dollars in the collection of environmental data[1] for scientific research and regulatory decision-making. In addition, the regulated community may spend as much as an order of magnitude more each year to respond to Agency compliance requirements. Furthermore, EPA is increasingly involved in the use of environmental technology for pollution control and waste clean-up, often specifying the use of particular technologies in permits and regulations.

Environmental data are critical inputs to decisions involving the protection of the public and the environment from the adverse effects of pollutants from natural and man-made sources. Such sources may include waste operations and industrial discharges. Similarly, environmental data are key inputs to decisions and actions pertaining to environmental protection efforts in air, land, forests, fresh water, oceans, estuaries, and ground water. The success of environmental technology in abating pollutant emissions and effluent discharges, or in remediating waste sites, depends largely on the design of the technology, its proper fabrication and construction, and its proper operation. Consequently, quality assurance (QA) and quality control (QC) practices are needed to ensure that environmental technology successfully performs its intended role.

It is EPA policy (EPA Order 5360.1 CHG 1) that all organizations conducting environmental programs by or on behalf of EPA establish and implement effective quality systems to support those programs. Part of this quality system is the requirement to document their quality system[2] in an EPA-approved Quality Management Plan (QMP). This requirement is externalized through several mechanisms, including

- 48 CFR Part 46, Federal Acquisition Regulations, for contractors;
- 40 CFR Parts 30, 31, and 35 for assistance agreement recipients;

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[1]Environmental data include any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes and conditions and effects of pollutants on human health and the ecology, including results from laboratory analyses or from experimental systems representing such processes and conditions.

[2]A quality system is a structured and documented management system describing the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications. A more complete definition is given in the appendix.

- and other mechanisms, such as consent agreements in enforcement actions.

The QMP is the blueprint for how the organization will plan, implement, and assess its quality system for the environmental work to be performed. The QMP defines an organization's QA-related:

- policies and procedures,
- criteria for and areas of application, and,
- roles, responsibilities, and authorities.

1.2 QMPs, THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4

EPA Order 5360.1 CHG 1 establishes a mandatory Agency-wide Quality System that applies to all organizations performing work for EPA as well as to EPA. (The authority for the requirements defined by the Order are contained in the applicable regulations for extramural agreements.) These 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. The QMP 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 provides the basis for the quality system for an organization's environmental programs. The document provides the requisite management and technical area elements necessary for developing and implementing a quality system. The document first describes the quality management elements that are generally common to environmental problems, regardless of their technical scope. The document then discusses the specifications and guidelines that apply to project-specific environmental activities involving the generation, collection, analysis, evaluation, and reporting of environmental data. Finally, the document contains the minimum specifications and guidelines that apply to the design, construction, and operation of environmental technology.

The ANSI/ASQC E4 standard requires two principal forms of quality system documentation: the QMP and the quality assurance project plan (QAPP). The QMP documents how an organization structures its quality system, defines and assigns QA and QC responsibilities, and describes the processes and procedures used to plan, implement, and assess the effectiveness of the quality system. The QMP may be viewed as the "umbrella" document under which individual projects are conducted. The requirements defined by EPA for QAPPs are given in *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (EPA 1998).

1.3 SUPERSESSION

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

1.4 PERIOD OF APPLICABILITY

Per EPA Order 5360, this document shall be valid for a period of five years from the official date of publication. After five years, this document shall either be reissued, revised, or removed from the EPA Quality System.

1.5 ADDITIONAL RESOURCES

Guidance on preparing QMPs may be found in a companion document, *EPA Guidance for Quality Management Plans (QA/G-2)* (in progress). This guidance discusses the application of the QMP requirements given in this document to both EPA and non-EPA organizations and provides examples of how the QMP requirements may be satisfied.

In addition to this guidance, the EPA Quality Assurance Division has developed a standard operating procedure (SOP) for reviewing EPA QMPs, which may be applied to extramural QMPs as well. Copies of this SOP are available on the QAD website (URL:http://es.epa.gov/ncerqa/qa/index.html). The same SOP is included an appendix to the QA/G-2 document described above.

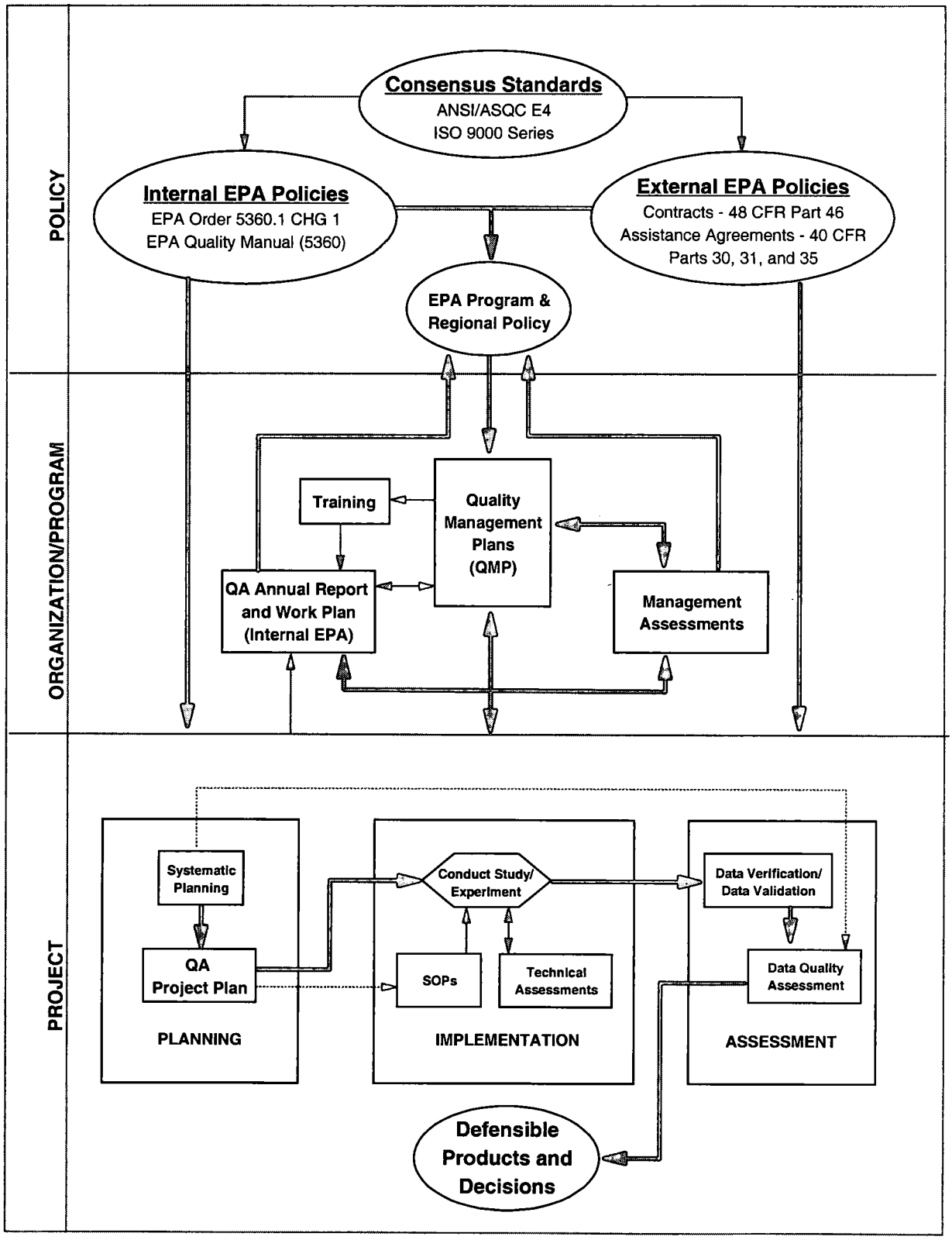

Figure 1. The EPA Quality System

CHAPTER 2

QUALITY MANAGEMENT PLAN PREPARATION, SUBMISSION, REVIEW, AND APPROVAL

2.1 POLICY

All work performed by extramural organizations on behalf of EPA that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be covered by an Agency-approved QMP. Work performed on behalf of EPA includes activities performed under contracts, assistance agreements, or interagency agreements. These requirements will be negotiated into interagency agreements, including sub-agreements, and, in some cases, included in enforcement consent agreements and orders.

2.2 PURPOSE

Quality management begins with the QMP. The QMP is the management "blueprint" for applying QA and QC to environmental programs. The QMP defines the unique quality system for planning, implementing, and assessing the effectiveness of activities supporting environmental data operations and other environmental programs. The QMP provides the principal basis for management reviews of an organization's quality system.

2.3 APPLICABILITY

These QMP requirements apply to all organizations having environmental programs that acquire, generate, or compile environmental data and that are performed on behalf of EPA. These operations include work performed through contracts, cooperative agreements, interagency agreements, State-EPA agreements, State, local, and Tribal Financial Assistants/Grants, Research Grants, and in response to statutory or regulatory requirements and consent agreements. These requirements will be negotiated into interagency agreements, including sub-agreements, and, in some cases, included in enforcement consent agreements and orders. Where specific Federal regulations require QA and QC, QMPs shall be prepared, reviewed, and approved in accordance with the specifications contained in this document unless explicitly superseded by the regulation.

2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS

This document describes the quality management practices which are considered to be critical to a quality system and which must be addressed and documented in a QMP. Some elements are mandatory to ensure consistency across EPA-related quality systems. Other elements may be mission-specific and may not apply to every organization. Each organization should evaluate these key elements to see if they are applicable to their quality system. Where a

particular element is not relevant, a brief explanation of why it is not relevant should be provided in the QMP. On the other hand, if the QMP preparer determines that additional quality management elements are useful or necessary for an adequate quality system, these elements should be developed and discussed in the QMP.

The QMP is a management tool whose contents may be appropriately tailored to the needs of the organization and which defines how its quality management objectives will be attained. The QMP must be sufficiently inclusive, explicit, and readable to enable managers and supervisors to understand the priority which management places on QA, the established QA policies and procedures, and their respective QA roles. The QMP must be constructed and written so that an assessment of the suitability and effectiveness of the organization's quality system following implementation can be accomplished. Such assessments will enable management to determine whether or not the quality system is meeting the needs of the organization's mission and goals for its environmental programs. In practice, the QMP 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. The level of detail in the QMP should be based on a common sense, graded approach[3] that establishes QA and QC requirements commensurate with the importance of the work, the available resources, and the unique needs of the organization.

2.5 QMP PREPARATION RESPONSIBILITY

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

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

[3]A graded approach to QA and QC bases the level of managerial controls on the intended use of the results and the degree of confidence needed in the quality of the results.

2.6 QMP SUBMISSION AND EPA APPROVAL

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

When review and approval of a QMP by EPA is required either by statute, contractual requirement, or assistance agreement condition, the QMP must be submitted for review to the EPA organization responsible for the work to be performed. For example, the review of a State QMP that has been submitted as part of a request for an assistance agreement will be performed by the Region or Office making the decision on the assistance request. EPA will approve those QMPs that include acceptable QA policies, procedures, administrative criteria, and management systems for key QA elements including systematic planning; preparation, review, and approval of QAPPs; review and approval of other, applicable QMPs (such as for subcontractors); use of Standard Operating Procedures (SOPs); use of management and technical assessments; and oversight of delegated programs.

EPA approval of a QMP will be valid for five years for State and local governments or the length of the extramural agreement for all other extramural agreement holders. EPA policy requires that each approved QMP be reviewed at least annually to reconfirm the suitability and effectiveness of the approved quality management practices. Revisions to an EPA-approved QMP resulting from a review are covered in Section 2.7.

2.7 QMP REVISIONS

EPA policy requires that all quality systems supporting agency quality systems be reviewed at least annually by their organizations to reconfirm the suitability and effectiveness of the approved quality management practices. This assessment must also include an evaluation of the effectiveness of the QMP. The process of developing and then annually updating the QMP provides an opportunity for management and staff to clarify roles and responsibilities, address problem areas, and acknowledge successes so that they may be fostered and rewarded. Having an accurate QMP at all times is an essential element in every quality system. It is EPA policy that changes in QA policy and procedures shall be documented in timely fashion by QMP revisions.

In general, a copy of any QMP revision(s) made during the year should be submitted to EPA as a report when such changes occur. In some cases, however, it may be necessary to re-submit the entire QMP if significant changes have been made to the quality system that significantly affects the performance of work for the Agency. It is recommended that all appropriate personnel in the organization performing work covered by the scope of the QMP be notified of all changes to the quality system and the QMP to keep them informed of the current

requirements. This practice should also be extended to include active sub-contractors for relevant work.

EPA recognizes that the QMP has broader applicability for an organization than just the period of performance for an extramural agreement. While the value to the organization of having a quality system conforming to ANSI/ASQC E4 may extend beyond the organization's relationship with EPA, the QMP must be valid for the full period of performance for any work performed on behalf of EPA and all EPA requirements for review and assessment must be met.

CHAPTER 3

QUALITY MANAGEMENT PLAN REQUIREMENTS

3.1 CONTENT REQUIREMENTS

The QMP describes how the organization plans and implements the necessary quality management practices, including QA and QC, to help management to ensure that the results of technical work are of the type and quality needed for their intended use.

Accordingly, the QMP shall document:

- 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 process(es) used to plan, implement, and assess the work performed,
- the process by which measures of effectiveness for QA and QC will be established and how frequently effectiveness will be measured, and
- continual improvement based on lessons learned from previous experience.

The QMP must reflect the organization's commitment to quality management principles and practices, tailored, when appropriate, by senior management to meet the organization's needs. For the purposes of uniformity and to ensure a consistent and complete review of the QMP, it is preferable, but not necessary, that the QMP address the specifications in the same order as presented below. If an existing, approved QMP adequately addresses each of these topics, but in a different order, it should not be rewritten simply to conform to the outline provided here.

There are 10 elements to be addressed in a QMP: management and organization; quality system and 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 within each of these program elements are in sections 3.2 through 3.11. If an organization believes that an element is not applicable to its quality system, then it must state why this is the case when submitting a QMP for EPA approval.

3.2 MANAGEMENT AND ORGANIZATION

Provide the following management and organizational items:

- a statement of the organization's policy on quality assurance, including:
  - the importance of QA and QC to the organization and why,
  - the general objectives/goals of the quality system, and
  - the policy for resource allocation for the quality system;
- 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 (and any QA staff) that documents the independence of the QA Manager from groups generating, compiling, and evaluating environmental data;
- a discussion of the responsibilities and authorities of the QA Manager and any other QA staff;
- a discussion of the technical activities or programs that are supported by the quality system and to which it applies; that is, the specific programs that require extensive quality management controls; where oversight of delegated, contracted, or other extramural programs is needed to assure data quality; and where internal coordination of QA and QC among the group's organizational units needs to occur;
- a discussion of the QA and QC roles and responsibilities of management, technical staff, and any other staff, and how these roles and responsibilities are incorporated into assessments of performance;
- a discussion of how management will assure that applicable elements of the quality system are understood and implemented in all environmental programs; and
- an approval page for the signatures of the management, the QA manager of the organization, and for the responsible EPA official. The EPA official may include the contracting officer's representative (for example, the project officer for contracts, the work assignment manager for work assignments, or the delivery order project office for delivery orders), the award official (for assistance agreements), and the EPA QA manager. This approval page may be part of a title page or a separate sheet following the title page.

3.3 QUALITY SYSTEM AND DESCRIPTION

Discuss the principal components or "tools" comprising the quality system and how and when they are to be applied to individual projects and tasks. These components include, but are not limited to:

- QMPs
- management assessments (self and independent)
- systematic planning processes
- QAPPs
- standard operating procedures
- technical assessments (self and independent)
- data quality assessments

The discussion shall include the roles and responsibilities of all management and staff involved in planning and implementing the quality system.

3.4 PERSONNEL QUALIFICATION AND TRAINING

State the policy regarding training for management and staff. Describe the processes and the management and/or staff responsible for:

- identifying statutory, regulatory, or professional certifications that may be required to perform certain operations; and

- identifying, designing, performing, and documenting technical, quality, and project management training.

Describe how staff proficiency in critical technical disciplines is maintained and documented.

3.5 PROCUREMENT OF ITEMS AND SERVICES

Describe and discuss the organization's process for ensuring that contracted and subcontracted activities that involved or affect environmental programs produce results of acceptable quality, including, as appropriate:

- procurement source evaluation and selection,

- evaluation of objective evidence of quality furnished by the supplier,

- source inspections,

- supplier audits, and
- examination of deliverables.

3.6 DOCUMENTATION AND RECORDS

Describe or reference the process:

- for identifying quality-related documents and records requiring control;
- for handling documents and records to assure their accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities for management and staff;
- by which all technical guidance documents are prepared, reviewed, approved, issued, used, and revised; and
- by which all planning documents (e.g., QAPPs, Sampling and Analysis Plans) are prepared, reviewed, approved, issued, used, and revised; and
- for ensuring compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs and that provides adequate preservation of key records necessary to support the mission of the organization.

Documents and records, including revisions, must be reviewed for conformance with the quality system requirements and approved by authorized personnel for general use.

Describe or reference the management process that ensures that records accurately reflect completed work and/or fulfill statutory and contractual requirements. The maintenance of records includes defining requirements and responsibilities for record transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrievability. Identify how the disposition of records, in accordance with regulatory requirements, schedules, or directives from management, is accomplished.

3.7 COMPUTER HARDWARE AND SOFTWARE

Describe or reference:

- the process for ensuring that computer hardware used in environmental programs meets technical requirements and quality expectations;

- how changes to hardware shall be controlled to assess the impact of the change on performance;

- the process for developing computer software, for validating, verifying, and documenting the software for its use, and for assuring that the software meets the requirements of the user;

- how purchased software is evaluated to meet user requirements and to comply with applicable contractual requirements and standards; and

- describe or reference the process for ensuring that data and information produced from or collected by computers meet applicable information resource management requirements and standards.

These descriptions shall include the roles and responsibilities assigned to management and staff. 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, and data bases.

3.8 PLANNING

3.8.1 Systematic Planning

Environmental data operations shall be planned using a systematic planning process that encompasses principles based on the scientific method. The planning process shall use a common sense, graded approach to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the available resources. Minimum elements of a systematic planning approach that must be documented in the QMP include:

- identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers);

- description of the project goal, objectives, and questions and issues to be addressed;

- identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory and contractual requirements);

- identification of the type of data needed and how the data will be used to support the project's objectives;

- determination of the quantity of data needed and specification of performance criteria for measuring quality;

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

- 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.);

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

A systematic planning process shall ensure that all organizations and/or parties who contribute to the quality of the environmental program or use the results are identified and that they participate in this process. The planning process shall also provide for direct communication between the customer and the supplier to ensure that there is a clear understanding by all participants of the needs and expectations of the customer and the product or results to be provided by the supplier.

EPA has developed a systematic planning process called the Data Quality Objectives (DQO) Process (EPA 1994). The DQO Process is based on the scientific method and employs statistical methods to create project planning results. The resulting designs are expressed in terms of acceptable allowed error in the project results. While not mandatory, this process is the recommended planning approach for many EPA data collection activities.

Describe the process for planning environmental programs, including identification of who is responsible and how general project planning is documented. Describe who uses the planning "tools" (as defined in the Quality System Description section of the QMP) and the roles and responsibilities of all management and staff involved in planning.

3.8.2 Quality Assurance Project Plans

Discuss how the results of planning for environmental data operations shall be documented in a QAPP (EPA 1998). The process for developing, reviewing, submitting for approval, implementing, and revising a QAPP, must be described in this section of the QMP.

Describe or discuss how data obtained from sources outside EPA that did not use an EPA-approved QAPP (or equivalent planning document) for data collection shall be evaluated and qualified for use. Discuss the process for qualifying such data, including the application of any statistical methods used.

3.9 IMPLEMENTATION OF WORK PROCESSES

Describe the process of how and by whom work shall be implemented within the organization for:

- ensuring that work is performed according to plan;
- developing and implementing procedures for appropriate routine, standardized, special, or critical operations, including those that address, but are not limited to:
  - identification of operations needing procedures;
  - preparation of procedures, including form, content, and applicability; and
  - review and approval of procedures; and
- use of QA and QC "tools" such as standard operating procedures (SOPs).

Describe how appropriate measures for controlling the release, change, and use of planned procedures are implemented. These measures shall provide for the 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.

To help to assure consistency in common procedures, SOPs are encouraged for appropriate routine, standardized, or special/critical operations. The QMP shall describe the organization's process for identifying the need for SOPs, the process for developing SOPs, and the policy for using SOPs. The QMP shall also describe the process by which SOPs are reviewed for initial and subsequent use.

3.10 ASSESSMENT AND RESPONSE

Describe how and by whom assessments of environmental programs are planned, conducted, and evaluated. Describe the process by which management chooses a particular assessment tool, and the expected frequency of their application to environmental programs. Available assessment tools include audits, data quality assessments, management systems reviews, peer reviews and technical reviews, performance evaluations, readiness reviews, technical systems audits, and surveillance. Senior management shall assess (at least annually) the adequacy of the quality system.

Discuss or address the following items pertaining to management and technical assessments:

- how the process for the planning, scheduling, and implementation of assessments works, as well as how the organization shall respond to needed changes;

- responsibilities, levels of participation, and authorities for all management and staff participating in the assessment process; and

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

Describe how the level of competence, experience, and training necessary to ensure the capability of personnel conducting assessments are determined. Personnel conducting assessments shall be qualified, based on project-specific requirements, to perform the assigned assessment. Management is responsible for choosing the assessors, defining acceptance criteria, approving audit procedures and check lists, and identifying goals prior to initiation of an assessment. Assessors shall be technically knowledgeable with no real or perceived conflict of interest. If the assessors are chosen from within the organization, they must have no direct involvement or responsibility for the work being assessed, except for self-assessments.

Describe how personnel conducting assessments shall have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom to identify quality problems; identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products; propose recommendations for resolving quality problems; and independently confirm implementation and effectiveness of solutions.

Describe how assessment results are documented, reported to, and reviewed by management. Describe how management shall respond to the results (or findings) and recommendations from assessments in a timely manner. When conditions needing corrective action are identified, the appropriate response must be made promptly. Indicate how follow-up action shall be taken and documented to confirm the implementation and effectiveness of the response action. Describe how disputes, if encountered, as a result of assessments are addressed and by whom.

3.11 QUALITY IMPROVEMENT

Describe how the organization shall detect and prevent quality problems and for ensuring continuous quality improvement, including:

- the management process and identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities;

- a corrective action program to ensure that conditions adverse to quality are identified promptly and corrected as soon as practical.

Corrective actions shall include the identification of root causes of problems, the determination of whether the problem is unique or has more generic implications, and a recommendation of procedures to prevent recurrence.

Describe how staff at all levels are encouraged to identify and establish communications among customers and suppliers, identify process improvement opportunities, identify problems, and offer solutions to those problems.

REFERENCES

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

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

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

Title 48, Part 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 Order 5360, July 1998. *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 5360.1 CHG 1 (July 1998), *Policy and Program Requirements to Implement the Mandatory Quality Assurance Program*, U.S. Environmental Protection Agency, Washington, DC.

U.S. Environmental Protection Agency, 1998. *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*, EPA/600/R-98/???, Office of Research and Development.

U.S. Environmental Protection Agency, 1994. *Guidance for the Data Quality Objectives Process (QA/G-4)*, EPA/600/R-96/055, Office of Research and Development.

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

APPENDIX A

TERMS AND DEFINITIONS

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. 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.

completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions.

contractor - any organization or individual that contracts to furnish services or items or perform work.

client - 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 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.

data quality objectives (DQO) process - a systematic planning tool to facilitate the planning of environmental data collection activities. Data quality objectives are the qualitative and quantitative outputs from the DQO Process.

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

entity - that which can be individually described and considered, such as a process, product, item, organization, or combination thereof.

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 monitoring - the process of measuring or collecting environmental data.

environmental processes - manufactured or natural processes that produce discharges to, or that impact, the ambient environment.

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.

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.

finding - an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative, and is normally accompanied by specific examples of the observed condition.

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.

guideline - a suggested practice that is non-mandatory in programs intended to comply with a standard.

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.

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 systems 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.

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.

observation - an assessment conclusion that identifies a condition (either positive or negative) which does not represent a significant impact on an item or activity. An observation may identify a condition which does not yet cause a degradation of quality.

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 (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.

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 (QAPP) - 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 (QMP) - 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.

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.

research (applied) - a process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

research (basic) - a process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

scientific method - the principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

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

service - the result generated by activities at the interface between the supplier and the customer, and by supplier internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and/or field analysis, repair, and installation.

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 (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.

traceability - the ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for quality for the project.

user - an organization, group, or individual that utilizes the results or products from environmental programs or a customer for whom the results or products were collected or created.

validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.