EPA
QUALITY MANUAL
FOR
ENVIRONMENTAL PROGRAMS

5360 A1

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United States Environmental Protection Agency
Office of Environmental Information
Quality Staff
Washington, D.C. 20460

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CHAPTER 1
QUALITY SYSTEM POLICY AND RATIONALE

1.1 Introduction

EPA Order 5360.1 CHG 2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, provides requirements for the conduct of quality management practices, including quality assurance (QA) and quality control (QC) activities, for all environmental data collection and environmental technology programs performed by or for this Agency. The primary goal of the Agency-wide Quality System is to ensure that environmental programs and decisions are supported by data of the type and quality needed and expected for their intended use, and that decisions involving the design, construction, and operation of environmental technology are supported by appropriate quality assured engineering standards and practices. The *EPA Quality Manual for Environmental Programs* provides program requirements for implementing the mandatory Quality System defined in EPA Order 5360.1 CHG 2.

All EPA organizational units conducting environmental programs shall comply with EPA Order 5360.1 CHG 2. Work performed on behalf of EPA through appropriate extramural agreements shall comply with the quality system requirements defined by EPA Order 5360.1 CHG 2 or applicable regulations, unilateral orders, and negotiated agreements. Environmental data are any measurements or information that describe environmental processes or conditions, 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 technology includes treatment systems, pollution control systems and devices, and waste remediation and storage methods.

In accordance with EPA Order 5360.1 CHG 2, EPA requires that environmental programs be supported by a quality system that complies with the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, incorporated herein by reference. ANSI/ASQC E4-1994 is a national consensus standard authorized by the American National Standards Institute (ANSI) and developed by the American Society for Quality (ASQ) that provides a basis for planning, implementing, documenting, and assessing an effective quality system for collecting and evaluating environmental data for decisions and for use in the design, construction, and operation of environmental technologies. Copies of the standard may be obtained from:

ASQC Quality Press
P.O. Box 3005
Milwaukee, WI 53201-3005
Phone: (800) 248-1946

By invoking this American National Standard as the basis for its internal Quality System, EPA recognizes that environmental programs are diverse and impact many constituencies, including Federal, State, local, and Tribal governments and industry. EPA realizes that a uniform, consistent set of quality management criteria are essential to assure effective environmental programs by Government and industry alike. ANSI/ASQC E4-1994 provides a stable foundation upon which quality systems supporting all environmental data and technology work across the Agency may be based.

1.2 Scope

The scope of this Manual includes applicable environmental programs involving:

- the collection, evaluation, and use of environmental data by and for the Agency, and
- the design, construction, and operation of environmental technology by the Agency.

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.

Decisions concerning environmental and human health protection often result in requiring the design, construction, and operation of pollution control or waste remediation systems. For example, environmental technologies are required to reduce contamination levels in the environment and to maintain the levels at concentrations that do not threaten the environment or human health and safety.

1.3 Applicability

1.3.1 Applicability to Environmental Programs

This Manual contains the minimum specifications for quality management functions and activities necessary to support EPA environmental programs and satisfy the requirements of EPA Order 5360.1 CHG 2. Such programs may include activities encompassing the:

- characterization of environmental or ecological systems and the health of human populations;
- characterization of ambient conditions in air, water, sediments, and soil in terms of physical, chemical, radiological, or biological characteristics;

- characterization of radioactive, hazardous, toxic, and mixed wastes in the environment and their health and ecological effects;

- characterization and quantification of waste and effluent discharges to the environment from processes and operations (e.g., energy generation, metallurgical processes, chemicals production), during either normal or upset conditions (i.e., operating conditions that cause pollutant or contaminant discharges);

- performance assessment of environmental technology used for pollution prevention; pollution control; waste treatment, storage, and disposal; and waste remediation;

- demonstration of environmental technology (e.g., treatability and pilot studies);

- investigation of chemical, biological, physical, or radioactive constituents in environmental and ecological systems, and their behavior and associated interfaces in those systems, including exposure assessment, transport, and fate;

- definition and evaluation of methods for use in the collection, analysis, and use of environmental data;

- development, evaluation, and use of computer or mathematical models (and their input data) that characterize environmental processes or conditions;

- use of environmental data collected for other purposes or from other sources (also termed “secondary data”), including literature, industry surveys, compilations from computerized data bases and information systems, results from computerized or mathematical models of environmental processes and conditions; and

- collection and use of environmental data pertaining to the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical dosimetry, radiation dosimetry).

1.3.2 Applicability to Other EPA Programs

This Manual applies to the collection and use of medical testing data from Government and non-Government personnel in EPA facilities for determination of substance abuse.

1.4 Organizational Applicability

1.4.1 EPA Organizations

The Agency-wide Quality System requirements established in EPA Order 5360.1 CHG 2 shall apply to all EPA organizations and components thereof in which the environmental programs conducted involve the activities described in Section 1.2 above.

1.4.2 Extramural Agreements

The Agency-wide Quality System requirements defined by Order 5360.1 CHG 2 shall apply to non-EPA organizations as defined by terms and conditions in EPA-funded extramural agreements. Compliance with the Agency-wide Quality System requirements may be specified in applicable regulations for these extramural agreements. In other cases, such requirements may be invoked as part of negotiated agreements such as memoranda of understanding. These extramural agreements include:

- Any organization or individual under direct contract to EPA to furnish services or items or perform work (i.e., a contractor) under the authority of 48 CFR 46, (including applicable work assignments, delivery orders, and task orders);

- Institutions of higher education, hospitals, and other non-profit recipients of financial assistance (e.g., Grants and Cooperative Agreements) under the authority of 40 CFR 30;

- State, local, and Tribal governments receiving financial assistance under the authority of 40 CFR 31 and 35; and

- Other Government Agencies receiving assistance from EPA through interagency agreements.

Extramural (non-EPA) quality systems that provide objective evidence (such as a Quality Management Plan, quality manual, or audit report acceptable to EPA) of complying fully with the specifications of ANSI/ASQC E4-1994 are in compliance with EPA policy.

1.5 Exemptions

Statutory requirements for quality may supersede the specifications in this Manual or be more rigorous. In such cases, affected programs shall be exempt from the requirements of this Manual. EPA organizations conducting exempted activities shall comply with EPA Order 5360.1 CHG 2 in all other respects. The following exemptions from these requirements apply:

- The collection of environmental data under the authority of Good Laboratory Practices as defined by 40 CFR 792, for the Toxic Substances Control Act.

- The collection of environmental data under the authority of Good Laboratory Practices as defined by 40 CFR 160, for the Federal Insecticide, Fungicide, and Rodenticide Act.

Requests for exemptions should be directed to the Office of Environmental Information (OEI) Quality Staff. Exemptions shall be made by the Assistant Administrator for the OEI (AA/OEI).

CHAPTER 2
QUALITY SYSTEM IMPLEMENTATION

2.1 Introduction

This chapter addresses the implementation of quality management activities to satisfy EPA Order 5360.1 CHG 2, including limitations on the use of extramural support to implement quality systems for programs involving environmental data operations; reporting requirements; requirements for extramural agreements; requirements for reporting results from applicable environmental programs; QA and QC requirements and guidance documents; user-specific QA and QC guidance; and dispute resolution.

2.2 Implementation of Quality System Functions

2.2.1 Background

Many quality system activities involving environmental data operations are inherently governmental functions and must be performed only by EPA personnel or by personnel explicitly authorized by EPA based on statute, regulation, or by the terms of an extramural agreement. Such representatives may include other governmental personnel and with specific authorization, contractor personnel. When such quality management tasks are performed by a contractor, the contract must be appropriately managed and must remain under the control of the authorized EPA contracting representatives. EPA cannot use cooperative agreements or grants to provide quality management activities such as QA and QC services for EPA because it is an inappropriate use of financial assistance (Office of General Counsel memorandum, August 2, 1994).

This section describes the quality management tasks necessary to comply with the Order and identifies those tasks that may be performed by non-government personnel under appropriate management controls.

Two types of quality management functions are described:

- Exclusively EPA Functions - inherently governmental work which must be performed only by responsible EPA officials, including the QA Managers (QAMs), or authorized EPA representatives.

- Discretionary Functions - activities that may be performed either by EPA personnel or by non-EPA personnel under the specific technical direction of and performance monitoring by the QA Manager or other responsible EPA or

Government official under an approved contract, work assignment, delivery order, task order, etc.

In the situations involving the other associated functions, there may be instances involving sensitive contracting services, advisory and assistance services, and vulnerable contracting practices as defined by the Federal Acquisition Regulations, Office of Federal Procurement Policy (OFPP), and the EPA Contracts Management Manual (EPA Order 1900). Such situations are identified by *italicized text* in the following sections. In addition, management approval of services contracts as defined by OFPP Letter 93-1 must be obtained for many of the associated tasks.

Technical direction or other instructions to an extramural organization, relating to performance of an extramural agreement, shall be provided only by authorized EPA or other Government representatives in accordance with the terms of the applicable extramural agreement. Only authorized EPA or other Government representatives are to provide direction or instructions to an extramural organization providing quality systems support for environmental programs. This is to avoid such actions as:

- the providing of directions or instructions that are inconsistent with the terms of an extramural agreement,
- unauthorized access to confidential business information (CBI), or
- unauthorized access to information that may allow an extramural organization to gain an unfair competitive advantage.

2.2.2 Mandatory Quality Management Tasks and Descriptions

This section describes the activities and tasks integral to an effective quality system. These tasks are required to implement EPA Order 5360.1 CHG 2.

2.2.2.1 Manage and Coordinate the Quality System

Exclusively EPA functions that must be performed by EPA QA personnel include:

- managing the day-to-day implementation of the mandatory quality system.
- acting as liaison between the organization and the OEI Quality Staff on matters of QA policy.
- coordinating with senior management the development of and preparation of the organization's Quality Management Plan.

- coordinating with senior management changes to the Quality System as needed to assure its continued effectiveness and assisting in reporting the results annually to management and to the OEI Quality Staff in the QA Annual Report and Work Plan.

- managing organization resources designated for the quality system.

- maintaining records of pertinent quality system activities performed by the organization.

2.2.2.2 Review and Approve Procurement and Financial Assistance Documents for QA Requirements

Exclusively EPA functions that must be performed by EPA QA personnel include:

- reviewing procurement and financial assistance documents (e.g., statements of work, scopes of work, applications for assistance, funding requests, and purchase requests) to confirm any need for QA requirements, providing any necessary special language or conditions for such QA requirements, and approving by signature the appropriate Quality Assurance Review Form.

- participating directly or indirectly in the solicitation or agreement review process to advise the Project Officer on the suitability of the offeror's quality system or QA and QC approach for the particular project.

- reviewing work assignments, delivery orders, and task orders to certify that appropriate QA and QC requirements have been established and that the necessary instructions are being communicated to the contractor to carry out the required QA and QC tasks. Approving by signature appropriate Quality Assurance Review Form (EPA Order 1900, Chapter 2).

2.2.2.3 Review and Approve QA Planning Documents

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- reviewing Quality Assurance Project Plans (QAPPs) for all projects, work assignments, delivery orders, task orders, grants, cooperative agreements, and interagency agreements involving data acquisition, data generation, and/or measurement activities that are performed on behalf of EPA.

- approving all QAPPs for implementation in all applicable projects, work assignments, delivery orders, task orders, grants, cooperative agreements, and interagency agreements performed on behalf of EPA.

- coordinating the correction of deficient QAPPs with the Project Officer and his/her management.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- *reviewing, at the specific technical direction of the QAM, QA Project Plans and other QA-related planning documents, such as sampling and analysis plans, Data Quality Objectives (DQO) specifications, etc., and providing specific substantiated recommendations to the QAM on the adequacy of the QA approach in meeting the criteria provided by the QAM. (The reviews should identify specific technical deficiencies in the planning documents.)*

2.2.2.4 Track and Report Quality System Deliverables

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- tracking critical quality system deliverables for the organization and make periodic reports to senior management on the status of reporting actions and deliverables.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- compiling/logging administrative and management information including turnaround times to correct deficient QAPPs, responses to audits (e.g., responses and corrective actions), and quality reviews of final reports.

2.2.2.5 Manage Contractor Support Work Assignments, Delivery Orders, and Task Orders

Exclusively EPA functions that must be performed by EPA QA personnel include:

- serving as the Contracting Officer Representative (for example, Project Officer, Work Assignment Manager, or Delivery Order Project Officer) for specific QA support contracts, work assignments, delivery orders, and task orders.

2.2.2.6 Plan and Conduct Management Assessments

Exclusively EPA functions that must be performed by EPA QA personnel include:

- planning, directing, and conducting assessments of the effectiveness of the quality system being applied to environmental data operations and reporting results to senior management. Such assessments may be conducted using the Management Systems Review (MSR) process.

- coordinating with senior management any revision of the quality system as necessary based on the findings of the assessment.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- providing technical support to the EPA QAM in the planning phase of management assessments. (Such activities are limited to the assembly and compilation of background information and data, guidance documents, technical reports, etc., available in the public domain, for use by EPA in designing the assessment goals and specifications.)

2.2.2.7 Plan and Conduct Technical Assessments

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- planning and directing with the responsible EPA project officials the implementation of periodic technical assessments of ongoing environmental data operations to provide information to management to assure that technical and quality objectives are being met and that the needs of the customer are being satisfied. Such assessments may include technical systems audits, surveillance, performance evaluations, and data quality assessments.

- determining conclusions and necessary corrective actions (if any) based on the findings of the assessments.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- *performing technical assessments of environmental data producing activities, both intramural and extramural (on-site and off-site) according to a specific plan approved by the QAM. Preparations for such assessments may include the*

acquisition or development of audit materials and standards. Results (findings) are summarized, substantiated, and presented to the QAM or authorized EPA representative.

A determination of whether an authorized Agency representative should accompany a contractor's personnel should be made on a case-by-case basis only after coordination between the responsible organization and contracting officer. Such coordination should include consideration of the purpose of the accompaniment and clear definition of the Agency representative's role and responsibility during the contractor's performance of the audit or technical assessment to avoid the appearance of a personal services relationship.

2.2.2.8 Prepare and Present QA Training Materials and Courses

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- developing and presenting detailed guidance and training for QA and QC activities based on interpretation of Agency-wide requirements and guidance.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- providing or coordinating quality-related training for the organization in special skill areas identified by the Agency and not generally available to the organization.

- *providing allowable technical and/or logistical assistance in preparing and presenting quality-related technical training (within the Agency's implementation of special management and control measures and the constraints of potential for conflict of interest, of revealing confidential business information, or of appearing to be interpreting or representing Agency policy).*

2.2.2.9 Review and Approve Final Reports for Quality Documentation

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- establishing criteria for the acceptability of quality documentation in the organization's published papers and reports; that is, defining what is required for an adequate discussion of the quality of the project results and the usability of the information reported.

- approving for publication those papers and reports that meet the defined criteria.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- *conducting a substantiated technical review of all reports produced by the organization using the qualitative and quantitative specifications obtained from the DQO process or other criteria provided by EPA. This quality review complements the peer review process.*

2.2.3 Non-Mandatory Quality Management Tasks and Descriptions

This section describes other activities and tasks integral to an effective quality system. They are not explicitly required to implement EPA Order 5360.1 CHG 2, but if implemented, they must be implemented as described below.

2.2.3.1 Review and Assist in the Development and Preparation of Environmental Data Collection Survey Designs

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- interpreting Agency policy and requirements pertaining to the development and preparation of environmental data collection survey/experimental design requirements.

- providing corrective action, technical assistance, and guidance to intramural and extramural personnel (in accordance with terms of the extramural agreement) conducting environmental data operations to enable them to produce in a timely manner satisfactory design documents.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- *reviewing environmental data collection survey designs using criteria provided by the QAM and providing the QAM with a substantiated technical assessment of the strengths and weaknesses in the design.*

2.2.3.2 Prepare and Present Quality Management Information in the Technical Literature and at Meetings/Symposia

Exclusively EPA functions that must be performed by EPA QA personnel or their authorized EPA representative include:

- transferring information on EPA quality management subjects to other Agency, public, or scientific groups through participation in technical meetings and symposia, and papers or articles in the technical literature, including peer reviewed journal papers, oral presentations, and panel discussions.

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- transferring information on quality management subjects to other groups through participation in technical meetings and symposia and through the technical literature, with appropriate disclaimer that the information does not represent EPA policy or position. (NOTE: Only EPA personnel may represent the Agency in an official role.)

2.2.3.3 Research Relative to Quality Management Issues

Discretionary functions that may be performed by either EPA personnel or non-EPA personnel include:

- providing information to the QAMs on the state-of-the-art in quality management.

- performing searches of the technical and quality management literature relative to specific QA and QC issues. This may include compiling summaries of alternative sampling and analytical methods, identifying QC reference materials, and availability of standard operating procedures for calibrating certain instrumentation.

- performing studies of quality management issues having a mathematical or statistical foundation with the objective of optimizing QA and QC protocols and procedures.

2.3 Reporting Requirements

2.3.1 Quality Management Plans

All Agency organizational units governed by EPA Order 5360.1 CHG 2 shall document their quality system in a Quality Management Plan (QMP). The QMP is a policy statement describing how an EPA organization shall comply with the requirements of EPA Order 5360.1 CHG 2. Quality systems encompass the management and technical activities necessary to plan, implement, and assess the effectiveness of QA and QC operations applied to environmental programs. The QMP provides the blueprint for how an individual EPA Program Office, Region, and National Laboratory or Center

will plan, implement, and assess its quality system for the environmental work to be performed as part of its mission. QMPs are reviewed and approved by the OEI. Approval is valid for a period of up to five years. Specific QMP requirements are described in Chapter 3.

2.3.2 Quality Assurance Annual Report and Work Plan (QAARWP)

All Agency organizations subject to the requirements of EPA Order 5360.1 CHG 2 must submit a Quality Assurance Annual Report and Work Plan (QAARWP) annually to the OEI. The QAARWP shall summarize the results of having implemented the quality system the previous fiscal year and describe QA activities planned for the fiscal year beginning in October. The QAARWP may be used to identify limited changes or updates to the organizations's approved QMP. The QAARWP should provide helpful information to management by documenting the past fiscal year's activities and estimating the current year's workload based on the prior year and the expected activities in the current year. QAARWPs are described in Chapter 4.

2.4 Requirements for Extramural Agreements

All environmental data operations performed under extramural agreements shall comply with the Agency-wide Quality System requirements as defined by the relevant regulations. Accordingly, all acquisitions and assistance agreements must be reviewed by an authorized QA Manager, Officer, or Coordinator, as specified in the organization's Quality Management Plan, to determine if environmental data operations are to be performed and, if so, to ensure that appropriate QA and QC specifications are included or identified in the acquisition and assistance agreement solicitation package. Upon their receipt in response to the solicitation, proposals or applications must be reviewed by the QA approval authority to evaluate the adequacy with which the offeror or applicant addressed stated specification, as well as the adequacy of Quality Management Plans and QA Project Plans when submitted.

2.4.1 Contracts

The requirements for QA and QC activities in contracts are given in 48 CFR 46 and in the Contract Management Manual, EPA Order 1900. The requirements and the specifications set forth in this Manual extend to all contract forms involving environmental programs, including work assignments, delivery orders, and task orders.

The Quality Assurance Review Form (QARF) (EPA Order 1900, Chapter 2) provides confirmation to the Office of Acquisition Management (OAM) that appropriate QA and QC requirements have been determined. OAM officials shall then incorporate the necessary standard clauses or conditions to assure that the minimum specifications for compliance with EPA policy are included. The specific statement of work may include additional QA and QC specifications and requirements identified by the project officer in consultation with the organization's QAM.

Approved QARFs are required for work assignments, delivery orders, and task orders. For level-of-effort and delivery order contracts, only general QA and QC requirements are specified in the contract. Since not all work assignments, delivery orders, and task orders issued involve data collection, QA and QC specifications may not be necessary. The QARF attached to the work assignment shall identify clearly those work assignments that need QA and QC specifications and shall identify the necessary requirements.

2.4.2 Assistance Agreements

The regulatory requirements for QA and QC activities in assistance agreements are given in 40 CFR 30, for assistance to institutions of higher education, hospitals, and other non-profit organizations, and in 40 CFR 31, for assistance agreements to State, local, and Tribal governments. The requirements and the specifications set forth in this Manual extend to all assistance agreement forms involving environmental programs, including grants and cooperative agreements.

2.4.3 Interagency Agreements

EPA cannot unilaterally require other Federal agencies to comply with Agency-wide Quality System requirements for interagency agreements funded by EPA. QA and QC specifications for interagency agreements must be negotiated between EPA and the other agency. When agreement is reached on the QA and QC specifications, the specifications must be included in the interagency agreement.

When EPA receives funding from another Agency through an interagency agreement, the EPA QA and QC requirements shall apply in addition to any specifications provided by the funding organization. If the funding agency does not specify any requirements, EPA QA and QC requirements given by the Order and this Manual shall apply.

2.5 Requirements for Reporting Environmental Data

2.5.1 Technical Reports

Published Agency reports containing environmental data shall be accompanied by a readily-identifiable section or appendix that discusses the quality of the data and any limitations on the use of the data with respect to their original intended application. Published EPA reports include those reports printed by the Government or distributed through publication services to the general public. This requirement does not apply to papers, journal articles, etc., that undergo peer review processes external to EPA.

Agency reports shall be reviewed by the QA manager (or other authorized official) before publication to ensure that an adequate discussion of QA and QC activities is enclosed. Adequacy is

a subjective determination that should be based on the nature of the environmental data operations performed and the intended and likely use of the data by others, or on the objectives of the study. The purpose of the review is to ensure that sufficient information is provided to enable a knowledgeable reader to determine if the technical and quality goals were met for the intended use of the data. Reports should include applicable statements regarding the use of any environmental data presented as a caution about possible misuse of the data for other purposes.

2.5.2 Data Management and Storage

Data management and electronic transfer and storage of environmental data shall conform with applicable Agency information resources management policies and procedures, or with applicable American National Standards. Agency policy requires that environmental data shall have their location reported and documented as well (2100, Chapter 13). Other applicable EPA Orders include 2180.1, 2180.2, 2180.3, and 7500.1A.

2.6 QA and QC Requirements and Guidance Documents

2.6.1 Agency-wide Requirements and Guidance Documents

The OEI Quality Staff shall develop quality management practices and "tools" for use Agency-wide to enable effective planning, implementation, documentation, and assessment of individual quality systems. The Quality Staff produces the following types of documents for this purpose:

- *Requirements Documents (QA/R-Series)*

  Requirements Documents contain mandatory, minimum specifications or procedures for use by non-EPA organizations that must comply with Agency-wide Quality System requirements. These documents are usually invoked through regulations. Requirements Documents are designated the QA/R-series and are issued by the AA/OEI as Agency Policy documents following appropriate review and approval.

- *Guidance Documents (QA/G-Series)*

  Guidance Documents contain non-mandatory guidelines for use by EPA and non-EPA organizations in implementing quality management practices or QA and QC activities. Such documents often provide suggestions on how to meet specifications

given in Requirements Documents. Guidance Documents are designated the QA/G-series and issued as OEI reports following peer review and approval.

All EPA quality-related Requirements Documents and Guidance Documents shall be valid for a period of five (5) years from the approval date. After five years, some action must be taken to reaffirm the document's validity, revise it, or delete it from the Agency-wide Quality System. Any changes to approved documents must comply with the procedures used for the original review and approval.

2.6.2 Development of User-Specific QA and QC Guidance Documents

Additional user-specific QA and QC requirements and guidance that are tailored to a particular organization and its mission may be appropriate given the diversity of Agency programs. For the purposes of this Manual, "user-specific QA and QC guidance" includes but is not limited to written documents, computer software, and videos (if used to provide instructions). Such guidance shall be developed by the organization itself, consistent with Agency policy and the organization's QMP.

Management shall ensure that all changes to the guidance documents are available to all personnel using that guidance, including active contractors and assistance agreement recipients (e.g., grantees, cooperative agreement holders). The changes do not become binding on contractors and assistance agreement holders until the Office of Acquisition Management or the Office of Grants and Debarment revises the extramural agreement at the request of the EPA project officer.

2.7 QA and QC Requirements in Regulations

EPA regulations often require the regulated community to collect and submit environmental data to EPA or the State as part of compliance or enforcement actions. Some regulations include specific QA and QC requirements while others are less specific. Because critical decisions are often made based on data collected from the regulated community, the adequacy of those data are very important, both to EPA and to the regulated community. The inclusion of appropriate QA and QC requirements in EPA regulations helps to assure that data of the type and quality needed for a particular decision are obtained. The authoring organization shall ensure that appropriate and effective specifications for QA and QC activities are included in proposed regulations.

2.8 Dispute Resolution

Oversight responsibilities for QA and QC activities may sometimes result in disagreements between the oversight group and the program reviewed regarding the results of the activity. Such disputes may occur in situations involving technical issues (e.g., audits, surveillance, data quality assessments) and management issues (e.g., QMP reviews, management systems reviews). This section discusses the process for resolving such disputes.

2.8.1 Technical Disputes

For those situations in which technical issues regarding QA and QC activities are in dispute, resolution should be sought at the lowest management level practicable. All parties should make every effort to resolve disputes through discussion and negotiation. If unsuccessful, final resolution should be made by the senior manager for the organization.

It is recommended that an organization's QMP include a process for dispute resolution within that organization. While the process described below (Section 2.8.2) may be used for technical disputes, an organization may develop a process that meets its particular needs.

2.8.2 Management Systems Disputes

Implementation of the Agency-wide Quality System may create disagreements arising from the results of the review and approval of Quality Management Plans (QMPs) and from the performance of management assessments using Management Systems Reviews (MSRs). The dispute resolution process should only be used when parties cannot achieve mutual resolution of their disagreement at the lowest possible administrative level. The dispute resolution process is terminated at any point where resolution is achieved and the issue resolved.

Disagreements should be resolved at the lowest administrative level possible. The dispute resolution officials for management systems issues are as follows:

- Within the components of the OEI - the AA/OEI.

- Between OEI and the National Program Offices or Regional Offices - the AA/OEI and the respective National Program Office Assistant Administrator (AA) or Regional Administrator (RA).

Should agreement not be reached at this level, the issue shall be resolved by the Deputy Administrator.

The dispute resolution process has the following steps:

(1) The process begins when either disagreeing party declares an issue to be unresolvable and sends a memorandum to the other party invoking this dispute resolution process, defining the disputed issue, and presenting supporting arguments for the first party's position on the issue.

(2) Within 30 days, the second party must send a draft dispute resolution package to the first party. As soon as possible after this, the two parties, working together, must submit a dispute resolution package to the dispute resolution official. This package would contain both party's arguments, both party's rebuttals, and any supporting materials.

(3) The dispute resolution official shall schedule a meeting for resolving the dispute within 30 to 60 days from receipt of the dispute resolution package, and for notifying both parties of this date. Both parties are invited to attend the resolution meeting to present arguments and answer questions. The dispute resolution official may get advice from third parties. The decision of the dispute resolution official shall be binding on both parties.

2.9 Performance Agreements

Successful implementation of the Agency-wide Quality System requires that EPA managers and staff perform specific quality management functions. Performance agreements for senior managers, supervisors, and applicable staff shall contain critical element(s) to commensurate with the quality management responsibilities assigned by EPA Order 5360.1 CHG 2, this Manual, and the organization's Quality Management Plan.

CHAPTER 3
QUALITY MANAGEMENT PLANS

3.1 Introduction

All Agency organizational units governed by EPA Order 5360.1 CHG 2 shall document their quality system in a Quality Management Plan (QMP). The QMP is a policy statement describing how an EPA organization shall comply with the requirements of EPA Order 5360.1 CHG 2. Quality systems encompass the management and technical activities necessary to plan, implement, document, and assess the effectiveness of QA and QC operations applied to environmental programs. The QMP provides the blueprint for how an individual EPA Program Office, Region, and National Laboratory or Center will plan, implement, document, and assess its quality system for the environmental work to be performed as part of its mission.

The QMP defines an organization's QA-related:

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

The QMP, therefore, is a management tool that should be appropriately tailored to the needs of the organization. The QMP must be sufficiently inclusive, explicit, and readable to enable managers and supervisors to understand the priority that senior 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 its effectiveness following implementation can be made. This enables managers to determine whether or not the quality system is being implemented in a way that ensures successful results from environmental programs. The QMP should focus on the processes used to plan, implement, document, and assess the programs to which it is applied. The level of detail should be based on a common sense, graded approach that establishes QA and QC requirements commensurate with the importance of the work, the available resources, and the unique needs of the organization.

QMPs shall be tailored to individual requirements and modified as the requirements change. This chapter describes the quality management practices which are normally considered to be critical to an effective quality system. Each Agency organization shall evaluate these key elements to see if they are applicable to its quality system. Where a particular element is not relevant, a brief explanation of why it is not relevant shall be provided in the QMP. If the QMP preparer determines that additional quality management elements are useful or necessary for an adequate quality system, these elements shall be developed and discussed in the QMP.

3.2 Preparation, Submission, Review, and Approval

3.2.1 QMP Preparation Responsibility

The senior manager for each EPA organization is responsible for the preparation of a QMP that covers all environmental programs for which the manager is accountable. A senior manager is a manager who is responsible and accountable for mission accomplishment and overall operations. Senior management shall ensure that the quality system documented in the QMP complies with the requirements in this Manual.

If desired by an organization's management, a draft of the QMP may be submitted to the OEI Quality Staff one time for informal comment prior to the formal review and approval process. However, an informal review by the Quality Staff shall not be used to replace a thorough review of the quality system and the proposed QMP by the management of the organization preparing the plan.

3.2.2 Internal Submission and Approval

The QMP must be approved and signed by the senior manager of the organization preparing the QMP. The senior manager shall indicate his/her approval of the QMP on the signature page of the document. The senior managers are designated as follows:

Organization Preparing the QMP	Senior Manager
Headquarters Office	Office Director
Headquarters Field Component	Office Director
Laboratory/Center/Office	Laboratory/Center/Office Director
Regional Office	Regional Administrator

The QMP must also be approved and signed by the QA manager of the organization, the OEI Quality Staff Director, and the AA/OEI. The senior manager may require the concurrence on the QMP by appropriate subordinate line managers to encourage the acceptance and implementation of the quality system. Subordinate line managers may include Division Directors, Branch Chiefs, and other supervisory personnel as defined for a particular organization.

3.2.3 Agency Review and Approval of the QMP

The QMP must be submitted to the OEI Quality Staff for review and approval. Each QMP will be reviewed to determine compliance with Agency-wide Quality System requirements. The review of the QMP shall focus on the substance of the group's QA management process and not on format or technical details. QMPs that address all mandatory program elements and include acceptable QA policies, procedures, administrative criteria, and management systems for key QA

elements including systematic planning processes, QA Project Plans, other QMPs, Standard Operating Procedures, assessments, and oversight of delegated programs shall be approved. QMP approval shall be valid for a period not to exceed five years.

3.2.4 QMP Revisions

Although the QMP approval by the Agency is valid for up to five years, all Agency quality systems must be reviewed at least annually by their organizations to reconfirm the effectiveness of the approved quality management practices. This assessment must include an evaluation of the effectiveness of the QMP. The process of developing and annually updating the QMP provides an opportunity for management and staff to review and clarify roles and responsibilities, to address problem areas, and to acknowledge successes. Having an accurate QMP at all times is an essential element in every quality system. Changes in QA policy and procedures shall be documented in a timely fashion by QMP revisions. In general, a copy of any QMP revision(s) made during the year should be submitted to the OEI Quality Staff as an attachment to or as part of the QA Annual Report and Work Plan (see Chapter 4).

A revised QMP may be submitted at any time, but is required under certain conditions including:

- expiration of the five-year life of the approved QMP,
- a major reorganization that requires "Directive Clearance" review (EPA, 1995),
- a significant change in the organization's mission, such as may occur in the reauthorization or revision of enabling environmental legislation, or
- any major change to the organization's quality system.

All appropriate personnel performing work for the organization, including active contractors and assistance agreement holders, shall be notified of all changes to the quality system and the QMP that may affect their work for EPA and to keep them apprised of the current requirements.

3.3 Quality Management Plan Requirements

3.3.1 General Requirements

The QMP describes the processes by which the organization plans, implements, documents, and determines the effectiveness of quality management practices, including QA and QC activities, to help management to obtain results of its technical work that are of the type and quality needed for their intended use. Specifically, the QMP must discuss:

- the mission and quality policy of the organization,
- the specific roles and responsibilities of management and staff with respect to QA and QC activities,
- the means and structure by which effective communications are assured,
- the process(es) used to plan, implement, and assess the work performed,
- the process(es) by which measures of effectiveness for QA and QC activities will be established and how frequently effectiveness will be measured, and
- the process for continual improvement of the organization's quality system.

The QMP should reflect the organization's commitment to quality management principles and practices, tailored by senior management to meet the organization's needs.

To reduce duplication between QMPs and QAPPs, the QMP shall include discussion of those activities, policies, and procedures that are common to all projects. Such discussions provide an "umbrella" under which individual project activities may be performed.

There are ten elements contained in a QMP. If an element is not applicable to an organization's quality system, then the QMP must state why this is the case. Specific requirements for each of the elements follow (Sections 3.3.2 - 3.3.11).

3.3.2 Management and Organization

Provide or address the following management and organizational items:

- a statement of the organization's policy on QA, including the importance of quality in its products to the organization and its mission, and why; the general objectives/goals of the quality system; and the policy for resource allocation for the quality system, including personnel, extramural funding, and travel funding;
- 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 confirms and 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 brief 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 activities among the group's organizational units needs to occur;

- a discussion of the QA and QC roles and responsibilities of line management, technical staff, and any other staff, and how these roles and responsibilities are incorporated into performance standards;

- a discussion of the organization's process for resolving disputes regarding quality system requirements, QA and QC procedures, assessments, or corrective actions;

- a discussion of how management shall 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 senior manager, senior line management (as appropriate), the QA manager of the organization, the OEI Quality Staff Director, and the AA/OEI. This approval page may be part of a title page or a separate sheet following the title page. Approving officials whose signatures must be contained on the approval page are described in section 3.2.2.

3.3.3 Quality System and Description

Discuss the principal components (or "tools") comprising the quality system and how they are used to implement the quality system. These components include, but are not limited to QMPs, management assessments (self and independent), systematic planning processes, QA Project Plans, Standard Operating Procedures, technical assessments (self and independent), and Data Quality Assessments. This discussion shall also identify how and when the components of the quality system are to be applied to individual projects and tasks.

3.3.4 Personnel Qualifications and Training

State the organization's 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.

3.3.5 Procurement of Items and Services

Describe and discuss the organization's process for ensuring that all appropriate extramural agreements, including grants, cooperative agreements, and contracted and subcontracted activities, involving or affecting environmental programs shall:

- contain appropriate QA and QC requirements in all applicable documents;
- receive the same review and approval for changes as for the original documents;
- address satisfactorily all QA and QC requirements in applicable responses to solicitations and include QA as an integral criterion in the evaluation criteria;
- provide objective evidence of quality furnished by suppliers and subcontractors for applicable items and services, including source selection, source inspections, supplier audits, and examination of deliverables; and
- provide evidence of the suppliers capability to satisfy EPA QA and QC requirements as defined in the extramural agreement or applicable regulation (e.g., 40 CFR 30, 40 CFR 31, 48 CFR 46).

Describe how procurement documents or financial assistance agreements shall require suppliers (i.e., contractors, subcontractors, or financial assistance recipients) to have a quality system consistent with EPA requirements. This requirement applies only to those suppliers who provide services or items that directly affect the quality of results or products from environmental programs.

3.3.6 Documents and Records

Describe or provide a reference to 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., QA Project Plans, Sampling and Analysis Plans) are prepared, reviewed, approved, issued, used, and revised; and

- that ensures 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 before general use.

Describe or provide a reference to the management process that ensures that records accurately reflect completed work and/or fulfill statutory and contractual requirements, including any specific record keeping requirements defined in EPA Order 2160 and EPA Directive 2100, Chapter 10. 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 senior management, is accomplished.

3.3.7 Computer Hardware and Software

Describe or discuss:

- how applicable EPA requirements for information resources management are addressed (EPA Directive 2100) including Year 2000 compliance, security, and privacy requirements (Chapters 5, 8, and 11 of EPA Directive 2100, respectively);

- the process for ensuring that computer hardware used in environmental programs meets technical requirements and quality expectations (i.e., configuration testing);

- 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 (EPA Directive 2182);

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

- the process for ensuring that data and information produced from or collected by computers meet applicable EPA information resources management requirements and standards (EPA Directive 2100).

These discussions shall include the roles and responsibilities assigned to management and staff. The QMP shall document how the organization manages its computer hardware and software operations that directly impact the quality of the results of environmental programs. Computer programs covered by this Manual include, but are not limited to, design, design analysis, data handling, data analysis, modeling of environmental processes and conditions, operations or process control, and data bases.

3.3.8 Planning

3.3.8.1 Systematic Planning

Environmental data operations shall be planned using a systematic planning process that is based on the scientific method. The planning process shall be based on 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. Elements of a systematic planning approach that shall be documented 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 requirements, 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 Process (EPA, 1994). 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.

3.3.8.2 Quality Assurance Project Plans

Discuss how the results of planning for environmental data operations shall be documented in a Quality Assurance Project Plan (QAPP) (see Chapter 5) and approved by authorized personnel for implementation. The process for developing, reviewing, approving, implementing, and revising a QAPP, must be described in this section of the QMP. Identify the staff who is authorized to approve QAPPs.

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.

3.3.9 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;

- development and implementation of 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 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 contain 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.

3.3.10 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 surveillances. 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.

The QMP shall also discuss conditions under which a “stop work” order may be needed and when and how authority for such decisions shall be made.

Describe how assessment results shall be 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.

3.3.11 Quality Improvement

Describe how the organization shall detect and prevent quality problems. Describe the organization's process for ensuring continual quality improvement, including the management process for determining, planning, implementing, and evaluating the effectiveness of quality improvement activities; who (organizationally) is responsible for quality improvement; and the

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.

The QMP shall 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.

CHAPTER 4
QUALITY ASSURANCE ANNUAL REPORT AND WORK PLAN

4.1 Background

Careful annual planning is necessary to the success of the Agency-wide Quality System. In order for management to budget adequate resources to implement the quality system for an organization, estimates of the quality system workload are needed. Moreover, management must give priority to quality system resource needs with respect to other mission requirements.

All Agency organizations subject to the requirements of EPA Order 5360.1 CHG 2 shall submit a Quality Assurance Annual Report and Work Plan (QAARWP) annually. The QAARWP shall summarize the results of having implemented the quality system the previous fiscal year and describe QA activities planned for the fiscal year beginning in October. The QAARWP may be used to identify limited changes or updates to the organizations's approved Quality Management Plan (QMP) (see Chapter 3). The QAARWP should provide helpful information to management by documenting the past fiscal year's activities and estimating the current year's workload based on the prior year and the expected activities in the current year.

4.2 Use of QAARWP Submissions

The contents of the QAARWPs shall be used by OEI Quality Staff to evaluate the overall effectiveness of the Agency-wide Quality System. As problems related to QA are identified by EPA organizations, the Quality Staff shall use the QAARWP information to identify systemic or Agency-wide problems and shall initiate plans to address such problems. The QAARWPs shall not be approved as are QMPs.

4.3 Requirements

The QAARWP must be submitted under the signature of the senior manager for the organization to the AA/OEI. Organization is defined here as an ORD Center, Laboratory, or Office; individual Program Office one level under an AA-ship; or Region. In order to simplify the submittal, the QAARWP and its attachments may be submitted electronically to the OEI Quality Staff Director along with a copy of the original signature page. The QAARWP has two parts, the annual report for the previous fiscal year and the proposed work plan for the new fiscal year. Specifications for the QAARWP are contained in Sections 4.3.1 - 4.3.2.

4.3.1 QA Annual Report

4.3.1.1 Quality Management Resources

Resources provided here may be estimated if not strictly accounted for by position or expense tracking. For example, if 10% of the time of all project officers is spent on quality assurance activities, then an estimate can be made by multiplying 10% times the number of project officers. If such an estimate is made, the algorithm should be provided to clarify the response.

- Provide a current estimate of the organization's filled FTE positions.

- State the total EPA (and other Federal) FTE (to the nearest tenth of an FTE) involved in the management of QA and QC activities. Examples of these activities include providing input to management on the need for and use of QA resources, disseminating Agency QA policy, developing and ensuring the implementation of the organization's QMP (including document tracking, auditing, and training), and acting as a liaison with OEI Quality Staff. Vacancies should be listed separately.

- State the total EPA (and other Federal) FTE involved in QA and QC support activities. Examples of these activities include writing and reviewing QAPPs and Standard Operating Procedures (SOPs) and validating data.

- If your organization uses contractor support to implement the quality system, state the total contractor FTEs involved in QA and QC support activities. Include the technical QA and QC support activities of Senior Environmental Employment Program (SEEP) grantees or other grantees.

- State the total FTEs involved in other non-technical QA and QC support activities. This category would include the non-technical SEEP employees and clerical staff.

- State the total dollar amounts (rounded to nearest $K) of other QA supporting funds, not including travel funds or training.

- State the total dollar amounts of travel funds used for QA activities such as oversight, surveillance, and audits/assessments.

- State the total dollar amount of funds used for QA and QC training, including travel for training, and the total number of people who attended the training. Include training for QA staff.

- Discuss the adequacy of the above listed resources in relation to their impact on your quality system, including the ability to implement last year's work plan.

4.3.1.2 Training

- Briefly describe the method used to assess the organization's QA training needs and the results of the assessment; i.e., what needs were identified. Discuss separately any needs assessment made of other organizations participating in your quality system (i.e., States, Tribes, Regions).

- List courses and name the supplier(s) for QA and QC courses given to your organization and other non-EPA organizations participating in your quality system. The courses attended by the QA staff, while critically important for educating new QA staff members, are not the primary concern. For example, contract administration and field/lab equipment techniques are not considered QA courses. Statistics courses, however, are considered related to QA in terms of project planning and data analysis.

- List the attendance for each course. If course attendees included persons from outside your organization, identify the total attendance by each organization represented.

- For each course, indicate whether the course goals were achieved; that is, were the training needs fulfilled? If not, please indicate why and what you believe needs to be done to satisfy the remaining needs.

4.3.1.3 Management Accomplishments

- Discuss any innovative quality management practices you have developed and used in planning, implementing, or assessing your quality system. Include any proposed revisions to your Quality Management Plan reflecting changes to your operating practices for QA and QC activities.

- Summarize the technical assessments that were performed by your organization on itself and others participating in your quality system. For each assessment, identify the type of assessment performed, the organization and project which were the subject of the assessment, when the assessment was performed, and who did the assessment. Also provide a general statement of the assessment results and any corrective actions. For example, the QA staff members performed technical systems audits of these projects: (list). Note, if this information is indicated on an attached quality system tracking program output, give the totals here.

- Summarize the technical assessments that were performed on your organization by others. For each assessment, identify the type of assessment performed, the organization and project which were the subject of the assessment, when the assessment was performed, and who did the assessment. Also provide a general statement of the assessment results and any corrective actions.

- Summarize technical assistance given on planning, data review, etc. For QAPPs, the numbers of QAPPs reviewed (or re-reviewed) and an indication of average turnaround time is sufficient. Note, if tracking program outputs are attached, give totals for intramural and extramural projects. Include QA assistance given by the organization or individuals to non-EPA organizations, including states, private industry, and foreign countries. Organizations participating in your quality system that have QMPs reviewed and approved by you should also be listed.

- List any new or revised QA guidance developed by your organization. It is not necessary to list SOPs written and revised during the past year. The numbers of both new and revised SOPs is sufficient.

- List any publications and presentations concerning QA and QC practices and results by your organization. QA guidance listed above need not be repeated. Internet or other electronic document forms should be included.

- List any awards or recognition related to QA given to your organization or to individual staff members.

4.3.1.4 Management Assessment of the Approved Quality System

- Summarize the management assessments (i.e. management systems reviews) that were performed by your organization on itself and others participating in your quality system. Include the part of the implemented program that was examined and what was learned (including positive findings). If corrective actions were indicated, summarize the response actions taken, and discuss progress toward their implementation. Report on their effectiveness, if known.

- Summarize the management assessments that were performed by others (including the OEI Quality Staff) on your quality system. Include the part of the implemented program that was examined and what was learned. If corrective actions were indicated, briefly summarize the response actions taken, and discuss progress toward their implementation. In particular, highlight any incomplete corrective actions resulting from the Quality Staff assessments. Report on the effectiveness of the corrective actions, if known.

4.3.2 Work Plan

4.3.2.1 Quality Management Resources

- State the total EPA (and other Federal) FTE (to the nearest tenth of an FTE) proposed for supporting quality management activities in your organization. Examples of these activities include providing input to management on the need for and use of QA resources, disseminating Agency QA policy, developing and ensuring the implementation of the organization's QMP (including document tracking, auditing, and training), and acting as a liaison with the OEI Quality Staff. Vacancies should be listed separately.

- State the total EPA (and other Federal) FTE proposed for QA and QC support activities. Examples of these activities include writing and reviewing QAPPs and SOPs and validating data.

- If your organization uses contractor support to implement the quality system, state the total contractor FTEs proposed for the QA and QC support activities.

- State the total FTEs proposed for other non-technical QA and QC support activities. This category would include Senior Environmental Employment Program employees, other grantees, and clerical staff.

- State the total dollar amounts (rounded to nearest $K) of proposed QA and QC support funds, not including travel funds or training.

- State the total dollar amounts of proposed travel funds for QA activities such as oversight, surveillance, and audits.

- State the total dollar amounts of proposed funds for training, including travel.

4.3.2.2 Activities

- List and briefly describe anticipated major QA and QC activities expected during the year including QA and QC-related training to be given, taken, or developed, guidance to be developed or revised, technical and management assessments of your organization and others participating in your quality system, and implementation of corrective actions from prior MSRs of your quality system.

CHAPTER 5
QUALITY ASSURANCE PROJECT PLANS

5.1 Introduction

EPA policy requires that all work performed by or on behalf of EPA involving the collection of environmental data shall be implemented in accordance with an Agency-approved Quality Assurance Project Plan (QAPP). The QAPP defines and documents how specific data collection activities shall be planned, implemented, and assessed during a particular project. This chapter presents detailed specifications on the information that must be addressed in a QAPP for environmental data operations performed by or on behalf of EPA and on the procedures for its review and approval. Guidance on developing QAPPs, including examples of QAPP elements, may be found in *Guidance on Quality Assurance Project Plans (QA/G-5)* (EPA 1998).

The QAPP is a critical planning document for any environmental data operation since it documents how environmental data operations are planned, implemented, documented, and assessed during the life cycle of a program, project, or task. The ultimate success of an environmental program or project depends on the adequacy and sufficiency of the quality of the environmental data collected and used in decision-making. This may depend significantly on the adequacy of the QAPP and its effective implementation. Quality planning (Section 3.3.8.1) is an absolutely essential component of project management and the QAPP provides the mechanism for documenting the results of the planning process. This planning must include the "stakeholders" (i.e., the data users, data producers, decision makers, etc.) to ensure that all needs are defined adequately at the outset and that the planning for quality addresses the specific needs defined.

In the sections to follow, the elements of the QAPP are discussed in detail. These elements represent the information generally required for most data operations involving the characterization of environmental processes and conditions. Because of the diversity of Agency programs, some elements described in this chapter may not be applicable to all programs. The final decision on the applicability or use of any or all of these elements for QAPPs shall be made by individual EPA organizations. EPA organizations may tailor these requirements in their own implementation documents to better fit their specific needs.

5.2 QAPP Responsibilities and Application

5.2.1 QAPP Preparation Responsibilities and Approvals

The EPA organization's Quality Management Plan (QMP) establishes how, when, and by whom development, review, approval, and effective oversight of QAPPs occurs, including situations in which QAPPs are prepared by extramural (non-EPA) organizations. In some cases, it

may be necessary to add special requirements to the QAPP. The EPA organization sponsoring the work shall define any specific requirements beyond those listed in this manual.

No environmental data collection work shall be started until the QAPP has been approved and distributed to project personnel except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers. Some non-data collection activities such as equipment procurement, instrument calibration, etc., may be conducted prior to the approval of the QAPP. In limited circumstances, EPA *may* grant conditional approval to a QAPP to permit some work to begin while non-critical deficiencies in the QAPP are being resolved.

5.2.2 QAPP Implementation and Revision

All QAPPs shall be implemented as approved by EPA. The organization performing the work shall implement the approved QAPP and ensure that all personnel involved in the work have copies of the approved QAPP and all other necessary documents. Personnel implementing the approved QAPP should understand the requirements prior to the start of data generation activities.

Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. The EPA Project Manager, with the assistance of the QA Manager as appropriate, must determine the impact of such changes on the technical and quality objectives of the project. When a substantive change is warranted, the originator of the QAPP shall modify the QAPP to document the change and submit the revision for approval by the same authorities that performed the original review. Only after the revision has been approved and received (at least verbally with written follow-up) by project personnel, shall the change be implemented.

It is essential that the QAPP be kept current and that all personnel involved in the work have easy access to a current version of the QAPP. For programs or projects of long duration, such as multi-year monitoring programs, the QAPPs shall be reviewed at least annually by the Project Manager. If revisions are necessary to reflect current needs, the QAPP must be revised and resubmitted for review and approval.

5.2.3 Applicability of QAPPs

The QAPP requirements in this chapter apply to all (intramural and extramural) environmental data operations that acquire, generate, or compile environmentally-related data and that are performed by or on behalf of EPA. Extramural data operations may include contracts and work assignments, delivery orders, task orders, cooperative agreements, interagency agreements, State-EPA agreements, State, local, and Tribal Financial Assistance/Grants, Research Grants, and responses to statutory or regulatory requirements and to consent agreements negotiated as part of

enforcement actions. QA and QC requirements shall be negotiated into applicable interagency agreements, including sub-agreements since EPA cannot unilaterally impose its QA and QC requirements in these agreements. Where specific Federal regulations require QA and QC activities, QAPPs shall be prepared, reviewed, and approved in accordance with the specifications contained in this document for the data collection activity unless superseded by the regulation.

5.3 QAPP Elements and Requirements

Environmental data operations encompass diverse and complex activities, including rule making, compliance with regulations, and research. As a result, some environmental data operations may only require a qualitative discussion of the experimental process and its objectives while others may require extensive documentation in order to adequately describe a complex environmental program. The content and level of detail in each QAPP may vary according to the nature of the work being performed and the intended use of the data. The final decision on QAPP content and level of detail belongs to the EPA organization responsible for the work to be done, consistent with the approved QMP.

5.3.1 General Content Requirements

The QAPP must provide sufficient detail to demonstrate that:

- the project technical and quality objectives (e.g., Data Quality Objectives) are identified;
- the intended measurements or data acquisition methods are appropriate for achieving project objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

Most environmental data operations require the coordinated efforts of many individuals, possibly including managers, engineers, scientists, statisticians, and others. The QAPP must integrate the contributions and requirements of everyone involved into a clear, concise statement of what needs to be accomplished, how it shall be done, and by whom. It must provide understandable instructions to those who must implement the QAPP, including the field sampling team, the analytical laboratory, and the data reviewers. The use of standard operating procedures and national standards and practices is encouraged in all aspects of the QAPP.

In order to be effective, the QAPP must specify the level or degree of QA and QC activities needed for the particular environmental data operations. The QA and QC technical requirements of a project should commensurate with:

- the purpose of the environmental data collection (e.g., enforcement action, research and development),
- the type of work to be done (e.g., monitoring, site characterization, bench level proof of concept), and
- how the results shall be used (e.g., regulatory enforcement, permit approval).

The QAPP must be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. The QAPP elements that follow are presented in that order and have been arranged for convenience into four general groups. The four groups of elements and their intent are summarized as follows:

- A. Project Management - These elements cover the basic area of project management, including the project history, project objectives, and roles and responsibilities of the participants. These elements document that the project has a defined goal and that the participants understand the goal and the approach to be used.
- B. Measurement/Data Acquisition - These elements cover all aspects of measurement systems design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and are properly documented.
- C. Assessment/Oversight - These elements address the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities. The purpose of assessment is to ensure that the QAPP is implemented as prescribed.
- D. Data Validation and Usability - These elements cover the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

All applicable elements defined by the EPA organization sponsoring the work must be addressed in the QAPP. Documentation, such as an approved Work Plan, Standard Operating Procedures (SOPs), etc., may be referenced in response to a particular required QAPP element to reduce the size of the QAPP and the time required for preparation and review. All referenced

documents must be attached to the QAPP itself or be placed on file with the appropriate EPA office and available for routine referencing when needed. Such references must be kept current by the submitter. The QAPP shall also address related QA planning documentation (e.g., Quality Management Plans) from subcontractors or suppliers of services critical to the technical and quality objectives of the project or task.

5.3.2 Group A, Project Management

This group of QAPP elements covers the basic area of project management, including:

A1	Title and Approval Sheet
A2	Table of Contents
A3	Distribution List
A4	Project/Task Organization
A5	Problem Definition/Background
A6	Project/Task Description
A7	Quality Objectives and Criteria for Measurement Data
A8	Special Training Requirements/Certification
A9	Documentation and Records

5.3.2.1 A1. Title and Approval Sheet

Include the title of the plan, name of the organization(s) implementing the project, and names, titles, signatures of appropriate approving officials and their approval dates. Approving officials include the Organization's Project Manager, Organization's Quality Assurance Manager, EPA Project Manager, and EPA Quality Assurance Manager, as appropriate. Other officials, as needed, may include the field operations manager, laboratory manager, State officials, and other Federal Agency officials.

5.3.2.2 A2. Table of Contents

List the sections, figures, tables, references, and appendices. Document control format may be required at the option of the Project Manager and QA Manager. When required, use a document control format on each page following the Title and Approval Sheet. For example, the following may be placed on the upper right hand corner of each page:

Section No. _____
Revision No. _____
Date _____
Page ___ of ___

5.3.2.3 A3. Distribution List

List the individuals and their organizations who shall receive copies of the approved QAPP and any subsequent revisions. Include all persons responsible for implementation (including managers), the QA managers, and representatives of all groups involved.

5.3.2.4 A4. Project/Task Organization

Identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. Include the principal data users, the decision-makers, the project QA manager, and all persons responsible for implementation. The project quality assurance manager must be independent of the unit generating the data. (This does not include being independent of senior officials, such as corporate managers or agency administrators, who are nominally, but not functionally, involved in data generation, data use, or decision-making.) If someone other than the project manager is responsible for approving and accepting final products and deliverables, then that individual shall be identified. The individual responsible for maintaining the official, approved QAPP shall also be identified.

Provide a concise organization chart showing the relationships and the lines of communication among all project participants. Include other data users who are outside of the organization generating the data, but for whom the data are nevertheless intended; e.g., modelers, risk assessors, design engineers, toxicologists, etc. The organization chart must also identify any subcontractor relationships relevant to environmental data operations. Where direct contact among project managers and data users does not occur, such as a Superfund Potentially Responsible Party and the EPA Risk Assessment staff, the organization chart should show the pathway by which information is exchanged.

5.3.2.5 A5. Problem Definition/Background

State the specific problem to be addressed or decision to be made. Include sufficient background information to provide the historical perspective for the project.

5.3.2.6 A6. Project/Task Description

Provide a description of the work to be performed and schedule for implementation. This discussion may not need to be lengthy or overly detailed, but it should give an overall picture of how the project shall resolve the problem or question described in A5. Describe in general terms the following, as needed:

- Measurements that will be made during the course of the project.

- Applicable technical, regulatory, or program-specific quality standards, criteria, or objectives.
- Any special personnel and equipment requirements.
- The assessment tools needed (i.e., program technical reviews, surveillances, and technical audits as needed by the project or specified by the QMP) for the project.
- A schedule for the work to be performed.
- Project and QA and QC records required, including the types of reports needed.

5.3.2.7 A7. Quality Objectives and Criteria for Measurement Data

Provide a statement of the project quality goals or objectives and measurement performance criteria. EPA requires the use of a systematic planning process and prefers that most project planning be accomplished using the DQO Process. For details on the DQO Process and when it may be used, see the *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA, 1994).

5.3.2.8 A8. Special Training Requirements/Certification

Identify and describe any specialized training or certification requirements needed by personnel in order to successfully complete the project or task. Discuss how such training shall be provided and how the necessary skills shall be assured and documented.

5.3.2.9 A9. Documentation and Records

Describe the process and responsibilities for ensuring that the most current approved version of the QAPP is available.

Itemize the information and records which must be included in a data report package and specify the desired reporting format. Documentation can include raw data, field logs, instrument printouts, and results of calibration and QC checks. Specify the level of detail of the field sampling and/or laboratory analysis narrative needed to provide a complete description of any difficulties encountered during sampling or analysis. The narrative refers to an annotated summary of the analytical work performed by a laboratory that describes in narrative form what activities were performed and identifies any problems encountered that provides additional information to users in interpreting the data received.

Specify any requirements for the final disposition of records and documents from the project, including location and length of retention period.

5.3.3 Group B, Measurement/Data Acquisition

This group of QAPP elements covers all aspects of measurement systems design and implementation, including:

B1 Sampling Process Design (Experimental Design)
B2 Sampling Methods Requirements
B3 Sample Handling and Custody Requirements
B4 Analytical Methods Requirements
B5 Quality Control Requirements
B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
B7 Instrument Calibration and Frequency
B8 Inspection/Acceptance Requirements for Supplies and Consumables
B9 Data Acquisition Requirements (Non-direct Measurements)
B10 Data Management

5.3.3.1 B1. Sampling Process Design (Experimental Design)

Describe the experimental design or data collection design for the project, including as appropriate the types and numbers of samples required, the design of the sampling network, sampling locations and frequencies, sample matrices, measurement parameters of interest, and the rationale for the design. Classify each measurement as critical (i.e., required to achieve project objectives) or non-critical (informational purposes only).

5.3.3.2 B2. Sampling Methods Requirements

Describe the procedures for collecting samples and identify the sampling methods and equipment, including any implementation requirements, sample preservation requirements, decontamination procedures, and materials needed. Identifying sampling methods by number, date, and regulatory citation (as appropriate) is often sufficient. If a method allows the user to select from various options, then the method citations should state *exactly* which options are being selected. Describe specific performance requirements for the method. For each sampling method, identify any support facilities needed. The discussion should also address what to do when a failure in the sampling or measurement system occurs and who is responsible for corrective action and how the effectiveness of the corrective action shall be determined and documented.

Describe the process for the preparation and decontamination of sampling equipment, including the disposal of decontamination by-products; the selection and preparation of sample containers, sample volumes, preservation methods, and maximum holding times to sample extraction and/or analysis.

5.3.3.3 B3. Sample Handling and Custody Requirements

Describe the requirements and provisions for sample handling and custody in the field, laboratory, and transport, taking into account the nature of the samples, the maximum allowable sample holding times before extraction or analysis, and available shipping options and schedules. Sample handling includes preservation, packaging, shipment from the site, and storage at the laboratory. Examples of sample labels, custody forms, and sample custody logs should be included.

5.3.3.4 B4. Analytical Methods Requirements

Identify the analytical methods and equipment required, including subsampling or extraction methods, laboratory decontamination procedures and materials (such as in the case of hazardous or radioactive samples), waste disposal requirements (if any), and any specific performance requirements for the method. Address what to do when a failure in the analytical system occurs and who is responsible for corrective action and how the effectiveness of the corrective action shall be determined and documented.

Identifying analytical methods by number, date, and regulatory citation (as appropriate) is often sufficient. If a method allows the user to select from various options, then the method citations should state *exactly* which options are being selected. For non-standard methods, such as unusual sample matrices and situations, appropriate method performance study information is needed to confirm the performance of the method for the particular matrix. If previous performance studies are not available, they must be developed during the project and included as part of the project results.

5.3.3.5 B5. Quality Control Requirements

Identify QC procedures needed for each sampling, analysis, or measurement technique. For projects at or beyond the "proof-of-concept" stage and projects employing well-characterized methods, this section should list each required QC procedure, along with the associated acceptance criteria and corrective action. Because standard methods are often vague or incomplete in specifying QC requirements, simply relying on the cited method to provide this information is usually insufficient.

Identify required measurement QC checks for both the field and the laboratory; for example, blanks, duplicates, matrix spikes, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC check, and the spike compounds sources and levels. State or reference the required control limits for each QC check and corrective action required when control limits are exceeded and how the effectiveness of the corrective action shall be determined and documented.

Describe or reference the procedures to be used to calculate each of the QC statistics, including the QC checks described in the preceding paragraph as well as precision and bias. Copies of the formulas are acceptable as long as the accompanying narrative or explanation specifies clearly how the calculations will address difficult situations such as missing data values and "less than" or "greater than" values.

5.3.3.6 B6. Instrument/Equipment Testing, Inspection, and Maintenance Requirements

Describe how inspections and acceptance testing of environmental sampling and measurement systems and their components shall be performed and documented to assure their intended use as specified by the design. Identify and discuss the procedure by which final acceptance shall be performed by independent personnel (e.g., personnel other than those performing the data collection work) and/or by the EPA Project Officer. Describe how deficiencies are to be resolved, and when re-inspection shall be performed and how the effectiveness of the corrective action shall be determined and documented.

Identify the equipment and/or systems requiring periodic maintenance. Describe or reference how periodic preventive and corrective maintenance of measurement or test equipment shall be performed to ensure availability and satisfactory performance of the systems. Discuss how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems, shall be ensured and maintained.

5.3.3.7 B7. Instrument Calibration and Frequency

Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data collection activities affecting quality that must be controlled and, at specified periods, calibrated to maintain performance within specified limits. Describe or reference how calibration shall be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Identify the certified equipment and/or standards used for calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument.

5.3.3.8 B8. Inspection/Acceptance Requirements for Supplies and Consumables

Describe how and by whom supplies and consumables shall be inspected and accepted for use in the project. State acceptance criteria for such supplies and consumables. They include, but are not limited to: sample bottles, calibration gases, reagents, hoses, materials for decontamination of sampling equipment, deionized water, and potable water.

5.3.3.9 B9. Data Acquisition Requirements (Non-direct Measurements)

Identify any types of data needed for project implementation or decision making that are obtained from non-measurement sources such as computer data bases, spreadsheets, programs, and literature files. Define acceptance criteria for the use of such data in the project. Discuss any limitations on the use of the data resulting from uncertainty in its quality and from the impact of adding more error to the results.

5.3.3.10 B10. Data Management

Describe the project data management scheme, tracing the path of the data from their generation in the field or laboratory to their final use or storage. Describe or reference the standard record-keeping procedures, document control system, and the approach used for data storage and retrieval on electronic media. Discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data reduction (i.e., calculations), data reporting, and data entry to forms, reports, and databases. Provide examples of any forms or checklists to be used.

Identify and describe all data handling equipment and procedures to process, compile, and analyze the data including procedures for addressing data generated as part of the project as well as data from other sources. Include any required computer hardware and software and address any specific performance requirements for the hardware/software configuration used. Describe the procedures that shall be followed to demonstrate acceptability of the hardware/software configuration required.

Describe the process for assuring that applicable Agency information resource management requirements (EPA Directive 2100) are satisfied. Agency policy requires that locational data be collected and reported with environmental data. If other Agency data management requirements are applicable, such as the Chemical Abstract Service Registry Number Data Standard (EPA Order 2180.1), Data Standards for the Electronic Transmission of Laboratory Measurement Results (EPA Order 2180.2), or the Minimum Set of Data Elements for Ground-Water Quality (EPA Order 7500.1A), discuss how these requirements are addressed.

5.3.4 Group C, Assessment/Oversight

This group of QAPP elements addresses the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities, including:

C1 Assessments and Response Actions
C2 Reports to Management

5.3.4.1 C1. Assessments and Response Actions

Identify the number, frequency, and type of assessment activities needed for this project. Assessments include, but are not limited to surveillance, management systems review, readiness review, technical systems audit, performance evaluation, audit of data quality, and data quality assessment.

List and describe the assessments to be used in the project. Discuss the information expected and the success criteria (i.e., goals, performance objectives, acceptance criteria specifications, etc.) for each assessment proposed. List the approximate schedule of activities. For any planned self-assessments (utilizing personnel from within the project groups), identify potential participants and their exact relationship within the project organization. For independent assessments, identify the organization and person(s) that shall perform the assessments if this information is available. Describe how and to whom the results of the assessments shall be reported.

Define the scope of authority of the assessors, including stop work orders. Define explicitly the unsatisfactory conditions under which the assessors are authorized to act and provide an approximate schedule for the assessments to be performed.

Discuss how response actions to non-conforming conditions shall be addressed and by whom. Identify who is responsible for implementing the response action. Describe how response actions shall be verified, validated, and documented.

5.3.4.2 C2. Reports to Management

Identify the frequency and distribution of reports issued to inform management of the status of the project; results of performance evaluations and system audits; results of periodic data quality assessments; and significant quality assurance problems and recommended solutions. Identify the preparer and the recipients of the reports.

5.3.5 Group D, Data Validation and Usability

This group of QAPP elements covers the QA activities that occur after the data collection phase of the project is completed, including :

- D1 Data Review, Validation, and Verification Requirements
- D2 Validation and Verification Methods
- D3 Reconciliation with User Requirements

5.3.5.1 D1. Data Review, Validation, and Verification Requirements

State the criteria used to review and validate - that is, accept, reject, or qualify - data, in an objective and consistent manner. Provide examples of any forms or checklists to be used. Identify any project-specific calculations required.

5.3.5.2 D2. Validation and Verification Methods

Describe the process to be used for validating and verifying data, including the chain of custody for data throughout the life cycle of the project or task. Discuss how issues shall be resolved and the authorities for resolving such issues. Describe how the results are conveyed to data users.

5.3.5.3 D3. Reconciliation with User Requirements

Describe how the results obtained from the project or task shall be reconciled with the requirements defined by the user. Describe how issues shall be resolved. Discuss how limitations on the use of the data shall be reported to decision makers.

APPENDIX A
GLOSSARY

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.

bias - the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

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 (DQOs) - qualitative and quantitative statements derived from the DQO Process that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

data quality objectives 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.

document - any compilation of information which describes, defines, specifies, reports, certifies, requires, or provides data or results pertaining to environmental programs.

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 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; and 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 applies to hardware-based systems; however, it also applies 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.

extramural agreement - a legal agreement between EPA and an organization outside EPA for items or services to be provided. Such agreements include contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements.

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

graded approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of 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.

management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

management assessment - the qualitative assessment of a particular program 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 results needed are obtained. A management assessment may either be performed by those immediately responsible for overseeing and/or performing the work (i.e., a management self-assessment) or by someone other that the group performing the work (i.e., a management independent assessment).

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.

measurement and testing equipment - tools, gauges, instruments, sampling devices or systems used to calibrate, measure, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

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.

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. In the context of this Manual, an EPA organization is an office, region, national center or laboratory.

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.

precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed generally in terms of the standard deviation.

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 customer.

quality assurance manager (QAM) - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.

quality assurance project plan (QAPP) - a 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 a quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, 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.

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.

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 assessment - the evaluation process used to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may include qualitative and quantitative evaluations. A technical assessment may either be performed by those immediately responsible for overseeing and/or performing the work (i.e., a technical self-assessment) or by someone other that the group performing the work (i.e., a technical independent assessment).

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.

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.

APPENDIX B
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."

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U.S. Environmental Protection Agency, 1994. Memorandum from Ray E. Spears, Associate General Council, to H. Matthew Bills, Director for Modeling, Monitoring Systems and Quality Assurance, “Use of Extramural Support to Implement Quality Systems for Environmental Programs Involving Environmental Data Operations.”