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EPA Requirements for Quality Assurance Project Plans

EPA QA/R-5

Quality

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FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Assurance Project Plan (QA Project Plan) as a tool for project managers and planners to document the type and quality of data needed for environmental decisions and to describe the methods for collecting and assessing those data. The development, review, approval, and implementation of the QA Project Plan is part of EPA's mandatory Quality System. The EPA Quality System requires all organizations to develop and operate management structures and processes to ensure that data used in Agency decisions are of the type and quality needed for their intended use. The QA Project Plan is an integral part of the fundamental principles and practices that form the foundation of the EPA Quality System.

This document provides the QA Project Plan requirements for organizations that conduct environmental data operations on behalf of EPA through contracts, financial assistance agreements, and interagency agreements; however, it may be used by EPA as well. It contains the same requirements as Chapter 5 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs*, which has been developed for internal use by EPA organizations. A companion document, *EPA Guidance for Quality Assurance Project Plans (QA/G-5)* (EPA 1998) provides suggestions for both EPA and non-EPA organizations on preparing, reviewing, and implementing QA Project Plans that satisfy the requirements defined in this document.

This document is one of the *EPA Quality System Series* documents which describe EPA policies and procedures for planning, implementing, and assessing the effectiveness of a quality system. Questions regarding this document or other *EPA Quality System Series* documents should be directed to:

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www.epa.gov/quality

ACKNOWLEDGMENTS

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

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

Environmental programs conducted by or funded by the U.S. Environmental Protection Agency (EPA) involve many diverse activities that address complex environmental issues. The EPA annually spends several hundred million dollars in the collection of environmental data for scientific research and regulatory decision making. In addition, non-EPA organizations may spend as much as an order of magnitude more each year to respond to Agency requirements. If decision makers (EPA and otherwise) are to have confidence in the quality of environmental data used to support their decisions, there must be a structured process for quality in place.

A structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications is called a quality system. All organizations conducting environmental programs funded by EPA are required to establish and implement a quality system. EPA also requires that all environmental data used in decision making be supported by an approved Quality Assurance Project Plan (QA Project Plan). This requirement is defined in EPA Order 5360.1 A2 (EPA 2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, for EPA organizations. Non-EPA organizations funded by EPA are required to develop a QA Project Plan through:

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

The QA Project Plan integrates all technical and quality aspects of a project, including planning, implementation, and assessment. The purpose of the QA Project Plan is to document planning results for environmental data operations and to provide a project-specific "blueprint" for obtaining the type and quality of environmental data needed for a specific decision or use. The QA Project Plan documents how quality assurance (QA) and quality control (QC) are applied to an environmental data operation to assure that the results obtained are of the type and quality needed and expected.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this may depend significantly on the adequacy of the QA Project Plan and its effective implementation. Stakeholders (i.e., the data users, data producers, decision makers, etc.) shall be involved in the planning process for a program or project to ensure that their needs are defined adequately and addressed. While time spent on such planning may seem unproductive and costly, the penalty for ineffective planning

includes greater cost and lost time. Therefore, EPA requires that a systematic planning process be used to plan all environmental data operations. To support this requirement, EPA has developed a process called the Data Quality Objectives (DQO) Process. The DQO Process is the Agency's preferred planning process and is described in the *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000b). The QA Project Plan documents the outputs from systematic planning.

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

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

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

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

A Quality Management Plan, or equivalent Quality Manual, documents how an organization structures its quality system, defines and assigns QA and QC responsibilities, and describes the processes and procedures used to plan, implement, and assess the effectiveness of the quality system. The Quality Management Plan may be viewed as the "umbrella" document under which individual projects are conducted. EPA requirements for Quality Management Plans are defined in *EPA Requirements for Quality Management Plans (QA/R-2)* (EPA 2001). The

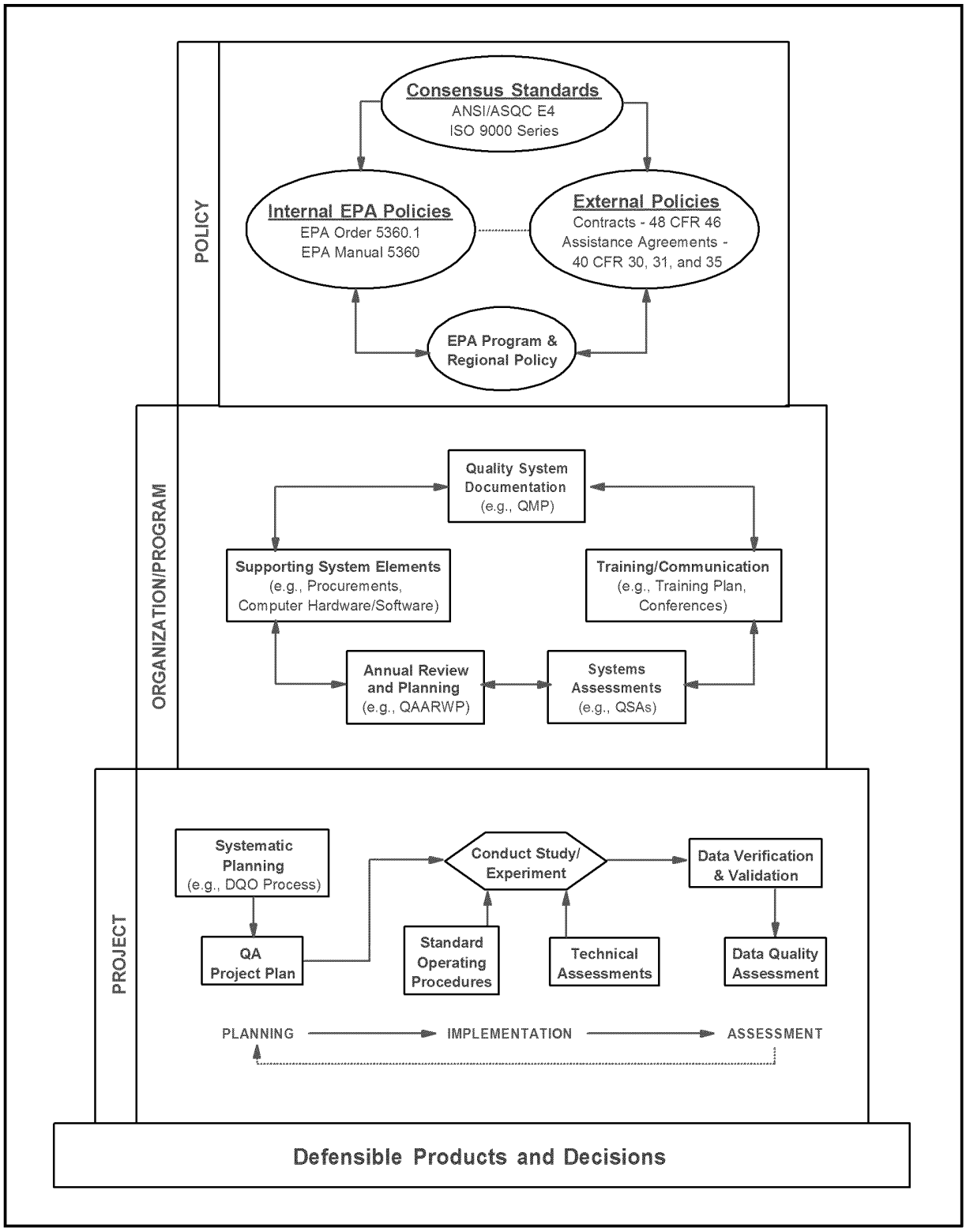

Figure 1. EPA Quality System Components and Tools

Quality Management Plan is then supported by project-specific QA Project Plans. In some cases, a QA Project Plan and a Quality Management Plan may be combined into a single document that contains both organizational and project-specific elements. The QA Manager for the EPA organization sponsoring the work has the authority to determine when a single document is applicable and will define the content requirements of such a document.

1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM

Recognizing that a "one size fits all" approach to quality requirements will not work in organizations as diverse as EPA, implementation of the EPA Quality System is based on the principle of graded approach. Applying a graded approach means that quality systems for different organizations and programs will vary according to the specific objectives and needs of the organization. For example, the quality expectations of a fundamental research program are different from that of a regulatory compliance program because the purpose or intended use of the data is different. The specific application of the graded approach principle to QA Project Plans is described in Section 2.4.2.

1.4 INTENDED AUDIENCE

This document specifies the requirements for developing QA Project Plans for organizations that conduct environmental data operations funded by EPA through contracts, financial assistance agreements, and interagency agreements. EPA organizations may also use this document to develop QA Project Plans since this document is clearer and more user-friendly than the equivalent requirements defined in Section 5.3 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs* (an internal policy document). However, the preparation, submission, review, and approval requirements for EPA organizations are still contained in Section 5.2 of EPA Order 5360 A1 as these represent internal EPA policy.

1.5 PERIOD OF APPLICABILITY

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

1.6 ADDITIONAL RESOURCES

Guidance on preparing QA Project Plans may be found in a companion document, *EPA Guidance for Quality Assurance Project Plans (QA/G-5)* (EPA 1998). This guidance discusses the application of the QA Project Plan requirements and provides examples. Other documents that provide guidance on activities critical to successful environmental data operations and complement the QA Project Plan preparation effort include:

- *Guidance for the Data Quality Objectives Process (QA/G-4)*, (EPA 2000b)
- *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)*, (EPA 1995)
- *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*, (EPA 2000a)

1.7 SUPERSESSION

This document replaces QAMS-005/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (EPA 1980) in its entirety.

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CHAPTER 2

QA PROJECT PLAN REQUIREMENTS

2.1 POLICY

All work funded by EPA that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be implemented in accordance with an approved QA Project Plan. The QA Project Plan will be developed using a systematic planning process based on the graded approach. No work covered by this requirement shall be implemented without an approved QA Project Plan available prior to the start of the work except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

2.2 PURPOSE

The QA Project Plan documents the planning, implementation, and assessment procedures of, and how specific QA and QC activities will be applied during a particular project. The QA Project Plan demonstrates conformance to Part B requirements of ANSI/ASQC E4-1994.

2.3 APPLICABILITY

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

2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS

2.4.1 General Content

The QA Project Plan must be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. Chapter 3 of this document describes specific elements to address for QA Project Plans submitted to EPA. In some cases, it may be necessary to add special requirements to the QA Project Plan. The EPA organization sponsoring the work has the authority to define any special requirements beyond

those listed in this document. If no additional requirements are specified, the QA Project Plan shall address all required elements. Each EPA organization defines their organizational-specific requirements for QA Project Plan documentation in their Quality Management Plan. All applicable elements defined by the EPA organization sponsoring the work must be addressed.

While most QA Project Plans will describe project- or task-specific activities, there may be occasions when a *generic* QA Project Plan may be more appropriate. A generic QA Project Plan addresses the general, common activities of a program that are to be conducted at multiple locations or over a long period of time; for example, it may be useful for a large monitoring program that uses the same methodology at different locations. A generic QA Project Plan describes, in a single document, the information that is not site or time-specific but applies throughout the program. Application-specific information is then added to the approved QA Project Plan as that information becomes known or completely defined. A generic QA Project Plan shall be reviewed periodically to ensure that its content continues to be valid and applicable to the program over time.

2.4.2 Level of Detail

The level of detail of the QA Project Plan should be based on a graded approach so that the level of detail in each QA Project Plan will vary according to the nature of the work being performed and the intended use of the data. As a result, an acceptable QA Project Plan for some environmental data operations may require a qualitative discussion of the experimental process and its objectives while others may require extensive documentation to adequately describe a complex environmental program.

2.5 QA PROJECT PLAN PREPARATION AND APPROVAL

The QA Project Plan may be prepared by an EPA organization, a contractor, an assistance agreement holder, or another Federal agency under an interagency agreement. Except where specifically delegated in the Quality Management Plan of the EPA organization sponsoring the work, all QA Project Plans prepared by non-EPA organizations must be approved by EPA before implementation.

The QA Project Plan shall be reviewed and approved by an authorized EPA reviewer to ensure that the QA Project Plan contains the appropriate content and level of detail. The authorized reviewer, for example the EPA project manager[1] with the assistance and approval of the EPA QA Manager or by the EPA QA Manager alone, are defined by the EPA organization's Quality Management Plan. In some cases, the authority to review and approve QA Project Plans is delegated to another part of the EPA organization covered by the same Quality Management

[1] This term refers to the EPA official responsible for the project. This individual may also be called Project Officer, Delivery Order Project Officer, Work Assignment Manager, or Principal Investigator.

Plan. In cases where the authority to review and approve QA Project Plans is delegated in writing by EPA to another organization (i.e., a Federal agency or a State under an EPA-approved Quality Management Plan when the environmental data operation itself has been delegated to that organization for implementation), it is possible that the EPA project manager and EPA QA Manager may not be involved in the review and approval steps.

2.6 QA PROJECT PLAN IMPLEMENTATION

None of the environmental work addressed by the QA Project Plan shall be started until the QA Project Plan has been approved and distributed to project personnel except in situations requiring immediate action to protect human health and the environment or operations conducted under police powers. Subject to these exceptions, it is the responsibility of the organization performing the work to assure that no environmental data are generated or acquired before the QA Project Plan is approved and received by the appropriate project personnel. However, EPA may grant conditional approval to a QA Project Plan to permit some work to begin while non-critical deficiencies in the QA Project Plan are being resolved.

The organization performing the work shall ensure that the QA Project Plan is implemented as approved and that all personnel involved in the work have direct access to a current version of the QA Project Plan and all other necessary planning, implementation, and assessment documents. These personnel should understand the requirements prior to the start of data generation activities.

2.7 QA PROJECT PLAN REVISION

Although the approved QA Project Plan must be implemented as prescribed; it is not inflexible. Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. When such changes occur, the approving official shall determine if the change significantly impacts the technical and quality objectives of the project. When a substantive change is warranted, the originator of the QA Project Plan shall modify the QA Project Plan 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 received and approved (at least verbally with written follow-up) by project personnel, shall the change be implemented.

For programs or projects of long duration, such as multi-year monitoring programs or projects using a generic QA Project Plan, the QA Project Plans shall be reviewed at least annually by the EPA Project Manager (or authorized representative). When revisions are necessary, the QA Project Plan must be revised and resubmitted for review and approval.

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CHAPTER 3

QA PROJECT PLAN ELEMENTS

3.1 CONTENT REQUIREMENTS

The QA Project Plan is a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QA Project Plan must provide sufficient detail to demonstrate that:

- the project technical and quality objectives are identified and agreed upon;
- the intended measurements, data generation, 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, including managers, engineers, scientists, statisticians, and others. The QA Project Plan must integrate the contributions and requirements of everyone involved into a clear, concise statement of what is to be accomplished, how it will be done, and by whom. It must provide understandable instructions to those who must implement the QA Project Plan, such as the field sampling team, the analytical laboratory, modelers, and the data reviewers. In all aspects of the QA Project Plan, the use of national consensus standards and practices are encouraged.

In order to be effective, the QA Project Plan must specify the level or degree of QA and QC activities needed for the particular environmental data operations. Because this will vary according to the purpose and type of work being done, EPA believes that the graded approach should be used in planning the work. This means that the QA and QC activities applied to a project will be commensurate with:

- the purpose of the environmental data operation (e.g., enforcement, research and development, rulemaking),
- the type of work to be done (e.g., pollutant monitoring, site characterization, risk characterization, bench level proof of concept experiments), and
- the intended use of the results (e.g., compliance determination, selection of remedial technology, development of environmental regulation).

The QA Project Plan shall be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. These elements 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 - The elements in this group address the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.

B Data Generation and Acquisition - The elements in this group address all aspects of project design and implementation. Implementation of these elements ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and are properly documented.

C Assessment and Oversight - The elements in this group 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 QA Project Plan is implemented as prescribed.

D Data Validation and Usability - The elements in this group address the QA activities that occur after the data collection or generation 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, including the content and level of detail under each element, defined by the EPA organization sponsoring the work must be addressed in the QA Project Plan. If an element is not applicable, state this in the QA Project Plan. Documentation, such as an approved Work Plan, Standard Operating Procedures, etc., may be referenced in response to a particular required QA Project Plan element to reduce the size of the QA Project Plan. Current versions of all referenced documents must be attached to the QA Project Plan itself or be placed on file with the appropriate EPA office and available for routine referencing when needed. The QA Project Plan shall also address related QA planning documentation (e.g., Quality Management Plans) from suppliers of services critical to the technical and quality objectives of the project or task.

3.2 GROUP A: PROJECT MANAGEMENT

The elements in this group (Table 1) address project management, including project history and objectives, roles and responsibilities of the participants, etc. These elements document

that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.

Table 1. Group A: Project Management Elements	
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
A8	Special Training/Certification
A9	Documents and Records

3.2.1 A1 - Title and Approval Sheet

On the Title and Approval Sheet, include the title of the plan, the name of the organization(s) implementing the project, the effective date of the plan, and the names, titles, signatures, and approval dates of appropriate approving officials. Approving officials may include:

- Organization's Project Manager
- Organization's QA Manager
- EPA Project Manager
- EPA QA Manager
- Others, as needed (e.g., field operations manager, laboratory managers, State and other Federal agency officials)

3.2.2 A2 - Table of Contents

Provide a table of contents for the document, including sections, figures, tables, references, and appendices. Apply a document control format (Figure 2) on each page following the Title and Approval Sheet when required by the EPA Project Manager and QA Manager.

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

Figure 2. Example Document Control Format

3.2.3 A3 - Distribution List

List the individuals and their organizations who need copies of the approved QA Project Plan and any subsequent revisions, including all persons responsible for implementation (e.g., project managers), the QA managers, and representatives of all groups involved. Paper copies need not be provided to individuals if equivalent electronic information systems can be used.

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.) Identify the individual responsible for maintaining the official, approved QA Project Plan.

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. The organization chart must also identify any subcontractor relationships relevant to environmental data operations, including laboratories providing analytical services.

3.2.5 A5 - Problem Definition/Background

State the specific problem to be solved, decision to be made, or outcome to be achieved. Include sufficient background information to provide a historical, scientific, and regulatory perspective for this particular project.

3.2.6 A6 - Project/Task Description

Provide a summary of all work to be performed, products to be produced, and the schedule for implementation. Provide maps or tables that show or state the geographic locations of field tasks. This discussion need not be lengthy or overly detailed, but should give an overall picture of how the project will resolve the problem or question described in A5.

3.2.7 A7 - Quality Objectives and Criteria

Discuss the quality objectives for the project and the performance criteria to achieve those objectives. EPA requires the use of a systematic planning process to define these quality objectives and performance criteria.

3.2.8 A8 - Special Training/Certification

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

3.2.9 A9 - Documents and Records

Describe the process and responsibilities for ensuring the appropriate project personnel have the most current approved version of the QA Project Plan, including version control, updates, distribution, and disposition.

Itemize the information and records which must be included in the data report package and specify the reporting format for hard copy and any electronic forms. Records can include raw data, data from other sources such as data bases or literature, field logs, sample preparation and analysis logs, instrument printouts, model input and output files, and results of calibration and QC checks.

Identify any other records and documents applicable to the project that will be produced, such as audit reports, interim progress reports, and final reports. Specify the level of detail of the field sampling, laboratory analysis, literature or data base data collection, or modeling documents or records needed to provide a complete description of any difficulties encountered.

Specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period.

3.3 GROUP B: DATA GENERATION AND ACQUISITION

The elements in this group (Table 2) address all aspects of data generation and acquisition to ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and documented. The following QA Project Plan elements describe the requirements related to the actual methods or methodology to be used for the:

- collection, handling, and analysis of samples;

- data obtained from other sources (e.g., contained in a computer data base from previous sampling activities, compiled from surveys, taken from the literature); and

- the management (i.e., compiling, handling) of the data.

The methods described in these elements should have been summarized earlier in element A6. The purpose here is to provide detailed information on the methods. If the designated methods are well documented and are readily available to all project participants, citations are adequate; otherwise, detailed copies of the methods and/or SOPs must accompany the QA Project Plan either in the text or as attachments.

Table 2. Group B: Data Generation and Acquisition Elements	
B1	Sampling Process Design (Experimental Design)
B2	Sampling Methods
B3	Sample Handling and Custody
B4	Analytical Methods
B5	Quality Control
B6	Instrument/Equipment Testing, Inspection, and Maintenance
B7	Instrument/Equipment Calibration and Frequency
B8	Inspection/Acceptance of Supplies and Consumables
B9	Non-direct Measurements
B10	Data Management

3.3.1 B1- Sampling Process Design (Experimental Design)

Describe the experimental data generation or data collection design for the project, including as appropriate:

- the types and numbers of samples required,
- the design of the sampling network,
- the sampling locations and frequencies,
- sample matrices,
- measurement parameters of interest, and
- the rationale for the design.

3.3.2 B2 - Sampling Methods

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 for projects involving physical sampling. Where appropriate, identify sampling methods by number, date, and regulatory citation. 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, 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, and preservation methods; and maximum holding times to sample extraction and/or analysis.

3.3.3 B3 - Sample Handling and Custody

Describe the requirements 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 for projects involving physical sampling. Sample handling includes packaging, shipment from the site, and storage at the laboratory. Examples of sample labels, custody forms, and sample custody logs should be included.

3.3.4 B4 - Analytical Methods

Identify the analytical methods and equipment required, including sub-sampling 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. Where appropriate, analytical methods may be identified by number, date, and regulatory citation. Address what to do when a failure in the analytical system occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented. Specify the laboratory turnaround time needed, if important to the project schedule.

List any method performance standards. 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 method applications, such as for 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.

3.3.5 B5 - Quality Control

Identify QC activities needed for each sampling, analysis, or measurement technique. For each required QC activity, list the associated method or procedure, 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. QC activities for the field and the laboratory include, but are not limited to, the use of blanks, duplicates, matrix spikes, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC activity, and the spike compounds sources and levels. State or reference the required control limits for each QC activity 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 applicable statistics (e.g., precision and bias). Copies of the formulas are acceptable as long as the accompanying narrative or explanation specifies clearly how the calculations will address potentially difficult situations such as missing data values, "less than" or "greater than" values, and other common data qualifiers.

3.3.6 B6 - Instrument/Equipment Testing, Inspection, and Maintenance

Describe how inspections and acceptance testing of instruments, equipment, and their components affecting quality will be performed and documented to assure their intended use as specified. Identify and discuss the procedure by which final acceptance will be performed by independent personnel (e.g., personnel other than those performing the work) and/or by the EPA project manager. Describe how deficiencies are to be resolved, when re-inspection will be performed, and how the effectiveness of the corrective action shall be determined and documented.

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

3.3.7 B7 - Instrument/Equipment Calibration and Frequency

Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data generation or collection activities affecting quality that must be controlled and, at

specified periods, calibrated to maintain performance within specified limits. Describe or reference how calibration will 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.

3.3.8 B8 - Inspection/Acceptance of Supplies and Consumables

Describe how and by whom supplies and consumables (e.g., standard materials and solutions, sample bottles, calibration gases, reagents, hoses, deionized water, potable water, electronic data storage media) shall be inspected and accepted for use in the project. State acceptance criteria for such supplies and consumables.

3.3.9 B9 - 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, programs, literature files, and historical data bases. Describe the intended use of the data. Define the acceptance criteria for the use of such data in the project and specify any limitations on the use of the data.

3.3.10 B10 - Data Management

Describe the project data management process, tracing the path of the data from their generation to their final use or storage (e.g., the field, the office, the laboratory). 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, 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. This includes 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 will be followed to demonstrate acceptability of the hardware/software configuration required. Describe the process for assuring that applicable information resource management requirements are satisfied.

Describe the process for assuring that applicable Agency information resource management requirements (EPA Directive 2100) are satisfied (EPA QA Project Plans only). 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), the Minimum Set of Data Elements for Ground-Water Quality (EPA Order 7500.1A), or new data standards as they are issued by EPA, discuss how these requirements are addressed.

3.4 GROUP C: ASSESSMENT AND OVERSIGHT

The elements in this group (Table 3) address the activities for assessing the effectiveness of project implementation and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed.

Table 3. Group C: Assessment and Oversight Elements	
C1	Assessments and Response Actions
C2	Reports to Management

3.4.1 C1 - Assessments and Response Actions

Describe each assessment to be used in the project including the frequency and type. Assessments include, but are not limited to, surveillance, management systems reviews, readiness reviews, technical systems audits, performance evaluations, audits of data quality, and data quality assessments. 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 assessment 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 each assessment shall be reported.

Define the scope of authority of the assessors, including stop work orders, and when assessors are authorized to act.

Discuss how response actions to assessment findings, including corrective actions for deficiencies and other non-conforming conditions, are to be addressed and by whom. Include details on how the corrective actions will be verified and documented.

3.4.2 C2 - Reports to Management

Identify the frequency and distribution of reports issued to inform management (EPA or otherwise) of the project status; for examples, reports on the 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, and any specific actions recipients are expected to take as a result of the reports.

3.5 GROUP D: DATA VALIDATION AND USABILITY

The elements in this group (Table 4) address the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements determines whether or not the data conform to the specified criteria, thus satisfying the project objectives.

Table 4. Group D: Data Validation and Usability Elements

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

3.5.1 D1 - Data Review, Verification, and Validation

State the criteria used to review and validate -- that is, accept, reject, or qualify -- data, in an objective and consistent manner.

3.5.2 D2 - Verification and Validation Methods

Describe the process to be used for verifying and validating data, including the chain-of-custody for data throughout the life 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. Precisely define and interpret how validation issues differ from verification issues for this project. Provide examples of any forms or checklists to be used. Identify any project-specific calculations required.

3.5.3 D3 - Reconciliation with User Requirements

Describe how the results obtained from the project or task will be reconciled with the requirements defined by the data user or decision maker. Outline the proposed methods to analyze the data and determine possible anomalies or departures from assumptions established in the planning phase of data collection. Describe how reconciliation with user requirements will be documented, issues will be resolved, and how limitations on the use of the data will be reported to decision makers.

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REFERENCES

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

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

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

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

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

EPA Directive 2100 (1998), *Information Resources Management Policy Manual*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2180.1 (June 1987), *Chemical Abstract Service Registry Number Data Standard*, U.S. Environmental Protection Agency, Washington, DC.

EPA Order 2180.2 (December 1988), *Data Standards for the Electronic Transmission of Laboratory Measurement Results*, U.S. Environmental Protection Agency, Washington, DC.

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

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

EPA Order 7500.1A (October 1992), *Minimum Set of Data Elements for Ground-Water Quality*, U.S. Environmental Protection Agency, Washington, DC.

U.S. Environmental Protection Agency, 2001. *EPA Requirements for Quality Management Plans (QA/R-2)*, EPA/240/B-01/002, Office of Environmental Information.

U.S. Environmental Protection Agency, 2000a. *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*, EPA/600/R-96/084, Office of Environmental Information.

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

U.S. Environmental Protection Agency, 1998. *Guidance for Quality Assurance Project Plans (QA/G-5)*, EPA/600/R-98/018, Office of Research and Development.

U.S. Environmental Protection Agency, 1995. *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents (QA/G-6)*, EPA/600/R-96/027, Office of Research and Development.

U.S. Environmental Protection Agency, 1980. *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans,* QAMS-005/80, Office of Research and Development.

APPENDIX A

CROSSWALKS AMONG QUALITY ASSURANCE DOCUMENTS

A.1 BACKGROUND

This appendix contains crosswalks between this document and other QA planning documents. The first crosswalk compares this requirements document with its predecessor document, QAMS 005/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (EPA 1980). The second crosswalk compares the elements of the QA Project Plan defined in this document with the steps defined in *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000b), the Agency's preferred systematic planning process for environmental decision making. This crosswalk is provided to assist the reader in determining how the outputs from the DQO Process can be integrated into a QA Project Plan.

A.2 CROSSWALK BETWEEN EPA QA/R-5 AND QAMS-005/80

QAMS-005/80 ELEMENTS		QA/R-5 ELEMENTS	
1.0	Title Page with Provision for Approval Signatures	A1	Title and Approval Sheet
2.0	Table of Contents	A2	Table of Contents
3.0	Project Description	A5	Problem Definition/Background
		A6	Project/Task Description
4.0	Project Organization and Responsibility	A3	Distribution List
		A4	Project/Task Organization
		A8	Special Training/Certification
		A9	Documents and Records
5.0	QA Objectives for Measurement Data (PARCC)	A7	Quality Objectives and Criteria
6.0	Sampling Procedures	B1	Sampling Process Design
		B2	Sampling Methods
7.0	Sample Custody	B3	Sample Handling and Custody
8.0	Calibration Procedures and Frequency	B7	Instrument/Equipment Calibration and Frequency

QAMS-005/80 ELEMENTS		QA/R-5 ELEMENTS	
9.0	Analytical Procedures	B4	Analytical Methods
10.0	Data Reduction, Validation, and Reporting	D1	Data Review, Verification, and Validation
		D2	Verification and Validation Methods
		B9	Non-direct Measurements
		B10	Data Management
11.0	Internal Quality Control Checks and Frequency	B5	Quality Control
12.0	Performance and Systems	C1	Assessments and Response Actions
13.0	Preventive Maintenance	B6	Instrument/Equipment Testing, Inspection, and Maintenance
14.0	Specific Routine Procedures Measurement Parameters Involved	D3	Reconciliation with User Requirements
15.0	Corrective Action	C1	Assessments and Response Actions
16.0	QA Reports to Management	C2	Reports to Management

A.3 CROSSWALK BETWEEN THE DQO PROCESS AND THE QA PROJECT PLAN

Elements	Requirements	DQO Overlap
PROJECT MANAGEMENT		
A1 Title and Approval Sheet	Title and approval sheet.	N/A
A2 Table of Contents	Document control format.	N/A
A3 Distribution List	Distribution list for the QA Project Plan revisions and final guidance.	Step 1: State the Problem
A4 Project/Task Organization	Identify individuals or organizations participating in the project and discuss their roles, responsibilities and organization.	Step 1: State the Problem
A5 Problem Definition/ Background	1) State the specific problem to be solved or the decision to be made. 2) Identify the decision maker and the principal customer for the results.	Step 1: State the Problem Step 2: Identify the Decision
A6 Project/Task Description	1) Hypothesis test, 2) expected measurements, 3) ARARs or other appropriate standards, 4) assessment tools (technical audits), 5) work schedule and required reports.	Step 1: State the Problem Step 2: Identify the Decision Step 3: Identify the Inputs to the Decision Step 6: Specify Limits on Decision Errors
A7 Quality Objectives and Criteria	Decision(s), population parameter of interest, action level, summary statistics and acceptable limits on decision errors. Also, scope of the project (domain or geographical locale).	Step 4: Define the Boundaries Step 5: Develop a Decision Rule Step 6: Specify Limits on Decision Errors
A8 Special Training/ Certification	Identify special training that personnel will need.	N/A
A9 Documents and Records	Itemize the information and records that must be included in a data report package, including report format and requirements for storage, etc.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data

Elements	Requirements	DQO Overlap
DATA GENERATION AND ACQUISITION		
B1 Sampling Process Design (Experimental Design)	Outline the experimental design, including sampling design and rationale, sampling frequencies, matrices, and measurement parameter of interest.	Step 5: Develop a Decision Rule Step 7: Optimize the Design for Obtaining Data
B2 Sampling Methods	Sample collection method and approach.	Step 7: Optimize the Design for Obtaining Data
B3 Sample Handling and Custody	Describe the provisions for sample labeling, shipment, chain-of-custody forms, procedures for transferring and maintaining custody of samples.	N/A
B4 Analytical Methods	Identify analytical method(s) and equipment for the study, including method performance requirements.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data
B5 Quality Control	Describe quality control procedures that should be associated with each sampling and measurement technique. List required checks and corrective action procedures.	Step 3: Identify the Inputs to the Decision
B6 Instrument/Equipment Testing, Inspection, and Maintenance	Discuss how inspection and acceptance testing, including the use of QC samples, must be performed to ensure their intended use as specified by the design.	Step 3: Identify the Inputs to the Decision
B7 Instrument/Equipment Calibration and Frequency	Identify tools, gauges and instruments, and other sampling or measurement devices that need calibration. Describe how the calibration should be done.	Step 3: Identify the Inputs to the Decision
B8 Inspection/Acceptance of Supplies and Consumables	Define how and by whom the sampling supplies and other consumables will be accepted for use in the project.	N/A

Elements	Requirements	DQO Overlap
B9 Non-direct Measurements	Define the criteria for the use of non-measurement data, such as data that come from databases or literature.	Step 1: State the Problem Step 7: Optimize the Design for Obtaining Data
B10 Data Management	Outline the data management scheme including the path and storage of the data and the data record-keeping system. Identify all data handling equipment and procedures that will be used to process, compile, and analyze the data.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data
ASSESSMENT AND OVERSIGHT		
C1 Assessments and Response Actions	Describe the assessment activities needed for this project.	Step 7: Optimize the Design for Obtaining Data
C2 Reports to Management	Identify the frequency, content, and distribution of reports issued to keep management informed.	N/A
DATA VALIDATION AND USABILITY		
D1 Data Review, Verification, and Validation	State the criteria used to accept or reject the data based on quality.	Step 7: Optimize the Design for Obtaining Data
D2 Verification and Validation Methods	Describe the process to be used for verifying and validating data, including the chain-of-custody for data throughout the lifetime of the project.	Step 3: Identify the Inputs to the Decision
D3 Reconciliation With User Requirements	Describe how results will be evaluated to determine if performance criteria have been satisfied.	Step 7: Optimize the Design for Obtaining Data

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APPENDIX B

TERMS AND DEFINITIONS

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

audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

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.

chain-of-custody - an unbroken trail of accountability that ensures the physical security of samples, data, and records.

contractor - any organization or individual that contracts to furnish services or items or perform work; a supplier in a contractual situation.

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

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

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

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

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

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

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

environmental programs - work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

environmental technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

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

information resources management - the planning, budgeting, organizing, directing, training and controls associated with information. The term encompasses both information itself and related resources such as personnel, equipment, funds and technology.

inspection - an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic.

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.

method - a body of procedures and techniques for performing an activity (e.g., sampling, modeling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

participant - when used in the context of environmental programs, an organization, group, or individual that takes part in the planning and design process and provides special knowledge or skills to enable the planning and design process to meet its objective.

performance evaluation - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

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

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

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

quality management plan - a document that describes 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.

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

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

validation - 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.