United States
Environmental Protection
Agency

Office of Environmental
Information
Washington, DC 20460

EPA/240/R-02/009
December 2002

Guidance for Quality Assurance Project Plans

EPA QA/G-5

Draft

FOREWORD

This document, *Guidance for Quality Assurance Project Plans*, provides guidance to EPA employees and other organizations involved in developing Quality Assurance (QA) Project Plans that address the specifications listed in *EPA Requirements for QA Project Plans (QA/R-5)* (May 2001). It replaces all earlier versions of this guidance in their entirety including the version dated February 1998 (EPA/600/R-98/018).

This document does not impose legally binding requirements on EPA or the public and may not apply to a particular situation, based on the circumstances. EPA retains the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. Interested parties are free to raise questions about the recommendations in this document and the appropriateness of using them in a particular situation, and EPA and other parties should consider whether the recommendations in the document are appropriate for the particular situation. EPA may periodically revise this guidance without public notice.

EPA works every day to produce quality information products. The information used in these products are based on Agency processes to produce quality data, such as the quality system described in this document. Therefore, implementation of the activities described in this document is consistent with EPA's Information Quality Guidelines and promotes the dissemination of quality technical, scientific, and policy information and decisions.

This document is one of the *U.S. Environmental Protection Agency Quality System Series* documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. This document is valid for a period of up to five years from the official publication date. This document will then be reissued without change, revised, or withdrawn from the *U.S. Environmental Protection Agency Quality System Series* documents. Questions regarding this document or other *Quality System Series* documents should be directed to the Quality Staff at:

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

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CHAPTER 1

INTRODUCTION

Many activities involve developing a QA Project Plan: modeling projects, geospatial information projects, projects solely using existing information, and those involved with the collection of new information, e.g., the sampling and analysis type of project. This document, *Guidance for Quality Assurance Project Plans*, is a companion document to the specifications listed in *EPA Requirements for QA Project Plans (QA/R-5)* (May 2001) and in the EPA Quality Manual. It is written with additional details, suggestions, and examples to help step a user through the QA Project Plan development process. The first chapter answers frequently asked questions. The second chapter focuses primarily on the twenty-four elements of a QA Project Plan as they pertain to a basic environmental data collection activity, whether a research project or a basic monitoring project. The third chapter focuses on the use of existing information when developing a QA Project Plan.

Although reference to modeling and geospatial projects will be made below, the reader is referred to the following guidance documents available on the EPA quality website. See *Guidance on QA Project Plans for Modeling (EPA/QA G-5m)* (EPA, 2002e) and *Guidance on Geospatial Data Quality Assurance Projects (EPA/QA G-5g)* (EPA, 2002d).

1.1 AN OVERVIEW OF QUALITY ASSURANCE PROJECT PLANS

What is a QA Project Plan? A QA Project Plan describes the activities of an environmental data operations project involved with the acquisition of environmental information whether generated from direct measurements activities, collected from other sources, or compiled from computerized databases and information systems.

What is the purpose of the QA Project Plan? The QA Project Plan documents the results of a project's technical planning process, providing in one place a clear, concise, and complete plan for the environmental data operation and its quality objectives and identifying key project personnel.

What is the difference between a Quality Management Plan and a QA Project Plan? A Quality Management Plan describes an organization's quality system, i.e., its systematic approach to quality assurance, while a QA Project Plan describes the necessary QA procedures, quality control (QC) activities, and other technical activities that will be implemented for a specific project or program.

May I combine a Quality Management Plan and a QA Project Plan into one document? Yes. With permission of the QA Manager of the organization sponsoring the work, these two documents may be combined into a single document for small programs, grants, and contracts. The combined document should address satisfactorily all the elements of both documents.

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What are the benefits of a QA Project Plan? The benefits of a QA Project Plan are to communicate, to all parties, the specifications for implementation of the project design and to ensure that the quality objectives are achieved for the project. It does not guarantee success every time, but the prospects are much higher with a QA Project Plan than without one.

Up-front planning eliminates approaches that do not work well (or not at all), which has the potential to reduce the cost of lost time and rework. Implementation as prescribed, with appropriate QC practices employed, increases efficiency and provides for early detection of problems, either in the field or in the laboratory. This again can save time and money from the rework and enable the ability to make decisions more expeditiously. For example, following calibration procedures will help to assure the credibility and usability of data generated by laboratory instruments.

When should a QA Project Plan be prepared? A QA Project Plan is prepared either as part of or after the project planning process. But in all cases, the QA Project Plan should be completed and approved before the project is started.

Why am I writing a QA Project Plan? It is EPA policy that all work funded by EPA in which environmental data will be collected, evaluated, used, or reported (including the use of existing data and modeling), or which involves the design, construction, and operation of environmental technology, have approved QA Project Plans, or equivalent documents as defined by the funding organization's Quality Management Plan, quality manual, or similar quality system description. This policy applies to all EPA-funded work, whether the project is an intramural project, or whether it is an extramural project EPA is funding through a grant, contract, or other financial assistance agreement. EPA's Quality System is based on an American National Standard [*Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (E4-1994)*]. This is described in EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System,* (EPA, 2000e), and is called the Order.

How do I develop a QA Project Plan? The following is a brief summary of the process:

1. Find out what needs to be done, based on what is known about the site or situation.
2. Assemble a project team with the necessary expertise.
3. Plan what can be done, or what will be done to obtain data of known quality that are good enough to support the decisions to be made or the study questions to be answered.
4. Write the QA Project Plan.
5. Submit the QA Project Plan for peer review, input, and approval, revising it as needed.
6. Distribute the approved QA Project Plan to all pertinent individuals involved with the project.
7. Begin work while implementing the plan, but remember to:

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- document any changes in the QA Project Plan,
- get re-approval before initiating the change, and then
- distribute the updated version.

1.2 EPA POLICY

Where can I find EPA's policy for QA Project Plans? You can find EPA's policies and other tools and guidance on the Quality Staff's web site, *www.epa.gov/quality*. EPA Order 5360.1 A1, *EPA Quality Manual for Environmental Programs* (EPA, 2000a), (Quality Manual) contains the internal EPA policies. EPA policies for non-EPA organizations are defined in the Federal procurement and financial assistance regulations for each type of extramural agreement.

Should a QA Project Plan be approved before work begins? Yes. All work involving the collection or use of environmental data, by or on behalf of EPA, is to be done with an approved QA Project Plan. This policy applies to work performed by or on behalf of EPA. A QA Project Plan should generally be approved before any environmental data collection operation starts. Examples of exceptions include:

- circumstances warrant immediate action to protect human health and/or the environment, or
- operations are conducted under police powers.

Advance approval ensures that all of the planning steps, including connecting actions with needs, are completed. Clear documentation increases the likelihood that the project will achieve its intended results. If the plan is not approved before work begins, a stop-work order may be issued.

What has to go into a QA Project Plan? For EPA projects, see Chapter 5 of the Quality Manual. For extramural work, see the EPA specifications in *EPA Requirements for QA Project Plans (QA/R-5)* (EPA, 2001a). EPA allows flexibility in the actual contents of the QA Project Plan depending on the kind of work being proposed, the intended use of the data, and the risk involved in using inadequate data for the project. The content is also discussed in Section 1.3.

Where can I get information on the graded approach to QA Project Plan contents? The term "graded approach" appears in the Quality Manual where it states that the level of detail in the quality management plan should be "based on a common sense, graded approach that establishes QA and QC activities commensurate with the importance of the work, the available resources, and the unique needs of the organization." In referring to the QA Project Plan, the Quality Manual states that EPA organizations may tailor these QA Project Plan specifications in their own implementation documents to better fit their specific needs. Therefore, consult with the project officer or QA Manager regarding the application of the graded approach to your project.

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When should I revise my QA Project Plan? When changes affect the scope, implementation, or assessment of the outcome, the plan is revised to keep project information current. The Project Manager, with the assistance of the QA Manager, determines the impact of any changes on the technical and quality objectives of the project.

For long-term projects, such as multi-year monitoring programs, the QA Project Plan is reviewed annually by the Project Manager to determine the need for revision.

When should I submit a revised QA Project Plan for review? When a substantive change is warranted, the originator of the QA Project Plan revises the plan to document the change, and then submits the revised plan to the approving authority. Implement the change only after the revision has been approved. Send the revised plan to all the individuals cited in the distribution list.

How long is a QA Project Plan kept after the project ends? Document retention should comply with the approving organization's specifications first, and the specifications of the organization performing the work second.

1.3 CONTENT OF A QA PROJECT PLAN

What is generally contained in a QA Project Plan? The QA Project Plan is divided into four basic element groups: Project Management; Data Generation and Acquisition; Assessment and Oversight; and Data Validation and Usability. Each group consists of standard elements, 24 in all, that pertain to various aspects of the project. These elements are discussed in Chapter 2.

A QA Project Plan that addresses the basic elements will define and describe the following:

- who will use the data;
- what the project's goals/objectives/questions or issues are;
- what decision(s) will be made from the information obtained;
- how, when, and where project information will be acquired or generated;
- what possible problems may arise and what actions can be taken to mitigate their impact on the project;
- what type, quantity, and quality of data are specified;
- how "good" those data have to be to support the decision to be made; and
- how the data will be analyzed, assessed, and reported.

What if some of the 24 elements do not apply? QA Project Plans will vary in their level of complexity, based both on the nature of the work being performed (such as the collection of new data or the use of previously collected information), available resources, and the intended use of the data.

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Following the principle of the graded approach, if an element is not applicable, then indicate why it is not relevant.

Can additional information be specified beyond the standard 24 elements? The organization sponsoring or overseeing the work may specify additional information to clarify project-specific information.

If this information is documented in other places, do I rewrite that information into this QA Project Plan? Referring to existing documents can reduce QA Project Plan preparation and review time and length. Any documents prepared before the QA Project Plan, such as standard operating procedures (SOPs), sampling and analysis plans (SAPs), work plans, environmental site assessments, literature files, and data sets from other projects, may be appended. Alternatively, they may be incorporated by reference, if those sources are readily available to both reviewers and project personnel who will implement the QA Project Plan. [See *Guidance for the Preparation of Standard Operating Procedures (G-6)* (2001b) for further information concerning SOPs.]

How long is a QA Project Plan? A QA Project Plan should have enough information to describe project objectives and details. The number of pages needed to address this information will vary with the complexity of the project and intended use of the information. A plan for some environmental data operations may involve a qualitative discussion of the experimental process and its objectives, while a plan that describes a complex environmental project may involve extensive documentation to adequately describe activities.

May I use the same QA Project Plan for standard activities? Multi-year projects, and projects conducted at multiple sites, having the same project objectives and sampling and analytical processes, may be described in a generic QA Project Plan. You may describe site specific activities in supplements, for example, separate field sampling plans. Review generic plans annually to determine if any changes are necessary.

1.4 QA PROJECT PLANS AND THE EPA QUALITY SYSTEM

How does the QA Project Plan fit into the EPA Quality System? EPA's Quality System consists of three levels or tiers: a policy level, a program level, and a project level. (See Figure 1 for an illustration of EPA's Quality System Components.) The Project Level addresses project-specific activities. The tools for this level include:

- Systematic Planning;
- Quality Assurance Project Plans;
- Standard Operating Procedures;
- Technical Audits;

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- Data Verification and Validation; and
- Data Quality Assessment.

What is the role of systematic planning in developing the QA Project Plan? Systematic planning is a process in which you identify the problem to be investigated or the decision to be made, and then define the project's objectives, the type, quantity and quality of information needed, the technical and quality control activities, and the level of oversight that will ensure project criteria are satisfied. EPA stresses systematic project planning (for example, the Data Quality Objectives or Performance and Acceptance Criteria Planning Processes) for all environmental data operation projects.

See the following documents at *www.epa.gov/quality* for further information on project planning: *Guidance for the Data Quality Objectives Process (G-4),* 2000c; and *Guidance on Systematic Planning for Environmental Data Collection Using Performance and Acceptance Criteria*, 2002f.

1.5 DEVELOPING, REVIEWING, AND APPROVING A QA PROJECT PLAN

Who is included in developing the QA Project Plan? Project planning necessitates the coordinated efforts of many individuals, such as those who will generate information and those who will use the information or make decisions based on that information. These individuals include: decision makers, project managers, regulators, stakeholders, modelers, risk assessors, and technical staff (for example, hydrologists, chemists, data validators, samplers, and statisticians). In addition, peer reviewers and individuals with varied expertise ensure that technical areas are sufficiently addressed, thus helping to minimize problems during implementation.

Who is responsible for ensuring that the Plan is written? Those who are both involved in planning the project and experienced in environmental data operations, prepare and/or assist in the preparation of the QA Project Plan.

For internal EPA projects, the Project Manager or Principal Investigator is generally responsible for overseeing plan preparation. For externally funded projects, the recipient of the funds is usually responsible for project plan development. In the case of another Federal agency receiving funds from EPA, as through an interagency agreement, the award indicates who is responsible for QA Project Plan preparation. When EPA receives project funds from another Federal agency, EPA personnel usually write the QA Project Plan.

Who reviews the plan? This varies with each organization. Reviewers with expertise in the project specific areas, such as program managers (decision makers), QA staff independent of project management, and project field and laboratory technical staff, should review the plan.

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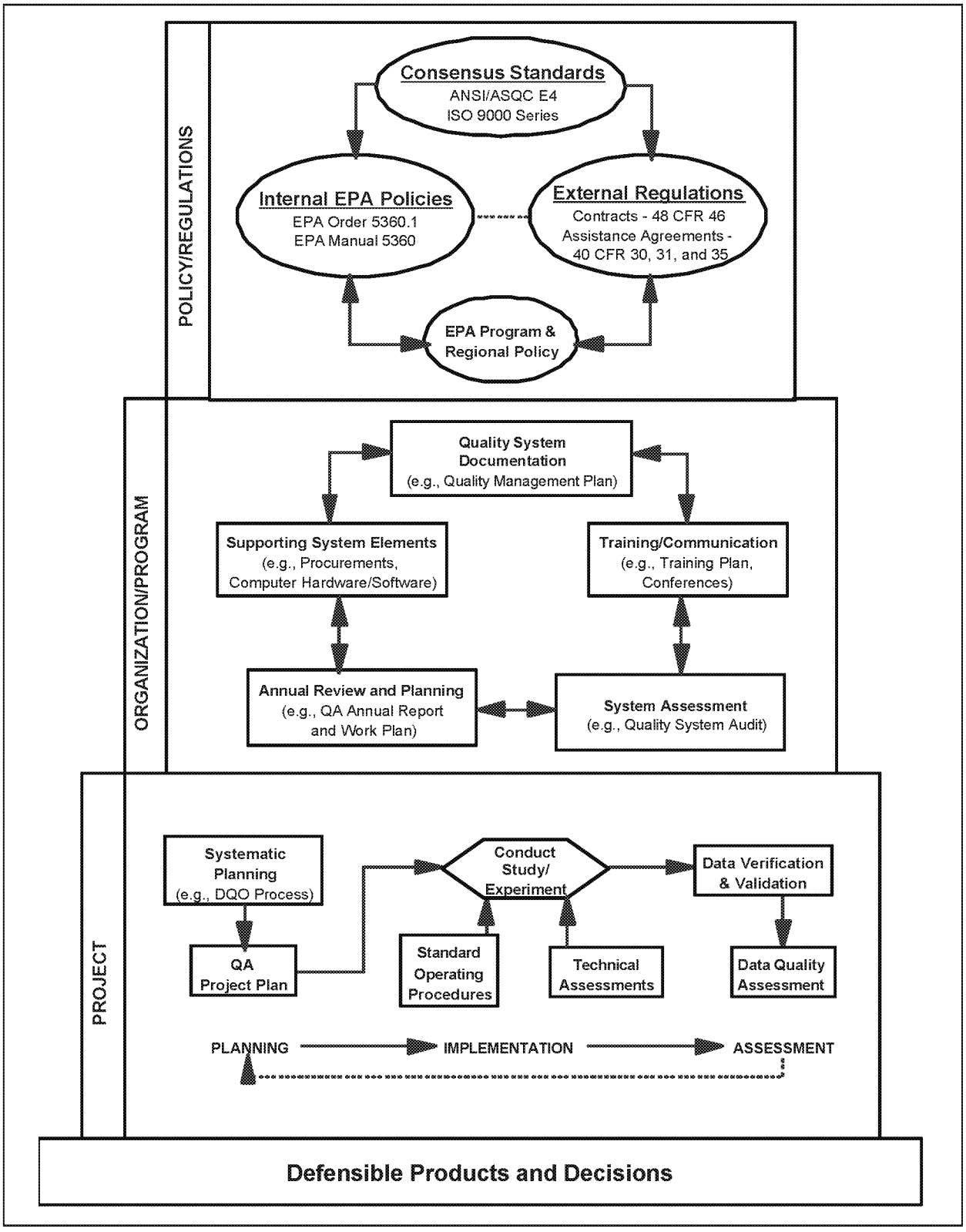

Figure 1. EPA Quality System Components and Tools

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What is included in a QA Project Plan review? Reviewers should:

- Ensure that the information is accurate and complete;
- Ensure that all appropriate elements are addressed;
- Ensure that the plan identifies the project's technical and quality objectives, and that the intended measurement and data acquisition methods will satisfy these objectives;
- Confirm that the planned assessment procedures will be adequate to evaluate the project; and
- Confirm that there is a process to identify any limitations on the use of the data.

These reviewers may also use tools, such as a checklist, in their review. An example checklist is located in Appendix C.

Who approves the QA Project Plan? The approving authority will vary with the individual organization. The EPA organization's Quality Management Plan establishes how, when, and by whom development, review, approval, and effective oversight of QA Project Plans should occur. This includes processes for extramural (non-EPA) organizations that prepare QA Project Plans. For EPA projects, the Project Manager or Project Officer, and the QA Manager usually approve the QA Project Plan. For extramural projects, the responsible organization's Project Manager, or Principal Investigator, and QA Manager may review and approve the QA Project Plan, and then submit it for EPA approval (unless that EPA organizational has specifically delegated approval in its Agency-approved Quality Management Plan). It is also beneficial if other key staff, such as the laboratory directors and prime contractors and subcontractors, sign the plan to indicate their review and approval.

What types of approvals exist? In situations where only non-critical deficiencies in a QA Project Plan have not been resolved (such as a final organizational chart or a data analysis procedure that will not be followed for weeks), conditional approval *may* be given to allow the project to start while these deficiencies are being resolved. The plan is then resubmitted for approval when the information is finalized. The concept of conditional approval, however, will vary with individual organizations; some organizations may not permit conditional approval of a QA Project Plan.

1.6 DISTRIBUTING THE QA PROJECT PLAN

Who gets a copy of the QA Project Plan? All personnel involved in the project should retain or have access to the current version of the QA Project Plan. This may include the Project Manager, laboratory manager, field team leader, modeler, QA Manager, data reviewers, and any essential contractor and subcontractor personnel involved with the project.

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1.7 IMPLEMENTING THE QA PROJECT PLAN

Who is responsible for implementing the QA Project Plan? The organization performing the work is responsible for ensuring that the QA Project Plan is implemented as written and approved, whether this work is conducted by contract personnel or in-house personnel. Ultimately the Project Manager is responsible for project activities. A clearly written QA Project Plan will help the Project Manager implement the plan, because all project personnel will understand the specifications before the start of data generation activities.

1.8 RESOURCES

Who do I contact if I have questions about my QA Project Plan? For direct recipients of EPA funds, contact the EPA Project Manager, who will probably introduce you to the appropriate QA Manager who reviews and authorizes the plan. For internal EPA projects, contact the QA Manager of the sponsoring office for information on QA-related matters. A list of QA Managers, contact information, may be found on the EPA Quality Staff website: *www.epa.gov/quality*.

What kind of training is provided by EPA? A variety of topics related to EPA's Quality System policy, program and project activities, and tools can be found on the EPA Quality Staff website at *www.epa.gov/quality*. Additionally, individual EPA Program Offices, Regions, and Research and Development Centers and Laboratories may also have guidance documents and training activities specific to their programs.

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CHAPTER 2

QA PROJECT PLAN ELEMENTS

QA Project Plan specifications are detailed in EPA's Quality Manual and in *EPA Requirements for QA Project Plans (QA/R-5)* (EPA, 2001a). These documents describe the QA Project Plan as divided into four basic element groups covering project management, data generation and acquisition, assessment and oversight, and data validation and usability activities. Each element group is subsequently divided into elements covering different topics; there are 24 elements (Table 1). Not all elements will pertain to every project. In addition, the extent or level of detail written in the QA Project Plan for each element will depend on the type of project, the data to be obtained, the decisions to be made, and the consequences of potential decision errors. For example, for a modeling project or a project using existing information, the elements concerning collecting samples may not pertain. For a basic research project, complete information for many elements may not be available at the start of the project and the plan will be revised as needed.

Table 1. List of QA Project Plan Elements

Group A. Project Management	Group B. Data Generation and Acquisition	Group C. Assessment and Oversight
A1 Title and Approval Sheet	B1 Sampling Process Design (Experimental Design)	C1 Assessments and Response Actions
A2 Table of Contents	B2 Sampling Methods	C2 Reports to Management
A3 Distribution List	B3 Sample Handling and Custody	
A4 Project/Task Organization	B4 Analytical Methods	**Group D. Data Validation and Usability**
A5 Problem Definition and Background	B5 Quality Control	D1 Data Review, Verification, and Validation
A6 Project/Task Description	B6 Instrument/Equipment Testing, Inspection, and Maintenance	D2 Verification and Validation Methods
A7 Quality Objectives and Criteria	B7 Instrument/Equipment Calibration and Frequency	D3 Reconciliation with User Requirements
A8 Special Training/ Certifications	B8 Inspection/Acceptance of Supplies and Consumables	
A9 Documentation and Records	B9 Non-direct Measurements	
	B10 Data Management	

It is not necessary to follow the sequence of elements listed herein. However, some organizations may choose to mandate this format.

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2.1 GROUP A: PROJECT MANAGEMENT

There are nine elements in this group (Table 2). These address project administrative functions and project concerns, goal(s), and approach(es) to be followed.

Table 2. Group A Elements

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

2.1.1 Title and Approval Sheet

Suggested Content for Title and Approval Sheet

- Project title
- Organization name
- Names, titles, signatures, and signature dates of the approving officials

What is the purpose of this element? This element identifies key project officials and documents their approval of the QA Project Plan. The signature dates indicate the earliest date when the project can start (its effective date).

This approval information is typically the first page of the QA Project Plan, and called a Title and Approval Sheet. It can also be a separate memorandum depending on the organization's administrative policy.

What information should be included in this element? The information included here is administrative project information. It consists of the title of the project and the name of the organization(s) involved in various aspects of that project. The names, titles, signatures, and signature

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dates of those approving the plan are also placed on this page. Those approving officials usually include the organization's Technical Project Manager and QA Manager, and the EPA (or other funding agency) Project Manager and QA Manager.

Their signatures indicate both their approval of the plan and commitment to follow the procedures noted. Other key staff who may sign the plan are the laboratory director(s), the field operations manager, other QA officer(s), prime contractors, and subcontractors.

2.1.2 Table of Contents

Suggested Content for Table of Contents

- Table of Contents;
- List of Figures, Tables, References and Appendices
- Document control format

What is the purpose of this element? The Table of Contents allows the reader of the QA Project Plan to locate the different information sections.

What information should be included in this element? The Table of Contents will generally list QA Project Plan elements, as well as any tables, figures, references, and appendices necessary to the project. If the QA Project Plan writer prefers to divide the plan into different sections other than the 24 elements, a table can be inserted here to cross-reference where the information for each element may be found. This can simplify its review.

If SOPs are not already available, they should be included in the appendices. Depending on the type of project, sampling methods, analytical research protocols, or data management procedures may be attached. The appendices may also include information concerning previous studies such as their QA Project Plans and SOPs.

When specified by the organization, a document control notation system may be used, starting with the first page of the plan. This notation system is placed on each page to uniquely identify the plan and the page number in relation to the total number of pages. Document control formats may include the information shown in Figure 2 or additional information, such as an organization's name.

Project #/Name _____
Revision No. _____
Date _____
Page ____ of ____

Figure 2. Example Document Control Format

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2.1.3 Distribution List

What is the purpose of this element? This list identifies all individuals who should get a copy of the approved QA Project Plan, either in hard copy or electronic format, as well as any subsequent revisions.

Suggested Content for Distribution List

Names of individuals and organization(s) to receive a copy of the approved QA Project Plan

What information should be included in this element? The names of key project personnel responsible for project implementation and/or funding, and who should have the currently approved QA Project Plan, are listed here along with their project titles or positions, organization names, and their telephone numbers. Key personnel to consider include:

- Project manager;
- Laboratory manager;
- Field team leader;
- Data processor or statistician;
- Modeler;
- QA officer;
- Data reviewers; and
- Essential contractor and subcontractor personnel.

Individuals receiving a copy of the plan for informational purposes only, or at their request, should be so identified. A reader then would not expect to see project duties defined for them in the section on project organization.

Note that if each copy of the QA Project Plan is numbered, it will be easier to ensure that all older versions of the QA Project Plan are retrieved when those named on the distribution list receive the updated QA Project Plan. (See Section 2.1.4 for table information.)

Suggested Content for Project/Task Organization

- List of individuals and organizations involved with the project, identifying their roles and responsibilities
- Documentation of project QA Manager's independence
- Identification of the individual responsible for maintaining the official, approved QA Project Plan
- Organizational chart showing relationships and lines of communication among project personnel

2.1.4 Project/Task Organization

What is the purpose of this element? This element allows you to rapidly identify the roles and responsibilities of those individuals involved in the

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project and their different organizations. It also quickly identifies lines of authority and reporting between these individuals and organizations.

What information should be included in this element? Those individuals involved with the major aspects or phases of the project are listed here, and their project responsibilities are discussed, indicating, for example, who can make changes and who is responsible for maintaining and updating the QA Project Plan. These individuals may include those who will use the information or make decisions based on that information, such as:

- Principal data user and
- Decision maker or regulator,

and the information producers, for example,

- Lead organization's project and QA managers;
- Field team leader;
- Laboratory manager;
- Database researchers;
- Data processors or modelers;
- Contractors and subcontractors staff; and
- Any essential backup personnel who may be called.

Within a small organization, a single individual may have more than one responsibility; however, this information should clearly show that the QA Officer is independent of those generating project information.

Consider including information such as their telephone and fax numbers, email addresses, and how to contact them after work hours. Table D-1 in Appendix D shows an example format for a table that conveniently combines contact information along with the QA Project Plan copy control number.

The addition of a project organizational chart is extremely helpful, because it illustrates the group hierarchy. The type of information found in an organization chart is illustrated in Figure 3. If more than one organization or group is involved in this project, use a separate chart for each. Then indicate the lines of communication between the different groups.

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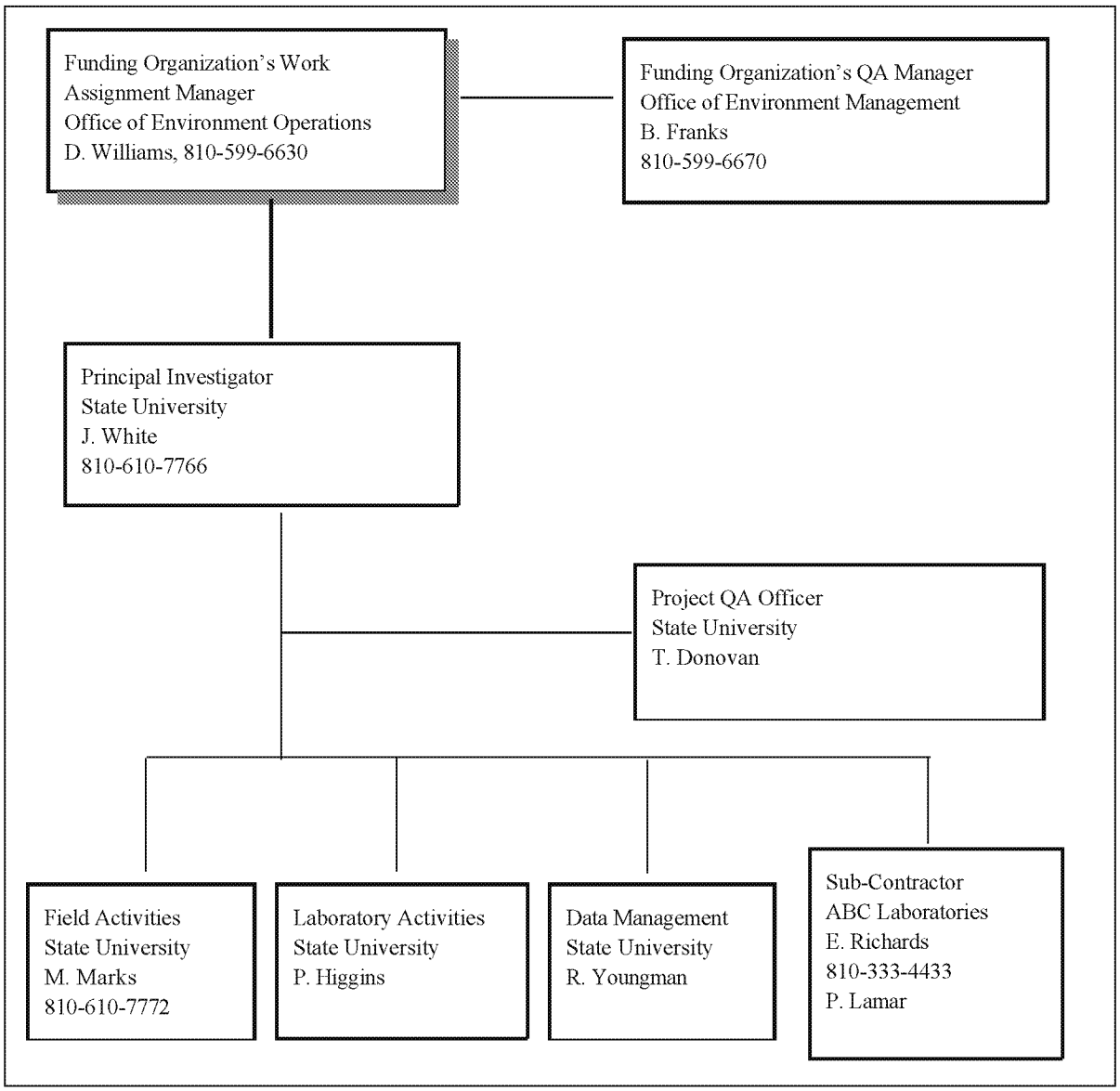

Figure 3. Example Project Organization Chart

2.1.5 Problem Definition/Background

What is the purpose of this element? This element gives the reader an overview of the problem to be solved, along with any pertinent background information for the project. It describes why the project will be done and what needs to be done.

Suggested Content for Problem Definition/Background

- Statement of specific problem to be solved, decision to be made, or outcome to be achieved
- Background information

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Equally important, the development and documentation of this element ensure that all clearly understand and agree on the underlying purpose of the project, increasing the likelihood that the project design will address and accomplish that purpose.

What information should be included in this element? Indicate why the project is being done by first describing the problem and what you want to accomplish, i.e., your goals and objectives. They form the foundation for the entire study. Next, summarize any known information, indicating also what information is not known. Then, identify the intended use of the information and those who need this information.

Problems that are more complex will lead to more extensive information in this section. The reader should be able to understand the importance or context of the project.

For example, for a basic or applied research project, indicate what you are trying to do, such as developing a method. State what other methods are currently being used and describe any problems with those methods. For an enforcement case involving determination of a potential violation or health hazard, specify the statutes to be enforced, appropriate action limits, and how nonconformance will be verified. If a project involves collecting information from previous projects (an existing data usage project), state the new use of this information and how it is relevant for your new study. If this is a questionnaire survey, justify why this survey is needed. For example, "This is to satisfy an Information Collection Request." For a modeling project, for example, indicate whether this is a model application project, i.e., evaluating existing models to determine whether they can perform the needed modeling to predict a future environmental condition in useable outputs, or whether this is a project to develop a new model because you know no applicable model exists.

Virtually all the sections of the QA Project Plan that follow will contain information consistent with the goals and objectives stated in this section.

2.1.6 Project/Task Description

What is the purpose of this element? This element is a management overview or summary of the work to be detailed in the remaining sections of the QA Project Plan. It describes the approach taken to address the project's objectives, connecting what is needed to how it will be obtained.

Suggested Content for Project/Task Description

- Summary of work to be performed and products
- Project schedule
- Maps, tables, etc. showing geographic locations

What information should be included in this element? Summarize what work will be done and what information will be newly collected or collected from previous studies. Indicate, for example, the

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contaminants of concern, chemical compounds expected to be at the site, and sampling locations and concentrations of contaminants from previous investigations. Describe the measurement processes and techniques that will be used to collect the information.

For example, if this were a field project, you would describe the field operation, including the sample type and numbers to be collected and a general schedule for collecting those samples. For projects using existing data, describe the type of data to be obtained and how it will be identified and used in this project. For modeling projects, identify the model or modeling routines that will be developed, calibrated, and tested.

Include maps or tables where appropriate, and provide a work schedule, either in graphical or tabular format. Indicate critical points in the project, such as starting and ending dates, dates for sampling, test runs/trials, and dates by which analyses are to be completed, literature databases researched, reports written, or modeling subroutines completed. When preparing this work schedule, consider potential disruptions or downtime due to such things as vehicle or computer failure, equipment defects, personnel lacking necessary training, and the uncertainty of funding. If the schedule is set by funding or regulatory deadlines, include that information in the plan. For response to emergency situations, a generalized work schedule can be formulated. Table D-2 (Appendix D) can be used to indicate project time-lines of critical activities.

2.1.7 Quality Objectives and Criteria for Measurement Data

What is the purpose of this element? This element describes quality specifications at two levels: (1) at the level of the decision or study question, and (2) at the level of the measurements used to support the decision or study question.

What information should be included in this element? The results of the systematic planning process used to plan and design the study that is the subject of the QA Project Plan are documented (or referenced) as part of this element. The outputs from the Agency's recommended systematic planning process, the Data Quality Objectives (DQO) Process, are ideally suited to addressing the first component of this element. The DQO process results in the full set of specifications needed to support the qualitative and quantitative design of a data collection effort including statements regarding the tolerable limits on the

Suggested Content for Quality Objectives and Criteria for Measurement Data

- Outputs from the systematic planning process (e.g., DQOs) used to design the study
- Measurement performance or acceptance criteria established as part of the study design. These relate the quality of data needed to the established limits on the chance of making a decision error or of incorrectly answering a study question

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probability of making a decision error. DQOs are also used to assess the adequacy of data (new or existing) in relation to their intended use.

In the final step of the DQO process, an optimal design for obtaining data is developed and it is during this step that alternative sample collection designs are evaluated. During the design process, the document *Guidance on Choosing a Sampling Design for Environmental Data Collection* (EPA QA/G5S) will be of great use. This guidance focuses on how to determine the number of samples needed, and how to allocate these samples across space (within the boundaries of the study) and across time (within the temporal boundaries of the study), in order to lower uncertainty related to heterogeneity to the greatest extent possible. Associated with each alternative is a set of design assumptions that form the basis for setting quality specifications for the measurement system. These statements comprise the measurement performance criteria (for new studies) or acceptance criteria (for the inclusion of existing data into the project).

Measurement performance criteria for new data collection efforts are stated in terms of the desired (assumed) level of uncertainty in data that will be used to address the study question or support the decision. When possible, it is desirable to state measurement performance criteria in quantitative terms, such as limits on analytical imprecision, bias and method detection limits, and limits on the overall variance of study results (to include spatial and temporal variability). Measurement performance criteria expressed in qualitative terms should be used with care as their interpretation may be subject to observer bias. For example, the concept of a representative sample has different interpretation depending on whether the observer is a field researcher or a laboratory chemist.

When a study is to be based either entirely or in part on secondary data (data that was previously collected for a different intended use), acceptance criteria are used in place of measurement performance criteria. In general, these criteria are used to assess data adequacy, and to evaluate uncertainty in the results derived from the use of these data sources. In such cases, this section of the QA Project Plan is used to explain the criteria for determining which sources of data are sufficient to support the goals of the current project. In addition to existing sources of quantitative analytical measurement data, qualitative terms of acceptance criteria are sometimes used to convey sociological and economic information.

Performance and acceptance criteria are often expressed in terms of data quality indicators. The principal indicators of data quality are precision, bias, accuracy, representativeness, comparability, completeness, and sensitivity. These Data Quality Indicators (DQIs) are defined for purposes of this document in Table 3, as well as in the method(s) for their determination. (Note that these definitions do not constitute the Agency's official use of the terms for other purposes, including regulatory purposes, and should not be construed to alter or supplant other terms in use.) Measurement quality objectives (MQOs) are the acceptance thresholds or goals for this project's data, usually based on the individual DQIs for each matrix and analyte group or analyte.

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For some projects, criteria can be presented in a table, such as that illustrated in Table D-3, Appendix D, for typical chemistry data. For more discussion on DQIs see *Guidance on Data Quality Indicators* (EPA/QA G-5i) (EPA, 2002b).

Table 3. Data Quality Indicators (DQIs)

DQI	Definition	Example Determination Methodologies
Precision	The measure of agreement among repeated measurements of the same property under identical, or substantially similar conditions; calculated as either the range or as the standard deviation. May also be expressed as a percentage of the mean of the measurements, such as relative range or relative standard deviation (coefficient of variation).	Use the same analytical instrument to make repeated analyses on the same sample. Use the same method to make repeated measurements of the same sample within a single laboratory or have two or more laboratories analyze identical samples with the same method. Split a sample in the field and submit both for sample handling, preservation and storage, and analytical measurements. Collect, process, and analyze collocated samples for information on sample acquisition, handling, shipping, storage, preparation, and analytical processes and measurements.
Bias	The systematic or persistent distortion of a measurement process that causes errors in one direction.	Use reference materials or analyze spiked matrix samples.
Accuracy	A measure of the overall agreement of a measurement to a known value; includes a combination of random error (precision) and systematic error (bias) components of both sampling and analytical operations.	Analyze a reference material or reanalyze a sample to which a material of known concentration or amount of pollutant has been added; usually expressed either as percent recovery or as a percent bias.

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Table 3. Data Quality Indicators (DQIs)

DQI	Definition	Example Determination Methodologies
Representativeness	A qualitative term that expresses "the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition." (ANSI/ASQC 1995)	Evaluate whether measurements are made and physical samples collected in such a manner that the resulting data appropriately reflect the environment or condition being measured or studied.
Comparability	A qualitative term that expresses the measure of confidence that one data set can be compared to another and can be combined for the decision(s) to be made.	Compare sample collection and handling methods, sample preparation and analytical procedures, holding times, stability issues, and QA protocols.
Completeness	A measure of the amount of valid data needed to be obtained from a measurement system.	Compare the number of valid measurements completed (samples collected or samples analyzed) with those established by the project's quality criteria (Data Quality Objectives or performance/acceptance criteria).
Sensitivity	The capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest.	Determine the minimum concentration or attribute that can be measured by a method (method detection limit), by an instrument (instrument detection limit), or by a laboratory (quantitation limit).

2.1.8 Special Training/Certification

What is the purpose of this element? This element identifies any special or non-routine training or certifications that are necessary for project personnel or the laboratory to successfully complete the project.

Suggested Content for Special Training/Certification

- Any specialized training or certifications needed by personnel
- Plans for providing, documenting, and assuring this training

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What information should be included in this element? Special training or certifications are sometimes necessary for project personnel and laboratories associated with projects. Identify this information. This may include such things as having project personnel complete helicopter safety training, being skilled in the collection of samples for trace metal analysis (called the 'clean hands-dirty hands' technique), being trained in global positioning technology, or being certified samplers. Or, project personnel may need special security clearances to obtain information from confidential file sources or expertise in code development or performance testing in a special computer language. Laboratory certification for the analysis of certain types of samples may also be necessary.

Specify how this information will be documented and where the records will be kept. For example, training may be documented in personnel files. Indicate who is responsible for ensuring that they are met, and that qualified personnel are available to perform the work.

Table D-4 (Appendix D) can be inserted into the QA Project Plan to list special training/certification needs of personnel, and to identify where those records are to be kept.

2.1.9 Documents and Records

What is the purpose of this element? This element includes information concerning the management of project documents and records, including this QA Project Plan. Management of project data is covered later in Element B10, Data Management.

What information should be included in this element? Describe the process and responsibilities for making sure that project personnel will receive the most recently approved QA Project Plan, Standard Operating Procedures, and other documents used throughout the project operation. Tell how these documents will be updated and this information communicated.

Suggested Content for Documents and Records

- Description of how the most current approved QA Project Plan will be distributed to project staff
- List of records to be included in the data report package
- List of any other project documents to be produced
- Information on the final disposition of records and documents, including location and retention schedule

Summarize the information to be included in the project data package and its format. This might include:

- sampling collection and handling records such as field notebooks or operational records, Global Positioning System data, chain-of-custody forms, sample receipt records, including sample tags and shipping bills;

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- analytical log books;
- test method raw data and QC sample records;
- Standard Reference Material and/or proficiency test sample data;
- instrument, equipment, and model calibration information; and
- computer documentation such as model input and output files as results of code and database test procedures.

Other project records that should be mentioned here are:

- inspection or assessment reports and corrective action reports;
- interim progress reports and final reports;
- billing receipts;
- computer system user guides, programmer software and hardware maintenance documents;
- code description documents, model evaluation summaries; and
- presentations to be made during and after the project, for example, to management or at scientific meetings.

For projects involving collection of information from existing databases and literature files, indicate how those records will be identified, documented, and retained.

State where all project documents and records will be stored and for how long. Include backup procedures for any data stored electronically and cite the protocols for access to, retrieval from, and photocopying of information archives. Retention and final disposition of some records may be regulated, as well as access to this information. Table D-5 in Appendix D is an example of a table that can be used for recording some of this information.

2.2 GROUP B: DATA GENERATION AND ACQUISITION

The elements in this group (Table 4) address data generation and data acquisition and management activities.

Table 4. Group B Elements

Data Generation and Acquisition	
B1	Sampling Process Design (Experimental Design)
B2	Sampling Methods
B3	Sample Handling and Custody

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Table 4. Group B Elements

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

2.2.1 Sampling Process Design (Experimental Design)

Suggested Content for Sampling Process Design

Description of project's experimental design

What is the purpose of this element? This element describes the project's data collection or research experimental design. Keys to this element are the assumptions made and how the data will be obtained. This element explains the "how and why" of the project's information collection design to ensure that the appropriate data are collected for this project.

What information should be included in this element? Sampling is the selection of a portion of a larger target population, universe, or body, with the characteristics of that sample being inferred as applicable to the target population. Define the size of the area, shape, volume, or time that is to be represented by a sample (called the scale of representativeness) as part of the justification for how the sampling sites and durations will be selected. Next, detail the schedule for sampling and analytical activities, test runs, and reviews.

There are two classes of sampling designs to consider: probability-based and judgmental. The former are sometimes called statistical designs, and the latter as directed sampling information. The two classes have very different properties. Strong statistical conclusions are available with probability-based designs but not with judgmental designs. Use of professional expertise and/or historical knowledge about the site can improve development of statistical and judgmental sampling designs. Advice on selecting the appropriate design may be found in Chapter 2 of *Guidance for Choosing a Sampling Design for Environmental Data Collection (QA/G-5s)* (EPA, 2002a).

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Key questions to be considered are:

- Is this project to be comparable with previous sampling or analytical efforts, or with a health-based or regulation standard?
- Can samples or measurements be taken according to a probability-based design?
- Is the objective of the sample to estimate an average or to find a hot spot?
- Is there a reference or background population that can be used as a comparison to the target population?
- Will sampling sites be chosen ahead of time or in the field based on visual or other evidence; and, if the latter, what are your criteria for selection?
- Will you use a network of sampling sites that will be visited periodically or where sampling will be performed continuously?
- Do all the samples need to be taken simultaneously?
- Is the target population approximately homogeneous or is it heterogeneous in nature needing stratification or division into approximately homogeneous areas?
- Can samples be composited?

The answers to these questions should have been considered during the planning process and help to determine allocation of resources for obtaining samples.

After you determine of the type of sampling design, you should obtain some related information. Record here the following elements:

- number of samples,
- how many sampling locations,
- number of samples at each location,
- number of composites (if any),
- support for the sample (the area or part of the target population that a single sample is supposed to represent),
- number of QC samples (field replicates, etc.); and,
- your plan for obtaining replacement samples essential to the integrity of the project.

As part of the rationale for the study design, explain if any sample types are critical or are secondary to the study. For example, arsenic levels may be critical data in your project while data on lead may be useful for trend analysis; or literature databases may be preferentially reviewed for the last five years and then scanned for the previous ten years.

Indicate how these sampling sites will be located (for example, through use of a randomized grid or by using a global positioning system), and what you would do if any of the sampling locations

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become inaccessible. Chapter 13 of EPA's Informational Resources Management Policy Manual, Directive 2100, provides guidance on EPA's locational policy (www.epa.gov/irmpoli8/polman).

Briefly describe how samples will be obtained and treated before shipping to the laboratory for analysis. This is described in more detail in the other elements.

Other important information includes identifying the role of any potential sources of variability which would affect the sampling period, such as tidal cycles, seasonal differences, and rain and wind patterns. Where possible, include detailed diagrams, and use tables to illustrate this information.

2.2.2 Sampling Methods

What is the purpose of this element? This element details how samples or information will be collected consistently between locations and by all sampling teams, with no contamination being introduced during collection. If a portion of the data collection will be performed without the collection of discrete samples, as *in situ* or remote sensing monitoring, this element details how the instruments will be deployed and operated to ensure that the electronic data will not be corrupted or lost.

Suggested Content for Sampling Methods

- Description of sample/data collection procedures
- List of equipment needed
- Identification of performance requirements
- Description of corrective actions to be taken if problems arise

What information should be included in this element? For each type of sample, describe what constitutes a sample. Tell how much sample is needed (sample volumes), what types of sample containers are to be used, how samples will be collected, and whether any sample is to be split in the field or subsamples taken. Reference or attach any SOPs and indicate any options to be followed in any standard method. If any evaluations or preparations for these are necessary, for example, triple acid rinsed bottles, note that in the plan. If any of these samples will be homogenized, composited, or split, also indicate how this will be accomplished. For example, "A plastic-lined sediment corer will be used to collect an 18-cm core which will then be sliced into 3-cm sections with a stainless steel blade."

For continuous monitoring, indicate what averaging time will be used, and whether the instruments will store and maintain all the raw data or only the data averages over that time. In addition, indicate how the data will be averaged, stored, downloaded, reported (telemetered), etc.

For remote sensing, indicate the area to be imaged and the spatial resolution needed, the degree of overpass, and the film type (black and white, true-color, or false color). For side-scan sonar, note also the resolution needed and the overlap during passes over the area.

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Next, identify any limitations and specific performance criteria. If a nonstandard methods or unusual equipment are to be used, indicate the rationale for their use and describe validation studies to confirm the performance of the method for that particular matrix, and that precision, accuracy, and detection limits will be adequate for the intended use of the data. As for location information, specify the need for accuracy.

List what sampling equipment is appropriate for the project and what support facilities are to be used. Support facilities might include such things as a flat-bottom boat, docking facilities, a plastic/stainless steel bucket, Ponar dredge, submersible pump, or an enclosure on the boat for compositing or weighing samples out of the wind.

Indicate what your backup plans are for when things go wrong. This may be a generic statement about obtaining backup supplies or equipment. Indicate how this information will be communicated to management, identifying who is responsible for corrective action and how corrective action will be documented. For example,

- What happens when someone drops one or more sample bottles or a vehicle, meter, or computer breaks down?
- Are replacements going to be borrowed or do they need to be procured?

Indicate whether monitoring equipment, and samplers, will be cleaned and/or decontaminated. Detail how this would be done to ensure that there is no carryover from one sampling location to the next. Remember to include information on how decontamination by-products will be disposed, in accordance with local, state, and federal regulations.

Careful planning, and the use of standardized methods and trained personnel, help to ensure that samples are collected consistently both between sampling locations and teams. Table D-6 in Appendix D can be used to summarize some of this information.

2.2.3 SAMPLE HANDLING AND CUSTODY

What is the purpose of this element? This element describes your efforts to have each collected sample retain its original physical form and chemical composition through collection to final disposal. It also identifies maintenance of custody, i.e., possession, of the sample. For *in situ* and remote sensing measurements, the same issues apply to the records of these measurements.

Suggested Content for Sample Handling and Custody

Description of sample handling requirements and transfer, and for ultimate disposal

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What information should be included in this element? Describe conditions that will be necessary for these samples to keep their original condition during sample collection, transportation, and storage. This may include the use of preservatives such as the addition of acid to the sample bottle before transportation and ice to the transport container, appropriate packing material, and a freezer for long-term storage.

Give maximum holding times for each type of sample. Holding times will vary with the analyte/matrix and are designed to ensure stability of the analyte/sample.

Tell who will maintain the field notebooks and who is responsible for sample custody in the field and sample receipt, custody, and ultimate disposal in the laboratory. For example, does the laboratory have a sample receipt department, or will the sample be given directly to the analyst? Will the analyses use the entire sample? For in-situ or remote sensing measurements, whether discrete or continuous, the same issues apply to the measurement records.

Explain the project's sample tracking system to identify where and when samples were obtained. A unique project numbering system helps to track each sample through the entire process to ensure samples are not switched accidentally.

The term "chain-of-custody" is often used to designate legal custody procedures that enable tracing the possession and handling of a "sample" (for example, a physical environmental sample, a confidential document, or critical maps) during transfer, i.e., from sample collection through laboratory analysis, so that its physical possession is known at all points of the project. This may include sample custody tags and written documentation to be signed by each person who handles the samples, and the use of a container sealed with custody tape. If such a procedure will be followed, describe it fully so that it can be done. Chain-of-custody procedures may be specified for projects where the data may be used in court as evidence.

Indicate the types of sample tags, labels, custody seals, and forms to be used to the QA Project Plan so that the samplers know what label to use and how it is to be filled out. Figure 4 is an example of a sample label and custody seal. See Table D-7 in Appendix D as an example of how some of this information can be summarized.

Suggested Content for Analytical Methods

- Description of analytical methods to be used
- Identification of any performance criteria
- Description of corrective actions when problems arise

2.2.4 Analytical Methods

What is the purpose of this element? This element identifies the procedures to analyze samples,

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(Name of Sampling Organization)

Sample Description:_____
_____

Sample Location: _____

Date:_____ Time:_____

Matrix: _____
Sample Type: _____
Preservative: _____

Sampled By: _____
Sample ID #: _____

Remarks:_____

CUSTODY SEAL

_____
Date

_____
Signature

CUSTODY SEAL

_____
Date

_____
Signature

Figure 4. Examples of a Sample Label and a Custody Seal

and how good these have to be, i.e., their performance criteria, to support any decisions to be made with the data.

What information should be included in this element? The analytical procedures to be followed in the field, the fixed laboratory, and/or the office are identified here. These methods can range from chemical analysis of water or soil samples, to biological sample processing such as sorting and subsampling, field screening methods using immunological assays, and the analysis of remote sensing data sets and images.

Cite the analytical SOPs if they are already available, or include them as appendices to the QA Project Plan. If an EPA standard method is to be followed, then simply cite the number and date. Describe and justify any deviations here. If the method allows any method options or modifications, such as sub-sampling, preparation, and extraction procedures, explain and detail the modifications to be

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followed. For example, for analysis of fish tissue with high lipid content, a preparation procedure may be needed to avoid matrix interference. Projects designed to demonstrate conformance to applicable regulations, such as drinking water regulations, will normally follow the methods specified in those regulations, or an explanation will be needed here.

If the laboratory is using a nonstandard or unapproved method, as might occur when unusual matrices are being analyzed, provide method validation data to confirm that it will be adequate for the intended use of the data. This includes information such as determination of detection limits, quantitation limits, typical recoveries, and analytical precision and bias. Ultimately, the data will indicate the laboratory's ability to demonstrate control of the method and document the quality of the data obtained. With a performance-based measurement system (known as PBMS), the data quality needs, mandates, or limitations of a program or project are specified. These serve as criteria for selecting measurement processes which will meet those needs in a cost-effective manner, rather than the use of a specific method.

In this element, also include any specific method performance specifications. If no method currently exists, as might occur in some research projects, method performance criteria will be discussed here. Consider, for example, if the project involves a decision focused on an action level identified in Element A5 (Section 2.1.5), Problem Definition/Background. Review Table D-8 in Appendix D as one means to concisely record some of this information, for example, action level, method detection level, and achievable laboratory limits.

Identify the activities to be followed when problems arise.

In Appendix D, Table D-9 summarizes analytical services information, such as identifying which laboratory or laboratories will analyze the different types of samples and indicating time limits for reporting analytical results.

2.2.5 Quality Control

What is the purpose of this element? There is potential variability in any sample collection, analysis, or measurement activity, with field variability generally contributing more than laboratory variability. In an environmental monitoring project, total study error can be divided into between-sampling-unit variability (influenced by sampling design error and inherent spatial variability) and within-sampling-unit variability (due to small-scale within unit variability, and

Suggested Content for Quality Control

- List of QC activities needed for sampling, analytical, or measurement techniques, along with their frequency
- Description of control limits for each QC activity and corrective actions when these are exceeded
- Identification of any applicable statistics to be used

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variability due to sampling, analytical, and data manipulations). This section lists those checks that can be performed to estimate that variability.

For a more detailed discussion of sampling unit variability, review EPA's *Guidance for Choosing a Sampling Design for Environmental Data Collection* (*QA/G-5s)* 2002a.

What information should be included in this element? QC activities are those technical activities routinely performed, not to eliminate or minimize errors, but to measure or estimate their effect. The actual QC data needs are based on the decision to be made and the data quality specifications for the project. Here you should list all the checks you are going to follow to assess/demonstrate reliability and confidence in your information.

For example, contamination occurs when the analyte of interest, or another compound, is introduced through any one of several project activities or sources, such as contaminated equipment, containers, and reagents. Blanks are "clean" samples used to measure the sources of contamination at different collection and measurement stages.

Bias is systematic error. A variety of QC samples can be used to determine the degree of bias, such as analysis of samples with a known concentration of the contaminant of concern. These are known as standards, matrix spike samples, and matrix-specific QC samples. For example, calibration drift is a nonrandom change in a measurement system over time and is often detectable by periodic re-measurement of calibration check standards or samples.

Imprecision is random error, observed as different results from repeated measurements of the same or identical samples. Replicate samples and split samples are commonly used to denote the level of precision in the measurement or collection system. For example, a sample split in the field and sent to two different laboratories can be used to detect interlaboratory precision. A sample split in a laboratory and then analyzed separately can indicate analytical precision, while a sample repetitively measured with one instrument can determine instrumental precision.

For each measurement activity, identify those QC checks that will be followed in this project, and indicate at what frequency each will occur. This can include items such as field collocated, duplicate, and matrix spike samples and laboratory duplicate, matrix spike, and control samples. The QA Project Plan may identify and describe the documentation procedures for QC activities such as:

- One in ten field samples or one per batch will be a replicate sample, with a batch being defined as twenty or fewer samples per preparation test method;
- The spike compound will be analyzed at a concentration of five to seven times the suspected concentration level;
- A proficiency test (PT) sample will be evaluated once per quarter.

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Table 5 lists some QC check samples often included in QA Project Plans, and details the information each provides. Note that these QC samples may be also described in other elements, such as Element B3 (Section 2.2.3), Sampling Handling and Custody, and Element B4 (Section 2.2.4), Analytical Methods, and may not necessarily be repeated here.

Table 5. Project Quality Control Checks

QC Check	Information Provided
Blanks	
bottle blank	cleanliness of sample bottles
field blank	transport, storage, and field handling bias
reagent blank	contaminated reagent
rinsate or equipment blank	contaminated equipment
method blank	response of an entire laboratory analytical system
Spikes	
matrix spike	analytical (preparation + analysis) bias
matrix spike replicate	analytical bias and precision
analysis matrix spike	instrument bias
surrogate spike	analytical bias
Calibration Check Samples	
zero check	calibration drift and memory effect
span check	calibration drift and memory effect
mid-range check	calibration drift and memory effect
Replicates, splits, etc.	
field collocated samples	sampling + measurement precision
field replicates	precision of all steps after acquisition
field splits	shipping + interlaboratory precision
laboratory splits	interlaboratory precision
laboratory replicates	analytical precision
analysis replicates	instrument precision

When you identify the QC activity control limits (described in Section 2.2.4), tell what is to be done when these are exceeded. For example, what will happen when the "blank" sample comes out positive for the contaminant-of-concern? Cited methods usually do not provide this information or it may be insufficient for the needs of your project.

State how the effectiveness of control actions will be determined and documented. For example, if the senior taxonomist determines that the junior taxonomist has misidentified x% of macro-

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invertebrate samples, retraining may be specified until accuracy, i.e., correct identification has improved, and the retraining is recorded in the project files. For these QC samples, identify also the procedures, formulae, or references for calculating applicable statistics, such as estimating sample bias and precision.

It is useful to summarize QC activities depending on whether they are in the field or the laboratory. This way, appropriate personnel can quickly identify the QC samples that apply to their activities. Tables D-10 and D-11 in Appendix D are examples of tables that can be used to denote sampling and analytical QC activities.

Remember that QC activities vary considerably between environmental monitoring programs and between different agencies. They do incur a cost to the project, which should be included during project planning by management and/or decision makers. In other words, the x% of samples to be analyzed as blanks should be considered to be an inherent part of the analytical process, not as an expendable add-on.

2.2.6 Instrument/Equipment Testing, Inspection, and Maintenance

What is the purpose of this element? This element describes how project personnel will know that the equipment will work properly when needed.

What information should be included in this element? In this element list any equipment or systems that will be used during the project that should be inspected or tested before use, or what maintenance is conducted on a routine basis. Describe what will be done to test, inspect, and maintain the project's instruments and equipment, and identify where critical spare parts will be located. Indicate also, how often this will be done and who is responsible for doing it. For example,

- The dissolved oxygen membrane probe will be checked for holes daily before each use by the first individual using the meter;
- The analytical balance is to be checked out by an instrument specialist annually;

Suggested Content for Instrument/ Equipment Testing, Inspection, and Maintenance

- List of equipment and/or systems needing periodic maintenance, testing, or inspection, and the schedule for such
- Description of how inspections and periodic preventive maintenance procedures will be performed and documented
- Discussion on how critical spare parts will be supplied and stocked
- Description of how re-inspections will be performed and effectiveness of corrective actions

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- The mercury column in a thermometer will be examined for breaks before each use; and
- The field team leader will supply the fresh batteries before leaving.

SOPs that contain this information may be referenced or attached. In addition, much of this information may be summarized in a table, such as Table D-12 in Appendix D.

2.2.7 Instrument/Equipment Calibration and Frequency

What is the purpose of this element? This element identifies how you will ensure continual quality performance of any equipment and instruments.

What information should be included in this element? List any equipment and instruments needing calibration either in the field, in the fixed laboratory, or in the office. Identify any applicable criteria and measurement and testing equipment that will be used.

For example, field equipment to be calibrated might include items such as pumps, flow meters, gauges, pH meters, and temperature sensing devices. Laboratory equipment might include items such as pH meters, dissolved oxygen probes, balances, and spectrophotometers.

Suggested Content for Instrument/ Equipment Calibration and Frequency

- List of all project tools, gauges, instruments, and other sampling, measuring, and test equipment which should be calibrated
- Description of calibration method and identification of any certified equipment and/or standards to be used
- Details of how calibration records will be maintained and traceable to the instrument/ equipment

Models in development and existing models used in new conditions will also need to be "calibrated" to assure the model's equations represent the environmental conditions being modeled. Test performance criteria usually provide the acceptable difference between the model output and values measured in the field or laboratory to be used in statistical tests for goodness-of-fit.

Test methods should be discussed, or referenced as SOPs, as appropriate. Test criteria and standards or certified equipment to be used might include statements such as the following:

- Accuracy is to be ± 0.05 ml or ± 0.2° C;
- A NIST-traceable thermometer is to be used annually for calibrating all temperature sensing devices;
- Balances are to be calibrated with Class One weights before each use.

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Models in development will also need to be "calibrated." Test criteria for models in development might involve statistical methods such as regression analyses and goodness-of-fit methods where model output is compared to actual measurement data.

Tell how frequently these activities are to be done to ensure the quality of the results. For example, sensitive or critical equipment may need to be calibrated before each use. Describe also how the data calibration or information will be recorded and analyzed. Then indicate how the records will be maintained so as to be traceable to the hardware, software, instrument, or equipment in question, and to the standards to be used, for example, lot number and expiration date. For a large laboratory with several pieces of similar equipment with exchangeable components, this tracking system takes considerable effort. Cite or attach any SOPs that document this information. This information can be recorded in a table, such as is shown in Table D-13.

2.2.8 Inspection/Acceptance of Supplies and Consumables

What is the purpose of this element? Not all projects will need supplies or consumables considered as "critical" to the project. For those projects that do, this element documents your system for having the right critical field and laboratory supplies and consumables available.

What information should be included in this element? Here you should identify what project supplies are critical, and who is responsible to make sure that they are available. Where applicable, document the following information so that these supplies can be located and similar items purchased when the listed items are exhausted:

- supply source (vendor);
- procedures for identifying, tracking, storing, and retrieving these supplies;
- identification of those responsible for maintaining these supplies; and
- any acceptance criteria for these items, for example, certificates of cleanliness, testing, health, or taxonomic identification.

Examples of supplies and consumables that may be used in a project are:

- filters or cartridges for air monitoring;
- reference toxicant chemicals for toxicity testing;
- test organisms for toxicity testing;

Suggested Content for Inspection/Acceptance of Supplies and Consumables

- A list of project supplies and consumables that may directly or indirectly affect the quality of the results
- The acceptance criteria for them
- Identification of those responsible

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- film and photographic paper for geospatial projects;
- bottles of known cleanliness for specialized chemical analyses, such as for trace metals analysis;
- reagent water or reagent-grade quality; and
- reference standards for calibrating instrumentation.

Describe your acceptance criteria for these items, such as the minimum percent organism viability.

Table D-14 in Appendix D can be used to list inspection or acceptance testing activities and to indicate who is responsible for such testing, as well as where and how this material will be stored. Alternatively, Table D-15 can be used to list critical consumables and supplies, tracking numbers, dates of receipt and expiration, and to indicate whether they meet the inspection criteria.

2.2.9 Non-direct Measurements

What is the purpose of this element? This element addresses data obtained from existing data sources, not directly measured or generated in this project. In addition to listing the information to be obtained, discuss here your intended use of that information, for example, whether it is central or ancillary to the project, and your criteria for accepting and limiting use of that information. For a complete discussion of existing data, see Chapter 3 of this document.

Suggested Content for Non-direct Measurements

- Identification of any existing data that will be obtained from non-measurement sources, such as literature files and historical databases
- Description of how you intend to use the data
- Your acceptance criteria and any limitations for using such data

What information should be included in this element? Data to be identified may be qualitative or quantitative in nature, for example:

- existing sampling and analytical data and files from a previous effort (current project and/or related project);
- photographs or topographical maps produced outside this project;
- information from the published literature;
- background information from facility or state files;
- measurements that are ancillary to addressing the project's objectives (for example, meteorological data, primarily used to better predict or explain dispersion and concentration of airborne toxic compounds in a localized area).

If you have not yet decided upon the sources of these data (outside of knowing that sources exist), document the process you will use to identify these sources and select the data. Along with specifying

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these types of data, specify how you will acquire (or did acquire) these data (for example, describe the literature search method).

Next, address how the types of data mentioned in the previous paragraph will be used, either exclusively or in combination with newly collected data, in certain phases of project implementation (for example, project scoping, design) or in decision-making. Element A6 (Section 2.1.6), Project/Task Description, mentions that such data would be used, but Element B9 documents the *intended use*. You would have identified this through the project's systematic planning process. For example, when following EPA's *Guidance for the Data Quality Objectives Process (EPA QA/G-4)* (EPA, 2000c), the third step is "Identify the Inputs to the Decision."

Document the measures of data quality that you will use to judge whether the data are acceptable for their intended use, i.e., performance/acceptance criteria or data quality objectives. The criteria may be qualitative or quantitative, such as:

- scientific literature, from which candidate data may be selected, originating from peer-reviewed studies (qualitative),
- specific DQIs (Table 3) (qualitative and quantitative),
- measurement process limits, for example, method detection and quantitation limits (quantitative).

Note that the quality objectives and performance criteria documented in the element, "Quality Objectives and Criteria" (Section 2.1.7), apply to measurements taken as part of the project while the criteria in Element B9 apply to existing data.

Chapter 3 illustrates a process to determine whether existing data meet a project's acceptance criteria. It uses some of the features of the data quality assessment process, which is addressed in the element "Reconciliation with User Requirements," and is performed at the end of the project to determine whether the data achieved their purpose. For example, were the data collected from a population sufficiently similar to the population of interest for this project? Were the site locations and the sampling and analytical methods used to generate the original data satisfactory for the current needs? Just because a set of data has been collected according to some documented, peer reviewed, quality protocol does not mean that it is "acceptable" for your study.

Document programmatic, legal, or any other constraints on the use of existing data and their impact on the project. Note that limitations may result from the specific objectives of the project and, therefore, may not have been associated with the data in any previous use. Here are some examples of constraints:

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- Only staff with the necessary clearance have access to proprietary or confidential data (for example, confidential business information).
- You have to use data that do not meet acceptance criteria (they are the only data available and you need to proceed with the project).
- You may be unable to evaluate data due to a lack of background information (for example, information on target population, sampling and analysis methods, associated QA and QC measures, etc.)

2.2.10 Data Management

What is the purpose of this element? In Element A9 (Section 2.1.9), you described managing project documents, such as this QA Project Plan and records from the project. This element gives an overview of the management of the data generated throughout the project.

What information should be included in this element? Identify the process and hardware and software equipment for data/information handling and storage throughout the life cycle of the project, i.e., from the field notes and laboratory results or from secondary (existing) data sources, to the office's data or model system. This includes:

- recording, transcribing, digitizing, and downloading,
- transformation and reduction (mathematical operations),
- transmittal,
- management,
- storage, and
- retrieval.

Suggested Content for Data Management

- Description of the project data management process
- Description of or reference to the office's standard record-keeping procedures and document control, data storage, retrieval, and security systems
- Identification of data handling equipment and procedures to process, compile, and analyze project data
- Discussion of data handling procedures to detect and correct errors and loss during data processing
- Examples of any forms or checklists to be used
- Identification of any specific computer hardware/software performance requirements and how configuration acceptability will be determined
- Description of how applicable information resource management requirements will be satisfied, as well as any applicable Agency information resource management requirements (EPA Directive 2100) (EPA QA Project Plans only)

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In doing so, indicate the project organization's standard record-keeping practices and document control system for both hard-copy and electronic media. Next, identify where the information can be found and for how long.

Describe here control mechanisms for detecting and correcting errors, such as manual calculations on a spot-check basis and review of field data sheets before transmittal to the office, backup procedures. Also, identify who is responsible for these separate activities. For example, the technician performing the analysis is to review the data before handing the information to the laboratory's QA officer. If there are any forms or checklists to be used, attach them to the plan. If there is a flowchart that diagrams any part of this process, include it.

Indicate how the computerized information systems will be maintained. For example, indicate what hardware and software items are necessary, how they will be routinely tested, and upgraded when software changes occur.

For EPA personnel writing a QA Project Plan, identify also how all applicable EPA information management specifications will be met. For projects involving data processing or modeling and computer data storage, discuss EPA software/hardware configuration specifications, such as identifying project coding standards; design configurations; users and maintenance manuals, and indicate how these will satisfy EPA specifications. See, for example, *Information Resources Management Policy Manual* (EPA Directive 2100) (EPA, 1998) (*www.epa.gov/irmpoli8/polman*) and EPA's Environmental Data Registry (*www.epa.gov/edr*). For projects requiring sampling, address how EPA's locational or geospatial data specifications will be satisfied. Where any of this information is already incorporated in an organization's Quality Management Plan, simply refer to that document and section.

2.3 GROUP C: ASSESSMENT AND OVERSIGHT

Assessments or evaluations are designed to determine whether the QA Project Plan is being implemented as approved (conformance/nonconformance), to increase confidence in the information obtained, and ultimately to determine whether the information may be used for their intended purpose. The elements in this group (Table 6) detail what assessments or evaluations will occur both during and after the project. Data assessments, such as data verification and validation, are discussed in the Group D elements.

Table 6. Group C Elements

Assessment and Oversight	
C1	Assessments and Response Actions
C2	Reports to Management

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2.3.1 Assessments and Response Actions

What is the purpose of this element? This element gives information concerning how a project's activities will be assessed during the project to ensure that the QA Project Plan is being implemented as approved.

What information should be included in this element? A wide variety of internal (self) and external (independent) assessments can be conducted during a project. The types of assessments to be conducted, and the frequency for conducting these assessments, will depend on the intended use of the information and the confidence needed and expected in the quality of the results. For example, a high-profile or a long-term project is more likely to have assessments conducted on its activities (and they are more likely to be unannounced assessments) than a project such as development of an analytical method, a basic research project, or a project in which only a few samples will be collected.

Suggested Content for Assessments and Response Actions

- Description of project assessments planned and a brief discussion of the information expected
- Approximate schedule for these assessments and their reports
- For any planned self-assessments, identification of potential participants and their relationship within the project organization
- For independent assessments, identification of the organization and person(s) that will conduct the assessments
- Identification of how, when, and to whom the results of each assessment will be reported and

Assessments are best done throughout the project to identify potential problems early in the project and allow for timely corrective action. This reduces the impact of non-conformance such as occurrences of questionable data and faulty conclusions. Assessments should be considered as a routine part of the project, rather than being conducted on an "as-needed" basis. Cost, influenced by the type of audit to be conducted, supplies needed, and the availability of technical personnel, should be balanced with the potential savings such as not having to repeat measurements having deficiencies.

For typical field/laboratory projects, assessments may consist of:

- readiness reviews;
- surveillance;
- proficiency testing (PT); and
- technical systems audits of field, laboratory, or data management activities.

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Definitions of each of these assessments may be found in Appendix B, with a full discussion in: *Guidance on Technical Audits and Related Assessments (G-7)* (EPA, 2000d), which is available on the EPA quality website.

For existing data use projects, data may be assessed to determine suitability for their intended use and to identify whether project specifications were met. For model performance evaluations, assessments may be made to qualitatively and quantitatively assess model performance, for example, uncertainty analyses, model verification tests, and internal and external peer reviews. Model assessments may also involve peer review on the mathematical basis for the model, algorithm checks, code verification, model evaluation, data quality assessment of input data, and evaluation of model output uncertainty and variability.

In this element, supply information for each type of assessment, such as what type of assessment will be conducted, when and how often. Discuss when assessments results will be reported, so that these evaluations can affect changes in the project as it progresses. When identifying who will conduct these assessments, indicate also their position within the project's organization or from another organization, and the scope of their authority, for example, issuing stop work orders.

Attach any checklists to be used. For an example of a project assessment table to summarize this information, review Table D-16 in Appendix D.

2.3.2 Reports to Management

What is the purpose of this element? This element documents how management will be kept informed of project oversight and assessment activities and findings.

What information should be included in this element? Identify here what project status reports will be written during the project. These might include:

- assessment reports;
- results of proficiency test samples;
- calibration reports; and
- model evaluation reports.

Suggested Content for Reports to Management

- Frequency and distribution of reports to inform management (EPA or otherwise) of the project's status
- Identification of report preparer and recipients, as well as any specific actions or recommendations recipients are expected to make

In addition, indicate those responsible for writing these reports, when, and how often these reports will be written, and identify who will be notified of audit findings. Table D-17 in Appendix D contains a sample table that could be used to summarize this information. Projects of short duration

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may only have a final report which includes assessment results, along with project results and conclusions.

2.4 GROUP D: DATA VALIDATION AND USABILITY

The elements in this group (Table 7) address the final project checks to see if the data or product obtained will conform to the project's objectives, and to estimate the effect of any deviations. For projects that use existing data, these elements focus on evaluating how data values from these acquired data sets will be used to determine the quality objectives for the new data use. For a modeling project, this process is similar to confirming that the steps in the modeling process were followed correctly to produce the model outputs and that the results meet project objectives.

Table 7. Group D Elements

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

2.4.1 Data Review, Verification, and Validation

Suggested Content for Data Review, Verification, and Validation

State the criteria for deciding to accept, reject, or qualify project data in an objective and consistent manner

What is the purpose of this element? This element lists your criteria for deciding to accept, reject, or qualify project information to be obtained. In a sense, this lists the final critical checks that will be done on the information obtained to decide whether they satisfy the quality criteria listed previously [for example, Element A7 (Section 2.1.7) - Quality Objectives and Criteria for Measurement Data] and whether that information can be used.

What information should be included in this element? Data review is the in-house examination to ensure that the data have been recorded, transmitted, and processed correctly. That includes, for example, checking for data entry, transcription, calculation, reduction, and transformation errors. It may also mean ensuring that there is a complete list of sample information available, such as sample matrixes, blanks, duplicates, shipping dates, preservatives, holding times, etc., and ensuring that there

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are no programming errors. It is also a completeness check to determine if there are any deficiencies, such as data missing or integrity lost (for example, due to corruption or loss in storage or processing).

Data verification is the process for evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual specifications. It essentially evaluates performance against pre-determined specifications, for example, in an analytical method, or a software or hardware operations system.

Data validation, however, is an analyte- and sample-specific process that extends the evaluation of data beyond method, procedure, or contractual compliance (i.e., data verification) to determine the quality of a specific data set relative to the end use. It focuses on the project's specifications or needs, designed to meet the needs of the decision makers/data users and should note potentially unacceptable departures from the QA Project Plan. The potential effects of the deviation will be evaluated during the data quality assessment.

Data verification is generally done first, internally by those generating the data or by an organization external to that group. Data validation is generally performed on the verified data later in the process and by someone independent or external to the data generator and the data user. These processes may occur both during and at the end of the project.

The criteria for deciding whether the data meet the project's quality specifications are listed here for review, verification, and validation. Therefore, each component of the project for which criteria were listed previously in the QA Project Plan (in the data generation and acquisition elements) should be identified here. For example, discuss the criteria for sample collection procedures, such as precision for location data. Indicate what tolerances are allowed for deviations from sampling locations, pH values, blank contaminations, satellite imagery (coverage and quality), etc. If data are to be flagged, state the criteria. For a modeling project, describe the criteria for code verification and/or indicate whether the model will be evaluated by comparing model predications with data used during model development.

The level of detail and frequency for performing data review, verification, and validation activities will depend on the complexity of the project, and the importance of the decision to be made based on it.

2.4.2 Verification and Validation Methods

What is the purpose of this element? This element identifies the methods or processes for verifying and then validating project information.

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What information should be included in this element? Much of the information previously listed in other elements will be discussed here for the series of final checks on the data that will be conducted. The data may be reviewed to verify how it was:

- recorded or formatted;
- transformed (for example, log values, calculations of replicate measurements, dry weight to wet weight values);
- reduced (for example, calculation of sample concentrations from peak areas), transferred (for example, software);
- analyzed (for example, using the organization's Laboratory Information Management System); and
- qualified.

Suggested Content for Verification and Validation Methods

- Description of how project data will be verified and validated
- Discussion of how any issues will be resolved and identification of who has the authority for resolving them
- Description of how results will be conveyed to data users
- Explanation of how validation issues differ from verification issues for this project
- Examples of any forms or checklists to be used and identification of any project-specific calculations

The methods to be used or processes to be followed can be identified as SOPs, if available, or described in the text. For example, indicate what data validation software will be used, if any. Those responsible for performing these functions should have been identified earlier in the plan (Element A4, Project/Task Organization); if not, then identify them here.

Describe the process to show how errors will be handled and this information given to the data users. Attach any necessary forms and checklists to the QA Project Plan.

Table D-18 can be used to summarize some of this information. For a more detailed description of the data verification and validation process, review *Guidance on Environmental Data Verification and Data Validation (EPA QA/G-8)* (EPA, 2002c).

2.4.3 Reconciliation with User Requirements

What is the purpose of this element? This element is to describe how you will evaluate the validated data to see if it answers the original questions asked, i.e., the measurement quality objectives or data quality objectives. This is the final assessment of the data quality and the culmination of the entire QA process for the project.

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What information should be included in this element? Describe in this element what statistical analyses or error estimates will be made based on total error, i.e., the cumulative error from field, laboratory, and data manipulations. This may involve some statistical analyses such as tests for outliers, trends, dispersion, etc., or a scientific evaluation of the information (for example, for content or reasonableness). Describe how data will be presented, e.g., tables or charts, to illustrate trends, relationships, and anomalies.

If a systematic planning was employed when developing the project technical and quality goals, use the Data Quality Assessment (DQA) process to evaluate how well the validated data can support their intended use. The DQA process is a five-step process described in *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (EPA G-9)* (EPA, 2000b). This document is specifically written for non-statisticians and provides many graphical and statistical tools.

Suggested Content for Reconciliation with User Requirements

- Description of how project results will be reconciled with the requirements defined by the data user or decision maker
- An outline of methods proposed to analyze the data and determine possible anomalies or departures from assumptions made when the project was planned
- Description of 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

If the project is to collect data without using a statistically based (probability based) design, analysis and inference becomes limited to simple descriptions of the data with no extrapolation to more general cases. Qualitative statements about the data are valid, but quantitative estimates are highly suspect.

Discuss how limitations on the use of the data will be handled and reported to the decision makers. For example, what will be done if data quality indicators do not meet performance criteria?

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CHAPTER 3

PROJECTS USING EXISTING DATA

3.1 WHEN EXISTING DATA ARE USED ON AN ENVIRONMENTAL PROJECT

What does "existing data" mean? Data or information that you plan to use but that have not been newly generated by your project are called "existing data." They may also be known as "secondary" data or non-direct measurements.

Why should I consider using existing data on a project? When working on an environmental task or project, some project objectives (for example, to answer a given question or to gain more knowledge in a given area) may be met by using data previously generated, but which are still relevant to your current needs. It is less expensive, easier, and sometimes solves sampling access problems. Existing data may have certain characteristics that may be advantageous. For example, existing data may provide more detailed and exhaustive information than your project would be able to generate (such as data covering a longer time span), thereby allowing decision makers to have a greater understanding of the situation and providing a greater statistical basis for any decision to be made.

What are some examples of typical sources of existing information for environmental projects? Examples of the many types and sources of existing information include the following:

- data from publicly available databases, such as data from the Census Bureau, data represented within EPA's Environmental Information Management System, and data cataloged in EPA's Environmental Data Registry;
- data from published literature, reports, and handbooks;
- data generated and submitted by third parties, including compliance data when used for purposes other than its primary purpose (i.e., to assess compliance);
- data from state and local monitoring programs;
- results from unpublished research;
- output generated by executing existing models;
- data obtained from previously performed pilot studies; and
- existing maps, Geographical Information System (GIS) layers, plots, photographs, or land surveys.

What are considerations when using existing data? Data collection is designed to meet a project's performance criteria. Existing data from other projects may not have been generated to meet the specific quality criteria established for your project, i.e., you did not get to choose the processes for collecting these data that are appropriate for your intended use. Even though some existing data

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sources may be well-respected and their data handling may be appropriate for its original use, such data still should be evaluated for the appropriateness of their specific use on your project.

When planning to use existing data, evaluate the data relative to your project's own acceptance criteria by obtaining and reviewing available *metadata*. Metadata is information that describes the data and their quality criteria.

Because certain existing data sets, such as major regulatory databases, are frequently used on other environmental projects, EPA has developed tools to make it easier for a user to obtain the metadata and to standardize the information in the metadata. EPA's scientific environmental information management system (EIMS) is one of these tools. It is a repository of scientific documentation, such as data sets, databases, documents, models, multimedia, projects and spatial information, and its accompanying metadata. EIMS is located at www.epa.gov/eims. The descriptive information stored within EIMS is also consistent with the Federal Geographic Data Committee metadata content standards for spatial data, available at www.fgdc.gov.

When using existing data, you should assess any limitations associated with the data and how these may impact their use relative to your project's objectives. For example, the data may represent a target population that differs from the population targeted in your project, or may have been generated from analytical methods that yield measurement errors or used detection limits that are higher than are acceptable for your project. Lack of sufficient or adequate metadata for an existing data source may be a reason not to use it. Conversely, previously documented limitations on a data set may or may not prove to be limitations relative to your specific project's needs.

How do I determine whether or not to use existing data? Once possible existing data sources are identified, you should evaluate each source relative to the quality needs (i.e., acceptance criteria) of your project. The rigor of this evaluation is determined by the overall role and importance of those data relative to your intended use. Do not use any data without accessing whether they can meet your needs.

To help evaluate existing data see below:

1. Determine your data needs	∫	2. Identify existing data sources that might meet project needs	∫	3. Evaluate existing data relative to your project's data quality specifications	∫	4. Document quality issues in planning documents or the final report

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3.1.1 Determine Your Data Needs

First define the problem to be investigated or the decision to be made, identify a need for data and the types of data necessary to address this problem, and then determine criteria for the level of quality that these data will need to satisfy. Identify how you intend to use the data that you will generate or acquire on your project.

Your goal is to establish project data performance or acceptance criteria (or Data Quality Objectives) for projects involving formal decision-making. Different data elements may have different acceptance criteria, depending on their importance to the project.

3.1.2 Identify Existing Data Sources That May Meet Project Needs

Find out whether the data you need already exist in adequate quality to meet your project needs. Some data may be used to help scope the project and define project objectives, while other data may be used to validate model-generated predictions, to contribute to data collection, or to help interpret results. Certain phases of the project may have less stringent criteria for data quality than others (as addressed below). If getting the most appropriate data is critical, for example, in a risk assessment, then documenting the search is important.

Any programmatic, legal, or security specifications for the use of the data should be identified and evaluated. Verify the extent to which the data are consistent relative to any other data sources, thus allowing for comparisons between the data sources or to ensure that all important data fields are present. If some fields are missing, additional data sets may be needed to fill in data gaps. If data sources lack sufficient metadata, they will not be acceptable for use and should not be used.

If you continue with further evaluation, despite using data not meeting all of these basic project specifications, document the potential ramifications that using the data may have on your ability to ultimately meet your project needs. For example, a data set may complete a study of monitored concentrations that vary over time. The analytical method for one parameter may be unknown, but the user could note a potential bias based on that uncertainty and still use the data.

3.1.3 Evaluate Existing Data Relative to Your Project's Data Quality Specifications

Examples of questions that may be posed in this evaluation (preferably to be answered by the organization who collected the data) are given in Table 8. Metadata would be used to obtain answers to these questions. These answers would then be documented in the project's planning document (such as the QA Project Plan) or in the final report. If collecting and reviewing data sources will be done after the QA Project Plan is written, the QA Project Plan should indicate the types of metadata that will

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be used in the evaluation. The QA Project Plan would then be amended to give the results of the evaluation.

Table 8. Examples of Potential Data Sources and Related Questions

Potential Data Sources	Example Questions*
Data from handbooks or the scientific literature	How did you ensure that these data are the most up-to-date available? What are the assumptions implicit in the data? What are the limitations of the data?
Model outputs	What are the assumptions that these estimates are based upon? Has the quality of the modeling effort been evaluated? What are the limitations of the data?
Public-use data sets	Are the data correct for the problem, or can they be transformed so that they are? What are the limitations of the data (for example, uncertainty, representativeness, QC flags)?

* It is recommended that you involve the use of an expert on the potential data "type" if you are unfamiliar with the method or techniques for collection and/or use.

Standard data quality attributes that are recognized as important to environmental studies and are likely to be specified in the metadata are the Data Quality Indicators. [See the discussion in Element A7 (Section 2.1.7), Quality Objectives in this document and *Guidance on Data Quality Indicators (EPA/QA G-5i)* for more details.] Acceptance criteria placed on the data quality indicators of a given data set are sometimes referred to as *measurement quality objectives*. Acceptance criteria may also be placed on other important features of data quality, such as integrity, level of peer review, and the amount of data that are flagged, assigned special validity qualifiers, or censored (for example, below detection limits).

The possible outcomes of this evaluation on a given existing data source include the following:

1. documentation that the data meet the needs of this project and therefore can be used,
2. a finding that the data do not meet the needs of the project and therefore will not be used, or
3. documentation that the data can be used in the project with some caveats on the confidence or significance of the findings based on these data, after some other action is taken (for example, supplemental data collection), or after some relaxation of the acceptance criteria.

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The second outcome implies that some level of new data collection should be done. In the third outcome, reasons for accepting the data, and the associated caveats and revised acceptance criteria should be documented. Certain existing data sources might be acceptable for use, but conditional on new data collection to supplement the existing data.

3.1.4 Document Quality Issues in Planning Documents or the Final Report

Document in the QA Project Plan (or equivalent planning document) the needed confidence in the information that you obtain, along with the specific acceptance criteria associated with selecting existing data sources for the project. If the scope of your project is only to identify and evaluate existing data sources for some use on a future project, the outcome of this investigation would be documented in a final report. Provide enough detail to allow the reader to understand the process you followed and the criteria you developed to determine whether certain existing data sources are acceptable for your intended use.

Existing data sets with high data quality information (i.e., metadata) and known data limitations are preferred. Include this information when the QA Project Plan is being prepared. However, if such information is not yet known, include a description of the process that will be used to locate the data (for example, literature searches, contacting state agencies, on-line searches) and obtain the needed information. More information on what to document in a QA Project Plan on existing data sources is given in this guidance document in Chapter 2, and in the following discussion.

3.2 ISSUES ON PREPARING A QA PROJECT PLAN FOR PROJECTS USING EXISTING DATA

Why should I prepare a quality assurance planning document (such as a QA Project Plan) if my project uses only existing data? As described in Section 1.1 of this guidance, EPA Order 5360.1 A2 (May 2000) on data quality specifies that a QA Project Plan (or equivalent document defined by your organization's Quality Management Plan) be prepared for any project that generates *or uses* environmental data to support EPA's objectives.

How is the graded approach applied to writing a QA Project Plan? Your project's planning team may apply the graded approach to writing a QA Project Plan, and specify how the acquisition and use of existing data are to be addressed in the plan. Adequate documentation of all data sources to be used for decision making should be noted in the QA Project Plan. However, a QA Project Plan may not necessarily include incidental use of existing data or widely accepted parameter values from sources such as chemical handbooks. The level of detail associated with the documentation of a specific data source is ultimately determined by the project's planning team.

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What issues on the consideration and use of existing data should be addressed when preparing a QA Project Plan? Table 9 lists examples of specific items regarding the identification and use of existing data to be included within the various elements. In particular, the element "Non-direct Measurements" focuses on the process to identify and acquire existing data sources, the intended use of the data through the course of the project, and the acceptance criteria to be used to determine whether the data are of sufficient quality for their intended use on the project.

Table 9. QA Project Plan Elements That May Address Existing Data Issues

QA Project Plan Element	Considerations for the Use of Existing Data
GROUP A: PROJECT MANAGEMENT	
A1: Title and Approval Sheet	No special considerations likely.
A2: Table of Contents	Cite any appendices containing detailed information that may be relevant in assessing existing data relative to its intended use on this project (for example, QA Project Plan for the operation used to collect the data, audit reports, final reports). (Note that in most cases, these materials may be cited as references rather than included as appendices.)
A3: Distribution List	Identify those who will evaluate and assess existing data relative to the project's acceptance criteria and, where necessary, include representatives of operations that collected or maintain existing data sets.
A4: Project/Task Organization	Include in the Project Organizational Chart those evaluating existing data relative to use on the project, those responsible for identifying candidate existing data, and representatives of the sources of the existing data. Clearly state the roles and responsibilities of each group.
A5: Problem Definition/ Background	Identify why these data are relevant for consideration for the current project and, where relevant, include background information on how existing data were collected and are maintained.
A6: Project/Task Description	Discuss how existing data can be used to solve the problem, make the decision, or achieve the necessary outcome that was presented previously. Specify the types of existing data that may be used in key components of the project. Include: • an overview of how candidate existing data sources would be identified; • an overview of the criteria for accepting existing data for use on the study; and, any existing data sources that may have

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Table 9. QA Project Plan Elements That May Address Existing Data Issues

QA Project Plan Element	Considerations for the Use of Existing Data
	already been selected, with their intended uses and any special needs (for example, personnel, hardware/software) associated with accessing and working with these data. Details on these items would be provided in later sections of the QA Project Plan. The project schedule presented in this section would include milestones associated with identifying, evaluating, selecting, and obtaining existing data sources for use on the project.
A7: Quality Objectives and Criteria	This section would detail the acceptance criteria that existing data sources would need to satisfy to be used on the project (see Section 3.1). When acceptance criteria are expressed relative to certain data quality indicators (for example, bias, accuracy, representativeness, comparability, completeness, sensitivity), this section would describe how information on these data quality indicators (i.e., metadata) would be obtained for the various existing data sources. To support understanding of the acceptance criteria, this discussion can clarify the intended use of existing data sources, along with the types of existing data sources that would be considered. If both newly generated data and existing data are being used on the project, this section may focus more on the performance criteria associated with the newly generated data, while details on the acceptance criteria for existing data may appear in Element B9.
A8: Special Training/Certification	This section would cite any specialized training or qualifications that project personnel would need to have or acquire to properly identify, obtain, handle, and analyze existing data sources. For example, use of certain data may specify confidential business information (CBI) clearance or specific mathematical or statistical expertise. Training may be necessary for reviewers of scientific literature to abstract important information for use on the project.
A9: Documentation and Records	Information on existing data that need to be included within the project's data report package would be discussed in this section. This section would also discuss how the approach to identifying, selecting, and obtaining existing information for use on the project, along with the approach to determining that candidate data sources achieve the needs associated with their intended use on the project,

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Table 9. QA Project Plan Elements That May Address Existing Data Issues

QA Project Plan Element	Considerations for the Use of Existing Data
	and the outcome of these processes, would be properly documented.
GROUP B: DATA GENERATION AND ACQUISITION	
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 for Supplies and Consumables	These elements address various quality aspects of the design and procedures for collecting, handling, and analyzing environmental field samples and are relevant when collecting new data for purposes of addressing the project's objectives. Thus, these elements generally do not address issues regarding existing data sources. In some cases (for example, on projects using exclusively existing data), the project's principal investigator may decide to present certain procedures associated with the generation and use of existing data within these QA Project Plan elements rather than all appearing in Element B9. However, it is often more informative to have these elements focus only on newly generated data and to have the element "Non-direct Measurements" focus on existing data.
B9: Non-direct Measurements	This is the primary element of the QA Project Plan within which information on existing data, their intended uses, and their limitations is presented. This section also presents the acceptance criteria for specific data sources that were introduced in "Quality Objectives and Criteria." See Section 2.2.9 of this guidance for details on what should be presented in this section.
B10: Data Management	This section documents how existing data (as well as newly generated data) would be incorporated and managed into the project's data management system. Example topics include how existing data will be obtained from its source in a given format, how and what data will be entered and verified if obtained in hard copy format, and how certain security or confidentiality specifications will be incorporated into the project's data management system.

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Table 9. QA Project Plan Elements That May Address Existing Data Issues

QA Project Plan Element	Considerations for the Use of Existing Data
GROUP C: ASSESSMENT AND OVERSIGHT	
C1: Assessments and Response Actions	List assessments that involve the use of existing data, for example, assessments that: • existing data meet basic project specifications (for example, are of the proper type) and are appropriately relevant and suitable for their targeted use (for example, have an acceptable target population); • the quality of existing data meet the acceptance criteria specified and that a sufficient quantity of existing data is available to allow the project to meet criteria on data quality; • proper procedures and protocols were used in obtaining or abstracting existing data from their sources; • sufficient quality control information was obtained on the data; and, • the quality assurance techniques documented in the QA Project Plan have been followed in the use of the existing data. Assessments involving existing data generally address the process of acquiring, evaluating, selecting, and obtaining existing data for use on the project. A graded approach is used to determine the overall scope and level of detail in which the assessments are performed. Include the following information (as it would be for any type of assessment): • the role that these assessments play in the project's total set of assessments; • the schedule of assessments; • the organizations and individuals expected to participate in the assessments; • information expected from the assessment; • documentation needed for the assessment; and, • possible types of corrective action and levels of authority that would determine corrective action (for example, collect additional data, investigate other data sources, loosen acceptance criteria).

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Table 9. QA Project Plan Elements That May Address Existing Data Issues

QA Project Plan Element	Considerations for the Use of Existing Data
C2: Reports to Management	Cite any reports that need to be brought to the attention of management that may affect the extent to which the project relies on existing data.
GROUP D: DATA VALIDATION AND USABILITY	
D1: Data Review, Verification, and Validation	Document how the ability to use existing data to achieve the project's needs will be evaluated. While the assessments in Element C1 may have been performed initially on existing data, this section discusses the final set of assessments of how the data can be used to address project objectives. Although previous sections of the QA Project Plan address how an entire existing data source is determined to be acceptable for use on the project, this section would address how individual data values and information within the existing data source are determined to be acceptable for use or otherwise need to be qualified, when the procedures would be performed, and by whom.
D2: Verification and Validation Methods	Discuss any mathematical or statistical procedures (such as outlier analyses or goodness-of-fit tests) that will identify whether individual data values within existing data sets should be rejected, transformed, or otherwise qualified before any statistical analysis. In addition, if existing data need to be entered into a project database, detail the features of the data management system that verify the accurate entry of values for important data parameters into this database, along with any data reduction procedures (for example, averages of replicate measurements). Mention when these activities will be done.
D3: Reconciliation with User Requirements	The ultimate "adequacy" of the existing data used on this project relative to the data users' needs is determined by methods detailed in this section. This is done by describing statistical tools and other methods used to evaluate whether the existing data can be used to achieve their intended uses and are therefore justified to be used in addressing project objectives. Such statistical tools are documented

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Table 9. QA Project Plan Elements That May Address Existing Data Issues

QA Project Plan Element	Considerations for the Use of Existing Data
	in *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (EPA QA/G-9), QA00 Version* (EPA, 2000b). Discuss strategies in place to resolve or account for any issues that arise from investigating the data. These issues may include the impact of data limitations that were encountered, the need for new data collection or re-analysis, or the need to use data with caveats.

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APPENDIX A

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APPENDIX B

GLOSSARY OF QUALITY ASSURANCE AND RELATED TERMS

(Note that these definitions are for the purposes of this document only and do not affect the use of the terms for other purposes.)

acceptance criteria — address the adequacy of existing information proposed for inclusion into the project. These criteria often apply to data drawn from existing sources ("secondary" data).

accuracy — a measure of the overall agreement of a measurement to a known value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; EPA recommends using the terms *"precision"* and *"bias,"* rather than "accuracy," to convey the information usually associated with accuracy.

assessment — the evaluation process used to measure the performance or effectiveness of a system and its elements.

audit — 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 that causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

blank — a sample subjected to the usual analytical or measurement process to establish a zero baseline or background value. Sometimes used to adjust or correct routine analytical results. A sample that is intended to contain none of the analytes of interest. A blank is used to detect contamination during sample handling preparation and/or analysis.

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

collocated samples — two or more portions collected at the same point in time and space so as to be considered identical. These samples are also known as field replicates and should be identified as such.

comparability — a measure of the confidence with which one data set or method can be compared to another.

completeness — a measure of the amount of valid data obtained from a measurement system.

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conformance — an affirmative indication or judgment that a product or service satisfies the relevant specification, contract, or regulation.

corrective action — any measures taken to rectify conditions adverse to quality and, where possible, to prevent recurrence.

data quality — a measure of the degree of acceptability or utility of data for a particular purpose.

data quality assessment — the scientific and statistical evaluation of data to determine if data obtained from environmental operations are of the right type, quality, and quantity to support their intended use.

data quality indicators — the quantitative statistics and qualitative descriptors used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are bias, precision, accuracy (bias is preferred), comparability, completeness, representativeness, and sensitivity.

data quality objectives — the qualitative and quantitative statements derived from the DQO Process that clarifies study's technical and quality 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 objective process — a systematic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. DQOs are the qualitative and quantitative outputs from the DQO Process.

data reduction — the process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collating them into a more useful form. Data reduction is irreversible and generally results in a reduced data set and an associated loss of detail.

data validation — an analyte- and sample-specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set.

data verification — the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual specifications.

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

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detection limit — a measure of the capability of an analytical method to distinguish samples that do not contain a specific analyte from samples that contain low concentrations of the analyte; the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated level of probability. DLs are analyte- and matrix-specific and may be laboratory-dependent.

document control — the policies and procedures used by an organization to ensure that its documents and their revisions are proposed, reviewed, approved for release, inventoried, distributed, archived, stored, and retrieved in accordance with the organization's specifications.

environmental conditions — the description of a physical medium (for example, air, water, soil, sediment) or a 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. Compiled from other sources such as data bases or the literature.

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

environmental monitoring — the process of measuring or collecting environmental data.

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

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 used to remove pollutants or contaminants from, or to 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 can 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.

field blank — a clean analyte-free sample which is carried to the sampling site and then exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample. This blank is

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used to provide information about contaminants that may be introduced during sample collection, storage, and transport.

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

graded approach — the process of applying managerial controls 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.

guidance — a suggested practice that is not mandatory, intended as an aid or example in complying with a standard or specification.

holding time — the period of time a sample may be stored before analysis. While exceeding the holding time does not necessarily negate the veracity of analytical results, it causes the qualifying or "flagging" of any data not meeting all of the specified acceptance criteria.

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

inspection — the examination or measurement of an item or activity to verify conformance to specifications.

matrix spike sample — a sample prepared by adding a known amount of the target analyte to a specified amount of a matrix. Spiked samples are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

measurement quality objectives — the individual performance or acceptance goals for the individual Data Quality Indicators such as precision or bias.

metadata — information that describes the data and the quality criteria associated with their generation.

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

method blank — a blank prepared to represent the sample matrix as closely as possible and analyzed exactly like the calibration standards, samples, and quality control (QC) samples. Results of method

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blanks provide an estimate of the within-batch variability of the blank response and an indication of bias introduced by the analytical procedure.

outlier — an extreme observation that is shown to have a low probability of belonging to a specified data population.

parameter — a quantity, usually unknown, such as a mean or a standard deviation characterizing a population. Commonly misused for "variable," "characteristic," or "property."

performance criteria — address the adequacy of information that is to be collected for the project. These criteria often apply to new data collected for a specific use ("primary" data).

precision — a measure of agreement among repeated measurements of the same property under identical, of substantially similar, conditions; expressed generally in terms of the standard deviation.

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

proficiency test — a type of assessment in which a sample, the composition of which is unknown to the analyst, is provided to test whether the analyst/laboratory can produce analytical results within the specified acceptance criteria.

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

quality assurance — an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

quality assurance project plan — a formal document describing in comprehensive detail the necessary quality assurance procedures, quality control activities, and other technical activities that need to be implemented to ensure that the results of the work performed will satisfy the stated performance or acceptance criteria.

quality control — 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 specifications established by the customer; operational techniques and activities that are used to fulfill the need for quality.

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quality control sample — an uncontaminated sample matrix spiked with known amounts of analytes from a source independent of the calibration standards. Generally used to establish intra- laboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system.

quality management plan — a document that describes the quality system in terms of the organization's structure, the functional responsibilities of management and staff, the lines of authority, and the interfaces for those planning, implementing, and assessing all activities conducted.

quality system — a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out quality assurance procedures and quality control 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 before 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.

recovery — the act of determining whether or not the methodology measures all of the analyte contained in a sample.

representativeness - the measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

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

sensitivity — the capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest.

spike — a substance that is added to an environmental sample to increase the concentration of the target analyte by known amount; used to assess measurement accuracy (spike recovery). Spike duplicates are used to assess measurement precision.

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split samples — two or more representative portions taken from one sample in the field or in the laboratory and analyzed by different analysts or laboratories. Split samples are quality control samples that are used to assess analytical variability and comparability.

standard operating procedure — a document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps to be followed. It is officially approved as the method for performing certain routine or repetitive tasks.

surveillance (quality) — continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specifications are being fulfilled.

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

validation — an analyte- and sample-specific process that extends the evaluation of data beyond method, procedural, or contractural compliance (i.e., data verification) to determine the analytical quality of a specific data set.

verification — the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractural specifications.

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APPENDIX C

CHECKLIST USEFUL IN QA PROJECT PLAN REVIEW

This appendix contains a checklist that can be used when reviewing a QA Project Plan. It is intended as an example only, as each organization may develop checklists specific to their needs.

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EXAMPLE OF A QA PROJECT PLAN REVIEW CHECKLIST

This checklist is an example of what could be used to either write or review a QA Project Plan, especially those involving field sampling and laboratory analyses. The items noted follow those elements found in *EPA Requirements for QA Project Plans (QA/R-5)* (EPA, 2001a).

PROJECT TITLE: _____

Preparer:_____ **Date Submitted for Review:** _____
Reviewer:_____ **Date of Review:**_____

Note: A = Acceptable U = Unacceptable NI = Not Included NA = Not Applicable

ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
PROJECT MANAGEMENT						
A1. Title and Approval Sheet						
Contains project title						
Indicates revision number, if applicable						
Indicates organization's name						
Dated signature of organization's project manger present						
Dated signature of organization's QA manager present						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Other signatures, as needed						
A2. Table of Contents						
Lists QA Project Plan information sections						
Document control information indicated						
A3. Distribution List						
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization						
A4. Project/Task Organization						
Identifies key individuals involved in all major aspects of the project, including contractors						
Discusses their responsibilities						
Project QA Manager position indicates independence from unit generating data						
Identifies individual responsible for maintaining the official, approved QA Project Plan						
Organizational chart shows lines of authority and reporting responsibilities						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
A5. Problem Definition/Background						
States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained						
Clearly explains the reason (site background or historical context) for initiating this project						
Identifies regulatory information, applicable criteria, action limits, etc. necessary to the project						
A6. Project/Task Description						
Summarizes work to be performed, for example, measurements to be made, data files to be obtained, etc., that support the project's goals						
Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as sampling, analysis, data or file reviews, and assessments						
Details geographical locations to be studied, including maps where possible						
Discusses resource and time constraints, if applicable						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
A7. Quality Objectives and Criteria						
Identifies performance/measurement criteria for all information to be collected and acceptance criteria for information obtained from previous studies, including project action limits and laboratory detection limits and range of anticipated concentrations of each parameter of interest						
Discusses precision						
Addresses bias						
Discusses representativeness						
Identifies the need for completeness						
Describes the need for comparability						
Discusses desired method sensitivity						
A8. Special Training/Certifications						
Identifies any project personnel specialized training or certifications						
Discusses how this training will be provided						
Indicates personnel responsible for assuring these are satisfied						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Identifies where this information is documented						
A.9 Documentation and Records						
Identifies report format and summarizes all data report package information						
Lists all other project documents, records, and electronic files that will be produced						
Identifies where project information should be kept and for how long						
Discusses back up plans for records stored electronically						
States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individual responsible for this						
DATA GENERATION and ACQUISITION						
B1. Sampling Process Design (Experimental Design)						
Describes and justifies design strategy, indicating size of the area, volume, or time period to be represented by a sample						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Details the type and total number of sample types/matrix or test runs/trials expected and needed						
Indicates where samples should be taken, how sites will be identified/located						
Discusses what to do if sampling sites become inaccessible						
Identifies project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc.						
Specifies what information is critical and what is for informational purposes only						
Identifies sources of variability and how this variability should be reconciled with project information						
B2. Sampling Methods						
Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken						
Indicates how each sample/matrix type should be collected						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
If *in situ* monitoring, indicates how instruments should be deployed and operated to avoid contamination and ensure maintenance of proper data						
If continuous monitoring, indicates averaging time and how instruments should store and maintain raw data, or data averages						
Indicates how samples are to be homogenized, composited, split, or filtered, if needed						
Indicates what sample containers and sample volumes should be used						
Identifies whether samples should be preserved and indicates methods that should be followed						
Indicates whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of						
Identifies any equipment and support facilities needed						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented						
B3. Sample Handling and Custody						
States maximum holding times allowed from sample collection to extraction and/or analysis for each sample type and, for in-situ or continuous monitoring, the maximum time before retrieval of information						
Identifies how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt)						
Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible						
Discusses system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the plan						
Identifies chain-of-custody procedures and includes form to track custody						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
B4. Analytical Methods						
Identifies all analytical SOPs (field, laboratory and/or office) that should be followed by number, date, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures						
Identifies equipment or instrumentation needed						
Specifies any specific method performance criteria						
Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation						
Identifies sample disposal procedures						
Specifies laboratory turnaround times needed						
Provides method validation information and SOPs for nonstandard methods						
B5. Quality Control						
For each type of sampling, analysis, or measurement technique, identifies QC activities which should be used, for example, blanks, spikes, duplicates, etc., and at what frequency						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Details what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented						
Identifies procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data						
B6. Instrument/Equipment Testing, Inspection, and Maintenance						
Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this						
Identifies testing criteria						
Notes availability and location of spare parts						
Indicates procedures in place for inspecting equipment before usage						
Identifies individual(s) responsible for testing, inspection and maintenance						
Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
B7. Instrument/Equipment Calibration and Frequency						
Identifies equipment, tools, and instruments that should be calibrated and the frequency for this calibration						
Describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment						
Identifies how deficiencies should be resolved and documented						
B8. Inspection/Acceptance for Supplies and Consumables						
Identifies critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials						
Identifies the individual(s) responsible for this						
B9. Non-direct Measurements						
Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project						
Indicates the acceptance criteria for these data sources and/or models						
Identifies key resources/support facilities needed						
Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing						
B10. Data Management						
Describes data management scheme from field to final use and storage						
Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs						
Identifies data handling equipment/procedures that should be used to process, compile, analyze, and transmit data reliably and accurately						
Identifies individual(s) responsible for this						
Describes the process for data archival and retrieval						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Describes procedures to demonstrate acceptability of hardware and software configurations						
Attaches checklists and forms that should be used						
ASSESSMENT and OVERSIGHT						
C1. Assessments and Response Actions						
Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates						
Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process						
Describes how and to whom assessment information should be reported						
Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented						
C2. Reports to Management						
Identifies what project QA status reports are needed and how frequently						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
Identifies who should write these reports and who should receive this information						
DATA VALIDATION and USABILITY						
D1. Data Review, Verification, and Validation						
Describes criteria that should be used for accepting, rejecting, or qualifying project data						
D2. Verification and Validation Methods						
Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any						
Identifies who is responsible for verifying and validating different components of the project data/information, for example, chain-of-custody forms, receipt logs, calibration information, etc.						
Identifies issue resolution process, and method and individual responsible for conveying these results to data users						
Attaches checklists, forms, and calculations						

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ELEMENT	A	U	NI	NA	PAGE # SECTION #	COMMENTS
D3. Reconciliation with User Requirements						
Describes procedures to evaluate the uncertainty of the validated data						
Describes how limitations on data use should be reported to the data users						

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APPENDIX D

This appendix contains several tables for summarizing QA Project Plan information. Since the content and level of detail in a specific QA Project Plan will vary by program, by the work being performed, and by the intended use of the data, specific tables may not be applicable to all projects. These tables illustrate possible formats that can be used; columns may be deleted, rows expanded, or items added as needed. These tables were obtained from, and modified from, the Intergovernmental Data Quality Task Force (IDQTF) Workbook for QA Project Plans currently in development.

SAMPLE QA PROJECT PLAN TABLES

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Table D-1. Personnel Responsibilities and QA Project Plan Receipt

Name	Organizational Affiliation	Title	Contact Information[1]	QA Project Plan Receipt/Control #

B [1]Telephone number, fax number, email address.

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Table D-2. Project Schedule Time Line

Activity	Date (MM/DD/YY)		Deliverable	Deliverable Due Date
	Anticipated Date of Initiation	Anticipated Date of Completion		

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Table D-3. Measurement Performance Criteria

Matrix	
Analytical Parameter	
Concentration Level	
Sampling Procedure	
Analytical Method #	

Data Quality Indicators (DQIs)[1]	Measurement Performance Criteria	QC Sample and/or Activity Used to Assess Measurement Performance	QC Sample to Assess Error for Sampling (S), Analytical (A) or both (S&A)

[1]Data Quality Indicators (precision, accuracy/bias, sensitivity, data completeness, comparability, and representativeness)

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Table D-4. Special Personnel Training or Certification

Specialized Training Course Title or Description	Training Provider	Training Date	Personnel Receiving Training/ Organizational Affiliation	Location of Records & Certificates*

*If training records and/or certificates are on file elsewhere, then document their location in this column. If these training records and/or certificates do not exist or are not available, note this.

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Table D-5. Document and Record Retention, Archival, and Disposition Information

	Identify Type Needed*	Retention	Archival	Disposition
Sample Collection Records				
Field Records				
Analytical Records				
Data Records				
Assessment Records				
Modeling Reports				

* Consider confidential business information (CBI).

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Table D-6. Sampling Locations and Sampling Method/SOPs

Sampling Location[1,2]	Location ID Number	Matrix	Depth (Units)	Analytical Parameter	# Samples (include field duplicates)	Sampling SOP	Sample Volume	Containers #, size, type	Preservation (chemical, temperature, light protected)	Maximum Holding Time Preparation/ Analysis

[1]Indicate critical field sampling locations with "1".
[2]Indicate background sampling locations with "2".

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Table D-7. Sample Handling System

Sample Collection, Packaging and Shipment
Sample Collection:
Sample Packing:
Coordination of Shipment:
Type of Shipment (Courier):
Sample Receipt and Analysis
Responsible Organization:
Sample Receipt:*
Sample Custody and Storage:*
Sample Preparation:*
Sample Determinative Analysis:*
Sample Archival
Field Sample Storage (# days from sample collection):
Sample Extract/Digestate Storage (# days from extraction/digestion):
Sample Disposal
Responsible Organization:
Responsible Personnel:

* Identify primary responsible laboratory group or individual.

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Table D-8. Contaminants of Concern and Other Target Analytes

Analyte	Matrix	Project Action Limit (units, wet or dry weight)	Project Quantitation Limit (units, wet or dry weight)	Analytical Method		Achievable Laboratory Limits	
				MDLs[1]	Method[1]	MDLs[2]	QLs[2]

[1]Analytical Method Detection Limits (MDLs) and Quantitation Limits (QLs) documented in validated methods. QLs can be 3-10 times higher than the MDLs, depending on the specifications from the Data Quality Objectives established for the project.
[2]Achievable MDLs and QLs are limits that an individual laboratory can achieve when performing a specific analytical method.

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Table D-9. Analytical Services

Analytical Parameter	Matrix	Analytical Method/SOP	Modified for Method yes/no	Data Package Turnaround Time	Laboratory/Organization (Name, Address, Contact Person, Telephone Number)	Backup Laboratory/Organization (Name, Address, Contact Person, Telephone Number)

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Table D-10. Sampling QC

Matrix	
Sampling SOP	
Analytical Parameter	
Analytical Method/ SOP Reference	
# Sample Locations	

Field QC:	**Frequency/ Number**	**Method/SOP QC Acceptance Limits**	**Corrective Action (CA)**	**Person(s) Responsible for CA**	**Data Quality Indicator (DQI)**	**Measurement Quality Objectives**
Equipment Blanks						
Field Blanks						
Trip Blanks						
Cooler Temperature						
Field Duplicate Pairs						
Collocated Samples						
Field Splits						
Field Matrix Spikes						
Other:						

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Table D-11. Analytical QC

Matrix	
Sampling SOP	
Analytical Parameter	
Analytical Method/ SOP Reference	
# Sample Locations	

Laboratory QC:	**Frequency/ Number**	**Method/SOP QC Acceptance Limits**	**Corrective Action (CA)**	**Person(s) Responsible for CA**	**Data Quality Indicator (DQI)**	**Measurement Quality Objectives**
Method Blank						
Reagent Blank						
Storage Blank						
Instrument Blank						
Lab. Duplicate						
Lab. Matrix Spike						
Matrix Spike Dup.						
Lab. Control Sample						
Surrogates						
Internal Standards						
Others						

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Table D-12. Testing, Inspection and Maintenance of Sampling Equipment and Analytical Instruments

Equipment/ Instrument	Maintenance Activity	Testing Activity	Inspection Activity	Responsible Person	Frequency	Acceptance Criteria	Corrective Action	SOP Reference

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Table D-13. Equipment and Instrumentation Calibration

Equipment/ Instrument	Procedure	Frequency of Calibration	Acceptance Criteria	Corrective Action (CA)	Person Responsible for CA	SOP Reference

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Table D-14. Inspection/Acceptance Testing Requirements for Consumables and Supplies

Critical Supplies/ Consumables	Inspection/ Acceptance Specifications	Acceptance Criteria	Testing Method	Frequency	Responsible Individual	Handling/ Storage Conditions

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Table D-15. Critical Supplies and Consumables Tracking Log

Critical Supplies/ Consumables	Tracking Number	Date Received	Meets Inspection/ Acceptance Criteria (Y/N, if yes include date)	Retesting Needed (Y/N, if yes include date)	Expiration Date	Initials/Date

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Table D-16. Assessments

Assessment Type	Frequency	Internal or External	Organization Performing Assessment	Person, Title, Organizational Affiliation Responsible For:			
				Performing Assessment	Responding to Assessment Findings	Identifying and Implementing Corrective Actions	Monitoring Effectiveness of Corrective Actions

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Table D-17. QA Management Reports

Type of Report	Frequency (daily, weekly monthly, quarterly, annually, etc.)	Projected Delivery Date(s)	Person(s) Responsible for Report Preparation	Report Recipients

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Table D-18. Data Validation Summary

Medium/ Matrix	Analytical Parameter	Concentration Level	Validation Criteria	Validation Criteria Modified	Data Validator (Name, Title, and Organizational Affiliation)

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