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South Carolina Department of Health
and Environmental Control

Guidance Document

For Preparing

Quality Assurance Project Plans (QAPPs)

For

Environmental Monitoring Projects/Studies

Office of Quality Assurance
Bureau of Environmental Services
Environmental Quality Control

Revision 1.1, September 2008

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Assurance Project Plan (QAPP) as an important tool for project managers and planners to document the type and quality of data needed for environmental decisions and to provide a blueprint for collecting and assessing those data from environmental programs. The development, review, approval, and implementation of the QAPP is part of the mandatory Agency-wide Quality System that requires all organizations performing work for EPA or funded by EPA to develop and operate management structures and processes for ensuring that data collected or compiled for use in Agency decisions are of the type and quality needed and expected for their intended use. The QAPP is the integral part of the fundamental principals and practices that form the foundation of the South Carolina Department of Health and Environmental Control (SCDHEC) Quality System.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision- making. This depends significantly on the adequacy of the QAPP and its effective implementation. Proper planning must occur to ensure that all the needs of the user are defined with quality in mind.

This document presents specifications and instructions for the information that must be contained in a Quality Assurance Project Plan for environmental data operations performed by SCDHEC or on its behalf by extramural organizations. It discusses the procedures for review, approval, implementation, and revision of QAPPs. Users of this document should assume that all of the elements described herein are required in the QAPP unless otherwise directed by SCDHEC.

This document contains the same requirements as found in the EPA QA/G-5, Guidance for Quality Assurance Project Plans and EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations. Other information cited complies with mandatory Quality Management Programs as described in:

EPA QA/R-1 EPA Quality Systems Requirements for Environmental Programs

EPA QA/R-2 EPA Requirements for Quality Management Plans

Other references used include:

EPA QA/G-4 Guidance on Systematic Planning using the Data Quality Objectives Process

EPA QA/G8 Guidance on Environmental Data Verification and Data Validation

EPA/DOE/DOD Uniform Federal Policy for Quality Assurance Project Plans, 03/2005

EPA Draft Document: Using the Graded Approach for the Development of QMPs and QAPPs in the OAQPS Ambient Air Monitoring Program

It is the intent that the guide will assist the project manager in preparing the QAPP for submittal to the Department for approval. A thorough and well-written QAPP will help expedite the approval process to ensure that all applicable elements are addressed. All projects must have an approved QAPP before environmental monitoring may commence. Questions regarding this document may be directed to:

SC DHEC
Office of Quality Assurance
P.O. Box 72
State Park, SC 29147
Phone: 803-896-0862 or 803-896-0981 Fax: 803-896-0850

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Chapter I – An Overview of the QAPP

A Quality Assurance Project Plan (QAPP) is a formal document describing in comprehensive details the necessary quality assurance (QA), quality control (QC), and other technical activities that must be performed to satisfy the stated performance criteria. A QAPP presents every step that will be required to ensure that the environmental data collected are of the correct type and quality required for a specific decision or use. A QAPP aids in supporting management decisions in a resource-efficient manner.

This document presents detailed guidance on how to develop a Quality Assurance Project Plan (QAPP) for environmental data operations performed by or for the SC Department of Health and Environmental Control. It discusses how to address and implement the specifications in EPA QA/R-5, Requirements for QA Project Plans for Environmental Data Operations. This revision details the scoping and the graded-approach method for producing a QAPP. This revision includes more details about what is required in each section and examples.

The QAPP is the key component of the SCDHEC Quality System as shown in Figure 1. It is the principal product of a systematic planning process. It integrates all technical and quality aspects for the life-cycle of the project, including planning, implementation, and assessment.

A QAPP is composed of four sections of project-related information called "groups", which are subdivided into specific detailed "elements." These groups are discussed in detail in Chapter IV of this document. However, whether a QAPP element should be addressed and to what degree will be dependent on the specific project. Using a graded approach as outlined in Chapter III, an element may be omitted or great detail may be required—all dependent on how large or complex a project is or whether it is regulatory in nature.

This document provides a discussion and background of the elements of a QAPP that will typically be necessary. The final decision on the specific need for these elements for the project-specific QAPP will be made by the sponsoring SCDHEC Bureau/Program and/or Office of Quality Assurance.

Purpose

The SCDHEC Quality System is a structured management system describing policies, objectives, principles, organization, responsibilities, accountability, and implementation plan for ensuring quality in its work processes, products, and services.

EPA and SCDHEC policy require that all special projects involving the generation, acquisition, and use of environmental data be planned and documented and have an Agency-approved QAPP prior to the start of data collection. Because this is SCDHEC Policy, it does not matter what Agency is funding the project. Any special project (non-routine work) requires a QAPP.

The exceptions to this policy are routine work, situations involving immediate public health threats or situations involving a criminal investigation**.** For these exceptions, a generic document (usually a SOP) outlining acceptable methods for sampling and analysis will suffice. Additionally, while it is the goal to have an approved QAPP in place prior to any data generation, it is allowable, with authorization from OQA (see Appendix C), to generate preliminary data in order to determine possible sampling sites or other needed information for the QAPP. However, such data generation must consist of only one or two sampling events. In addition the results of this preliminary sampling should be discussed in the QAPP and how the results affected the study (sampling site locations, etc).

The primary purpose of the QAPP is to provide an overview of the project, describe the need for the measurements, and define QA/QC activities to be applied to the project, all within a single document. The QAPP should be detailed enough to provide a clear description for every aspect of the project and include information for every member of the project staff including samplers, lab staff, and data reviewers. Effective implementation of the QAPP assists project managers in keeping projects on schedule and within the resource budget.

The Role of the Office of Quality Assurance

The Office of Quality Assurance (OQA) has the responsibility of reviewing the QAPPs with the following questions in mind:

- What level of detail will be required for the QAPP? Is the study eligible for a Class 4 QAPP or does the project complexity or EPA requirements entail a Class 1 or 2 QAPP?
- Will a preliminary study with 1 or 2 sampling event(s) be allowed? Will this preliminary study affect the program or the classification of the site as per EPA or State regulations?
- Is the QAPP in the proper format? **Your QAPP must follow the format given in this guide.**
- Does the QAPP address all of the required items in each section completely or is a reason given why an item is not applicable? **Items must not be renumbered because a previous section was not required because of the graded approach (Chapter III).** *In a Class 3 QAPP, B9 does not become B8 because the B8 Section was not required for a Class 3 QAPP. Section B9, stays B9.*
- Are the analyses to be done listed with the correct method and is the laboratory that has been chosen certified for that analysis?
- Is the laboratory's limit of detection (LOD) lower than the action limit or trigger concentration?
- Are the laboratory's SOPs and QA Plan valid and complete? For SCDHEC Labs it is enough to list the SOP Manual that will be used. For external laboratories the SOPs should be attachments to the QAPP— however, for short procedures these can be incorporated in the QAPP.
- Is the plan for Data Review reasonable?

It is highly recommended that the project manager contact OQA prior to the QAPP being written. The project manager is also advised to contact OQA with any questions during the preparation of the QAPP. Lead time prior to the planned beginning of the project is extremely important. Upon receipt of the QAPP, the OQA requires 15 business days in which to respond to the QAPP. If revisions are necessary, the Office may need up to an additional 15 business days to respond to a revised QAPP. Therefore, please allow enough lead time prior to sampling for QAPP approval --minimum a three weeks for a full QAPP (class 1 or 2), however more time will be required if EPA must approve the QAPP.

Chapter II EPA/SCDHEC Policy on Quality Assurance Project Plans

EPA Policy

All work performed by extramural organizations on behalf of or funded by EPA that involves the collection or use of environmental data in Agency (SCDHEC) programs shall be implemented in accordance with a SCDHEC approved QAPP developed from a systematic planning process based on the "graded approach." [1] **No work funded by EPA and involving the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems, shall be implemented without an approved QAPP available prior to start of the work.**

SCDHEC Policy

- Any non-routine project involving the generation of data must have a QAPP in place prior to data generation. The only exceptions are criminal investigations and emergencies where the public health could be immediately impacted.

- "When this Agency (DHEC) enters a cooperative agreement with another agency, the lead agency (Project Manager) will be responsible for generating the project study plan (unless otherwise agreed upon). Data quality objectives must be clearly established to ensure the validity of the data collected. A QA Project Plan is necessary and should be completed in accordance with the guidance documents and the Agency's Quality Management Plan (QMP)" [2].

- Any laboratory producing data for a Program's direct utilization must have Standard Operating Procedures in accordance with U.S. EPA methods, Standard Methods for the Examination of Water and Wastewater, and/or other approved methods. The laboratory organization, structure, and areas of responsibility, must be available for review by the Program reviewing data. The organization must be certified by the State's Office of Environmental Laboratory Certification (where certified methods exist). Any laboratory that sub-contracts to another laboratory must determine if this sub-contracted laboratory has the required certification. The Project Officer should state in the QAPP that a contracting lab must ensure the approved certification status of the subcontracted lab. The QAPP must include the Certification numbers of all labs used for the study. The data received must be in a format determined by the Program area and must be of acceptable quality, scientifically valid, defensible, and of known and acceptable precision and accuracy.

Applicability

These QAPP requirements apply to all environmental programs that acquire, generate, or compile environmental data on behalf of or funded by EPA/SCDHEC. These operations include work performed through contracts, interagency agreements, and assistance agreements (e.g., cooperative agreements, grants). QAPPs shall be prepared, reviewed, and approved in accordance with the specifications contained in this document for the collection activity unless explicitly superseded by regulation.

Special Requirements

In some cases, it may be necessary to add special requirements to the QAPP. The SCDHEC organization sponsoring the work has the authority to define any special requirements beyond those listed in this requirements document. If none are specified, the QAPP shall address all required elements. If a specific element is not completely addressed in the appropriate section, attached documentation, such as an approved Work Plan, Standard Operating Procedures (SOPs), etc. must be referenced. This may reduce the size of the QAPP and the time required to prepare it; however, the reference must include the document name, the page number in the document and section number (if applicable). In addition, the references must not be so numerous that the QAPP is merely a listing of references. This must be a readable document. The QAPP should also address related QA planning documentation from subcontractors or suppliers of services critical to the technical and quality objectives of the project or task. In any case, all referenced documents must be attached to the QAPP or be placed on file with the appropriate SCDHEC office and available for referencing as needed.

Responsibilities

QAPPs may be prepared by SCDHEC personnel, contractors, cooperative agreement holders (university, environmental firm, etc.), or another State agency under an interagency agreement. Except where specifically delegated, all QAPPs prepared by non-SCDHEC organizations must be approved by SCDHEC before implementation. Writing a QAPP is a collaborative effort within an organization, or among organizations, and depends on the technical expertise, writing skills, knowledge of the project, and availability of the staff. Organizations are strongly encouraged to involve technical project staff (lab, sampling group, statisticians, etc.) and the QA Office in this effort to ensure that the QAPP has adequate detail and coverage.

Approvals

None of the environmental data collection work addressed by the QAPP may be started until the initial QAPP has been approved by the DHEC Sponsoring Program and State Quality Assurance Management Officer (SQAMO) or designee. In some cases, DHEC may grant conditional or partial approval to permit some of the work to begin while non-critical deficiencies in it are being resolved. The QA Officer should be consulted to determine the nature of the work that may continue and the type of work that may be performed under a conditionally approved QAPP. The following approvals are possible:

- **Full Approval:** No remaining identified deficiencies exist in the QAPP and the project may commence.

- **Partial Approval:** Some activities identified in the QAPP still contain critical deficiencies while other activities are acceptable. If the acceptable activities are not contingent upon the completion of the activities with deficiencies, a partial approval is granted for those activities to proceed. Work should continue to resolve the portions of the QAPP that are deficient.

- **Conditional Approval:** Approval of the QAPP or portions thereof will be granted upon agreement to implement specific conditions, specific language, etc. by parties required to approve the QAPP in order to expedite the initiation of field work. In most situations, the conditional approval is upgraded to final approval upon receipt, review, and sign off by all parties of the revised/additional QAPP pages.

Once approved, the organization performing the work is responsible for implementing the QAPP. This responsibility includes ensuring all personnel involved in the work have copies of or access to the approved QAPP along with all other necessary planning documents. Personnel should understand their responsibilities prior to the start of data generation activities.

Revisions

Organizations are responsible for keeping the QAPP current when changes to technical aspects of the project change. QAPPs must be revised to incorporate such changes. **Any revisions or additions to the QAPP must be re-approved by SCDHEC and distributed to all participants in the project (see A3-Distribution List).**

Footnotes

1 EPA QA/R-5, Page 5. A graded approach is the process of basing the level of application of managerial controls applied to an item or work on the intended use of the results and the degree of confidence needed in the quality of the results.

2 Quality Management Plan for SCDHEC, July 2008 Section 5.2.3

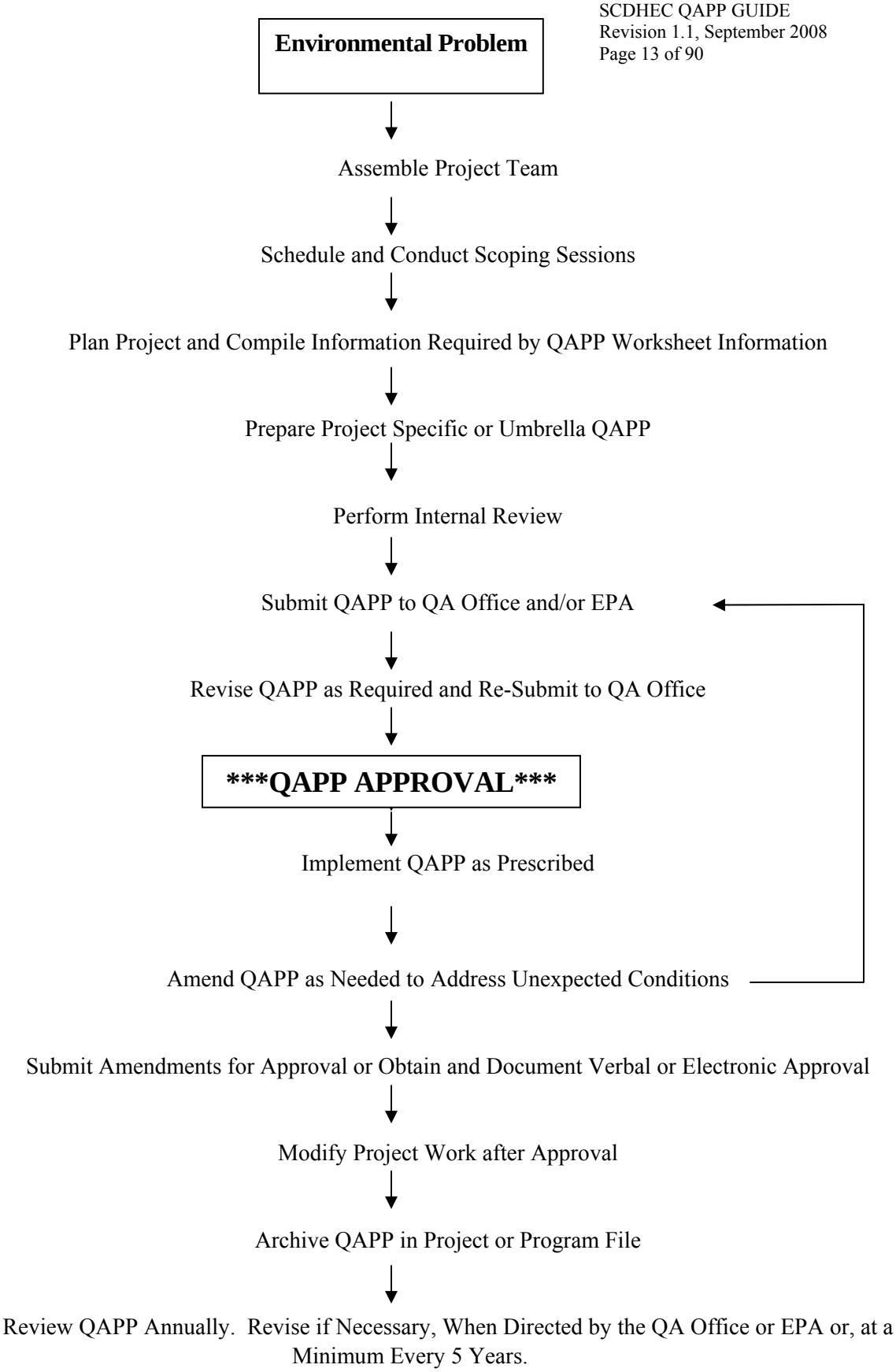

Figure 1 Life Cycle of a QAPP

Life Cycle of a QAPP

Figure 1 (previous page) presents the life cycle of a QAPP. In this cycle, each step is important, though these steps in individual QAPPs may be different from each other. For instance a short term project (like a Class 4) may not have an annual review because it is finished in 2 months; however there will be a review— so the basic step remains.

Steps in the QAPP Life Cycle:

1. An environmental problem has been identified and a project manager has been chosen.

2. The project manager assembles the project team which may consist of all or part of the following:

    a. Program personnel
    b. Laboratory personnel
    c. Sampling personnel
    d. Quality Assurance Office
    e. Stakeholders

3. Meetings are scheduled for the Team. During the meetings the project team may use the worksheets to begin assembling information that is needed. Depending on time, some of the meetings may be face-to-face where other meetings are via a conference call. These meetings can provide information for the QAPP, can serve to distribute information to all members of the team, and are useful for considering and deciding on issues pertaining to sampling, analysis and logistics. For instance:

    a. Program personnel may provide scheduling information and logistics
    b. Laboratory personnel supply SOPs and method references. They should also bring their latest certificate from the SCDHEC Office of Laboratory Certification. **Note: anyone performing field analyses (pH, residual chlorine, DO, temperature) must also be certified.**

        1. The team compares the limit of detection (LOD) of each method with action levels or needed detection limits. The team determines if the laboratory is certified for the desired methods.
        2. The team determines if the LOD is below the action limit and low enough for the project's needs.
        3. If the laboratory needs certification for one or more methods, they are informed and the process of certification can begin early in the planning stage.

    c. Sampling personnel coordinate with the laboratory for training. If field analysis will be part of the project, sampling personnel must be certified with the SCDHEC Office of Environmental Laboratory Certification*.

d. The Office of Quality Assurance (OQA) provides oversight or information on writing the QAPP.
e. Stakeholders are present in order to receive full notification but they may also provide information that is needed for the project.

4. The writing process begins. This is simplified for the author since the team has provided the basic information. The QAPP is shortened by use of tables to present information.

5. The QAPP is submitted back to the team for internal comment and approval. The approval page is signed by appropriate personnel on the team.

6. After internal approval, the QAPP is submitted to the OQA. OQA determines if all elements of the QAPP have been addressed and if the laboratory has the proper certification for the parameters desired.

7. If revisions are needed, these are submitted.

8. The QAPP is approved by the OQA, and if EPA approval is needed, the QAPP is submitted to EPA.

9. Once approved by all entities (see types of approval page), the QAPP is implemented. Note: No work can begin until the QAPP has been approved.

10. All persons/organizations on the Distribution List are sent a copy of the approved QAPP. The laboratory must be included in those receiving a copy of the QAPP. This includes the Regional Laboratories or ARESD, if either or both are involved.

11. If conditions are found that would warrant a change in what is being done, the QAPP must be amended. Amendments are made and these are submitted for internal and OQA review. If these are small changes, this may be done by phone or email. Once approved**, the amended pages or the entire QAPP—depending on the amount of changes—is sent to the persons/organizations on the Distribution List.

12. The project work is modified to reflect the changes once they are approved.

13. The final report is generated[+].

14. The project is finished and the QAPP and data are archived.

****At the discretion of the OQA, the approval signature page may just require signatures from the project manager and the OQA.**

[+]For ongoing projects, the QAPP is reviewed annually by the project manager or designee or as directed by the QAPP.

Chapter III The Graded Approach and the Development of QAPPs

Quality Assurance Project Plan Document

The QAPP document is the most frequently used format and applies to most environmental data collection work. It will apply to contracts, interagency agreements, large cooperative agreements and grants, etc. that include pre- and post-award environmental monitoring, sampling, analysis activities, and long term studies. The QAPP must be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment.

The elements of a QAPP are categorized into "groups" according to their function. All applicable elements (see Table 2) defined in this guide must be addressed. If an element is not applicable, state this in the QAPP.

The elements are:

Group A Project Management

This group of elements covers the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.

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

Group B Measurement/Data Acquisition

This group of QAPP elements covers all aspects of measurement systems design and implementation, ensuring that appropriate methods for sampling, data handling, and QC are employed and are documented.

B1 Sampling Process Design (Experimental Design)
B2 Sampling Methods Requirements
B3 Sample Handling and Custody Requirements
B4 Analytical Methods Requirements
B5 Quality Control Requirements

B6 Instrument/Equipment Testing, Inspection, Maintenance Requirements
B7 Instrument Calibration and Frequency
B8 Inspection/Acceptance Requirements for Supplies and Consumables
B9 Data Acquisition Requirements (Non-direct Measurements)
B10 Data Management

Group C Assessment/Oversight

This group of QAPP elements addresses the activities for assessing the effectiveness of the implementation of the project and associated QA/QC. The purpose of assessment is to ensure that the QAPP is implemented as prescribed.

C1 Assessments and Response Actions
C2 Reports to Management

Group D Data Validation and Usability

This group of QAPP elements covers the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements determines whether or not the data conform to the specified criteria, thus satisfying the project objectives.

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

QAPPs and the Graded Approach

Every project differs in its scope, time requirements and complexity. For personnel to produce a full QAPP for a very small project may require more time to develop than to complete the project. Thus, the concept of a Graded Approach came about. EPA developed four categories. Class 1, which must have all the QAPP Elements to Class 4 which includes only a few QAPP Elements. The following two tables describe each Class of project and what QAPP elements are required for that Class. Prior to development of the QAPP, the Office of Quality Assurance must be contacted to determine the proper Class for the Project. The term "flexible" DQOs refers to the fact that for this Class not all DQO steps must be addressed.—this is particularly true for investigative type projects.

Class	Description of Project	DQOs
Class 1	Large projects that are regulatory in nature fall under this class. This includes projects that directly support rulemaking, enforcement, regulatory, or policy decisions. This also includes research projects of significant national interest. Class 1 projects are typically stand-alone; that is the results from such projects are sufficient to make the needed decision without input from other projects. **All QAPPs that must go to EPA for approval must be Class 1 QAPPs.** A Program QAPP would be an example of a Class 1 QAPP.	Formal DQOs
Class 2	Projects that complement other projects in support of regulatory or policy decisions. Such projects are of sufficient scope and substance that their results could be combined with those from other projects of similar scope to provide necessary information for decisions. Class 2 projects may also include certain high visibility projects as defined by EPA or SCDHEC Management. External projects unless very limited in scope and duration would fall under a class 2 QAPP. External TMDL projects would be an example of this. Internal projects that are extensive in scope, regulatory in nature, or highly visible also fall under this class.	Formal DQOs
Class 3	Projects that are interim steps in a larger group of steps or projects. Such projects include those producing results that are used to evaluate and select options for interim decisions or to perform feasibility studies or preliminary assessments of unexplored areas for possible future work. External small projects with one or two parameters would be under this class. Internal projects that are long term (more than 1 year) and more than 2 parameters would fall under this class. (See the Appendix D for more information on Internal Plans)	Flexible DQOs
Class 4	Projects involved in studying basic issues, including proof of concepts, screen for particular analytical species and so on. These projects are non-regulatory and limited in either scope (1 or 2 parameters) or time (less than 1 year in length). (See the Appendix D for more information) **Only projects that use internal SCDHEC Labs for analysis and SCDHEC personnel for sample collection will fall under this class.**	Project Objectives or Goals.

Table 1 QAPP ClassesQAPP Element	Class Applicability
A1 Title and Approval Page	1,2,3,4
A2 Table of Contents	1,2,3
A3 Distribution List	1,2,3, 4
A4 Project/Task Organization	1,2,3 (external) 3, 4 – Internal- organizational chart, may be omitted if project is small and lines of authority are well described.
A5 Problem Definition/Background	1,2,3,4
A6 Project/Task Description	1,2,3,4
A7 Quality Objectives and Criteria for Measurement Data	1,2,3,4 (see DQO requirements in Table 1)
A8 Special Training Requirements/Certification	1, 2 3 - External projects 3,4 – Internal – special training only
A9 Documentation and Records	1,2,3 3- Internal: Item 1 and any special documentation. If there is an archive plan present, state that. 3- External: All items must be addressed.
B1 Sample Process Design	1,2,3*, and 4*
B2 Sampling Methods Requirements	1,2,3*, and 4*
B3 Sampling Handling and Custody Requirements	1,2,3*, and 4*
B4 Analytical Methods Requirements	1,2,3*, and 4*
B5 Quality Control Requirements	1,2,3*, and 4*
B6 Instrument/Equipment Testing, Inspection, Maintenance Requirements	1,2,3*, and 4*
B7 Instrument Calibration and Frequency	1,2,3*, and 4*
B8 Inspection/Acceptance Requirements for Supplies and Consumables	1
B9 Data Acquisition Requirements for Non-direct Measurements	1,2, 3, 4 – as applicable
B10 Data Management	1,2
C1 Assessments and Response Actions	1,2, 3 as applicable
C2 Reports to Management	1,2
D1 Data Review, Validation and Verification Requirements	1,2, 3 external plans- not required for Class 3 internal plans
D2 Validation and Verification Methods	1,2,3,4
D3 Reconciliation and User Requirements	1,2

Table 2 QAPP Elements and Class Applicability

***Class 4 QAPPs and Class 3 Internal QAPPs will reference SC DHEC EQC Environmental Investigations SOP and QA Manual, and the appropriate SC DHEC EQC Lab manuals for method requirements, handling, chain of custody, and analytical methods. Thus rather than repeating this information from section to section it will be combined in a single section called "B1-B7 Sampling and Analysis Design and Requirements."**

Note: For Class 2 and Class 3 QAPP which may be special studies under a Program-Wide or other Class 1 QAPP, it is allowable to refer to the Class 1 QAPP under which the project falls. However, the Class 1 QAPP must be included in the submission (or OQA must have a copy of it) and exact references are required (document name, section and page number).

Chapter IV QAPP Preparation

Section A Project Management

A1 Title and Approval Sheet

The purpose of the approval sheet (corresponds to worksheet 1 in Appendix F) is to enable officials to document their approval of the QAPP. The title page (along with the organization chart) also identifies the key project officials for the work. The title and approval sheet should also indicate the date of the revision and a document number, if appropriate.

This page must contain the following:

1. Name of the site or project
2. Site location
3. Name of the lead organization
4. Preparer's name, organization affiliation and contact information
5. Preparation date (day/month/year)
6. Approvals by all parties. These approvals should include the printed name, as well as the signature and date signed. The approving parties typically consist of:

    a. The Project Manager,
    b. The Organization's QA Manager (if one exists),
    c. The EPA's (or other funding agency) Project Officer,
    d. The Investigative Organization's Project Director and QA Director,
    e. The Laboratory Director of the Lab being used
    f. The SCDHEC Office of Quality Assurance QA Officer and
    g. Other key staff, such as the QA Officer of the Prime Contractor when a QAPP is prepared by a subcontractor organization.

Note: The investigative organization is an entity contracted by the lead organization for one or more phases of the project. The Investigative Organization is usually involved in data collection, but the role of this entity is not limited to data collection.

A2 Table of Contents

The table of contents lists all the elements, references, and appendices contained in a QAPP, including a list of tables and a list of figures that are used in the text. The major headings for most QAPPs must closely follow the list of required elements.

The table of contents of the QAPP must include a document control component. This information should appear in the upper right-hand corner of each page of the QAPP for document control format. For example:

Project No. or Name Revision No. Revision Date Document Control # Page___ of ____	Bowman Cement QAPP Revision No. 4 Revised 12/31/2005 Document Control # 22 Page 3 of 56

Figure 2 Document Control Examples

This is just an example; specifics such as page numbers may be placed elsewhere on each page. However, the revision number must be included. If this is the original, approved version, the revision number is "0". **(Revision numbers do not change during the QAPP Approval process.)** Document titles may be abbreviated. Document control should be applied to the QAPP beginning on the Title and Approval Page and including the Table of Contents and all figures, tables and diagrams.

For large projects it may be advisable to account for all copies of the QAPP. This can help to assure that the most current version is in use. A sequential numbering system is used to identify controlled copies of the QAPP. Controlled copies are assigned to individuals within an organization or team. Individuals receiving a controlled copy of the QAPP are provided with all revisions, addendums, and amendments to the QAPP. These individuals are responsible for updating their copy. Part of the Document Control System can also use a signature page that is signed by the recipient indicating that they have physically updated their QAPP when given updates. However, this system does not preclude making unofficial/unnumbered copies of the QAPP, but holders of the controlled copes are responsible for distributing revised or added material to update any copies within their organization.

A3 Distribution List

The distribution list documents those entities to which copies of the approved QAPP and any subsequent revisions will be sent. Table 3 shows an example of a Table that was filled out in the Scoping Meetings. (See Appendix F)

QAPP Recipients	Title	Organization	Telephone Number	Fax Number	E-mail Address	Doc Control Number
Joe Brown	Project Manager	L&WM	803-896-5555	803-896-7777	Brownje@dhec.sc.gov	1 of 25
Sandra Flemming	Lab Director	ARESD	803-896-0856	803-896-0868	flemmisa@dhec.sc.gov	2 of 25

Table 3 Distribution List

Once again, Document Control Numbers may not be necessary for a small project, but may be very necessary for a larger project. A complete copy of the QAPP must be sent to the project manager and key personnel. Key personnel are those working for the lead organization, including contractors or subcontractors. Examples include the lead field sampler, the project

manager, the Laboratory Director, data reviewer, statistician, risk assessor, assessment personnel, EPA project officer and the SCDHEC Office of Quality Assurance. For internal plans, it may only be necessary to include the region/program the person is in, phone number, fax number and email address. EPA has required all contact information including full addresses for full (Class 1) QAPPs.

Note: It is CRITICAL that the Laboratory receive a copy of the QAPP. The distribution list must include contacts from all laboratories involved in the project.

A4 Project/Task Organization

1. Identify key individuals involved in all the major aspects of the project. This includes contractors, labs, principle data users, and decision makers. **The laboratory information must include the SC DHEC Environmental Laboratory Certification Number for the Lab.**
2. Discuss each person's responsibilities.
3. Identify the individual who is responsible for maintaining the QAPP. This person would distribute the original QAPP, prepare any updates and redistribute as necessary.
4. Provide an organization chart. This chart should indicate that the project QA manager exists independently from the unit generating the data. The organization chart should also show lines of authority and reporting responsibilities. See the example Organization Chart below. This may be omitted if the project is small, a Class 3 or 4, and all communication and lines of authority are well defined within A4.

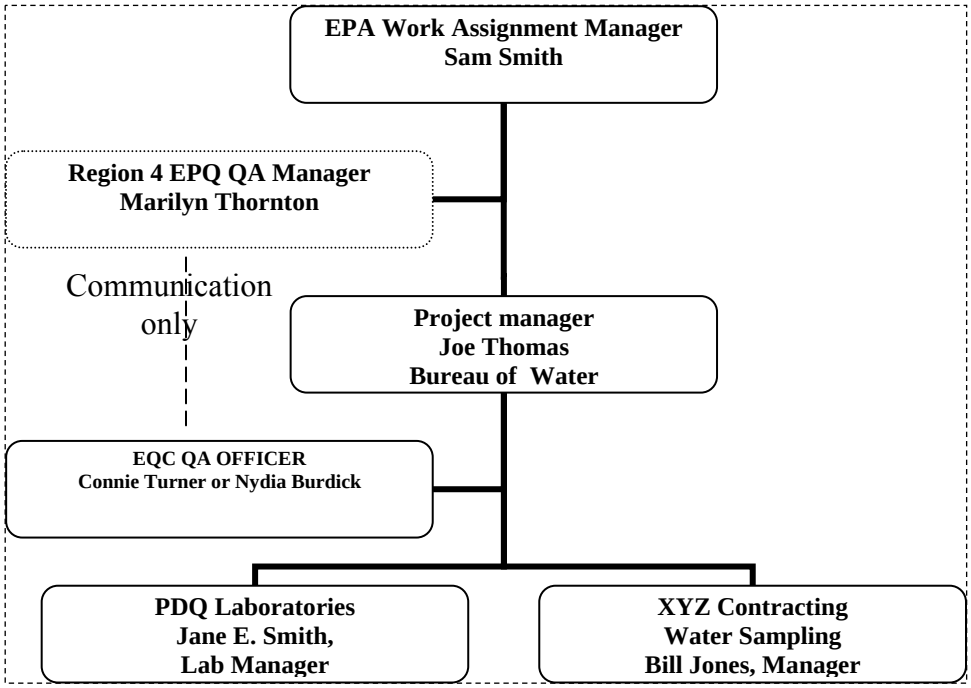

Figure 3 Example Organization Chart

A5 Problem Definition/ Background

1. Clearly explain the reason for the study. Include appropriate historical and/or site background information.
2. Explain what decisions are to be made (if applicable), actions to be taken or outcomes expected from the information to be obtained.
3. Identify regulatory information, applicable criteria and/or action limits that will impact this study.

The discussion must include enough information about the problem, the past history, any previous work or data, and any other regulatory or legal context to allow a technically trained reader to make sense of the project objectives and activities. This discussion should include:

- A description of the problem as currently understood, indicating its importance and programmatic, regulatory, or research context. This should include any pertinent history of the site including previous studies or preliminary results.
- A summary of existing information on the problem, including any conflicts or uncertainties that are to be resolved by the project;
- A discussion of initial ideas or approaches for resolving the problem there were considered before selecting the approach described in element A6, "Project/Task Description"; and
- The identification of the principal data user or decision maker (if known).

Note that the problem statement is the first step of the DQO Process (A7) and the decision/ specification is the second step of the DQO Process.

A6 Project/Task Description and Schedule

The requirements for this section include:

1. Summarizing the work to be done, for example what measurements are to be made both in the field and in the lab and include information concerning any data files which will be produced.
2. Giving work schedules including start and completion. Any other critical dates also may be included for activities such as sampling, analysis, data or file review. This can be done in a table if desired (See Table 4)
3. Detailing geographical locations to be studied. Maps should be included when possible.
4. If there are any time or resource (personnel, weather, money) constraints, include those factors as well since these may impact completion dates or how the study is conducted.

Activity	Organization	Anticipated Start Date(s)	Anticipated Date(s)of Completion
QAPP Approval	BAQ/DAQA	10/1/06	10/31/06
Sampling Begins	DAQA	1/1/06	6/30/07
Lab Report Received	DAQA	Quarterly beginning 4/30/06	Final lab report 7/30/07
Project Verification	DAQA	8/1/07	8/30/07
External Validation	EPA	9/1/07	10/1/07
Final Report Due	DAQA	10/15/07	11/1/07

Table 4 Project Schedule

A7 Data Quality Objectives (DQOs) and Data Quality Indicators (DQIs)

The requirements for this section include:

1. Identify the 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.
2. A discussion of the following DQIs (Data Quality Indicators) are required: precision, bias/accuracy, comparability, representativeness, completeness and method sensitivity. (See Appendix B for a discussion of these indicators)
3. In addition, Classes 1 and 2 require a formal DQO (Data Quality Objectives) process, Class 3 requires pertinent DQO steps and Class 4 requires just a discussion of project objectives or goals.

Item 1: In this item, the QAPP requires that all performance criteria be listed. This includes precision, limit of detection, and accuracy/bias criteria. Usually these are obtained from the Laboratory. However, there are times when increased sensitivity is required and this notifies the laboratory what is expected in terms of QC and detection. This is why it is essential for the laboratory to receive a copy of the QAPP. (In Section B5 there will be a discussion of the frequency of each type of QC activities, what will be done if the performance criteria is not met, and how any QC Statistics will be determined.)

For small projects with few parameters this item may be in the form of a paragraph. For projects with many parameters and many associated QC items, it is highly suggested that a table be used for this item (see Table 5 for an example). If the project dictates that there will be many analytical parameters and multiple matrices, a table is a must. Depending on the type of project, tables may be organized by matrix and/or analytical parameter. Note that the abbreviated name for the SOP references an attachment. If abbreviations or numbers are used for SOPs in Table 5, then the attached SOPs must have those same numbers/abbreviations or the abbreviations must be listed with the full name of the referenced SOP (see Table 16). As stated in Section B, Lab and Sampling SOPs are either attached or incorporated in the QAPP.

Item 2: If a formal DQO process is required, then this item will be covered in that discussion. If not, a short explanation concerning each of the DQIs is required. How will precision, comparability, accuracy, representativeness, completeness and sensitivity be determined? This includes any calculations that will be used. This can be done in a table form (see Table 5) and may include a description of the DQI and how this is important to the study.

Matrix: Water **Analytical Group:** Semi-Volatiles				
Sampling Procedure	**Analytical SOP**	**DQI**	**QC or Activity used to Assess Performance**	**Measurement Performance Criteria**
S-1*	Semis*	Precision- Field	Field Duplicates	RPD ≤ 30%
		Precision – Lab	Lab Duplicates	RPD ≤ 20%
		Accuracy/Bias	Surrogate Spikes	± 20%
		Accuracy/Bias	Calibration Check	± 20%
	.	Sensitivity	± 40% at Quantitation Limit	Lab fortified blank at Quantitation Limit

Table 5 QC Criteria

*There should be a note here stating what these abbreviations mean or what page they are defined

Item 3: A formal DQO process must be included for a full QAPP (Class 1 and 2). For a Class 3 QAPP, this process can be abbreviated. For a Class 3 QAPP, some items may be omitted because they will not be applicable. The reason for the omission must be stated. For instance, many Class 3 studies will be investigative—as in a survey type project and a decision statement may not be necessary. Here are the 7 Steps of the DQO process and what is expected in each part:

The DQO Process:

1. **State the problem**- This is a short statement of what was discussed in the background section.

2. **Identify the decision** – What decision will be made from the data obtained? In the case of an investigative study it is possible that this will not be applicable. (See Appendix C for a case where it is applicable).

3. **Identify inputs to the decision** – What data will you need to make the decision or carry out the study? Data to be addressed includes laboratory and field analysis, data from other sources, previous studies, etc.

4. **Define the study boundaries** – The boundaries include the date, length of time, and exactly where the study will take place. If wells are to be dug, this even includes how deep the wells are going to be.

5. **Develop an analytical approach and a decision rule** – Identify parameters that will allow you to make the decision and then state the decision rule. This is usually given as cause an effect--an "If-then format". If such a condition x exists, then the decision will be… This is not usually applicable for investigative studies.

6. **Specify Limits on decision error** – What situations will cause error in the study? There are two possibilities with every study: the resulting conclusions are either correct, or they are not. In this step, the writer should discuss how error will be limited in the study so that the chance of making the wrong decision, or coming to the wrong conclusions are minimized. This discussion must include all or some of the following: Data Quality Indicators (DQIs) including precision, bias, comparability, representativeness, plus items such as a discussion of sampling situations which would cause error, and so on. The discussion should include how such DQIs will be calculated.

7. **Optimize the design for obtaining the data** – If unlimited samples could be collected for unlimited lab analysis, certainly a site would be well characterized. Of course this is not possible--there are resource limits to all studies. The goal of Step 7 is to develop a resource-effective design for collecting and measuring environmental samples or for generating other types of information needed to address the problem. For any project what is needed is to have enough samples of sufficient quality to make a decision or come to a conclusion. In this section, the rationale for a particular sampling design must be discussed. This discussion may include such things as site sampling guidance documents; cost of analyses, time requirements, DQIs such as representativeness, and software tools (an example would be VPN software (Visual Sampling Plan).

A8 Training and Certification

1. Identifies and describes any specialized training or certification requirements
2. Discusses how training will be provided.
3. Indicates person responsible for assuring that personnel participating in the study receive the proper training.
4. Identifies where training is documented.

The purpose of this element is to ensure that any specialized training requirements necessary to complete the projects are known, furnished, and the procedures are described in sufficient detail to ensure that specific training skills can be verified, documented, and updated as necessary.

Requirements for specialized training for non-routine field sampling techniques, field analyses, laboratory analyses, or data validation should be specified. Depending on the nature of the environmental data operation, the QAPP may need to address compliance with specifically mandated training requirements. For example, contractors or employees working at a Superfund site need specialized training as mandated by the Occupational Safety and Health (OSHA) regulations. If hazardous materials are moved offsite, compliance with the training requirements for shipping hazardous materials as mandated by the Department of Transportation (DOT) in association with the International Air Transportation Association may be necessary. This element of the QAPP should show that the management and project teams are aware of specific health and safety needs as well as any other organizational safety plans.

Usually, the organizations participating in the project that are responsible for conducting training and health and safety programs are also responsible for ensuring certification. Training and certification should be planned well in advance for necessary personnel prior to the implementation of the project.

Because EQC has a well documented training system, this section will not be required for internal projects unless special training, directly associated with the project, is needed.

A9 Documentation and Records

This section addresses all the records and documents that will be generated by the study. Knowing exactly what records has been generated is important for the Project Manager, who may end up needing more information than was originally requested. The existence of this information may also need to be known during the Validation Process or it may be important in the event that the Project is reviewed some years in the future. In addition, this section requires summarization of the report package. This allows the Project Manager to dictate what must be submitted and those generating the data what will be required.

This section must:

1. Give a description of how project personnel will receive the most current version of the QAPP.
2. Identify the report format and summarize all data report package information. This consists of an itemized list of the information and records that must be included in the data report package and the desired reporting format for both hard copy and electronic forms.
3. Give an itemized list of any other records and documents applicable to the project such as audit reports, interim progress reports, and final reports that will be produced.
4. Identify where project information should be kept and for how long
5. Discuss back up plans for records stored electronically

Item 1: How will all parties receive the most current QAPP? The purpose of this section is planning. With the first item, the QAPP addresses how everyone will receive the most current version. The response should also include a statement about updating the QAPP when there is a revision. All of this could be just a sentence stating that the person in charge of updating the QAPP will do so and submit it to the QA Office for approval. Once the QAPP is approved, the updated QAPP is sent to those individuals on the distribution list.

Items to consider-

Does the entire QAPP need to be sent out? In cases where major changes are ubiquitous throughout the document, the answer is yes. If the changes only involve a few pages, these pages may be sent out with directions of which pages to pull out from the QAPP and which to insert. Does the project manager wish to have a signature page sent with the updated QAPP (or portions of the QAPP) so that the recipient must sign indicating that they have received the updates and are using them?

Item 2: What will be in the Data Report Package? The second item dictates what information the laboratory/contractors are to submit in their report and how they do it. Will it be hard copy or electronic, excel spreadsheets sent via email or a hard copy full report. The QAPP must also list what is to be sent as part of the report. This might include just the final results or the report package might include raw data. In addition, this list may be done by parameter or method. When possible, field and laboratory records should be integrated to provide a continuous reporting track. However, the chain of custody must have a unique numbering system acceptable to the Laboratory so that the sample is identifiable from start to finish. Associated field data must be submitted with the chain of custody.

The information required for the report package should be discussed during the scoping meetings and especially with the laboratory. The list of expected records can serve as the basis of a checklist as data is received from the laboratory to ensure data completeness (Data Verification). The selection of which records to include in a data reporting package must be determined based on how the data will be used and the expense.

Item	Analyte	Instrument	Type
Field Logs	All	NA	Hardcopy
Field Analysis Records	pH, Conductivity	Hydrolab	Hardcopy and Electronic
QA/QC Report and/or case narrative	All	NA	Hardcopy and Electronic
Sequence Logs	VOCs	GCMS	Hardcopy
Continuing Cal	VOCs	GCMS	Hardcopy
Raw data-peak areas and instrument calculations.	VOCs	GCMS	Hardcopy
Final Data-tables with all calculated parameters for each sample.	VOCs, Cr, Pb	Various	Electronic (Excel Spreadsheet) and Hardcopy
QA/QC Data- precision and accuracy on Lab Duplicates	VOCs	GCMS	Electronic and Hardcopy
Field Blanks Results	VOCs	GCMS	Electronic and Hardcopy
Field Duplicate Results	VOCs	GCMS	Electronic and Hardcopy
Reporting Limit Standard Recovery	VOCs	GCMS	Hardcopy and electronic
Sequence Logs	Cr, Pb	ICP	Hardcopy
QA/QC Data	Cr, Pb	ICP	Hardcopy
Instrument Raw Data	Cr, Pb	ICP	Hardcopy and Electronic
Precision Data	Cr, Pb	ICP	Hardcopy and Electronic

Table 6 Data Report Package Example

See the list under Item 3 for records to consider for inclusion and Table 6 for an example of data report package requirements. This is just an example, however, and does not include all records that will be required for a Final Report and may include items that would be cost prohibitive.

Item 3: What reports and records will be produced? Obviously a final report will be one of the items, however, consider exception reports, QA/QC reports, Internal Audit reports etc. All records generated in the study should be listed for this item. This is a good item to enlist help from both the laboratory and any contractors that provide sampling and field analysis for the project. They can provide a list of items that they will use throughout the project. The following itemization of the types of records that are produced in a typical project should also help in compiling this list. The following are examples of different records produced in a typical project.--some of which may be included in the data reporting package:

Field Operation Records

Information contained in these records document overall field operations. These records generally consist of the following (although exact documents can vary):

- *Sample collection records:* These records show that the proper sampling protocol was performed in the field. At a minimum, this documentation should include the names of the persons conducting the activity, sample number, sample collection points, maps and diagrams, equipment/method used, climatic conditions, and unusual observations. This can be documented on a chain of custody. Some sample collectors use bound field notebooks. These are generally used to record raw data and make references to prescribed procedures and changes in planned activities. They should be formatted to include pre-numbered pages with date and signature lines.

- *Chain-of-custody records:* Chain-of-custody records are legal records of the sample from collection to analysis. These records document the progression of samples as they travel from the original sampling location to the laboratory and finally to their disposal area and include information on field analysis results on the sample, time of collection, preservation, temperature at the arrival, etc.

- *QC sample records:* These records document the generation of QC samples, such as field, trip, and equipment rinsate blanks and duplicate samples. They also include documentation on sample integrity and preservation and include calibration and standards' traceability documentation capable of providing a reproducible reference point. Quality control sample records should contain information on the frequency, conditions, level of standards, and instrument calibration history.

- *General field procedures:* General field procedures record the procedures used in the field to collect data and outline potential areas of difficulty in gathering specimens. For EQC these procedures are in the EQC Environmental Investigations SOP & QA Manual (EISOP).

- *Corrective action reports:* Corrective action reports show what methods were used in cases where general field practices or other standard procedures were violated and include the methods used to resolve noncompliance.

- *Procedures, manifests and testing contracts*: If applicable, to show regulatory compliance in disposing of waste generated during the data operation; procedures, manifest, and testing contracts should be included in the field procedures section.

Laboratory Records

The following list describes some of the laboratory-specific records that should be compiled:

- *Sample Data:* These records contain the times that samples were analyzed to verify that they met the holding times prescribed in the analytical methods. Included should be the overall number of samples, sample location information, any deviations from the SOPs, time of day, and date. Corrective action procedures to replace samples violating the protocol also should be noted.

- *Sample Management Records:* Sample management records document sample receipt, handling and storage, and scheduling of analyses. The records verify that the chain-of-custody and proper preservation were maintained, reflect any anomalies in the samples (such as receipt of damaged samples), note proper log-in of samples into the laboratory, and address procedures used to ensure that holding time requirements were met.

- *Sample Analysis Report*

Test Methods Records

Analyses must be performed exactly as laid out in the SOP. This documentation should include a report of any deviations from the SOP, including sample preparation and analysis, instrument standardization, detection and reporting limits, and test-specific QC criteria. Documentation demonstrating laboratory proficiency with each method used could be included.

- *QA/QC Reports:* These reports will include the general QC records, such as initial demonstration of capability, instrument calibration, routine monitoring of analytical performance, calibration verification, etc. Project-specific information from the QA/QC checks such as blanks (field, reagent, rinsate, and analytical), spikes (matrix, matrix spike replicate, and surrogate spike as they are required by the methodology and SOPs), calibration check samples (zero check, span check, and mid-range check), replicates, splits, and so on should be included in these reports to facilitate data quality analysis.

Data Handling Records

- These records document protocols which will be used in data reduction, verification, and validation. Data reduction addresses data transformation operations such as converting raw data into reportable quantities and units, use of significant figures, recording of extreme values, blank corrections (if allowed by the method), etc. Data verification ensures the accuracy of data transcription and calculations, if necessary, by checking a set of computer calculations manually. Data validation ensures that QC criteria have been met. Many labs also use check lists to ensure that the data was checked by analyst and verifier.

Item 4: Archiving and disposal – Requirements for archiving and disposal must be spelled out. How long will the records be kept (this includes both electronic and hardcopy formats)? Where will the records be kept? For the laboratory, the lab's SOPs and QA/QC documents may be referenced, but for ANY reference to another document, the pertinent page numbers must be given.

Items 3 and 4 may be done in tabular format as seen in Table 7. This is just an example, however, and does not include all records that will be produced.

Item	Produced by:	Hardcopy/Electronic	Storage Location/Time	Archival	Disposal (Time)
Chain of Custody	Field/Lab	Hardcopy	Lab-Filed in Lab storage (project file)/until final report.	Archived after final report in archive room.	8 years, then destroyed.
Field Analysis Logs	Field	Hardcopy-Field Notebooks	With field personnel until project is finished.	Archived after project is finished.	8 years, then destroyed
Standard prep records	VOCs, metals	Hardcopy- Standards Notebook	In Lab until filled	Archived when notebook is filled.	8 years, then destroyed.
VOC Analysis Records	Lab	Hardcopy and Electronic- Includes sample raw data, and final sample records, calibration records, QC records.	Electronic stored on Instrument computer- After validation, backed up onto single write CD. Hardcopies kept with CD in Lab. Storage(project file) until final report issued	Electronic and Hardcopies moved to archive room after final report.	8 years, then destroyed.

Table 7 Record Locations, Archival and Disposal

Section B Measurement/Data Acquisition

The purpose of this element is to describe all the relevant components of the experimental design; define the key parameters to be estimated; indicate the number and type of samples expected; and describe where, when, and how samples are to be taken. The level of detail should be sufficient that a person knowledgeable in this area could understand how and why the samples will be collected. This element provides the main opportunity for QAPP reviewers to ensure that the "right" samples will be taken. Strategies such as stratification, compositing, and clustering should be discussed, and diagrams or maps showing sampling points should be included. Most of this information should be available as outputs from the final steps of the planning (DQO) process.

In addition to describing the design, this element of the QAPP should discuss the following:

- A schedule for project sampling activities,
- A rationale for the design (in terms of meeting DQOs),
- The sampling design assumptions,
- The procedures for locating and selecting environmental samples,
- A classification of measurements as critical or non-critical, and
- The validation of any nonstandard sampling/measurement methods.

B1 Sampling Process/Experimental Design

In this section the following must be covered:

1. A schedule detailing project sampling activities.
2. A description and justification for design strategy, indicating the area, volume or time period to be represented by a sample. The type and total number of samples expected or needed. This must include how many of each type of matrix or test runs/trials.
3. Sampling locations are specified as well as how the sites will be identified. This could include GPS measurements or a description or a reference to a map. Locations include not only where the site is on a map but items like the depth of a well or the height of an air sampling platform and so on.
4. A discussion of what to do if sampling sites become inaccessible. This could be as catastrophic as being shut out of a site, or as simple as having to re-locate a site. For instance, a well site had to be relocated because of a large underground rock formation.
5. Identification of project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc.
6. Specifies what information is critical and what is for information purposes only.
7. Identifies sources of variability and how this variability should be reconciled with project information.

Item 1: Schedule of project sampling activities: This element should give anticipated start and completion dates for the project as well as anticipated dates of major milestones, such as:

- A schedule of sample events.
- The schedule for analytical services by the laboratory.
- The schedule of phases of sequential sampling or testing (if applicable).
- The schedule of test or trial runs (such as a shakedown period).
- The schedule for peer review activities.

Item 2: Description and justification for design strategy must be described. The QAPP should describe the project teams' rationale for choosing the selection of sites. This may be a strategy such as a grid system for selecting soil samples, compositing samples, or collecting 24 hour air samples. It should describe the sampling design in terms of what matrices will be sampled, where the samples will be taken, the number of samples to be taken and the sampling frequency. If a biased sampling approach will be used instead of a statistical approach, the rationale for this must be discussed. An example of this would be following a pollutant's "plume" through groundwater or soil. It may be that only the rationale is available during QAPP development. In this case, the rationale may be enough. For example: The existence of private wells in the study area will be determined by a house to house survey and each actual well location will established by GPS. Each well found during the survey will be sampled.

Item 3: Specify the type and total number of samples expected or needed. For larger projects this can be through use of a table (see Table 8).
According to Table 8, four ground water samples will be taken from the MW-1 well. One sample will be analyzed for SVOCs one for VOAs and two for metals—one being a field duplicate. This may actually be one sample poured into the specific containers, so the QAPP must be detailed in all aspects of sample collection including dispensing aliquots for various analyses. This is also true for how a field duplicate is collected. Is it one large sample that is split, or is it two discreet samples, taken at the same time in different bottles? For internal SCDHEC this is specified in the EISOP and it is not necessary to use this table, just include a reference to the EISOP.

Sample Location ID	Matrix	Depth	Analytical Group	Conc. Level**	Number of samples (identify field duplicates)	Sampling SOP Reference	Rationale for Sampling Locations
MW-1*	GW	20 -30 Ft	VOAs	Low	1	S-1	Background
			SVOCs	Low	1	S-2	
			Metals	Low	1/1 field dup	S-3	

Table 8 Sampling Design

Note: *The example in Table 8 differentiates between not only analytical groups, but sampling of high and low concentration. In most situations, this is not necessary.. The SOP references may be an attachment number or an abbreviation of the actual name of the SOP, -but must be easily understood as to which sampling SOP is being referenced and where the reference is located. Although SOPs are usually attachments, they can also be incorporated within the QAPP.*

B2 Sampling Methods:

In this section the following points must be addressed (as applicable):

1. All sampling SOPs must be identified by number, date, and regulatory citation, indicating sampling options or modifications to be taken. This may be a reference to an attached SOP.
2. The QAPP must be clear in how each sample type/matrix will be collected—including how many of each type.
3. If in situ monitoring, indicate how instruments should be deployed and operated and maintained to avoid contamination and ensure collection of valid data.
4. If continuous monitoring is used as part of the project, indicate the averaging time and how instruments should store and maintain raw data, or data averages.
5. Indicate how samples are to be homogenized, composited, split, or filtered, if applicable.
6. Indicate what sample containers should be used and what sample volumes should be collected.
7. Identify whether samples should be preserved. If preserved indicate how preservation should be carried out (and with what).
8. Indicate whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done. If there are by-products (rinsates, for instances) discuss the disposal of those by-products.
9. Identify any equipment and support facilities needed. This may include things such as the lab coming to the site to pick up samples to meet hold times, Fed-Ex shipment, field analyses done by a different contactor and electricity to run bailers or sampling equipment.
10. Address the actions to be taken when problems occur and identify the individual(s) responsible for corrective action and how this should be documented

This section calls for a great deal of information to be given. Some of this may be addressed by listing attached SOPs; however exact page numbers and/or section(s) must be given with the referenced SOP. A table may simplify this process. The table would include parameter, matrix, sample containers, sample volumes, and preservation method (ice, acid, etc). If the table is large because there are many parameters and matrixes, it may be best to sort each table by sample matrix (i.e. soil, water etc).

An example table is given below, but this is only an example. Exact preservation, hold times, and containers vary with each lab and the sampling/analysis methods they use. This table meets the requirements for Items 1, 2, 6, and 7. However, Items 3, 4, 5, 8, 9 and 10 must still be addressed. These are best done in discussion form. Item 10 does require that someone be appointed to be responsible for corrective actions and documentation of those actions. This person may be specified by name or position (Field Sampling Manager, for instance).

SOP Identifier	Abbreviated Name	Method	Analyte	Matrix	Container Type /Sample Volume	Preservation	Hold Time
AI01	In-1	SM4500 H+B 20th Ed	pH	Ambient	Plastic, 1 Liter	N/A	Immediate Analysis
AI08	In-2	SM2320 B 20th Ed	Alkalinity	Ambient	Plastic, 1 Liter	Cool, 4ºC	14 Days
AO13	O-1	EPA 624	VOCs	Ambient	3-60 ml amber glass	Approx. 15 mg Sodium Thiosulfate 3 drops of 1:1 HCl; Cool, 4ºC	14 days

Table 9 Sampling References and Sample Handling Requirements

B3 Sample Handling and Custody

The following items must be included in this section:

1. The QAPP must state the 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.
2. A discussion of how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt).
3. This Section must indicate how sample or information handling and custody information should be documented, such as in field notebooks and forms, and it should identify the individual(s) responsible for the documentation.
4. A discussion of the system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the QAPP.
5. This Section should describe the chain-of-custody procedures and include the form that will be used to track custody.

Item 1: The hold times (or time from sample collection to extraction or analysis) could be given using the worksheet shown in Table 9. However, if this table is in a previous section a reference must be made in Section B3. For instance, "Hold times are shown in Table 9 in Section B2 on page 18".

Item 2: How will the samples get from the site to the lab? If they have to be iced are will they be stored in coolers? Is there a temperature blank in the cooler? Will the lab measure temperature on receipt? Where will the samples be stored once received? This last item will tie into Item 5 which is chain of custody, because placing samples in a secure area to limit access is one facet of sample custody. Sample custody covers the

history of the sample from collection until final disposal. It includes who handled the sample, how it was handled, and where it was stored. References to the Sampling SOPs and/or the Chain of Custody SOP can be used to help cover this item.

Item 3: This can refer to documentation in field workbooks, sample chain of custody, analysis request sheets, etc. Writers can reference specific SOPs to avoid repeating information. All references must be exact (SOP Name and page number).

Item 4: State how samples will be identified. For instance, a sample could be named after the site then a number for what number sample it is and the date. So that for a site called Wateree Coal Mine the sample numbers could be WCM01092607, WCM02092607, WCM03092607 to indicate that the samples are from Wateree Coal Mine(WCM), the first, second and third samples (01,02, and 03) taken on Sept 26, 2007 (092607). In addition to discussing how samples will be identified, will there be tags on the samples that have just this information, or will bar codes be used? Anything that is associated with sample identification must be discussed here.

Item 5: The chain of custody (COC) procedure will be what is planned to be done in the field as well as what procedure the courier and lab personnel use as each person receives the sample. The chain of custody form comes from the lab. A copy of the chain of custody that will be used must be included in the QAPP. If there is a procedure for Chain of Custody, that procedure may be an attachment and referenced. If more than one lab is used for the project, each COC used—along with the SOP—should be attached.

Note: If more than one lab is used there will be multiple chain of custody forms and SOPs that must be included with the QAPP.

B4 Analytical Methods

This section must:

1. Identify--by number, date, and regulatory citation--all analytical SOPs (field, laboratory and/or office) that should be followed. Any options or modifications to be taken, such as sub-sampling and extraction procedures must be discussed. If an EPA method is referenced in the SOP, this must also be given.
2. Identify all equipment or instrumentation that is needed.
3. Specify any specific method performance criteria.
4. Identify procedures to follow when failures occur, identify the individual responsible for corrective action and appropriate documentation.
5. Identify sample disposal procedures
6. Specify laboratory turnaround times needed
7. Provide method validation information and SOPs for nonstandard methods

Items 1-2: See Table 10.

Item 3: See Table 10. The Practical Quantitation Limit (PQL) should be stated for each analyte/parameter. This is based on the lowest standard concentration that the laboratory uses in the calibration curve during the analysis. Some laboratories will offer a MDL (method detection limit). The MDL is not as helpful in ascertaining the true sensitivity of the analysis since it is a mathematical calculation. The practical quantitation limit is more useful because it demonstrates that the laboratory can indeed identify and/or quantify an analyte at the stated concentration (see also Table 5—where the acceptance ranges for a standard run at the quantitation limit should be listed).

In addition, the writer should compare the PQL to the action or trigger limits for the study. It WOULD NOT BE advisable to have an action limit that is lower in concentration than the PQL (or MDL--if that is used), since the Lab cannot quantify or possibly even detect the action limit. In addition, the Lab's MDL should be 5-10 times less than the PQL requested. For instance, a certain contaminant in the environment has an action limit (or trigger) of 10 ppb. The requested PQL MUST is lower than this limit. The requested PQL for this parameter is 5 ppb. The Lab's MDL should be 0.5-1 ppb—which would be 5-10 times less than the PQL.

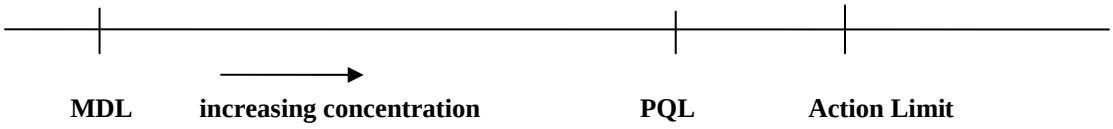

Figure 4 MDLs, PQLs, and Action Limits

Figure 4 illustrates the relationship that should exist between the MDL, PQL and Action Limit of a project.

Item 4: This may be addressed in an attachment such as the QA/QC Plan. If that is the case, then the document must be identified and section and page number given. If not, there must be an outline of what will be done if there is a failure in the laboratory. Failures in the laboratory could be a QC failure or instrument failure. How will the situation be dealt with, who will correct the problem, who will be notified, how will it all be documented?

Item 5: How long will the laboratory keep the samples before they are destroyed? How will disposal be documented?

Item 6: A statement about turnaround times must be made. The turnaround time is how long the laboratory takes from the receipt of the sample until the sample results are reported. This may be a general statement such as "The laboratory turnaround time shall be no more than 7 days from collection" or this may be done by parameter/analyte. This can happen because more complex analyses may only be done once a month, while parameters with short holding times may have to be run as soon as 48 hours after collection or even at the sampling site. This is an item which should be worked out in advance. The project may require shorter turn around times than the laboratory is accustom to and thus the laboratory must know ahead of time what is expected.

A table may be helpful—see Table 10. If the project will receive reports from the laboratory on a schedule, this should be stated. For instance: "The laboratory will generate results and tabulate them and send a quarterly report to the project manager. The report will be expected no later than the 15th day after the preceding quarter has ended."

Parameter/Analyte	Matrix	SOP Ref	Rev # and Date	Method Ref	Instrument	PQL	Turnaround time
Pb	water	Met-1	Rev 2 08/05	EPA 200.9	Graphite Furnace	5 ug/L	2 weeks
Semi-Volatiles	water	Sm-1	Rev 3 01/07	EPA 625	GCMS	Varies; see SM-1 pg 12 Table 1	6 weeks

Table 10 Analytical Methods and Performance Criteria

Item 7: This item addresses only those methods for which there is not an EPA approved method. A copy of the affected SOP must be included and all QC must be specified with acceptance limits noted. In addition the writer should state why a non-standard method is to be used. For nonstandard sampling methods, analytical methods, sample matrices, or other unusual situations, appropriate method validation study information may be needed to confirm the performance of the method for the particular matrix. The purpose of this validation information is to assess the potential impact on the representativeness of the data generated. For example, if qualitative data are needed from a modified method, rigorous validation may not be necessary. Such validation studies may include round-robin studies performed by EPA or by other organizations. If previous validation studies are not available, some level of single-user validation study or ruggedness study should be performed during the project and included as part of the project's final report. This element of the QAPP should clearly reference any available validation study information.

B5 Quality Control Requirements

This section must include the following:

1. For each type of sampling, analysis, or measurement technique, identify the QC activities (blanks, spikes, duplicates, etc.) which should be used and the frequency at which they should be run.
2. Give details of what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented.
3. Identify the procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data.

This Section addresses quality control samples only. Quality control (QC) is the set of activities that are performed for the purposes of monitoring, measuring, and controlling the performance of a measurement process. QC samples provide measurable data quality indicators used to evaluate the different components of the measurement system. This includes both sampling and analysis. While Section A7 required the acceptance limits for QC, this Section

requires the activities, the frequency of QC Samples, the action required when acceptance limits are not met and how the QC Statistics are calculated.

Item 1: The following tables (Tables 11 and 12) give examples of QC samples that should be considered when writing this section. Table 11 gives examples of frequency for some of the types of QC samples that would be associated with field work, while in Table 12 there are examples of QC items that would be associated with the laboratory. Please note that these are examples only. This is information that should be discussed during scoping meetings with the entities who are providing sampling and analytical services. The amount of QC and acceptance limits should be worked out by the project team prior to writing the QAPP. The laboratory will provide specifics on frequency of their internal QC checks. These checks are based on their Certification and the EPA Promulgated Methods which they use. This Table can end up being quite long because these QC checks will vary from method to method and be dependent on matrix.

NOTE: The Project Team should determine if the QC that is proposed by field and lab organizations is sufficient for the project.

Item	Data Quality Indicator (DQI)	Frequency
Field Blank	Contamination (Accuracy/Bias) Evaluates contamination introduced during sampling.	Minimum 1 per shipment for each analytical group (VOCs, metals, etc.).
Equipment Blank (rinsate blank)	Contamination (Accuracy/Bias) Evaluates effectiveness of cleaning procedure on sampling equipment.	Minimum 1 per day for each analytical group and each matrix for each sampling team.
VOC Trip Blank	Contamination (Accuracy/Bias) Evaluates contamination introduced from shipping.	One per trip. If multiple sampling teams are involved, then one per team.
Proficiency Testing (PT) Sample	Accuracy/Bias Evaluates the analytical abilities of the operator and the accuracy of the meter.	1 per calendar year for each parameter analyzed in the field for which a PT sample is available. Each operator must analyze all PT samples.
Field Duplicates	Precision	Minimum 5% per analytical group per matrix for each sampling team.

Table 11 Field QC Samples

If split samples are to be considered for inter-laboratory comparison, that information would be inserted in Table 12. **It should be noted that for round-robins/inter-laboratory comparisons both laboratories must analyze the samples using the same methodology.**

Item	Data Quality Indicator (DQI)	Frequency
Method Blank	Accuracy/Bias	SOPs M-1, M-2,O-1 Section 10
Instrument Blank	Accuracy/Bias	SOP O-2 Section 10
Lab Duplicates	Precision	SOP M-1, M-2,O-1 Section 8
Internal Standards	Precision , Accuracy/Bias	All Organic Standards, samples are spiked
Matrix Spike	Bias	(inorganic only) SOPs M-1, M-2,O-1 Section 8
PT Sample	Bias	As specified by the SC DHEC Dept of Laboratory Certification- generally one for each method.
Surrogate Spikes	Bias	All VOCs and Semi-volatile Organic Samples are spiked with surrogates.
Quality Control Sample	Bias	SOPs M-1, M-2,O-1 Section 8
Laboratory Fortified Blank (LFB)	Bias and Sensitivity	SOPs M-1, M-2,O-1 Section 8
Instrument Performance Check	Sensitivity	SOPs M-1, M-2,O-1 Section 8
Initial Calibration	Accuracy	SOPs M-1, M-2,O-1 Section 9
Continuing Calibration or Calibration Verification Checks	Accuracy	SOPs M-1, M-2,O-1 Section 8

Table 12 Analytical QC Samples

Item 2: In this Section, the QAPP must give details of what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented. This should partially be given in the Laboratory's QA/QC Plan—the appropriate Section/Page Number in the QA/QC Plan may be referenced. However, the project team should determine if what is in the plan is sufficient. Certainly the project team should be notified when QC has failed. They should also have an understanding of the different notes/flags that the laboratory may include in the report. This is very important in determining if the data is usable for the project.

Item 3: Identify the procedures and formulas for calculating applicable QC statistics. This may have been given earlier in the QAPP under DQIs and that may be referenced. However, the project team should contact the laboratory to ensure that this Section is complete. The types of QC statistics that may be used in the laboratory may include all or some of the following: RPD, % recovery, % difference, and outlier determination. If control charting is used on fortified blanks and/or duplicates this should be discussed. All of this may also be in the Lab's QA/QC Plan and/or SOPs and may be referenced, but the reference must include the document name, section number, and page number.

B6 Instrument/Equipment Testing, Inspection, and Maintenance

1. Identify all field and laboratory equipment needing periodic maintenance, and the schedule for this.
2. Identify the testing criteria for each instrument.
3. Note the availability and location of spare parts.
4. Indicate the procedures in place for inspecting equipment before usage.
5. Identify the individual(s) responsible for testing, inspection and maintenance.
6. Indicate how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented.

Item 1: All instruments that require any type of maintenance used in the field and the lab are listed. Identify what maintenance is needed and when it should be performed. An example is given in Table 13.

Instrument	Type of Maintenance	Frequency	Parts needed/Location	Person responsible
Hach Pocket Colorimeter	Batteries changed	As needed-minimally once per year	AA Batteries/Hall Cabinet Laboratory	Operator
DO Meter	Membrane changed	As needed-usually once per week	Membrane/ Hall Cabinet Laboratory	Operator
GCMS	Source cleaned	As needed-minimally once per month	Filament/Room 303 Laboratory	Analyst or other Chemist

Table 13 Instrument Maintenance

Item 2: What will be done to ensure that the instrument is performing properly? In the case of the Hach Meter listed in Table 10, this may be running a daily blank and two standards and having the standards read within 10% of the true value. For the GCMS, a tune is done and then a compound is analyzed to make sure that the instrument is working correctly. This information may come from the Lab and Sampling SOPs, but the reference must indicate what documents and the proper section and page number.

Item 3: All that is needed is a general statement about where spare parts are located. These may be different for some items—certainly for lab and field items there will be different areas. If spare parts are located in different places for many of the items, a place for location can be added to a table (see Table 13).

Item 4, 5, and 6: If there are SOPs for this, they may be referenced (give the exact SOP and page numbers). Otherwise, give the procedures used for inspecting each instrument that will be used. In each case, indicate who will perform inspections and maintenance. Also indicate what will be done if a deficiency is found and how the process will be documented. Table 14 gives an example of how to handle these items.

Instrument/Equipment	Type of Inspection	Requirement	Individual Responsible	Resolution of Deficiencies
Hach Pocket Colorimeter	Blank and a 0.5 and 1.0 Std run	Must be within 10% of known concentration, blank must be < 0.03 mg/L	Operator	See SOP CL-1 Page 24
Thermometer	Must calibrate quarterly with NIST traceable	Must be within 1 degree for both high and low temps	Jake Saunders	If > 1 degree, replace
GCMS, volatiles	Tune, run BFB	Tune must be within EPA parameters, BFB must pass	Kristin Meadows	See SOP Semi-1

Table 14 Instrument and Equipment Inspection

B7 Instrument Calibration and Frequency

1. Identify equipment, tools, and instruments that should be calibrated and the frequency for this calibration including both field and laboratory equipment/instruments.
2. Describe how calibrations should be performed and documented, indicating test criteria and standards or certified equipment.
3. Identify how deficiencies should be resolved and documented.

This may be best done in a table format – an example of both a field instrument and lab instrument is given in Table 15.

Instrument	Calibration Procedure	Frequency of Calibration	Acceptance Criteria	Corrective Action (CA)	Person Responsible for CA	SOP Reference*
Hach Pocket Colorimeter	Cal check – ICV; daily Run 0, 0.5 and 1.0 Permanganate standards.	ICV (all 6 stds run annually or with new DPD lot) 2 stds run daily.	Standards within 10% except 0.05 (acc 0.04-0.06)	Remake Stds; Clean interior; Replace scratched cells; Contact Hach.	Operator	EQC SOP Section 14
GCMS	Tune and check BFB;	Daily.	BFP passes	Re-tune. Clean source	Analyst	BV, Section 8, Page 24
GCMS	Continuing Calibration.	Daily. Full calibration every 6 months.	Calibration Standards within 30%	Recalibrate	Analyst	BV, Section 8, Page 24

Table 15 Instrument Calibration Criteria

For the SOP reference, either the full name may be given or the SOP may be given as an abbreviation. However, all abbreviations must defined (see Table 16). From Table 15 it is noted that the SOP is BV and Section 8, Page 24 is given. From Table 16 (The SOP Reference Table), the "BV" reference is identified as the Volatiles SOP. This is an acceptable way of listing references.

SOP Reference	Full SOP Identification #	Full SOP Name
BV	Acme-IX062206R2	Acme Volatile Organic SOP 6/22/06 Revision 2
Met1	Acme-XX05011997R1	Acme Metals by ICP 5/1/1997 Revision 1

Table 16 SOP Reference Table

B8 Inspection/Acceptance Requirements for Supplies and Consumables

1. Identify critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials.
2. Identify the individual(s) responsible for this.

The purpose of this section is to establish and document a system for inspecting and accepting all supplies and consumables that may directly or indirectly affect the quality of a project or task. It is also important to check and make sure that contractors are using the proper standards for calibration and sampling.

Although it might seem to be excessive to include nitrile gloves in this table, they are included to ensure that latex gloves are NOT used since latex gloves can actually contaminate some organics samples. In addition, EQC avoids latex due to the association with allergies.

Item	Vendor	Acceptance criteria	Handling/Storage Conditions	Person responsible for inspection and tracking.
Nitrile gloves	All	No holes; must be nitrile NOT Latex	1 box of appropriate size per vehicle; also used in Lab	Bob Martin (ABC Contractors)/ Remy Smith Roarke Labs
DO Meter Membranes	YSI	Must be proper size for DO meters, must be YSI brand	Office prep area-room temp	Bob Martin (ABC Contractors)/ Remy Smith Roarke Labs
pH buffers- ph 4, 7 and 10	All	Must be within expiration dates	Office Prep area-room temperature	Bob Martin (ABC Contractors)
VOC Standards	Supelco	Must be within expiration dates, must be sealed and not obviously low in volume	Freezer 1 <4 ºC Organic Lab	Michelle Lee; Organic Analyst, Roarke Labs

Table 17 List of Consumables and Acceptance Criteria

A discussion should also be done on how these consumables are logged in and tracked. The contractors and laboratories may have their own logging system and this should be described and/or illustrated by attaching their tracking form. Tracking should include at a minimum the date received, who received it, whether it met inspection/testing criteria, a listing of the expiration date, comments and who checked in the supplies. There should also be a note that personnel label the actual items like standards as to when it was received and when it was opened.

B9 Data Acquisition Requirements (Non-Direct Measurements)

1. Identify data sources, for example, computer databases or literature files, or models that should be accessed or used.
2. Describe the intended use of this information and the rationale for their selection, i.e., its relevance to project.
3. Indicate the acceptance criteria for these data sources and/or models.
4. Identify key resources/support facilities needed.

This element of the QAPP should clearly identify the intended sources of previously collected data and other information that will be used in this project and to ensure that it is of known quality.

Some examples of non-direct measurements are:

- 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 publicly available databases, such as data from the Census Bureau, data represented within EPA's Environmental Information System and data cataloged in EPA's Environmental Data Registry;
- Data from State and Local monitoring programs (including historical data)
- Results from unpublished research
- Data obtained from previously performed pilot or preliminary studies; and
- Existing maps, Geographical Information System (GIS) layers, plots, photographs, or land surveys.
- Weather data from the National Weather Service or other organizations

Information that is non-representative and possibly biased and is used uncritically may lead to decision errors. The care and skepticism applied to the generation of new data are also appropriate to the use of previously compiled data (for example, data sources such as handbooks and computerized databases). The acceptance criteria should discuss the possibility of the following (as applicable):

Representativeness: Were the data collected from a population that is sufficiently similar to the population of interest and the population boundaries? How were potentially confounding effects (for example, season, time of day, tidal stage, etc.) addressed so that these effects do not unduly alter the summary information?

Bias: Are there characteristics of the data set that would shift the conclusions? For example, has bias in analysis results been documented? Is there sufficient information to estimate and correct bias?

Precision: How is the spread in the results estimated? Does the estimate of variability indicate that it is sufficiently small to meet the objectives of this project as stated in Element A7?

Qualifiers: Are the data evaluated in a manner that permits logical decisions on whether or not the data are applicable to the current project? Is the system of qualifying or flagging data adequately documented to allow the combination of data sets?

Summarization: Is the data summarization process clear and sufficiently consistent with the goals of this project? (See Element D2 for further discussion.) Ideally, observations and transformation equations are available so that their assumptions can be evaluated against the objectives of the current project.

For models and modeling the following items need to be considered and discussed: What are the assumptions that these estimates are based on? Has the quality of the modeling effort been evaluated? What are the limitations of the data?

For weather measurements, the QAPP just needs to simply list where the data will be obtained. A more complex example would be the examination of data collected by another laboratory from the same area as the planned study—this may have been from a preliminary investigation or from a full study. In either case, the project manager or designee would investigate the previous study to determine whether enough samples were taken and analyzed properly. The examination would also include a determination if the methodology that was used is the same as what is to be done for this study (this is ESSENTIAL), if the SOPs from the two laboratories use the same QC requirements (for instance the detection limits are similar) and if the original lab was certified for the analyses. If the two studies compare favorably, then it can be concluded that the original data can be compared directly to the data that is being collected in the study.

B10 Data Management:

1. Describe the data management scheme from field to final use and storage.
2. Discuss standard record-keeping and tracking practices and the document control system or cite other written documentation such as SOPs (with specific page number references).
3. Identify data handling equipment/procedures that should be used to process, compile, analyze, and transmit data reliably and accurately.
4. Identify individual(s) responsible for this.
5. Describes the process for data archival and retrieval.
6. Describes procedures to demonstrate the acceptability of the hardware and software configurations.
7. Attaches any checklists or forms that are concerned with the above data management items.

Item 1: Can be done in paragraph form or in a diagram. Complex systems could require both the diagram and a discussion. (See Figure 5)

Item 2: Discuss any internal checks that will ensure data quality during the entire process. Include error checks and mechanism for correcting error and who is responsible for doing this. Discuss the typical scenario of the data from the entries on the COC to the final archive and disposal.

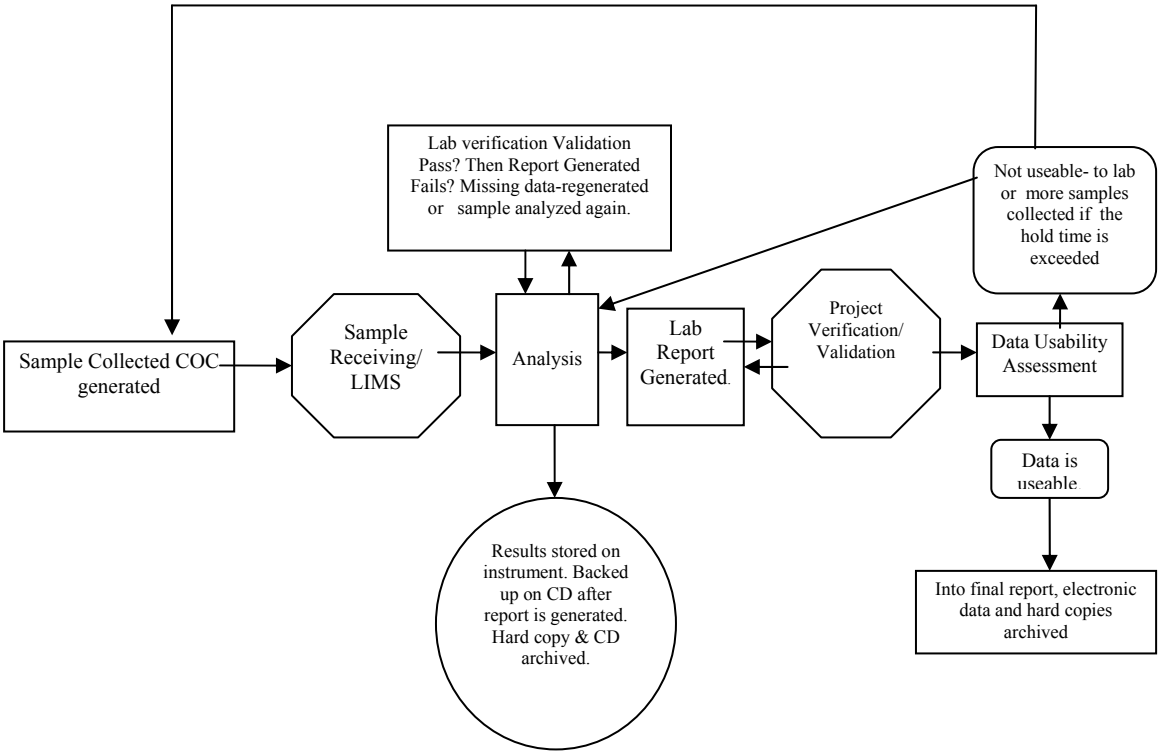

Figure 5 Example Data Management Flow Chart

Items 3 and 4**:** **Data Transformation** is the conversion of individual data point values into related values or possibly symbols using conversion formulas. The transformations can be reversible (e.g., as in the conversion of data points using a formula) or irreversible (e.g., when a symbol replaces actual values and the value is lost). The procedures for all data transformations should be described and recorded in this element. The procedure for converting calibration readings into an equation that will be applied to measurement readings should be documented in the QAPP. Data transmittal occurs when data are transferred from one person or location to another or when data are copied from one form to another. Some examples of data transmittal are copying raw data from a notebook onto a data entry form for keying into a computer file and electronic transfer of data over a telephone or computer network. The QAPP should describe each data transfer or transformation step and the procedures that will be used to characterize data transmittal/transformation error rates and to minimize information loss in these processes. As part of Item 4, the person(s)/entities responsible for this are to be identified.

Item 5: Simply state how data can be retrieved whether it is in hardcopy or electronic format.

Item 6: Indicate how 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. When these upgrades happen, how will it be ensured that the software will be able read previously archived electronic data?

Item 7: If there are forms and checklists that are used for data management, attach them and reference the attachments. This may include your document control system forms. This can also include the internal lab forms that are used to determine where the sample is in the system-who had it, analyzed it, checked the data for errors, logged the data into LIMs, etc.

Section C Assessment and Oversight

C1 Assessment and Response Actions:

1. List the number, frequency, and type of assessment activities that should be conducted, with the approximate dates.
2. Identify individual(s) or organizations responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process.
3. Describe how and to whom assessment information should be reported.
4. Identify how corrective actions should be addressed and by whom, and how they should be verified and documented. Time frames should be included.

A wide variety of internal (self) and external (independent) assessments can be conducted during a project. The types of assessments and the frequency of them 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 long-term project is more likely to have assessments on its activities (see Table 18). Some assessments may be unannounced. A short term or research project may have few assessments and may simply be composed of the yearly Proficiency Test Sample (PT) with a previously done assessment (like a Lab Certification Audit) listed. If no assessments are planned with a small project, then this must be stated.

Types of Assessments:

- **Readiness Review-** A systematic, documented review of readiness for the start-up or continued use of a facility, process or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiating a major phase of work.

Items 1-4 can be done in tabular form if desired (See Table 18).

Types of Assessments:

- **Field Sampling Technical System Audit (TSA)-** A thorough on-site audit during which sampling design, equipment, instrumentation, supplies, personnel, training, sampling procedures, chain of custody, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data review procedures are examined for conformance with the QAPP. At least one Field Sampling TSA should be performed at the start of field sampling activities.

- **On-Site Analytical TSA-** A thorough audit of on-site analytical procedures during which the facility, equipment instrumentation, supplies, personnel, training, analytical methods and procedures, laboratory procedures, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data review procedures are checked for conformance with the QAPP. This can be performed at any time during the project. EPA sometimes requires at least one On-Site Analytical TSA performed prior to

the start of sampling activities so that effective correction action measures can be implemented to mitigate the extent and impact of identified non-conformances. This is not needed for internal projects because internal SCDHEC are assessed every year by OQA. It is up to EPA and/or the project manager to determine if these are needed for external laboratories.

- **Off-site Laboratory TSA-** A thorough audit of an off-site laboratory--secondary lab or subcontracted lab--during which the facility, equipment, instrumentation, supplies, personnel, training, analytical methods and procedures, laboratory procedures, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data review procedures are checked for conformance with the QAPP. This can be performed at any time during the project. For a very large project, at least one Off-Site Laboratory TSA should be performed prior to the start of sampling activities so that effective correction action measures can be implemented to mitigate the extent and impact of identified non-conformances. This can sometimes be done with the QAPP review with the Laboratory's SOPs and information required to write the QAPP.

- **Split Sampling and Analysis Audit-** A comparison study to assess inter-laboratory precision and accuracy. The sampler collects one field sample and then physically splits it into two representative sample aliquots. The samples are then sent to different laboratories for analysis. For split samples to be truly comparable the splits must have identical sample handling and pretreatment, both laboratories must use the same analytical methods, and the QC items for the analytical runs must be the same. Split samples quantitatively assess the measurement error introduced by the organization's sample shipment and analysis system and must be accompanied by a PT Sample to establish the acceptance criteria. Split sample comparability criteria must be generated prior to sample collection and documented in the QAPP.

- **Proficiency Test (PT) Sample Tracking and Analysis-** Statistical analysis of PT Sample results provide information on routine laboratory performance and overall accuracy and bias of the analytical method. The QAPP should address the selection of the appropriate PT Samples. Factors to consider include analyte selection; whether PT samples are single or double blind, native or synthetic matrix, or spiked or natively contaminated or both; multiple matrices and concentrations; total number of PT Samples and analytical methods.

- **Data Review -** A thorough review of the complete data review process, including a review of the sampling analysis verification, sampling and analysis validation, and data usability assessment steps, to ensure that the process conforms to the procedures specified in the QAPP. The Data Review may also include an audit of the performance of the data reviewer. An audit includes determining if the data reviewer spotted problems when they surfaced and whether corrective action was applied to the problem.

- **Management Systems Reviews (MSR)-** A review of an organization or organizational subset to determine if the management structure, policies and procedures are sufficient to ensure that an effective quality system is in place that supports the generation of useable project data. This review is performed against the organization's QMP.

Assessment External or Internal*	Frequency Date & Expected Date	Organization Responsible	Individual Receives Report & Notification of Deficiencies**	Time-frame of Notification	Individual that Implements Corrective Actions?	Corrective Action Effectiveness Documented where?	Individuals Receiving Corrective Action Response**
PT /E	One per year-approx. January 2007	A2LA certified Proficiency Provider	Mitch Smith-Lab QA Officer	3 weeks after study ends	E. Slowinski	Memo to QA Officer and Project manager	Mitch Smith and Dennis Phillips , Proj Mgr
Readiness Review	Prior to sample initiation-tentatively 2/2007	SCDHEC	Mitch Smith and Dennis Phillips , Proj Mgr	1 week before study begins	Mitch Smith and Donald Baer	Readiness Report	Dennis Phillips , Proj Mgr and SCDHEC
Onsite TSA/E	Every 3 yrs, due 8/2008	SCDHEC	Mitch Smith-QA Officer	90 days	E. Slowinski	Response to Audit	Carol Smith, SCDHEC
Onsite TSA/I	1 is planned at approx. 6 months into the project. (7/2007)	Lab QA Office	Ellie Slowinski, Lab Manager	2 weeks	E. Slowinski	Response to Audit	Mitch Smith QA officer, Dennis Phillips, Project Manager
MSR/I	1 during the project-examine adherence to the QAPP	Project Manager	SC DHEC OQA and SQAMO	1 month	Lab QA Officer, Field Manager	Memo to Project Director	SC DHEC OQA and SQAMO
ADQ/I	Monthly - beginning 2/2007	Lab QA Office	Ellie Slowinski, Lab Manager	1 week	Ellie Slowinski	Memo, plus corrected Data. Data Error Report and QA Narrative.	Mitch Smith QA Officer, Dennis Phillips , Project Manager

Table 18 Project Assessments and Corrective Action

*E=External Assessment, I= Internal Assessment
**All contact information is located in the Distribution Table.

C2 Reports to Management:

1. Identify what project QA status reports are needed and how frequently they should be submitted.
2. Identify who should write these reports and who should receive this information.

Periodic QA Management Reports ensure that project staff are kept updated on project status and the result of all QA assessments. Efficient communication of project status and problems allows the project manager to implement timely and effective corrective actions so data generated can meet the project quality objectives.

The QAPP should describe the content of each QA Management Report that will be generated for the project including an evaluation of measurement error as determined from the assessments. Assessment checklists, reports, requests for corrective action letters, and the corrective response letters (see Table 18) are included in this description. Other items that may be included are the summary of the project QA/QC program and training conducted during the project, conformance or nonconformance of project activities to QAPP requirements and procedures, status of project, schedule delays, approved amendments to the QAPP, results of PT samples, results of data review activities in terms of amount of usable data generated, required corrective actions and effectiveness of the implemented corrective actions, data usability assessments in terms of DQIs (precision, accuracy, etc), and limitations on the use of the data generated.

Section D Data Validation and Usability

Overview of the Data Review Process

This Section is used as a final check on the data to determine if it meets project objectives and to estimate the impact 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 use of this existing data. 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.

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. The data review process involves verification, validation, and usability determinations. **Personnel performing data verification, validation and usability reviews need access to all records and to the QAPP.** In addition, validation will require a report from the verification process. Data usability reviews require the records, the QAPP and both the Verification Report and Validation Report. These reports may either be verbal (especially for small projects) or written. Any flags assigned to the data (See Appendix E) from these reviews must also be defined in the QAPP.

What is Data Verification and Data Validation?

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.

Data Validation is an analyte and sample specific process that extends the evaluation beyond method, procedural, or contractual compliance (in other words, beyond data verification) to determine the analytical quality of a data set.

These two terms are very similar and the processes they describe are related to each other. Put simply, verification is an overall look to determine that the way samples were collected, taken to the lab, analyzed, and reported was correct. However, it is mostly a completeness check. See Table 19 for an example of records that are examined during a Verification Review of the data.

Verification Review

The Verification Review may occur both during and at the end of the project. Data verification is routinely done by the laboratory (by the analyst and/or a QA Officer), but it is recommended that someone from the project also verify the data. It is best to include a checklist of what must be submitted in order to do the verification. This might include such things as a list of the samples that were collected, the laboratory reports, the narrative from the field and the lab concerning problems and quality control issues, actual raw data and so. Once this checklist is defined for a certain type of project, it may be useful for other QAPPs of that same type and only

adjusted as needed. The level of data requested will depend on the level of review performed during data validation. This, in turn, will be dictated in Section A9 as well Section B of the QAPP. These sections detail what will be in the report, what samples will be collected, what analyses will be conducted, what QC will be done and so on.

Once the verification is complete, the verifier must submit a report so that the individual(s) validating the data will know of any deficiencies detected during the verification step.

Records and Comments
Evidence of QAPP approval-- This would include making sure that any revisions were also approved.
Laboratory name on the reports – same as the Lab in the QAPP – Sub-contracted Labs must also be Certified Labs
Chain of Custody for each sample for field and Lab
Sampling instrument or equipment decontamination records and analytical results if submitted to the lab
Documentation of deviations from sampling methods or approved site location
Field instrument calibration records
Sampling notes and drilling logs
Sample plan and location
Sampling report (from field team leader to project manager describing the sampling activities)
Qualifier Flags defined (See examples given in EPA Qualifier Flags in the Appendixes)
Case narrative - Description of what happened to the sample from the field through the analysis in the lab to reporting. This may be in terms of only problems with the sample.
Sample conditions upon receipt and storage records
ID of QC samples
Associated PT results – PTs passed
Evidence of Lab Certification for all parameters during the entire study. **Data from a non-certified Lab cannot be used to make decisions**
Copies of internal or external assessments (Lab QA Office or SC DHEC Office of Environmental Laboratory Certification).
Copies of Lab notebook, records and prep sheets
Corrective Action reports
MDL study results (to determine the detection limit)
Detection Limit standard run (if required by the QAPP or the SOP)
Documentation of Corrective Action results
Documentation of individual QC results fore ach sample batch
Documentation of method deviations for Lab
Instrument calibration results or reports
QC Sample raw data
QC Summary report
Reporting forms, completed with actual results
Signatures for Lab sign-off (supervisor or Lab QA manager)
Standards traceability records (to trace standard source from NIST, for example)

Table 19 Examples of Verification Records

Validation Review

Data validation is an examination of the data package down to the level of the raw data. Validation helps to ensure that the samples have been collected and analyzed correctly and according to the requirements laid out in the QAPP. This includes a compliance check to make sure that requirements laid out in the QAPP such as preservation requirements, decontamination requirements for field sampling equipment, detection limit (sensitivity), SOP requirements, QC requirements, etc. were followed. In addition validation also includes a raw data from the instrument and a recalculation check. Validation also includes a look at the data set as whole to ensure that the data makes sense in terms of representativeness and comparability. Thus the Validator must refer to Section A7 of the QAPP to ensure that QC criteria (DQIs) were met. The Verifier must also refer to Section B of the QAPP to determine if the requirements for QC, detection limits, and other data quality objectives were met.

In addition, this part of the review looks for anomalies and attempts to find the cause of these and other problems. Once the cause is found, data validation includes an assessment of whether the effected data is valid or invalid and how this affects the entire set of data---and the project---as a whole. This portion of the data review can quite lengthy. Although verification steps cannot be streamlined, it is possible to stream-line some of the validation. As part of the planning for the QAPP, the project team may decide to only validate certain items or a certain percentage of the data. However, this should not be so stream-lined that the quality of the data will suffer. If a validation scheme is used, it must be stated and explained in Section D2 of the QAPP. The following are common schemes in stream-lining data validation:

- Only a specific percentage of all data sets will be validated (e.g. 10%) unless a problem is identified.

- Only a specific percentage of all data sets will be validated, however critical samples as identified in the QAPP will undergo full data review (review of raw data and recalculation).

- Only a specific percentage of all data sets will be validated, but that validation will include review and recalculation of raw data.

- All data will be validated, but only a percentage of raw data will be reviewed and recalculated.

Validation is performed on the verified data by someone independent or external to the data generator and the data user. This review is specific to the sets of data being used and to determine the quality of a specific data set relative to the end use. This is designed to ensure that the users of the data make sound decisions regarding the data and any deviations noted in the verification and validation process.

As previously stated, validation looks at the specific samples and the entire sample set in as a whole to determine if there are discrepancies, anomalies, and bias and if data integrity has been protected. There is also a general overview of the entire set to make sure that the data

makes sense in the context of what was expected, seen before, or in comparison to other samples. If deficiencies or deviations exist in the data, the validation process will determine the impact of those on the data.

Examples of Validation Outputs:

A Validator discovers from sample documentation that a sample could not be taken at a predetermined sampling site. In this case the Validator will assess the impact on the data. If the sample was collected about a foot away due to unforeseen circumstances, the impact will probably be minimal. However, if the sample was taken 100 yards away, the impact on the data could be substantial.

A Validator discovers that the Chain of Custody lists the sample collection time as 9 am. Also according to the Chain of Custody, the sample arrived at the Laboratory at 10 am. However, the sample was collected in Beaufort and arrived at a Columbia area Laboratory an hour later. The Validator must begin to ask questions about how the sample arrived in the lab in 1 hour instead of the 3 hours it should have taken to reach the Columbia Lab. This sort of finding can be a simple mistake or it can be associated with fraud.

A Validator discovers that the MDL given in the packet was 10µg/L. However, he notices that the trigger or action limit in the QAPP is 5µg/L. He must determine if the Lab was misreporting the MDL or if there was a problem. If the latter is true, the data must be flagged and discussed in the Validation Report.

Table 20 illustrates the types of items that are used for validation. Beside each item is a comment about the purpose of that item. **This Table should be considered an example and is not a complete list of each item that must be validated.** The Table lists examples of validation activities that should be considered when determining how the validation process will proceed. When considering what will be verified or validated, consider the requirements already laid out in the QAPP and/or SOPs for sample site, sample frequency, sample documentation, sampling requirements (hold times, temperature on receipt), associated field and lab QC requirements, and sensitivity requirements.

QA Item	Comments/Purpose
Verification Report	Allows the Validator to determine what is missing from the data package.
Case Narrative	Describes any deficiencies in sampling, analysis or reporting.
Chain-of-custody for each sample	This must include sampling location and include the handling of the sample from collection to final disposal. Preservation information and condition of the sample upon receipt to the lab must also be included. This allows the Validator to assess if sample treatment was according to the QAPP and allow the Validator to look for anomalies such as time travel (example: when the sample arrives at the lab before it has been collected).
Copies of field documentation associated with the samples.	Field notebooks, drilling logs, field analyses calibrations. The Validator assesses transcription and other documentation errors. The Validator assesses the impact of deviations on data quality (wrong sampling day, wrong location, wrong collection).
Methods and SOPs (sampling and analysis)	Must be checked against what was originally dictated in the QAPP. If deviations exist, the Validator would assess the impact.
Detection Limit information for each method and for each analysis.	The Validator would determine if the detection limit requirement was met by the lab. If not, the Validator would assess the impact of this on the study.
SC DHEC Office of Laboratory Certification Certificate for the laboratory analyzing the samples and for the group performing any field analyses.	This is checked before the QAPP is approved, but should be checked to determine that the laboratory still possesses certification for the analyses it is performing. This is determined during the QAPP process, but the Validator should determine if the Laboratory was certified throughout the process. **Data provided by a non-certified laboratory cannot be used to make environmental decisions.** Thus if Certification was lost during the Study, the Validator must assess the impact (percent data lost against the percent valid data required and/or if the data lost was critical to the study).
List of Qualifier Flags from the lab and an explanation for each.	Flags are a shorthand method of informing the data recipient that there was a problem with the sample. A flag may indicate a hold time exceeded, that a result was estimated, and other problems associated with the sample. The Validator would assess the impact of these flags.
Sample chronology (time of receipt, extraction and analysis)	Will allow the Validator to determine that the sample was within hold time when analyzed and to note anomalies.
QC Summary Report for each sample and analysis	This will inform the Validator that the QC passed or did not pass and the Validator must assess the impact of QC that failed.
Field Duplicate documentation and summary	The Validator would determine if the Precision requirement was met by the lab. If not, the Validator would assess the impact of this on the study.
Field Blank documentation and summary	The Validator would determine if the blanks were below the limit of detection (or any other requirement listed in the QAPP). If not, the Validator would assess the impact of this on the study.
Matrix Spike Sample documentation and summary	This would allow the Validator to determine the presence of interferences because of matrix effects. The Validator would assess the impact of the matrix effects on the study.
Repeat sample analysis summaries including sample dilutions	This would allow the Validator to ascertain that diluted sample results were calculated properly during a recalculation of the sample results from the raw data.

QA Item	Comments/Purpose
Raw instrument data for each sample analyzed including repeat analyses and dilutions	This may be on a percentage basis, depending on the complexity of the analysis. This would include a determination by the Validator for instance if the parameter of interest was determined correctly (correct line for AA, correct peak for chromatography) and would also include a recalculation of the sample data from the raw data to the final result.
QC raw data	Depending on the complexity, there may be only a certain percentage examined. This allows the Validator to determine if the correct conclusions were obtained by the analyst and it will allow the
Calibration Data associated with each sample analysis	The Validator will determine if the slope and intercept were calculated properly, that the calibration was run at the correct frequency, and that the curve exhibited linearity as outlined in either the SOP or QAPP.
Documentation of Laboratory Method/SOP Deviations	The lab may report this and the verifier will include it in the report. or the verifier may well note this as part of the verification process and report it. The Validator will assess the impact of this on the study.
Reporting Forms with actual results.	These are checked for transcription errors by the Validator.
Calculations used	These are checked to determine if they were used correctly and accurately by the Validator.
Corrective Action Reports	The Validator will determine if the corrective actions were effective. The Validator will determine if the original problem will impact the study.
Lab Assessment Reports	Both internal and external—as applicable and as demanded by the QAPP. The Validator will determine if a finding has an impact on the study.

Table 20 Examples of Records Needed for Validation

Other Examples of Validation Activities

Data Deliverables and the QAPP: Ensure that the report from verification was provided.

Deviations: Determine the impacts of any deviations from sampling or analytical methods and SOPs. For example, confirm that the methods given in the QAPP were used. If they were not used, determine if the data still meets method performance criteria and if the Lab was certified for the method they used.

Sampling Plan: Determine whether the sampling plan was executed as specified. That the number, location and type of field samples that were specified in the QAPP were collected and analyzed as specified in the QAPP.

Co-located Field Duplicates: Compare the results of collocated field duplicates with criteria established in the QAPP. If they do not meet the criteria this may mean that variability exists in the sampling portion of the study and must be addressed by the Validator to determine the impact on the study.

Project Quantitation Limits: Determine that quantitation limits were achieved as outlined in the QAPP and that the laboratory successfully analyzed a standard at the quantitation limit specified in the QAPP.

Confirmatory Analyses: Evaluate agreement of initial lab results with any confirmatory analyses.

Performance Criteria: Evaluate QC data against project-specific performance criteria in the QAPP. For instance, were the lab fortified blanks within ±20% recovery that was required by the QAPP?

Data Qualifiers: Determine that the data flags applied to samples in the verification process were those specified and defined in the QAPP and that any deviations from specifications were justified. (This would be a situation when a sample result is flagged with a letter or number that indicates that the sample was out of hold time-did the QAPP state that the results were to be thrown out completely, or included with this flag?)

Validation Report: Summarize the outcome of the comparison of data to the method performance criteria in the QAPP. Include qualified data and an explanation of all data qualifiers. Example: The sample was flagged with an "M". The definition of the flag (from a list that the Validator supplies) reveals that that the sample was used as a matrix spike and did not meet the performance criteria of ±30% due to matrix effects. There may or may not be anything that can be done, but the users are informed that the data may be erroneous because of noted matrix effects.

D1 Data Review, Verification and Validation

1. This section requires a description of the criteria that should be used for accepting, rejecting, or qualifying project data.

This section is the final critical check to make sure that the data that will be obtained will match what was required in Section A and Section B. To write this section a thorough review of the requirements in Section A7, and Section B should be done.

As seen in Table 19, many records will be scrutinized to determine the quality of the data. Only rarely can a determination that the data is valid be a professional opinion. Most of the time it must be based upon concrete requirements already set out in Section B of the QAPP. For Section D1 it is best to set up a table or list detailing the records that will be verified and validated and the criteria on which the records are accepted, rejected or qualified (flagged).

Consider sampling---Items to consider reviewing would include whether each data item met the quality objectives specified in Section B? Consider sampling—Items that should be reviewed would include whether the correct numbers of samples were collected at the correct sites given in Section B (verification and validation)? If not, will the data be acceptable? Was the QC data received or was some of it missing (verification)? Another item of importance to review would be sample holding times (to review this, the lab sample reports must include the date and time of analysis), and proper sample preservation (this will appear on the chain-of-custody form). All of those were validation items.

In Section A7 criteria is given for acceptability based on lab results of QC and field QC results. How will it be determined that the data that will be received meets those requirements? What will be checked to determine this? These are also validation items.

In each case, decide how data will be flagged and **define the flags in this section.** Determine if the error for which the data is flagged is substantial enough impact to the project that the data will be rejected totally or if the data can be accepted, but qualified. For instance, an out of hold time sample could be flagged with a "HT". If the data will be rejected for this situation then "HT" would be given without an accompanying result. If a sample was collected on the wrong day, the sample could be flagged with the term "date". In this section, however, it was noted that a sample that was collected on the wrong day would not be rejected, but just qualified. Thus the results would accompany the "date" flag.

See Tables 19 and 20 for commonly verified/validated items. See Table 21 for an example of data acceptability criteria and the associated flags. See Appendix E for EPA's table of Qualifier Flags.

Item	Criteria	If the criteria are not met is the sample flagged or rejected?	Flag (if applicable)	Comments
Hold Times-fecal coliforms	Samples must be at the lab within 6 hours of collection	Rejected	T-1	
Temperature upon Receipt-Fecal Coliforms	Samples must be <10ºC upon receipt at the Lab	Flagged	P-1	The results can be used for information only and not included in decision making.
Trip Blanks Missing	A trip blank must accompany every set of samples	Rejected	NA-1	
Trip Blank - VOCs	Trip blank concentrations must be <MDL	Flagged	B-2	Compounds detected in trip blank only.
LFB - VOCs	Lab Fortified Blank (LFB) is within ±20%	Rejected	Q-1	
LFM – VOCs	Lab Fortified Matrix is within ±30%	The sample used for the LFM is rejected	QM	
Laboratory loses their certification.	The lab must be certified by the SCDHEC Office of Laboratory Certification.	Flagged	CERT	The results can be used for information only and not included in decision making. No statistics may be calculated using this data.

Table 21 Data Criteria and Flags

D2 Validation and Verification Methods

1. Describe the process for data verification and validation, provide SOPs and indicate what data validation software should be used, if any.
2. Identify 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.

3. Identify issue resolution process and method and individual responsible for conveying these results to data users.
4. Attach checklists, forms, and calculations

General Comments:

If the laboratory or an outside party is performing the verification, then a case narrative (verification report) must be submitted in order for validation to be done. The case narrative must include any deficiencies in field QC, lab QC and procedure in the field or laboratory. Any flags that the laboratory or verifier uses on the data to qualify the data must be listed with the definition of the flag. Again verification is the check of completeness and correctness of the data.

As stated above, validation should be performed by a person or group that is not generating or using the data. The purpose is to provide a totally neutral look of the big picture. A Validator's job cannot be done without knowledge of specific project needs (the QAPP) and access to all records and the verification report. Because the Validator will look in depth at the records, the best person to choose is someone with experience. For laboratory records a chemist, aquatic biologist, microbiologist etc, can be used since they will be very familiar with laboratory procedures. The same is true for the field records. It is always a good practice to assign someone with field experience for review of field records.

The Validator looks for bias and at the impact of deviations from the sampling and analysis plans. It is absolutely necessary for the Validator to have information from the verification process—with a list of deviations, access to the data quality indicators that were laid out in Section B (and possibly the SOPs) PLUS all of the data he is expected to validate.

Item 1 and 2: In Section D1 a list of the criteria that are to be used for verification and validation was given for each item. In this section the process for validation and verification is described. The process can be a simple statement that verification will be done using a checklist or a SOP, who will do the verification, and a description of the report that will come out of the verification process. Any software that is used (maybe statistical analysis) must be identified. If a percentage of samples are being validated from the raw data and through the calculation process, this must be detailed here. The person validating the data must be identified. This might include statements that the Validator will have the verification report and will review the data as a whole. Statistical software that is used to find outliers and bias must be identified. This section should indicate that a validation report will be provided. This is especially important in large studies.

Item 3: For this requirement a plan must be detailed that describes what will be done if issues arise from the validation and verification. The individual responsible for conveying these results to data users must be identified. For instance if the requirement that 75% of the data is to be valid and this is not achieved then the Project Manager may contact the data users as well as the Field Sampling Staff and Laboratory that the project will be extended to increase the amount of valid data.

Item 4: Checklists and forms for verification and validation as well as documenting the process must be attached. Any calculation and/or calculation formulas that will be used--not previously given, must be listed here (or if previously given, they must be referenced).

D3 Reconciliation with User Requirements

1. Describe the procedures to evaluate the uncertainty of the validated data.
2. Describe how limitations on data use should be reported to the data users.

A usability assessment considers whether the data met project quality objectives as they relate to the decision or environmental assessment to be made. It evaluates whether the data are suitable for making that decision or assessment. All types of data are relevant to this assessment including field data, sampling information and laboratory reports. This assessment is the final step of data review and can be performed only on data of known and documented quality—in other words verified and validated data. In this element describe what statistical analyses or error estimates will be made based on total error. Total error is the cumulative error from field, laboratory and data manipulations.

Item 1 and 2: To accomplish these steps of data review the project team should do the following:

- Summarize the usability assessment process and all usability assessment procedures including interim steps and any statistics, equations and computer algorithms that will be used to assess the data. (See Table 20)

- Describe the documentation that will be generated by the usability report.

- Identify the personnel responsible for performing this assessment.

- Describe how usability assessment results will be presented so that they identify trends, relationships (correlations) and anomalies.

- Describe the evaluative procedures used to assess overall measurement error associated with the project and include DQIs described (see Appendix C for further definitions of the following)

- Determine who will write the usability report, who it will be distributed to and how it will be distributed.

DQIs -these will be part of the process for evaluating the usability of the data:

Precision: Assess the precision results-did they meet the requirements laid out in the QAPP. If not, identify and document how many did not. Is there enough data that meets the requirements to make the decision from the DQOs?

Bias/Accuracy: Discuss and compare overall contamination and accuracy/bias data from multiple data sets for each matrix, analytical group, and concentration level. Are the blanks uncontaminated, are the lab fortified blanks accurate, and are blind PT or QC samples within the acceptable ranges? Document what was not within the requirements. Is there enough data that meets the requirements?

Representativeness: This is the measure of the degree to which the data accurately and precisely represents the site that is being assessed. In order to meet the needs of the data users the results must be representative of the study site according to the requirements specified in the QAPP. The usability report should discuss and compare overall sample representativeness for each matrix, analytical group and concentration level. If the site was obviously non-homogenous because field duplicates or closely located sites have varying results, then this must be documented and more scoping meeting and subsequent resampling may be needed to collect data that is more representative.

Comparability: This is the degree to which different data sets agree. Comparability describes the confidence that two different parameters or data sets can contribute to the overall picture of the site. For instance, in the case of a plume of contamination by lead and chromium, one would expect that where there are higher lead levels, the chromium would also be higher. Screening analysis in the field should also compare somewhat to the analytical results for the parameters that were screened. In the usability report the writer should discuss and compare multiple data sets for each matrix, analytical group and concentration level

Sensitivity and Quantitation Limits: The project data must meet the PQLs or other quantitation limits specified in the QAPP.

Summarization for Usability Report: The entire project team should reconvene to perform the usability assessment. An example of an assessment instrument is shown in Table 22. **This is an example only.**

Item	Assessment Activity
Data Deliverables and QAPP	Was all the necessary information provided—including validation results?
Deviations	What is the impact of the following deviations to the usability of the data?
Sampling Locations Deviation	Determine if alterations to sampling locations will still satisfy the project objectives
Chain of Custody Deviation	Establish that any problems with documentation or custody procedures do not prevent the data from being used.
Holding Time Deviation	If holding times were exceeded in any case, determine if the data is still acceptable or not.
Damaged Samples Deviation	Determine whether the data from damaged samples are usable. If the data is not usable, determine if resampling is necessary.
PT Sample Results	Determine the implications of failed PTs on the usability of the data: will the lab be decertified? NOTE: If the lab is decertified SCDHEC QMP states that data will be for "information purposes only" and not for decision making.
SOPs and Methods Deviation	Evaluate the impact of deviations from the SOP and specified methods on the data quality.
QC Samples	Evaluate the implications of failed QC sample results on the data usability for the associated samples. For example, consider the effects of observed blank contamination.
Matrix	Evaluate matrix effects that bias the results.
Meteorological Data & Site Conditions	Evaluate the possible effects of meteorological (rain, temperature, wind) and site conditions on sample results. Review field reports to identify whether any unusual conditions were present and how the sampling plan was executed.
Comparability	Ensure that results from different data collection activities achieve an acceptable level of agreement.
Completeness	Evaluate the impact of missing data. Ensure that enough information was obtained for the data to be usable.
Background	Determine if background levels have been adequately established (if appropriate)
Critical Samples	Establish that critical samples and critical target analytes are defined in the QAPP, were collected and analyzed. Determine if the results meet criteria specified in the QAPP.
Data Restrictions	Describe the exact process for handling data that do not meet the performance quality objectives (precision, accuracy, sensitivity etc). Depending on how those data will be used, specify the restrictions on use of those data for environmental decision making.
Usability Decision	Determine if the data can be used to make a specific decision considering the implications of all deviations and corrective actions.
Usability Report	Discuss and compare overall precision, accuracy/bias, representativeness, comparability, completeness and sensitivity for each matrix, analytical group and concentration level. Describe limitations on the use of project data if criteria for data quality indicators are not met.

Table 22 Example of a Usability Assessment Instrument

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Appendixes

Appendix A - Acronyms/definitions

Acronyms

COC	Chain of Custody
DQA	Data Quality Assessment
DQIs	Data Quality Indicators
DQOs	Data Quality Objectives
EQC	Environmental Quality Control
EISOP	EQC Environmental Investigations SOP & QA Manual
EPA	Environmental Protection Agency
LOD	Limit of Detection
LFB	Laboratory Fortified Blank
LFM	Laboratory Fortified Matrix
LIMs	Laboratory information management system
OQA	Office of Quality Assurance
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
MDL	Method Detection Limit
MSR	Management System Review
PT	Proficiency Test/Testing
PQL	Practical Quantitation Limit
SCDHEC	South Carolina Department of Health and Environmental Control
SOPs	Standard Operating Procedures
TIC	Tentatively Identified Compounds
TSA	Technical System Audit

Glossary of Quality Assurance and Related Terms
Taken From EPA Guidance G5

Acceptance criteria — Specified limits placed on characteristics of an item, process, or service defined in requirements documents. (ASQC Definitions)

Accuracy — A measure of the closeness of an individual measurement or the average of a number of measurements to the true value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; the EPA recommends using the terms "precision" and "bias", rather than "accuracy," to convey the information usually associated with accuracy. Refer to Appendix D, Data Quality Indicators for a more detailed definition.

Activity — An all-inclusive term describing a specific set of operations of related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that, in total, result in a product or service.

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

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

Audit of Data Quality (ADQ) — A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

Authenticate — The act of establishing an item as genuine, valid, or authoritative.

Bias — The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value). Refer to Appendix D, Data Quality Indicators, for a more detailed definition.

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.

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

Calibration drift — The deviation in instrument response from a reference value over a period of time before recalibration.

Certification — The process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.

Chain of custody — An unbroken trail of accountability that ensures the physical security of samples, data, and records.

Characteristic — Any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

Check standard — A standard prepared independently of the calibration standards and analyzed exactly like the samples. Check standard results are used to estimate analytical precision and to indicate the presence of bias due to the calibration of the analytical system.

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 compared to the amount that was expected to be obtained under correct, normal conditions. Refer to Appendix D, Data Quality Indicators, for a more detailed definition.

Confidence Interval — The numerical interval constructed around a point estimate of a population parameter, combined with a probability statement (the confidence coefficient) linking it to the population's true parameter value. If the same confidence interval construction technique and assumptions are used to calculate future intervals, they will include the unknown population parameter with the same specified probability.

Confidentiality procedure — A procedure used to protect confidential business information (including proprietary data and personnel records) from unauthorized access.

Configuration — The functional, physical, and procedural characteristics of an item, experiment, or document.

Conformance — An affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting the requirements.

Consensus standard — A standard established by a group representing a cross section of a particular industry or trade, or a part thereof.

Contractor — Any organization or individual contracting to furnish services or items or to perform work.

Corrective action — Any measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

Data Quality Assessment (DQA) — 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. The five steps of the DQA Process include: 1) reviewing the DQOs and sampling design, 2) conducting a preliminary data review, 3) selecting the statistical test, 4) verifying the assumptions of the statistical test, and 5) drawing conclusions from the data.

Data Quality Indicators (DQIs) — The quantitative statistics and qualitative descriptors that are 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.

Data Quality Objectives (DQOs) — The qualitative and quantitative statements derived from the DQO Process that clarify 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 Objectives (DQO) Process — A systematic strategic 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 usability — The process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Deficiency — An unauthorized deviation from acceptable procedures or practices, or a defect in an item.

Demonstrated capability — The capability to meet a procurement's technical and quality specifications through evidence presented by the supplier to substantiate its claims and in a manner defined by the customer.

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

Design change — Any revision or alteration of the technical requirements defined by approved

and issued design output documents and approved and issued changes thereto.

Design review — A documented evaluation by a team, including personnel such as the responsible designers, the client for whom the work or product is being designed, and a quality assurance (QA) representative but excluding the original designers, to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Detection Limit (DL) — 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.

Distribution — 1) The appointment of an environmental contaminant at a point over time, over an area, or within a volume; 2) a probability function (density function, mass function, or distribution function) used to describe a set of observations (statistical sample) or a population from which the observations are generated.

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 requirements.

Duplicate samples — Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method, including sampling and analysis. See also collocated sample.

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

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

Environmental data operations — Any 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 programs — An all-inclusive term pertaining to any work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and

operation of environmental technologies; and laboratory operations on environmental samples.

Environmental technology — An all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from, or 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.

Estimate — A characteristic from the sample from which inferences on parameters can be made.

Evidentiary records — Any records identified as part of litigation and subject to restricted access, custody, use, and disposal.

Expedited change — An abbreviated method of revising a document at the work location where the document is used when the normal change process would cause unnecessary or intolerable delay in the work.

Field blank — A blank used to provide information about contaminants that may be introduced during sample collection, storage, and transport. A clean sample, carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample.

Field (matrix) spike — A sample prepared at the sampling point (i.e., in the field) by adding a known mass of the target analyte to a specified amount of the sample. Field matrix spikes are used, for example, to determine the effect of the sample preservation, shipment, storage, and preparation on analyte recovery efficiency (the analytical bias).

Field split samples — Two or more representative portions taken from the same sample and submitted for analysis to different laboratories to estimate interlaboratory precision.

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.

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

Flag — A notation to indicate that the data point associated must be qualified—that a deficiency or deviation exists that is associated with that sample. Flags often appear to resemble footnotes. The notation as to what the flag means is given further on in the document.

Goodness-of-fit test — The application of the chi square distribution in comparing the frequency distribution of a statistic observed in a sample with the expected frequency distribution based on some theoretical model.

Grade — The Class or rank given to entities having the same functional use but different requirements for quality.

Graded approach — The process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results. (See also Data Quality Objectives (DQO) Process.)

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

Guideline — A suggested practice that is not mandatory in programs intended to comply with a standard.

Hazardous waste — Any waste material that satisfies the definition of hazardous waste given in 40 CFR 261, "Identification and Listing of Hazardous Waste."

Holding time — The period of time a sample may be stored prior to its required 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.

Identification error — The misidentification of an analyte. In this error type, the contaminant of concern is unidentified and the measured concentration is incorrectly assigned to another contaminant.

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.

In-Situ Monitoring- Analysis or observations taken immediately at the site. For instance, pH analysis which must take place within 15 minutes of sample collection.

Inspection — The examination or measurement of an item or activity to verify conformance to specific requirements.

Internal standard — A standard added to a test portion of a sample in a known amount and carried through the entire determination procedure as a reference for calibrating and controlling the precision and bias of the applied analytical method.

Laboratory split samples — Two or more representative portions taken from the same sample and analyzed by different laboratories to estimate the interlaboratory precision or variability and the data comparability.

Limit of quantitation — The minimum concentration of an analyte or Class of analytes in a specific matrix that can be identified and quantified above the method detection limit and within specified

limits of precision and bias during routine analytical operating conditions.

Management — Those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management system — A structured, nontechnical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management Systems Review (MSR) — The qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

Matrix spike — A sample prepared by adding a known mass of a target analyte to a specified amount of matrix sample for which an independent estimate of the target analyte concentration is available. Spiked samples are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Mean (arithmetic) — The sum of all the values of a set of measurements divided by the number of values in the set; a measure of central tendency.

Mean squared error — A statistical term for variance added to the square of the bias.

Measurement and Testing Equipment (M&TE) — Tools, gauges, instruments, sampling devices, or systems used to calibrate, measure, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

Memory effects error — The effect that a relatively high concentration sample has on the measurement of a lower concentration sample of the same analyte when the higher concentration sample precedes the lower concentration sample in the same analytical instrument.

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

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

Mid-range check — A standard used to establish whether the middle of a measurement method’s calibrated range is still within specifications.

Mixed waste — A hazardous waste material as defined by 40 CFR 261 Resource Conservation and Recovery Act (RCRA) and mixed with radioactive waste subject to the requirements of the Atomic Energy Act.

Must — When used in a sentence, a term denoting a requirement that has to be met.

Nonconformance — A deficiency in a characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

Objective evidence — Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

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

Organization — A company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

Organization structure — The responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions.

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."

Peer review — A documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. Conducted by qualified individuals (or an organization) who are independent of those who performed the work but collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. Peer reviews are conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. An in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation (PE) — A type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Pollution prevention — An organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge into the environment.

Precision — A measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions expressed generally in terms of the standard deviation. Refer to Appendix D, Data Quality Indicators, for a more detailed definition.

Procedure — A specified way to perform an activity.

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.

Project — An organized set of activities within a program.

Qualified data — Any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Qualified services — An indication that suppliers providing services have been evaluated and determined to meet the technical and quality requirements of the client as provided by approved procurement documents and demonstrated by the supplier to the client's satisfaction.

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 (QA) — 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 client.

Quality Assurance Program Description/Plan — See quality management plan.

Quality Assurance Project Plan (QAPP) — A formal document describing in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QAPP components are divided into four classes: 1) Project Management, 2) Measurement/Data Acquisition, 3) Assessment/Oversight, and 4) Data Validation and Usability. Requirements for preparing QAPPs can be found in EPA QA/R-5.

Quality Control (QC) — The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality. The system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring the results are of acceptable quality.

Quality control (QC) 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 improvement — A management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality management — That aspect of the overall management system of the organization that

determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality Management Plan (QMP) — A formal 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 required interfaces for those planning, implementing, and assessing all activities conducted.

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

Radioactive waste — Waste material containing, or contaminated by, radionuclides, subject to the requirements of the Atomic Energy Act.

Readiness review — A systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Record (quality) — A document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. 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. Refer to Appendix D, Data Quality Indicators, for a more detailed definition.

Remediation — The process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

Repeatability — The degree of agreement between independent test results produced by the same analyst, using the same test method and equipment on random aliquots of the same sample within a short time period.

Reporting limit — The lowest concentration or amount of the target analyte required to be reported from a data collection project. Reporting limits are generally greater than detection limits and are usually not associated with a probability level.

Representativeness — A measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition. See also Appendix D, Data Quality Indicators.

Reproducibility — The precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

Requirement — A formal statement of a need and the expected manner in which it is to be met.

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

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

Research development/demonstration — The systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

Round-robin study — A method validation study involving a predetermined number of laboratories or analysts, all analyzing the same sample(s) by the same method. In a round-robin study, all results are compared and used to develop summary statistics such as interlaboratory precision and method bias or recovery efficiency.

Ruggedness study — The carefully ordered testing of an analytical method while making slight variations in test conditions (as might be expected in routine use) to determine how such variations affect test results. If a variation affects the results significantly, the method restrictions are tightened to minimize this variability.

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

Self-assessment — 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. Refer to Appendix D, Data Quality Indicators, for a more detailed definition.

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

Shall — A term denoting a requirement that is mandatory whenever the criterion for conformance with the specification permits no deviation. This term does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

Significant condition — Any state, status, incident, or situation of an environmental process or condition, or environmental technology in which the work being performed will be adversely affected sufficiently to require corrective action to satisfy quality objectives or specifications and safety requirements.

Software life cycle — The period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirement phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

Source reduction — Any practice that reduces the quantity of hazardous substances, contaminants, or pollutants.

Span check — A standard used to establish that a measurement method is not deviating from its calibrated range.

Specification — A document stating requirements and referring to or including drawings or other relevant documents. Specifications should indicate the means and criteria for determining conformance.

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

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 (QC) samples that are used to assess analytical variability and comparability.

Standard deviation — A measure of the dispersion or imprecision of a sample or population distribution expressed as the positive square root of the variance and has the same unit of measurement as the mean.

Standard Operating Procedure (SOP) — A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps and that is officially approved as the method for performing certain routine or repetitive tasks.

Supplier — Any individual or organization furnishing items or services or performing work according to a procurement document or a financial assistance agreement. An all-inclusive
term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surrogate spike or analyte — A pure substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them to establish that the analytical method has been performed properly.

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

Technical review — A documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness,

adequacy, completeness, and assurance that established requirements have been satisfied.

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

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

Trip blank — A clean sample of a matrix that is taken to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures.

Validation — Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs. See also Section D.

Variance (statistical) — A measure or dispersion of a sample or population distribution.

Verification — Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity. See also Section D.

Appendix B - Data Quality Indicators

From EPA QA/G-5

Data Quality Indicators (DQIs) are qualitative and quantitative descriptors used in interpreting the degree of acceptability or utility of data. The principal DQIs are precision, bias, representativeness, comparability, and completeness. Secondary DQIs include sensitivity, recovery, memory effects, limit of quantitation, repeatability, and reproducibility. Establishing acceptance criteria for the DQIs sets quantitative goals for the quality of data generated in the analytical measurement process. DQIs may be expressed for entire measurement systems, but it is customary to allow DQIs to be applied only to laboratory measurement processes. The issues of design and sampling errors, the most influential components of variability, are discussed separately in EPA QA/G-5S, Guidance on Sampling Designs to Support QAPPs.

Of the five principal DQIs, precision and bias are the quantitative measures, representativeness and comparability are qualitative, and completeness is a combination of both quantitative and qualitative measures.

The five principal DQIs are also referred to by the acronym PARCC, with the "A" in PARCC referring to accuracy instead of bias. This inconsistency results because some analysts believe accuracy and bias are synonymous, and PARCC is a more convenient acronym than PBRCC. Accuracy comprises both random error (precision) and systematic error (bias), and these indicators are discussed separately in this appendix. DQIs are discussed at length in EPA QA/G-5I, Guidance on Data Quality Indicators.

Precision

Precision is a measure of agreement among replicate measurements of the same property, under prescribed similar conditions. This agreement is calculated as either the range (R) or as the standard deviation (s). It may also be expressed as a percentage of the mean of the measurements, such as relative range (RR) (for duplicates) or relative standard deviation (RSD).

For analytical procedures, precision may be specified as either intralaboratory (within a laboratory) or interlaboratory (between laboratories) precision. Intralaboratory precision estimates represent the agreement expected when a single laboratory uses the same method to make repeated measurements of the same sample. Interlaboratory precision refers to the agreement expected when two or more laboratories analyze the same or identical samples with the same method. Intralaboratory precision is more commonly reported; however, where available, both intralaboratory and interlaboratory precision are listed in the data compilation.

When possible, a sample subdivided in the field and preserved separately is used to assess the variability of sample handling, preservation, and storage along with the variability of the analysis process.

When collocated samples are collected, processed, and analyzed by the same organization, intralaboratory precision information on sample acquisition, handling, shipping,

storage, preparation. and analysis is obtained. Both samples can be carried through the steps in the measurement process together

to provide an estimate of short-term precision. Likewise, the two samples, if separated and processed at different times or by different people and/or analyzed using different instruments, provide an estimate of long-term precision.

Bias

Bias is the systematic or persistent distortion of a measurement process that causes errors in one direction. Bias assessments for environmental measurements are made using personnel, equipment, and spiking materials or reference materials as independent as possible from those used in the calibration of the measurement system. When possible, bias assessments should be based on analysis of spiked samples rather than reference materials so that the effect of the matrix on recovery is incorporated into the assessment. A documented spiking protocol and consistency in following that protocol are important to obtaining meaningful data quality estimates. Spikes should be added at different concentration levels to cover the range of expected sample concentrations. For some measurement systems (e.g., continuous analyzers used to measure pollutants in ambient air), spiking samples may not be practical, so assessments should be made using appropriate blind reference materials.

For certain multi-analyte methods, bias assessments may be complicated by interferences among multiple analytes, which prevents all of the analytes from being spiked into a single sample. For such methods, lower spiking frequencies can be employed for analytes that are seldom or never found. The use of spiked surrogate compounds for multianalyte gas chromatography/ mass spectrometry (GC/MS) procedures, while not ideal, may be the best available procedure for assessment of bias.

Accuracy

Accuracy is a measure of the closeness of an individual measurement or the average of a number of measurements to the true value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that result from sampling and analytical operations.

Accuracy is determined by analyzing a reference material of known pollutant concentration or by reanalyzing a sample to which a material of known concentration or amount of pollutant has been added. Accuracy is usually expressed either as a percent recovery (P) or as a percent bias (P - 100). Determination of accuracy always includes the effects of variability (precision); therefore,

accuracy is used as a combination of bias and precision. The combination is known statistically as mean square error.

Mean square error (MSE) is the quantitative term for overall quality of individual measurements or estimators. To be accurate, data must be both precise and unbiased. Using the analogy of archery, to be accurate, one must have one’s arrows land close together and, on average, at the spot where they are aimed. That is, the arrows must all land near the bull’s-eye

(see Figure AD.1).

Mean square error is the sum of the variance plus the square of the bias. (The bias is squared to eliminate concern over whether the bias is positive or negative.) Frequently, it is impossible to quantify all of the components of the mean square error--especially the biases--but it is important to attempt to quantify the magnitude of such potential biases, often by comparison with auxiliary data.

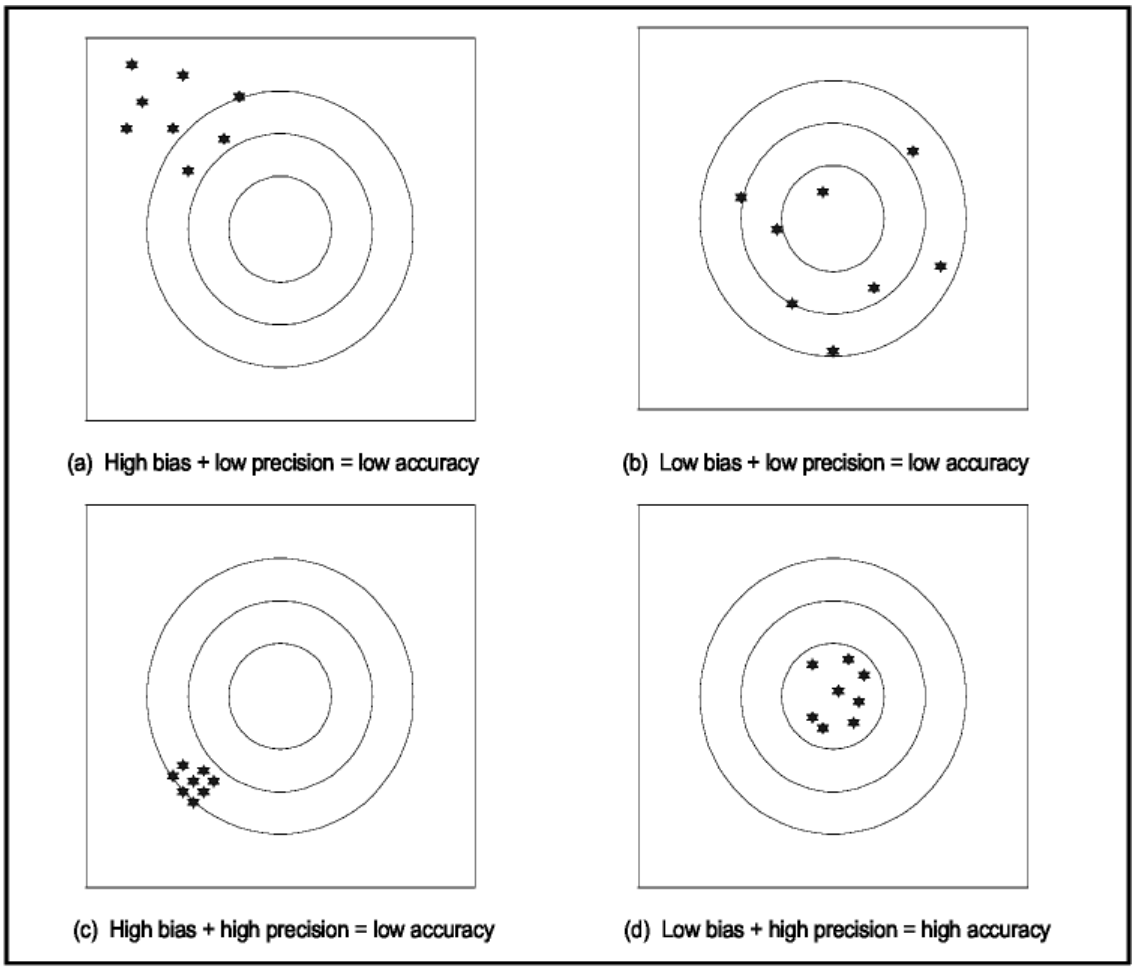

Figure AD1. Measurement Bias and Random Measurement Uncertainties: Shots at a Target

Representativeness

Representativeness is a measure of the degree to which data accurately and precisely represent a characteristic of a population parameter at a sampling point or for a process condition or environmental condition. Representativeness is a qualitative term that should be evaluated to determine whether in situ and other measurements are made and physical samples collected in such a manner that the resulting data appropriately reflect the media and phenomenon measured or studied.

Comparability

Comparability is the qualitative term that expresses the confidence that two data sets can contribute to a common analysis and interpolation. Comparability must be carefully evaluated to establish whether two data sets can be considered equivalent in regard to the measurement of a specific variable or groups of variables. In a laboratory analysis, the term comparability focuses on method type comparison, holding times, stability issues, and aspects of overall analytical quantitation.

There are a number of issues that can make two data sets comparable, and the presence of each of the following items enhances their comparability:

- two data sets should contain the same set of variables of interest;
- units in which these variables were measured should be convertible to a common metric;
- similar analytic procedures and quality assurance should be used to collect data for both data sets;
- time of measurements of certain characteristics (variables) should be similar for both data sets;
- measuring devices used for both data sets should have approximately similar detection levels;
- rules for excluding certain types of observations from both samples should be similar;
- samples within data sets should be selected in a similar manner;
- sampling frames from which the samples were selected should be similar; and
- number of observations in both data sets should be of the same order or magnitude.

These characteristics vary in importance depending on the final use of the data. The closer two data sets are with regard to these characteristics, the more appropriate it will be to compare them. Large differences between characteristics may be of only minor importance, depending on the decision that is to be made from the data.

Comparability is very important when conducting meta-analysis, which combines the results of numerous studies to identify commonalities that are then hypothesized to hold over a range of experimental conditions. Meta-analysis can be very misleading if the studies being evaluated are not truly comparable. Without proper consideration of comparability, the findings of the meta-analysis may be due to an artifact of methodological differences among the studies

rather than due to differences in experimentally controlled conditions. The use of expert opinion to classify the importance of differences in characteristics among data sets is invaluable.

Completeness

Completeness is a measure of the amount of valid data obtained from a measurement system, expressed as a percentage of the number of valid measurements that should have been collected (i.e., measurements that were planned to be collected).

Completeness is not intended to be a measure of representativeness; that is, it does not describe how closely the measured results reflect the actual concentration or distribution of the pollutant in the media sampled. A project could produce 100% data completeness (i.e., all samples planned were actually collected and found to be valid), but the results may not be representative of the pollutant concentration actually present.

Alternatively, there could be only 70% data completeness (30% lost or found invalid), but, due to the nature of the sample design, the results could still be representative of the target population and yield valid estimates. Lack of completeness is a vital concern with stratified sampling. Substantial incomplete sampling of one or more strata can seriously compromise the validity of conclusions from the study. In other situations (for example, simple random sampling of a relatively homogeneous medium), the lack of completeness only results in a loss of statistical power. The degree to which lack of completeness affects the outcome of the study is a function of many variables ranging from deficiencies in the number of field samples acquired to failure to analyze as many replications as deemed necessary by the QAPP and DQOs. The intensity of effect due to incompleteness of data is sometimes best expressed as a qualitative measure and not just as a quantitative percentage.

Completeness can have an effect on the DQO parameters. Lack of completeness may require reconsideration of the limits for the false negative and positive error rates because insufficient completeness will decrease the power of the statistical test.

The following four situations demonstrate the importance of considering the planned use of the data when determining the completeness of a study. The purpose of the study is to determine whether the average concentration of dioxin in surface soil is no more than 1.0 ppb. The DQOs specified that the sample average should estimate the true average concentration to within ±0.30 ppb with 95 % confidence. The resulting sampling design called for 30 samples to be drawn according to a simple random sampling scheme. The results were as follows:

	Study Results	Completeness	Outcome
1	1.5 ppb ± 0.28 ppb	97%	Satisfies DQOs and study purpose
2	500 ppb ± 0.28 ppb	87%	Satisfies DQOs and study purpose
3	1.5 ppb ± 0.60 ppb	93%	Does not satisfy either
4	500 ppb ± 0.60 ppb	67%	Fails DQOs but meets study purpose

For all but the third situation, the data that were collected completely achieved their purpose, meeting data quality requirements originally set out, or providing a conclusive answer to the study question. The degree of incompleteness did not affect some situations (situations 2 and 4) but may have been a prime cause for situation 3 to fail the DQO requirements. Expert opinion would then be required to ascertain if further samples for situation 3 would be necessary in order to meet the established DQOs.

Several factors may result in lack of completeness: (1) the DQOs may have been based on poor assumptions, (2) the survey design may have been poorly implemented, or (3) the design may have proven impossible to carry out given resource limitations. Lack of completeness should always be investigated, and the lessons learned from conducting the study should be incorporated into the planning of future studies.

OTHER DATA QUALITY INDICATORS

Sensitivity

Sensitivity is the capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest. Sensitivity is determined from the value of the standard deviation at the concentration level of interest. It represents the minimum difference in concentration that can be distinguished between two samples with a high degree of confidence.

Recovery

Recovery is an indicator of bias in a measurement. This is best evaluated by the measurement of reference materials or other samples of known composition. In the absence of reference materials, spikes or surrogates may be added to the sample matrix. The recovery is often stated as the percentage measured with respect to what was added. Complete recovery (100%) is the ultimate goal. At a minimum, recoveries should be constant and should not differ significantly from an acceptable value. This means that control charts or some other means should be used for verification. Significantly low recoveries should be pointed out, and any corrections made for recovery should be stated explicitly.

Memory Effects

A memory effect occurs when a relatively high-concentration sample influences the measurement of a lower concentration sample of the same analyte when the higher concentration sample precedes the lower concentration sample in the same analytical instrument. This represents a fault in an analytical measurement system that reduces accuracy.

Limit of Quantitation

The limit of quantitation is the minimum concentration of an analyte or category of analytes in a specific matrix that can be identified and quantified above the method detection limit and within specified limits of precision and bias during routine analytical operating conditions.

Repeatability

Repeatability is the degree of agreement between independent test results produced by the same analyst using the same test method and equipment on random aliquots of the same sample within a short time period.

Reproducibility

Reproducibility is the precision that measures the variability among the results of measurements of the same sample at different laboratories. It is usually expressed as a variance and low values of variance indicate a high degree of reproducibility.

DQIs and the QAPP

At a minimum, the following DQIs should be addressed in the QAPP: accuracy and/or bias, precision, completeness, comparability, and representativeness. Accuracy (or bias), precision, completeness, and comparability should be addressed in Section A7.3, Specifying Measurement Performance Criteria. Refer to that section of the G-5 text for a discussion of the information to present and a suggested format. Representativeness should be discussed in Sections B4.2 (sub-sampling) and B1 (Sampling Design).

Principal Types of Error

Types of Error	Sources of Error
Random precision; "P" in PARCC	Natural variability in the population from which the sample is taken. Measurement system variability, introduced at each step of sample handling and measurement processes.
Systematic accuracy/bias; "A" in PARCC	Interferences that are present in sample matrix. Loss (or addition) of contaminants during sample collection and handling. Loss (or addition) of contaminants during sample preparation and analysis. Calibration error or drift in the response function estimated by the calibration curve.
Lack of Representativeness "R" in PARCC	Sample is not representative of the population, which often occurs in judgmental sampling because not all the units of the population have equal or known selection probabilities. Sample collection method does not extract the material from its natural setting in a way that accurately captures the desired qualities to be measured. Sub-sample (taken from a sample for chemical analysis) is not representative of the sample, which occurs because the sample is not homogeneous and the sub-sample is taken from the most readily available portion of the sample. Consequently, other parts of the sample had less chance of being selected for analysis.
Lack of Comparability "C" in PARCC	Failure to use similar data collection methods, analytical procedures, and QA protocols. Failure to measure the same parameters over different data sets.
Lack of Completeness "C" in PARCC	Lack of completeness sometimes caused by loss of a sample, loss of data, or inability to collect the planned number of samples. Incompleteness also occurs when data are discarded because they are of unknown or unacceptable quality

Appendix C - Preliminary Sampling Form

Request for Preliminary Sampling for QAPP Development

This form is to request sampling prior as part of the development of a QAPP. **If this preliminary sampling is performed there will be a QAPP forthcoming.** It is expected that as part of the discussion in Section B concerning sampling rationales and site selection, these preliminary samples and their results WILL be discussed. Only one set of samples per site is allowed unless cleared through the Quality Assurance Office or a new request is submitted.

Person making the request_____ Region/Office_____

Please briefly give the background of the project for which the sampling is desired:

Please give a brief justification concerning why preliminary sampling is necessary in order to develop the sampling plan for the QAPP.

Please give the location of the proposed site(s) to be sampled and the date which sampling will take place: (Maps can be attached)

What parameters will be analyzed and what lab will do the analysis?
Parameter _____ Lab_____
Parameter _____Lab_____
Parameter _____Lab_____
Parameter_____ Lab_____

Do these sites have TMDLs and/or are they on the 303d List for these parameters?

Is there any other information that would help justify this preliminary sampling?

Approval Signatures:

Regional Director: _____Date:_____

Watershed Manager: _____ Date:_____

OQA: _____ Date:_____

Appendix D - QAPP Matrix – Internal SCDHEC Plans Only

The following is a matrix to help determine what Class QAPP will be required for simple internal projects.

Since the Class is determined from the length of the project as well as the number of parameters, this table was developed to help distinguish an internal Class 4 from an internal Class 3.

As it can be from the table, a project using 8 parameters and lasting for 6 months will fall under the Class 4 project, while a project with 11 parameters for 6 months will require a Class 3 QAPP.

		# of Parameters		
		1-2	3-9	10+
Length of project	< 1 year	Class 4	Class 4	Class 3
	1 year	Class 4	Class 4	Class 3
	>1 year	Class 4	Class 3	Class 3

Appendix E - Example Qualifier Flags

Flag	Flag Definition
A	The analyte was analyzed in replicate. Reported value is an average value of the replicates.
B	Analyte is present greater than the reporting limit in the associated blank
J	The identification of the analyte is acceptable, but the reported value is an estimate.
K	The identification of the analyte is acceptable; but the reported value may be biased high. The actual value is expected to be less than the reported value.
L	The identification of the analyte is acceptable; but the reported value may be biased low. The actual value is expected to be greater than the reported value.
P	Sample improperly preserved and/or collected
R	The presence or absence of the analyte can not be determined from the data due to severe quality control problems. The data are rejected and considered unusable.
U	The analyte was not detected at or above the reporting limit

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