Guidance Document
For Preparing
Quality Assurance Project Plans (QAPPs)
For
Environmental Monitoring Projects/Studies

Quality Assurance Management Office
Bureau of Environmental Health Services
Environmental Affairs
South Carolina Department of Health and Environmental Control

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 the EPA or funded by the 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 for their intended use. The QAPP is the integral part of the fundamental principles and practices that form the foundation of the South Carolina Department of Health and Environmental Control (DHEC) 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 consistency of processes from sample collection, to analysis, to data reduction and ending with the final report and conclusions drawn from the data. To ensure the uniformity of the process, communication is essential. QAPPs act as a means of communication to ensure that requirements are conveyed to everyone involved in the project. Therefore, adequacy of the QAPP and its effective implementation are vital. 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 addressed in a QAPP for environmental data operations performed by DHEC or on its behalf by extramural organizations. It provides detailed guidance on how to develop a QAPP. 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 DHEC.

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*. Other information cited complies with mandatory Quality Management Programs as described in the EPA Quality Documents especially the *EPA/DOE/DOD Uniform Federal Policy for Quality Assurance Project Plans, 03/2005.*

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:

DHEC
Bureau of Environmental Health Services
Office of Environmental Laboratory Certification
2600 Bull Street
Columbia SC 29201
Phone: 803-896-0970 Fax: 803-896-0980

Quality Assurance Management Office
BEHS EA Laboratories
8231 Parklane Road
Columbia, SC
803-896-0901

Table of Contents

List of Figures

List of Tables

Chapter 1– Introduction and an Overview of the QAPP

1.1 Frequently Asked Questions

What is a 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.

The QAPP is the key component of the DHEC Quality System. 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.

What is the purpose of a QAPP?

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.

It is a DHEC Environmental Affairs (EA) policy (along with EPA) that requires that all environmental 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 an EA 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 an 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 the Quality Assurance Manager (QAM) or the QAM's designee 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 along with how the results affected the study (sampling site locations, etc).

When is a QAPP required?

EA Policy requires a QAPP for any special project. However, EPA may require QAPPs to describe how quality is ensured in an entire program. These are called Programmatic or Generic QAPPs. In addition, even though a special study may not be funded by the EPA, the DHEC Quality Management Plan (QMP) still requires a QAPP.

A QAPP may be required for activities involving the use and/or creation of environmental data from

- Direct and indirect field and/or laboratory measurements;
- Evaluating the operation and performance of environmental technology;
- Inspections;
- Existing environmental data;
- Questionnaire survey development or application;
- Development and validation of sampling or analytical methods;
- Environmental model modification and/or development;
- Enforcement monitoring or assessments;
- Application of environmental management systems;
- Environmental safety and health monitoring;
- Scientific research;
- Regulatory development;
- Statistical or economic analyses of environmental data;
- Use of information technology (mathematical models);
- Use of information sources outside of direct EPA management controls or authority; and
- Use of other data sources (e.g., literature or the Internet)

The conclusion that should be reached is that a QAPP is not always a project involving sample collection and laboratory analysis.

Who is involved in developing a QAPP?

QAPP development typically involves the coordinated efforts of many individuals, possibly including managers, engineers, scientists, statisticians, information technology (IT) experts, modelers, stakeholders, and end users. In other words, all individuals or groups with information pertinent to the QAPP development should be involved.

How is the QAPP effective?

The QAPP should integrate the contributions and requirements of everyone involved into a clear, concise statement of what needs to be accomplished, how it will be performed, and by whom. It should provide understandable instructions to those who must approve or implement the QAPP, including the field sampling team, the analytical laboratory, and data users and reviewers. Beyond the general guidance provided in the QAPP, it should identify and integrate the use of related policies and procedures applicable to the project such as administrative procedures, laboratory procedures, data analysis methodologies, IT policies and procedures, and data handling and analysis policies. The QAPP will also incorporate plans for verifying and validating the data and include the responsible personnel. This ensures that the data produced will be of the quality required for the project as specified in the QAPP.

The QAPP must specify the level or degree of QA and QC activities needed for the particular environmental data or model operations with clear objectives, acceptance criteria, and QA/QC control strategies. The QA and QC technical requirements of a project should be commensurate

with the type of work to be performed (e.g., monitoring, site characterization, model simulation, and bench level proof of concept), the purpose of the project (e.g., regulatory enforcement, development work for rulemaking, permit approval, research publications, and/or journal articles), and the scale of the project such as a one-time assessment or a template for multiple assessments. Regardless of the complexity of the project, the QAPP documents how the project team will ensure that the quality of data is suitable for its intended use by documenting acceptance criteria against which assessments may be made.

How much work can be performed before the QAPP is approved?

None, however, short-term pre-QAPP sampling may be approved for determining final sampling sites. This approval will be in the form of a memo from the QAM or designee and addressed to the party seeking the approval as well as the laboratories that will be used. In some cases a partial or a conditional approval will be given so that some work may be performed. Refer to the Section on QAPP Approval.

How do I develop a QAPP?

QAPPs cannot be developed by one person. The QAPP development can begin with one person determining that a project needs to be performed with the project's scope. To determine the scope, questions such as the following should be asked:

Why is this study important?
What will be done in the study, for example samples to be taken, data to be collected etc?
Where will the data and/or samples be collected?
Will a laboratory be involved?
How long will the project last?

There will probably be more details to work out, but at this point the project manager can determine which people will most likely have the information that is needed. A brief summary of the process follows:

1. Determine the scope and objectives of the project and gather background information;
2. Assemble a project team with necessary project and QA expertise;
3. Conduct planning sessions to determine how to collect the specific type of data, the amount of data, and what the goals or acceptance criteria will be;
4. Develop a draft QAPP;
5. Circulate the draft QAPP for peer review, comment, and input for improvement;
6. Submit the final QAPP for approval;
7. After approval, distribute the QAPP to all persons involved with the project;
8. Proceed to implement the QAPP allowing for documentation of changes, re-approvals, and distribution of updated QAPPs.

Who approves the QAPP and when can work begin?

Approval of the QAPP is indicated by signatures on the Title and Approval Page by the project manager, the laboratory manager, the project QA Officer, and the QAM (or the QAM's

designee). For a QAPP required by and to be approved by the EPA, the QAPP should also be approved by the QAM (or designee).

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 QAM or designee. If the project is funded by the EPA then approval must be obtained from EPA Region 4 prior to the commencement of the project. In some cases, DHEC may grant conditional or partial approval to permit some of the work to begin while non-critical deficiencies in the QAPP are being resolved. The QAM or designee 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 the acceptable 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 technical aspects of the project may change. QAPPs must be revised to incorporate such changes. **Any revisions or additions to the QAPP must be re-approved by DHEC and distributed to all participants in the project (See A3-Distribution List).** If it is necessary to revise the QAPP, a revision history must be included in tabular form. See Table 24.

Do I have to use a certified laboratory for field parameters such as pH and DO (dissolved oxygen)?

If the project manager desires that the data from field measurements be accepted by DHEC, then the answer is “yes”. The analysts performing these parameters must be employed by a laboratory certified for those analyses and adhere to the requirement of the 15 minute holding time for field parameters. If the field measurement parameter data will not be submitted to DHEC and will be

used only to determine steady-state or equilibrium conditions, for instance, when developing a well, then these parameters do not need to be analyzed by a certified laboratory.

What is the role of the QAM?

The QAM or designee 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 a small project that is eligible for a Class 3 QAPP or does the project complexity or EPA requirements necessitate a full QAPP (Class 1)? (See Chapter 2)
- 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? **The QAPP must follow the format given in Section 1.2 of 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 due to the use of the graded approach.** (See Chapter 2) ***Therefore, 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 performed listed with the correct method and is the laboratory that will perform the analysis certified for that analysis? Note: For multi compound/analyte methods such as EPA Method 608, the specific method and compound/analyte must be identified on the certificate of accreditation. For example if the project includes the analysis of PCB 1016 by EPA Method 608, the laboratory's certificate of accreditation must document EPA Method 608 and the compound/analyte PCB 1016.
- Is the laboratory's reporting limit lower than the action limit or trigger concentration?
- Are the laboratory's SOPs and QA Plan valid and complete? For DHEC laboratories, 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? Who will verify the data besides the laboratory? Who will validate the data? The person validating the data cannot be the same person that generates the data.

How long will it take for the QAPP to be approved?

It is extremely important that the QAPP be submitted with sufficient time prior to the planned beginning date of the project. This will allow time for thorough review and revisions if necessary. The complexity of the QAPP must be taken into consideration since some projects will take a longer review time. **It is recommended that the project manager contact the QAM or designee with questions before writing the QAPP to ensure that all elements are addressed in the QAPP prior to submittal.** Upon receipt of the QAPP, the QAM or designee requires **20 business days** in which to respond to the QAPP. If revisions are necessary, the Office may need up to an additional 20 business days to respond to a revised QAPP.

How is a QAPP Organized?

A QAPP is composed of four sections of project-related information called "groups", which are subdivided into specific detailed "elements." The groups are listed in Section 1.2 and are discussed in detail in Chapter 3 of this document. Using a graded approach as outlined in Chapter 2, an element may be listed as not applicable, or may need to be explained in great detail. This is dependent on the complexity of the project and 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 DHEC Bureau/Program and/or the QAM or designee.

1.2 The Organization of a QAPP

QAPPs are divided into 4 main groups given below. All QAPPs submitted to EPA and the QAM must be organized in this format.

Group A- Project Management

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

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- Assessments

C1 Assessments and Response Actions
C2 Reports to Management

Group D- Data Validation and Usability

D1 Data Review, Validation, and Verification Requirements

D2 Validation and Verification Methods
D3 Reconciliation with User Requirements

Appendix
App1 Revision History
App2 Sampling and Analysis SOPs

1.3 The Life Cycle of a QAPP

In the FAQs in Section 1.1, the steps in developing a QAPP are discussed. The QAPP life cycle includes planning, development, approval, implementation, completion of the project, and generating a final report. Amending the QAPP will require going through the approval/implementation stages again. The steps in the QAPP life cycle appear below and an illustration is provided in Figure 1.

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: program personnel, laboratory personnel, sampling personnel, quality assurance personnel, stakeholders, and other interested or involved parties.
3. Meetings are scheduled for the project team. The following items may be discussed during the meeting or as a result of the meeting:
   - The data that will be collected is determined. For a typical laboratory driven environmental study this will include the number and types of parameters along with the types of samples collected.
   - The team determines the scope of the project: where it will take place, duration of the project, and how the sampling sites will be selected.
   - The team determines how sensitive the analytical methods must be. This may require determining if there is a trigger or action limit. Certainly, the analytical method must be sensitive enough to detect the parameters at the action limit.
   - The team compares the detection limits/reporting limits needed for the study against the possible method detection limit (MDL)/reporting limit (PQL) of the specified analytical methods.
   - The team determines which laboratory will be used and contacts that laboratory to determine if the laboratory is certified for all the desired methods. The laboratory must be certified for all required methods (unless there is no certification offered, e.g. air samples). If the laboratory needs certification for one or more methods, they are informed and the process of acquiring certification can begin early in the planning stage. Alternatively, the laboratory may subcontract analyses to a certified laboratory, but the team must be aware of this from the beginning of the project.
   - The DHEC Office of Environmental Laboratory Certification can provide a list of certified laboratories for specific parameters and/or methods. Contact this office by emailing labcerthelp@dhec.sc.gov.
4. The QAPP is written and then provided to the entire team for review.
5. A draft of the QAPP is submitted to the QAM or designee, usually via email. Within 20 days the team will be contacted about items that need to be revised or corrected. A copy of

the draft must also be submitted to the applicable DHEC program for review. The program area may have a separate set of comments for the QAPP.

6. Once the required corrections are made, the project team obtains signatures for the approval page and this page is sent to the QAM and/or designee to be signed.
7. If the QAPP is to be reviewed by the EPA, it must be submitted by the Project Manager. All signatures but those of the EPA must be present. Revisions that EPA requires will be completed by the team and then the final copy is submitted again to the EPA for approval. All signatures must be present before it is resubmitted to the EPA.
8. All persons/organizations on the Distribution List are sent a copy of the approved QAPP. The laboratory (and subcontract laboratory) must be included in those receiving a copy of the QAPP. This includes the DHEC Regional Laboratories or the Analytical Radiological Environmental Services Division (ARESD) Laboratory, if either or both are involved.
9. The QAPP is implemented and the project begins.
10. If conditions are found that would warrant a change in what is being performed, the QAPP must be amended. Amendments are made and these are submitted for internal and QAM review. If these are small changes, this may be accomplished by mail 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.
11. The project work is modified to reflect the changes once they are approved.
12. The final report is generated.
13. The project is finished and the QAPP and data are archived.

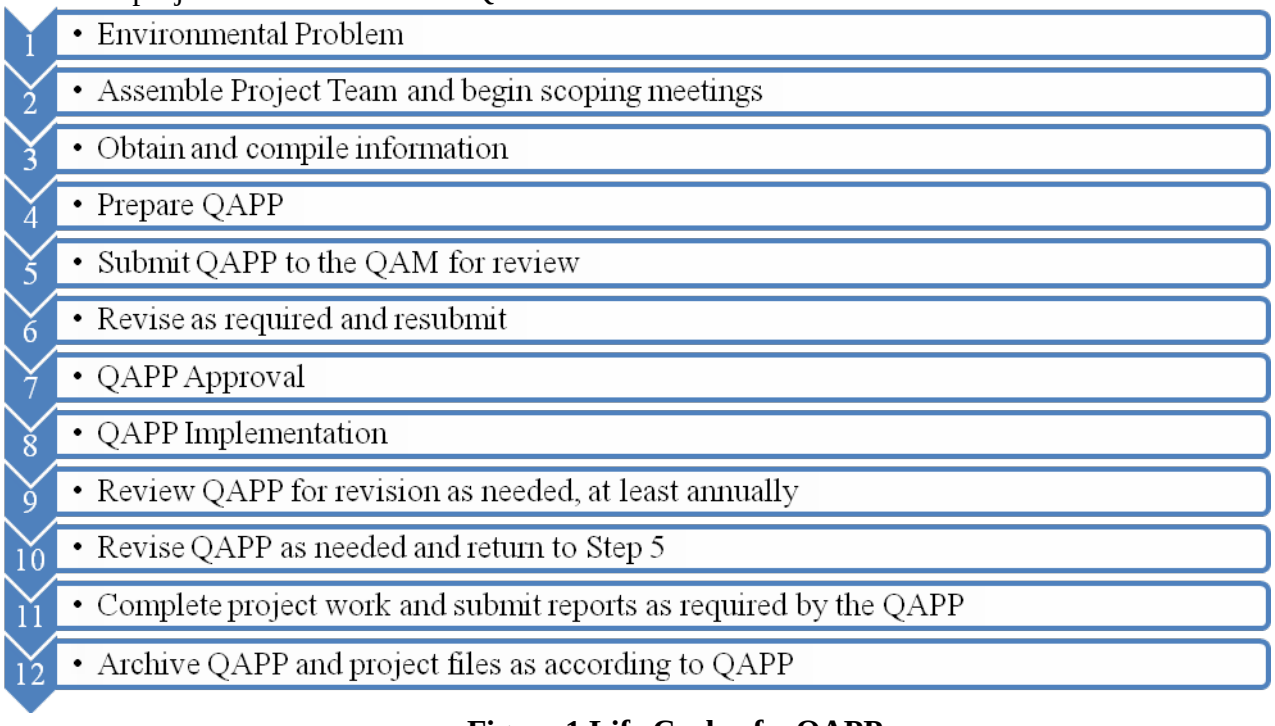

Figure 1 Life Cycle of a QAPP

Note: For ongoing projects, the QAPP is reviewed annually by the project manager and/or designee or as directed by the QAPP. If updates are necessary, the draft must have approval from DHEC (QAM/QAM designee) before distribution.

1.4 Types of QAPPs

Generic or Programmatic QAPPs

A generic QAPP also known as a Programmatic QAPP provides an overarching plan that describes the quality objectives and documents a comprehensive set of sampling, analysis, QA/QC, data review, and assessment procedures specific to a large program or long-term project. In contrast to the project specific QAPP, the generic QAPP serves as an umbrella under which multiple data collection, production and use activities may be conducted over an extended period of time.

Generic QAPPs may make sense in situations where multiple sites, systems, or projects will be sampled under a common sampling and analysis protocol/plan. A simple way to determine whether a generic QAPP is appropriate for a project is to consider whether there is sufficient consistency across the QA needs of multiple projects within a program which can be combined into a single, generic QAPP. The QAPP will:

- Ensure the necessary level of quality for all projects covered by the generic QAPP; and
- Require less time and resources to manage with a single generic QAPP than with multiple project specific QAPPs.

An approved generic QAPP should be supported by task or project specific addenda, which address the issues unique to each task or project. Project or task specific information that is not covered by the generic QAPP should be documented in detail in these addenda. The generic QAPP should specify the preparation, review, and approval of task or project specific addenda. EPA must always review and approve a Programmatic QAPP. However, after the approval of the Programmatic QAPP, EPA may authorize the organization to approve project specific addenda. These project specific addenda approvals are contingent upon a review and approval process that is fully documented in the approved generic QAPP. For example, the UST Programmatic QAPP has addenda provided by the contractor for a specific site and project. However, the programmatic QAPP specifies exactly what the contractor will provide in the addendum and how the contractor must proceed.

QAPP Addendums

In the situation when a programmatic QAPP will describe most processes, but not specific details of a location or situation, a QAPP addendum may be used. If possible, the possibility of one or more QAPP addendums is planned as part of the fabrication of the programmatic QAPP. The QAPP addendum will cover only those specifics which are not part of the QAPP under which it falls. It must follow the format of a full QAPP. In those sections covered by the programmatic QAPP, the addendum must reference the original QAPP. The QAPP addendum must not conflict with the original programmatic QAPP. Those participating in the project must adhere to specifics in the programmatic QAPP and the addendum. Thus all must have a copy of both documents.

Phased QAPPs

When there is significant uncertainty surrounding a project and additional clarity is expected as initial data or information are gathered, or for a project that is iterative in nature, it may be appropriate to use a phased approach for QAPP development. The phased QAPP should include a description of the decision points for the project.

Examples of when a phased QAPP might be appropriate include:

- Literature reviews in which the eventual direction and depth of the research is dependent upon the information found in the articles in the first round of the project;

- Investigations or phased project cycles where the results of the initial assessment will dictate the following steps (e.g., no contaminants found above thresholds leading to site closure vs. contaminants found above thresholds leading to a risk assessment and feasibility study);

- Analytical method development for a specific purpose (e.g., improved sensitivity) for which an early step in the process may determine the viability of continued effort; or

- Model development and implementation for which the project overview, objectives, and measurement performance criteria can be defined upfront, but until the model requirements are defined, the requirements for input data cannot be clearly established.

If a phased QAPP is developed, it should still contain all relevant elements of a QAPP. The efficiency to be gained from a phased QAPP may be realized by not spending time or resources to specify the detailed project requirements for each "what-if" scenario for the project. If a phased QAPP is developed, it is very important that it be updated as the direction of the project becomes clear. No project work should take place without an appropriate QAPP in place, so moving beyond the phase documented in the QAPP should not occur until the QAPP is updated. These updates should be described in the revision history (see Section 3.5)

In the circumstance where preliminary sampling and analysis must take place to determine the best place to perform sampling for a special project, the QAM and/or designee may be contacted for approval. As part of approval, the project manager must submit an official memo explaining why the sampling and analysis is needed, what parameters (and the associated methods) will be determined, and the date that the samples will be taken. No more than one set of samples may be taken for this determination unless specifically requested in the memo and the reasons for the request are explained. The data from this preliminary sampling may not be used to make environmental decisions with the exception of sample location selection. This information may be part of the historical/external information in Section B9.

Chapter 2 – The Graded Approach in the Development of QAPPs

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 was developed.

EPA originally developed four categories of QAPPs for the graded approach. For DHEC these have been reduced to three Classes. Class 1, which must have all the QAPP elements to Class 3 which includes only a few QAPP elements. The following two tables describe each Class and what QAPP elements are required for that Class. Prior to development of the QAPP, the QAM or QAM designee must be contacted to determine the proper Class for the Project. The term "flexible" DQOs refers to the fact that for the applicable Class, not all DQO steps must be addressed.

Class	Description of Project	DQOs
Class 1	Large projects or 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 be submitted to the EPA for approval must be Class 1 QAPPs. EPA requires all the QAPP elements. For an EPA QAPP the graded approach only impacts the length and detail in each section.**	Formal DQOs
Class 2 (formerly 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. External projects that will continue for more than 1 year and/or will involve more than 2 parameters must have a Class 1 or full QAPP.	Flexible DQOs
Class 3 (formerly Class 4)	Projects involved in studying basic issues, including proof of concepts, screen for particular analytical species, and most internal investigative studies. 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 E for more information) **Only projects that use internal DHEC Laboratories for analysis and DHEC personnel for sample collection will fall under this class.**	Project Objectives or Goals

Table 1 QAPP Classes

QAPP Element	Class Applicability
A1 Title and Approval Page	1,2,3
A2 Table of Contents	1,2,3
A3 Distribution List	1,2,3
A4 Project/Task Organization	1,2,3
A5 Problem Definition/Background	1,2,3
A6 Project/Task Description	1,2,3
A7 Quality Objectives and Criteria for Measurement Data	1,2,3 (see DQO requirements in Table 1)
A8 Special Training Requirements/Certification	1 and 2 3 – 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, and 3*
B2 Sampling Methods Requirements	1,2, and 3*
B3 Sampling Handling and Custody Requirements	1,2, and 3*
B4 Analytical Methods Requirements	1,2, and 3*
B5 Quality Control Requirements	1,2, and 3*
B6 Instrument/Equipment Testing, Inspection, Maintenance Requirements	1,2, and 3*
B7 Instrument Calibration and Frequency	1,2, and 3*
B8 Inspection/Acceptance Requirements for Supplies and Consumables	1
B9 Data Acquisition Requirements for Non-direct Measurements	1,2 and 3 as applicable
B10 Data Management	1
C1 Assessments and Response Actions	1 (2 as required by the QAM or program)
C2 Reports to Management	1 (2 as required by the QAM or program)
D1 Data Review, Validation and Verification Requirements	1 (2 as required by the QAM or program)
D2 Validation and Verification Methods	1,2, and 3
D3 Reconciliation and User Requirements	1,2

Table 2 QAPP Elements and Class Applicability

***Internal Class 3 QAPPs will reference DHEC Bureau of Environmental Health Services Field Quality Plan 2017 or Division/Bureau Field Sampling and Analysis SOPs plus the appropriate DHEC BEHS Laboratory 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."**

Chapter 3 – QAPP Preparation

3.1 Section A Project Management

A1 Title and Approval Sheet

The purpose of the approval sheet 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. At a minimum approving parties consist of: the project manager, the investigative organization's QA manager, the laboratory director, the QAM, and/or the QAM's designee. If EPA approval is required they may sign in addition to the QAM or in lieu of the QAM. Other parties which may sign the QAPP could include contractors and stakeholders.

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 in the document control format. For example:

Project No. or Name Revision No. Revision Date Document Control # Page___ of ____

Bowman Cement QAPP Revision No. 1 Revised 12/31/2013 Document Control # 22 Page 3 of 56

Figure 2 Document Control Examples

A revision number must always be included. If this is the original, approved version, the revision number is "0". **(Revision numbers do not change during the QAPP approval process.)** Subsequent revisions should be assigned new revision numbers (such as 1.0, 1.1, 2.0, etc). All revisions must include the date of the revision. Document titles may be abbreviated. Document control should be applied to the QAPP beginning on the Title and Approval Page, and include the Table of Contents and all figures, tables, and diagrams.

In the example above there is a document control number. This is optional. 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 copies 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 distribution list with document control numbers.

QAPP Recipients	Title	Organization	Telephone Number	Fax Number	E-mail Address	Document Control Number
Joe Brown	Project Manager	L&WM	803-898-5555	803-898-7777	Brownje@dhec.sc.gov	1 of 25
Michelle Amos	Lab Director	ACME Labs	803-555-6111	803-555-6566	M.Amos@acme.net	2 of 25
Elise Macon	Project Validator	L&WM	803-898-4444	803-898-5555	maconee@dhec.sc.gov	3 of 25
Jay Ellis	Project Verifier	ACME Labs	803-555-6565	803-555-6566	J.Ellis@acme.net	4 of 25
Denise Free	Area Director	DHEC Pee Dee EA Area	843-321-1222	843-321-2341	Freeda@dhec.sc.gov	5 of 25

Table 3 Distribution List

A copy of the approved QAPP must be sent the DHEC EA Area Director, the laboratory(s) to be used 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 (verifier and validator), statistician, risk assessor, assessment personnel, EPA project officer and the QAM. For internal plans, it may only be necessary to include the EA area/program the person is in, phone number, fax number and e-mail 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. This is also the reason the signature of the Laboratory Manager is a requirement for the approval page.

A4 Project/Task Organization

1. Identify the individual who is responsible for maintaining the QAPP. This person would distribute the original QAPP, prepare any updates, and redistribute the QAPP as necessary.
2. Identify each laboratory that will be used, the parameters that laboratory will analyze, and the laboratory's certification number. (All laboratories must be SC certified with the exceptions discussed in the EA QMP or when certification does not exist).
3. Identify key individuals involved in all the major aspects of the project and discuss each person's responsibilities. This list should include contractors, labs, the project data verifier, the project data validator, principle data users, and decision makers.
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. It is not necessarily a chain of command. See the example Organization Chart below. This may be omitted if the project is a Class 3.

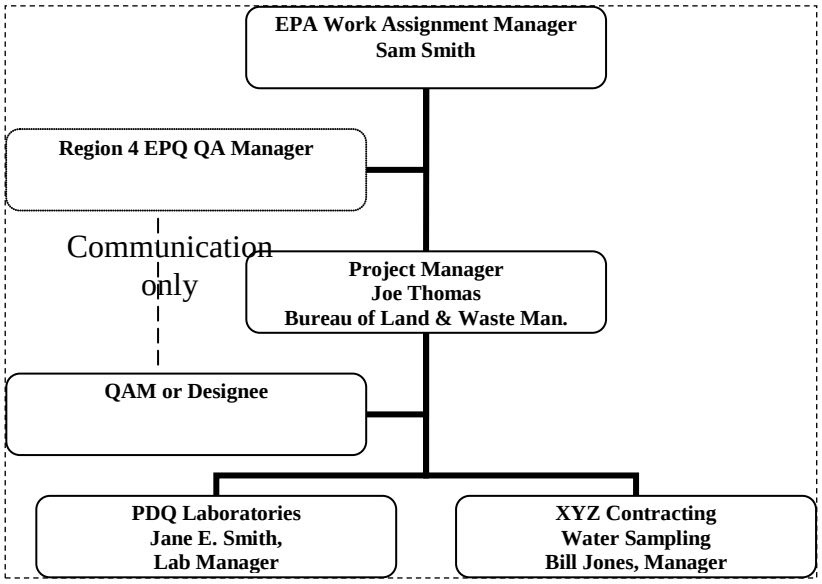

Figure 3 Example Organization Chart

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.

This section 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

understand 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 concerning 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 that 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).

A6 Project/Task Description and Schedule

The requirements for this section include:

- Summarizing the work to be performed, for example what measurements are to be made both in the field and in the laboratory and include information concerning any data files which will be produced.
- Providing work schedules including start and completion dates. Any other critical dates also may be included for activities such as sampling, analysis, data, or file review. This can be presented in a table if desired (See Table 4). Critical dates must include the start of sampling and analysis, any expected assessments by the project manager, the approximate dates verification will begin, the approximate date (this should be after all samples are collected and analyzed) that validation will begin, and the approximate date reports (including final reports) will be produced.
- Detailing geographical locations to be studied. Maps should be included when possible.
- 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)*	◆ Start Date from QAPP Approval	Anticipated Date(s)of Completion
QAPP Approval	BAQ/DAQA	10/1/14	0	10/31/14
Sampling Begins	DAQA	11/1/14	+30 days	7/1/2015
Laboratory Report Received	DAQA	Quarterly beginning 4/30/15	Every 90 days beginning at +120 days	Final laboratory report 7/30/16
Project Verification	DAQA	10/1/15	+ 1year	10/31/16
External Validation	EPA	12/1/15	+ 1yr and 60 days	2/1/16
Final Report Due	DAQA	3/1/16	+1 year and 180 days	4/30/2016

Table 4 Project Schedule

*Alternatively these can be related to QAPP approval—see the column marked with ◆ as an example.

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

The requirements for this section include:

1. The DQO process (Class 1), flexible DQOs (Class 2), or the goal of the project (Class 3). As part of the DQO process a discussion of the following DQIs (Data Quality Indicators) are required: precision, bias/accuracy, comparability, representativeness, completeness and method sensitivity is required.
2. List of the performance/measure criteria for all information to be collected and the acceptance criteria for all information obtained from previous studies including project action limits, laboratory detection limits/reporting limits, and the range of anticipated concentrations of each parameter of interest.

See Appendix C for a discussion of the DQIs.

Item 1: A formal DQO process must be included for a full QAPP (Class 1). For a Class 2 QAPP, this process can be abbreviated by omitting not applicable items, but the reason for the omission must be stated. For instance, many Class 2 studies will be investigative in nature such as a survey type project; therefore a decision statement may not be necessary. Below are the 7 Steps of the DQO process and what is expected for each step:

The DQO Process

1. **State the problem:** This is a short statement of what was discussed in the background section. If this has been previously stated, section and page number may be referenced instead of repeating what has previously been said.

2. **Identify the decision:** What decision will be made from the data obtained? In the case of a true investigative study, it is possible that this will not be applicable. A situation in which an investigative study will lead to a decision is when the study will determine what is in the environment but the results could lead to another study, more sampling, or remediation.

3. **Identify inputs to the decision:** What data will you need to make the decision or carry out the study? What regulations or standards would data be compared to? Data to be addressed includes laboratory and field analyses, data from other sources, previous studies, etc. It could also include interviews with stakeholders and other parties. If this is just laboratory data then state: inputs will be those laboratory parameters listed in Section B4 of the QAPP.

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 developed, this would include the well depth. If no height or depth is included, then just reference the geographical area listed in Section A6 of the QAPP.

5. **Develop an analytic approach and a decision rule:** Identify parameters and the population of interest (sample to sample comparison, the mean, historical data, background concentrations, risk assessments) that will allow the decision from step 2 to be made. State the decision rule(s). The decision rule is usually given as cause and effect, in an "If-then

format". If such a condition "x" exists, then the decision will be "y". The sampling and analytical approach should be able to support the potential site decisions.

Note: This step may or may not be applicable for investigative studies.

6. **Specify limits on decision error:** There are two possibilities with every study, the resulting conclusions are either correct, or they are not. This step in the DQO process should identify the types of error that would contribute to the total study error. In this step, the writer should identify the situations that will cause error and 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. The discussion should include how such DQIs will be calculated. This section must include a discussion of all of the following DQIs: **precision, accuracy/bias, comparability, completeness, representativeness**, **method sensitivity**, plus items such as a discussion of sampling situations which would cause error. The DQIs most important to the project must be specified. If one DQI is believed to be non-applicable then the QAPP must state this along with the reason. An example of a non-applicable DQI would be precision for a microbiological study. Bacterial analysis does not lend itself to precision measurements because of the nature of how bacteria grow in the environment. It is impossible to produce a sample in which bacteria are evenly dispersed. See Appendix C for more information about DQIs.

7. **Optimize the design for obtaining the data:** If unlimited samples could be collected for unlimited laboratory analysis, certainly a site would be well characterized. Of course this is not possible because 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 it is necessary 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).

Item 2: In this item, the QAPP requires that all performance criteria be listed. This includes precision, limits of detection/reporting limits, and accuracy/bias criteria. Usually these are obtained from the laboratory. If the limits of detection/reporting limits the laboratory has documented in the SOP are adequate for the project, then this section can reference the attached SOPs. However, there are times when increased sensitivity is required and this informs the laboratory what is expected in terms of QC and limits of detection/reporting limit. This is why it is essential for the laboratory to receive a copy of the QAPP. (In the QAPP, Section B5 will include a discussion of the frequency of each type of QC activity, what corrective action will be performed if the performance criteria are 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. As stated in Section B,

Laboratory and Sampling SOPs are either attached or incorporated in the QAPP. Some portions of the DQI discussion can be documented in a table format (see Table 5 below). In the case of a Programmatic QAPP, the table like the one below should be used due to the number of people involved and the complexity of the QAPP. Ideally the SOPs should be included in the appendix or attached to the QAPP, but an internal DHEC QAPP can reference the applicable SOPs. **References must include the name of the SOP, page number, and section number where the information is found.**

Parameter: Semi-volatiles			
DQI	**QC Item**	**Acceptance Criteria**	**Comments**
Precision-field	Field Duplicates	RPD ≤ 30%	
Precision Laboratory	Laboratory Duplicates	RPD ≤ 20%	
Accuracy	Surrogate Spikes	± 10% of true value	
Accuracy	Calibration Check	± 15% of true value	The Laboratory SOP specifies ±20%
Sensitivity	± 10% recovery at Practical Quantitation Limit (PQL)	Laboratory fortified blank at PQL	The Laboratory SOP specifies ±20%

Table 5 QC Criteria

A8 Training and Certification

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

***Note: For QAPPs going to the EPA, proof of laboratory certification must be provided. (a copy of the Laboratory's Certificate or a letter of certification from EPA) for each laboratory to be used. This can be put in an appendix to the QAPP.**

The purpose of this element is to ensure 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 (such as filtering samples in the field), 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 DHEC 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 will be generated is important for the Project Manager, who may require 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 will know what is required for submittal.

This section must:

1. Provide 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. Provide 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. This should include how the project will compile information from the laboratory.
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 (electronically, CD/DVD, hardcopy-postal service, etc). The response should also include a statement about updating the QAPP when there is a revision. This can be accomplished by stating that the person in charge of updating the QAPP will do so and submit it to the QAM for approval. Once the QAPP is approved, the updated QAPP is sent to all on the distribution list.

Things to consider: Does the entire QAPP need to be sent out? In cases where major changes are ubiquitous throughout the document and the document is in hardcopy format, the answer is yes. If the changes only involve a few pages, these pages may be sent out with directions of which pages must be removed from the QAPP and which pages to insert. If the document is in electronic format the entire document should be sent. In either case, the revision history (See Section 3.5, Table 24) must list all changes that were made to the QAPP.

Item 2: What will be in the Data Report Package? The second item dictates what information the laboratory/contractors are to submit in their data report and how it will be submitted. 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 data report. This might include just the final results with the quality control or the report package might also include the raw data. In addition, this list of items in the data report package may be documented by parameter and/or method. When possible, field and laboratory data reports should be integrated to provide a continuous reporting track. However, the chain-of-custody form must incorporate 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 form. Keep in mind also what will be needed for data verification and validation when considering what must be submitted.

Note: CLP Samples for CERCLA will be validated by EPA. Only the data will be provided by the contracting laboratory in their report to their client.

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 as well as the expense of the reporting package. Below is an example of a list of items required by a QAPP to be included in the data report package. This is an example and does not include all items that are typically requested.

Item	Parameter	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, Metals	ICP, ICP-MS, GCMS	Hardcopy, 10% of samples submitted
Calibration verification	Metals, pH, Conductivity	Hydrolab	Hardcopy and Electronic, 10% of samples submitted
Continuing Calibration	VOCs	GCMS	Hardcopy, 10% of samples submitted
Raw data-peak areas and instrument calculations.	VOCs	GCMS	Hardcopy, 10% of samples submitted.
Final Data-tables with all calculated parameters for each sample.	VOCs, Cr, Pb	Various	Electronic (Excel Spreadsheet) and Hardcopy
QA/QC Data	All	All	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
Instrument Raw Data	Cr, Pb	ICP	Hardcopy and Electronic, 10% of all samples submitted

Table 6 Data Report Package Example

See the list under Item 3 (below) for records to consider for inclusion and Table 6 for an example of data report package requirements. This is just an example; however, additional records may 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, exception reports, QA/QC reports, Internal Audit reports, etc may be produced by the study. All records generated in the study should be listed for this item. Enlist the help of the laboratory and any contractors that provide sampling and field analyses for the project to 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 these 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 information can be documented on the chain-of-custody. Some sample collectors use bound field notebooks and are generally used to record raw data and make references to prescribed procedures and changes in planned activities. The field notebook should be formatted to include pre-numbered pages with date and signature lines.

- *Chain-of-custody record:* A Chain-of-custody record is a legal record that documents the custody of the sample from collection to analysis. The chain-of-custody record documents the collection of the samples and the progression of samples as they are transferred from the original sampling location to the laboratory performing the analysis and include information such as the sample collector, field analysis results, date and time of collection, preservation, date and time of receipt by the laboratory, and temperature at the time of receipt by the laboratory.

- *QC sample records:* These records document the generation of QC samples, such as field, trip, and equipment blanks and duplicate samples. They also include documentation on sample integrity and preservation, and may also include calibration and standards' traceability documentation related to the field measurements. Quality control sample records should contain information on the frequency, conditions, concentrations of calibration standards, and instrument calibration history.

- *General field procedures:* General field procedures record the techniques used to collect data, and outline potential areas of difficulty in gathering samples/specimens. For EA these procedures are in the *Bureau of Environmental Health Services Field Quality Plan 2017* or in individual Bureau SOPs.

- *Corrective action reports:* Corrective action reports document 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 field 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 dates and times that samples were analyzed to verify that they met the prescribed holding times. Included should be the overall number of samples, sample location information, any deviations from the SOPs, the sample results, and the date and time of analysis. 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/Certificate of Analysis:* This is the formal report from the laboratory which includes the final sample results, the assigned sample ID number, the date/time of collection and analysis, analyst's initials, reporting limit, dilutions, analytical method employed, and may include a copy of the chain-of-custody.

Test Method Records

Analyses must be performed exactly as documented 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 (laboratory control sample, matrix spike, matrix spike duplicate, and surrogates as they are required by the methodology and SOPs), initial and continuing calibration standards, sample duplicates, and other pertinent QC required by the laboratory's SOP.

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 contamination issues, 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 laboratories also use checklists to ensure that the data was reviewed by analyst and verifier.

Item 4: The archiving and disposal of the records must be documented. How long will the records be kept (this includes both electronic and hardcopy formats)? Where will the records be kept? For the laboratory, the laboratory'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 performed in tabular format as seen in Table 7. This is just an example, and this table does not include all records that will be produced. It must also be noted that the record retention time, or the time after which records can be destroyed, may be dictated for many programs by State or Federal regulations.

Record	Produced by	Hardcopy/Electronic	Storage Location/Time	Archival	Disposal (Time)
Chain-of-Custody	Field/Laboratory	Hardcopy	Laboratory-Filed in Laboratory 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 Laboratory until filled	Archived when notebook is filled.	8 years, then destroyed.
VOC Analysis Records	Laboratory	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 Laboratory. 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

3.2 Section B Measurement/Data Acquisition

The purpose of this group 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 group 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 also 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, 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, etc.
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. Include field parameters. Include how samples will be delivered to the laboratory.
- The schedule of phases of sequential sampling or testing (if applicable).
- The schedule of test or trial runs (such as a shakedown test).
- The schedule for peer review activities.

If these have already been covered in Section A6, simply reference that section.

Item 2: The description and justification for the 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 this is the only rationale available during QAPP development, and in this case, the rationale can fulfill this requirement of the QAPP. The process for determining sampling sites or schedule must be included in the QAPP. For example:

The existence of private wells in the study area will be determined by a house to house survey and each discovered well location will be established by GPS. Each well found during the survey will be sampled. In this case, the QAPP did not give actual locations, but provided the logic used

to determine sampling locations.

Item 3: Specify the type and total number of samples expected or needed. For larger projects this can be documented using 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 with 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 also applies to the collection of a field duplicate. Is it collected as one large sample and split, or is it collected in two bottles at the same time?

Sample Location and ID	Matrix to be collected	Depth	Parameter	Number of samples (include and identify duplicates)	Rationale For Sampling Locations
MW-1 GPS coordinates W 34 07.252 N 081 14.622	Groundwater	20-30 Ft	VOAs SVOCs Metals	1 1 1/1 field dup	Background
SQ-7	Ambient Water	1 Foot	Metals	1	

Table 8 Sampling Design

Item 4: If it is possible that a site could become inaccessible, describe what will be done. If there will always be accessibility to the site state this. Weather and flooding, an owner withdrawing permission for egress, and road repair are some of the reasons that a site becomes inaccessible.

Item 5: Specify if samples will be stored or sent immediately to the laboratory. Include how the samples will be transported to the laboratory.

Item 6: This item addresses critical data and data for informational purposes only. If a data point is critical and a sample is "lost" (breakage, invalid laboratory results) then the sample will be recollected. The QAPP must also include the percentage of data that could be missing or lost without impacting the study. Data for informational purposes only would be data from an uncertified laboratory or a non-approved method.

Item 7: Sources of variability to environmental samples are things like rainfall, well design, stream flow, etc.

B2 Sampling Methods

In this section the following points must be addressed if 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 is performed, 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.

Note: Continuous monitoring is usually for air sampling only.

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 samples must be preserved, include the preservation procedures.
8. Include whether sampling equipment and samplers should be cleaned and/or decontaminated with the procedure. If there are by-products (rinsates, for instances) discuss the disposal of the by-products.
9. Identify any equipment and support facilities needed. This may include things such as the laboratory coming to the site to pick up samples to meet hold times, Fed-Ex shipment, field analyses performed 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

Some of the above requirements 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). The table can also be sorted according to sample matrix (i.e. soil, water etc).

Table 9 is given as an example, but the required preservation, holding times, and containers may vary with each laboratory and the sampling/analysis methods they may use. Note that Table 9 must specify whether the matrix is drinking water, wastewater, ambient (e.g. streams/lakes) water, soil, or hazardous waste. This is important because the methods and preservation requirements vary depending on the regulation. Preservation requirements can be found in the 40 CFR Part 141 (SDWA), 40 CFR Part 136 (CWA), and in the SW-846 Compendium. If the regulations do not include the preservation requirements, then refer to the approved analytical method employed. Where there are no preservation and holding time requirements, state "N/A".

Wastewater Parameters	Method	Composite or Grab	Filtered, Split, or Homogenized	Volume Required, Bottle used	Preservation	Holding Time
pH	SM 4500 H^+B-2011	*In-situ*	No	50 mL Plastic	N/A	*In-situ*
E.coli MPN	SM9223B-2004	Grab	No	125 mL sterile bottle	Cool <10°C	8 hours
Lead	EPA 200.7	Grab	Yes-filtered	250 mL, plastic	Nitric acid to a pH <2	180 days
BOD	SM 5210B-2011	Composite	No	1 L plastic	Cool <6°C	48 hours

Table 9 Sampling and Preservation

Table 9 meets the requirements for items 1, 2, 5, 6, and 7 of Section B2; however, items 3, 4, 8, 9 and 10 must still be addressed. These are best addressed in discussion form. Item 10 requires that someone be responsible for performing and documenting corrective actions. This person may be specified by name or position (Field Sampling Manager, for instance).

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 sample retrieval or data collection.
2. A discussion of how samples are physically handled and transported to the laboratory. Then how the samples are received and stored in the laboratory or office (including temperature upon receipt).
3. This section details how sample information must be handled. This includes discussing field notebooks and/or forms that are used to document sample collection, sampling conditions, and/or sampling problems. This section must also include the person(s) responsible for documenting sample collection. Examples of the forms to be used for field documentation must be included in the QAPP.
4. This section must include a discussion of the system used for identifying samples. This must include the numbering or identification system that will be employed for sample identification and how the samples are labeled.
5. This Section should describe the chain-of-custody procedures followed and include the form that will be used to track custody.

Item 1: The holding times (or time from sample collection to extraction or analysis) could be documented using Table 9. If a similar table is in a previous section, a reference with the page number must be made in Section B3. For instance, “Holding times are shown in Table 5 in Section B2 on page 18”.

Item 2: How will the samples be transported from the site to the laboratory? If they have to be iced, will they be stored in coolers? Is there a temperature blank in the cooler? Will the laboratory measure temperature on receipt? Where will the samples be stored once received in the laboratory? 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 section 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 identified using the initials of the site, followed by a number, and the date. For example, a sample collected from Wateree Coal Mine would be identified as WCM01092317, WCM02092317, WCM03092317 to document that the samples are collected from Wateree Coal Mine(WCM), the first, second and third samples (01,02, and 03) taken on Sept 23, 2017 (092317). In addition to discussing how samples will be identified, specify if tags, labels, and/or barcodes will be used. Anything that is associated with sample identification must be discussed here.

Item 5: The chain-of-custody procedure will address how the custody of the sample is tracked from the field to the laboratory. The chain-of-custody form normally is provided by the laboratory and is completed in the field at the time of sample collection. A copy of the blank chain-of-custody form that will be used must be included in the QAPP. If there is a procedure/SOP for chain-of-custody, that procedure may be an attachment and referenced. If more than one laboratory is used for the project, each chain-of-custody form (and associated SOP-if applicable) that will be used must be attached.

B4 Analytical Methods

This section must:

1. Identify all analytical SOPs (field, laboratory and/or office) that should be followed for each parameter. Any options or modifications, such as sub-sampling and extraction procedures must be discussed. Include the method reference for the SOP.
2. Identify all equipment or instrumentation that is used for each parameter.
3. Specify any required method performance criteria.
4. Identify procedures for corrective action when failures occur. This must include identifying the individual responsible for performing and documenting the corrective action. It should also include procedures for removing non-functioning equipment from use.
5. Identify procedures for corrective action when failures occur. This must include identifying the individual responsible for performing and documenting the corrective action. It should also include procedures for removing non-functioning equipment from use.
6. Identify sample disposal procedures.
7. Specify the laboratory turnaround times needed.
8. Provide method validation information and SOPs for nonstandard methods.

Items 1-2: See Table 10.

Item 3: If specific method performance criteria were already discussed in A7, a reference can be made to that section (for example see Table 5). The Practical Quantitation Limit (PQL)/reporting limit must be stated for each analyte/parameter. The PQL is based on the lowest standard concentration that the laboratory uses in the calibration curve during the calibration. Some laboratories will include an MDL (method detection limit). The MDL is not as helpful in ascertaining the true sensitivity of the analysis since it is a statistical calculation. The PQL may be more useful because it demonstrates that the laboratory can indeed identify and quantify analyte at the stated concentration. See Table 10.

Parameter	Matrix	SOP ID	Method Ref	Instrument	PQL	Turnaround time
Lead (Pb)	Wastewater	Metal 200.9	EPA 200.9	Graphite Furnace	5 µg/L	2 weeks
Semi-Volatiles	Wastewater	Semivolatiles	EPA 625	GCMS	Varies; see SM-1 pg 12 Table 1	6 weeks

Table 10 Analytical Methods

Note: The DHEC Bureau of Water has developed required PQLs for NPDES compliance samples. This table is available on The Office of Environmental Laboratory Certification website.

In addition, the writer should compare the NPDES PQLs to the action or trigger limits for the study. The PQL should be lower than the action limit, and the calculated MDL must be lower than the PQL. The laboratory's MDL should be 5-10 times less than the required PQL.

For instance, a certain contaminant in the environment has an action limit (or trigger) of 10 ppb. The requested PQL must be lower than this action limit. The required PQL for this parameter is 5 ppb. The laboratory's MDL should be 0.5-1 ppb, which is 5-10 times less than the PQL.

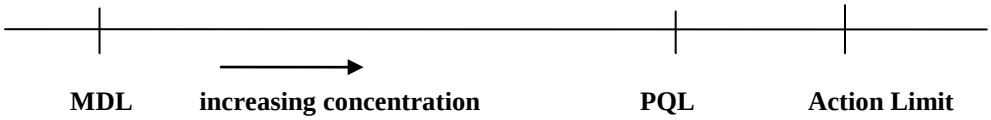

Figure 4 MDLs, PQLs, and Action Limits

Figure 4 illustrates the relationship that should exist between the MDL, PQL and action limit of a project. There are situations where sufficiently sensitive instrumentation is not available to meet the required action limit. For example, the trigger or action limit may be below the detection limit. In this case the laboratory may be instructed to report the PQL, the calculated MDL and any samples where the parameter is detected between the MDL and the PQL. The reported parameter must be flagged to indicate that it has a concentration below the PQL.

Item 4: Corrective action procedures may be addressed in an attachment such as the QA/QC Plan. If so, then the document must be identified with the pertinent section and page number. If not, then the corrective action procedure must be included to address the procedures followed when a QC or other failure occurs that prevents the reporting of data. Corrective action must address how the situation will be dealt with, who will correct the problem, who will be notified, and what documentation is required.

Item 5: This section will address how long samples will be kept once the analysis is completed, how the samples will be destroyed or disposed of, and what documentation is required pertaining to the disposal.

Item 6: This section will address sample turnaround times. The turnaround time is how long the laboratory takes to analyze the sample and report the results to the client. 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 addressed by parameter/analyte. Some analyses are more complex and may only be performed once a month, while other parameters with short holding times may be analyzed within 48 hours after collection or at the sampling site. Sample turnaround times must be worked out in advance. The project may require shorter turnaround times than the laboratory is accustomed to, so the laboratory must know in advance what is expected. 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."

Item 7: This section will address the use of non-standard methods. This covers parameters for which there is not an EPA approved method, for instance, caffeine in water. A copy of the 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 to determine if it is appropriate for the project. Thus the validation also becomes an assessment of the potential impact on the representativeness of the data generated. For example, if only qualitative data are needed from a modified method, rigorous validation may not be necessary and a screening test may be sufficient.

Validation studies may include round-robin studies performed by the 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. These documents must be available for review by the project validator. 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 analyzed, and the acceptance criteria.
2. Provide details of corrective actions when control limits are exceeded, and how effectiveness of the corrective actions will be determined and documented.
3. Identify the procedures and formulas for calculating applicable QC statistics including 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: Tables 11 and 12 give examples of QC samples that should be considered when writing this section. Table 11 gives examples of the frequency for some of the types of QC samples associated with field work, while Table 12 gives examples of QC items associated with the laboratory analyses. Please note that these are examples only. This is information that should be discussed during initial meetings with the entities who are providing sampling and analytical services. The amount of QC and the required acceptance limits should be determined by the project team prior to writing the QAPP and included in the QAPP. The laboratory will provide specifics on the frequency of internal QC checks. These QC checks are based on the approved EPA promulgated methods and applicable regulations. This table can be quite long because these QC checks will vary from method to method and may be dependent on the sample matrix and the requirements of the project. The acceptance criteria for each QC item must be listed in this

section or in Section A7. A reference must be made to Section A7 if the QC acceptance criteria are not provided in this section.

NOTE: The Project Team should determine if the QC that is proposed by field and laboratory organizations (frequency and acceptance criteria) is sufficient for the project.

Item	Frequency	Acceptance Criteria	Action if QC Fails
Field Blank	Minimum 1 per shipment for each analytical group (VOCs, metals, etc.).	Less than 10% of the PQL or LLOQ	Determine if parameters found in the field blank will impact the data.
Equipment Blank (rinsate blank)	Minimum 1 per day for each analytical group and each matrix for each sampling team.	Less than 10% of the PQL or LLOQ	Determine if parameters found in the field blank will impact the data.
VOC Trip Blank	One per trip. If multiple sampling teams are involved, then one per team.	Less than 10% of the PQL or LLOQ	Determine if parameters found in the trip blank will impact the data.
Proficiency Testing (PT) Sample	1 per calendar year for each parameter analyzed in the field for which a PT sample is available.	Acceptable results must be obtained	If a PT sample result is not acceptable, determine the cause, and institute corrective action. Obtain a new PT sample and provide documentation of corrective action to Laboratory Certification.
Field Duplicates	Minimum 5% per analytical group per matrix for each sampling team.	Within 20% RPD	Recalibrate and reanalyze if unacceptable results are obtained.

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	Acceptance Criteria/Corrective Action
Method Blank	Contamination	SOPs M-1, M-2,O-1 Section 10	< PQL/LLOQ Determine if parameters found in the field blank will impact the data.
Instrument Blank	Contamination	SOP O-2 Section 10	< PQL/LLOQ
Laboratory Duplicates	Precision	SOP M-1, M-2,O-1 Section 8	Inorganic ±20% RPD; Organics - see individual SOPs
Internal Standards	Precision , Accuracy/Bias	All Organic Standards, samples are spiked	See specific SOPs
Matrix Spike	Bias	(inorganic only) SOPs M-1, M-2,O-1 Section 8	±20% difference
PT Sample	Bias	1 per calendar year for each parameter analyzed in the field for which a PT sample is available.	Acceptable results. Unacceptable PT, determines cause, and takes corrective action. Analyze new PT and send corrective action to Laboratory Certification
Surrogate Spikes	Bias	All VOCs and Semi-volatile Organic Samples are spiked with surrogates.	See specific SOPs
Quality Control Sample	Bias	SOPs M-1, M-2,O-1 Section 8	Commercially purchased, within acceptance criteria
Laboratory Fortified Blank (LFB)	Bias and Sensitivity	SOPs M-1, M-2,O-1 Section 8	±10% difference
Instrument Performance Check	Sensitivity	SOPs M-1, M-2, O-1 Section 8	See specific SOPs
Initial Calibration Verification	Accuracy/Sensitivity	SOPs M-1, M-2,O-1 Section 8	±10% difference
Continuing Calibration or Calibration Verification Checks	Accuracy/Sensitivity	SOPs M-1, M-2,O-1 Section 8	±10% difference

Table 12 Analytical QC Samples

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
Laboratory 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	Annually per 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 13 QC and DQIs

Item 2: This section of the QAPP will document the procedures to be taken when control limits are exceeded, and how effectiveness of the corrective actions will be determined and documented. The laboratory's QA/QC Plan should address this and 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 for determination if the data is usable for the project.

Item 3: Identify the procedures and formulas for calculating the applicable QC statistics. If provided in the QAPP under DQIs, that section 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. If included in the laboratory's QA/QC Plan and/or SOPs, reference the document name, section number, and page number.

For example:

$$\%\,recovery = \frac{A}{T} \times 100\% \quad \text{and} \quad \%\,difference = \frac{A-T}{T} \times 100\%$$

Where A = the amount recovered from the analysis, and
T = the theoretical amount that should have been recovered.

B6 Instrument/Equipment Testing, Inspection, and Maintenance

1. Identify all field and laboratory equipment, required maintenance, and frequency.
2. Identify how the analyst ensures that each instrument is ready for use and is operating properly.
3. Note the availability and location of spare parts.
4. Document the procedures in place for inspecting equipment before usage.
5. Identify the individual(s) responsible for testing, inspection and maintenance.
6. Document how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented.

Item 1: All field and laboratory instruments that require any type of maintenance are listed. Identify what maintenance is needed and frequency performed. An example is given in Table 14.

Instrument	Type of Maintenance	Frequency	Parts needed/Location	Person responsible
HACH Pocket Colorimeter II	Batteries changed	As needed-minimally once per year	AA Batteries/Hall Cabinet Laboratory	Operator
DO Meter	Membrane check/Membrane changed	Daily/ 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 14 Instrument Maintenance

Item 2: What procedures are performed to ensure that the instrument is operating properly? For example, the analyst must examine the DO meter's membrane each day and change it as needed. For GCMS analysis, a daily tune check is performed to ensure that the instrument is working properly. If it does not, maintenance may need to be performed, such as cleaning the source as noted in Table 14. The maintenance procedures and frequency may be in the sampling and

laboratory SOPs, which can be referenced with the name of the SOP, section, and page number.

Item 3: Include a general statement about where spare parts are located for the laboratory and field equipment. If spare parts are located in different places for many of the items, a location can be added to the table covering instrument maintenance (see Table 13).

Item 4, 5, and 6: If there are SOPs documenting this information, provide the SOP name and page number. Otherwise, document the procedures used for inspecting the instruments as well as who will perform inspections and maintenance. Also document the process used if a deficiency is found and how the process will be documented. Table 15 gives examples of 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 analysis	Blank must be < 0.03 mg/L, Std. concentrations must be within 10% of true value	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 15 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.

The above may be presented in a table format. Examples for a field instrument and laboratory instrument are 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 – ICV*; daily Run 0, 0.5 and 1.0 Permanganate standards	ICV* (annually or with new DPD lot) 2 stds analyzed daily	Standards within 10%, except 0.05 which is 20%	Remake Stds; Clean interior; Replace scratched cells; Contact Hach	Operator	Chlorine SOP, pg 3, Calibration Section
GCMS	Tune and check BFB	Daily	BFP passes	Re-tune. Clean source See QA Manual pg 6	Analyst	BV, Section 8, Page 24
GCMS	Continuing Calibration	Daily. Full calibration every 6 months	Calibration Standards within 30%	Recalibrate See QA Manual pg 6	Analyst	BV, Section 8, Page 24

Table 16 Instrument Calibration Criteria

* ICV = annual calibration verification using 5 standards and a blank.

For the SOP reference, either the full name may be given or the SOP may be given as an abbreviation. However, all abbreviations must be defined (see Table 17). From Table 16 it is noted that the SOP is BV and Section 8, Page 24 is given. From Table 17 (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 17 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, latex should be avoided due to the association with allergies.) However, Nitrile gloves contain zinc and should not be used when zinc will be analyzed.

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 Laboratory	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 <0 ºC Organic Laboratory	Michelle Lee; Organic Analyst, Roarke Labs

Table 18 List of Consumables and Acceptance Criteria

This section must also address how these consumables are logged in for use 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. The QAPP (or a SOP) should also state that all reagents and standards are labeled with the date received and 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 any type of data needed for project implementation or decisions making that are obtained from non-measurement sources such as computer data bases, programs, literature files and historical data bases. Describe the intended use of the data. Define the acceptance criteria for the use of such data in the project and specify any limitations on the use of the data.
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;
- Existing maps, Geographical Information System (GIS) layers, plots, photographs, or land surveys; and
- 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: Where the data collected from a population that is sufficiently similar to the population of interest and the population boundaries? The population of interest could be each individual sample or the mean concentration of an analyte or compound across a given site to try and determine site conditions. This is where statistical analysis of a population of data comes into play and this population of interest should be defined in the QAPP and whether the sample design support your assessment of site conditions (or representativeness). 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 of non-direct measurements would be data collected from the same area as the planned study (this may have been from a preliminary investigation or from a completely different study). In this example, samples were collected by a different party and analyzed by a different laboratory. In either case, the project manager or designee would investigate the previous study to determine whether samples were collected and analyzed properly. The examination would also include a determination if the methodology that was used

is the same as what is used 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 laboratory was certified for the analyses it performed. 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. Describe the process for data archival and retrieval.
6. Describe procedures to demonstrate the acceptability of the hardware and software configurations.
7. Attach any checklists or forms that are concerned with the above data management items.

Item 1: This can be described 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, the mechanism for correcting error, and who is responsible for oversight and corrective action. Discuss the typical scenario of the data from the entries on the chain-of-custody to the final archive and disposal.

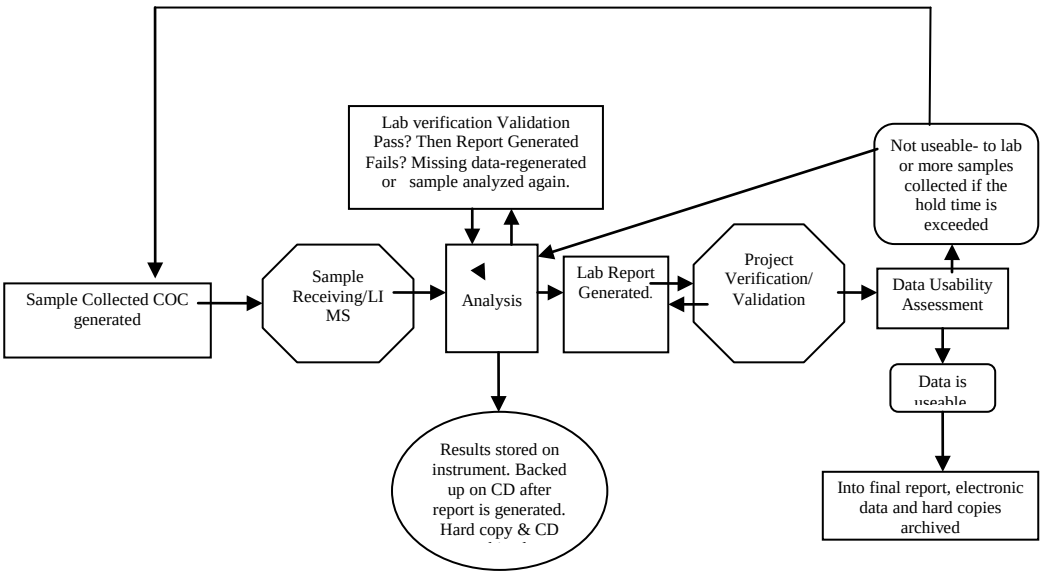

Figure 5 Example Data Management Flow Chart

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 original 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: Describe 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. Describe how they will be routinely tested and upgraded when software changes occur. When these upgrades happen, how will the project ensure that the upgraded 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 laboratory 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).

3.3 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 and frequency of assessments will depend on the intended use of the information and the confidence 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 19). Some assessments may be unannounced. A short term or research project may have few assessments and may simply be

composed of items such as a field assessment by the project manager or the yearly Proficiency Test (PT) sample, and a previous assessment (such as a Laboratory Certification Audit) listed. If no assessments are planned with a small project, then this must be stated. **Items 1-4 can be documented in tabular form if desired** (See Table 19)**.**

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.

- **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 recommends 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.

- **Off-site Laboratory TSA -** A thorough audit of an off-site laboratory, secondary laboratory or subcontracted laboratory, 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, laboratories must use the same analytical methods, and the QC items for the analysis must be the same. Split samples quantitatively assess the measurement error introduced by the organization's sample shipment and analysis system and they must be accompanied by a PT Sample to establish the acceptance criteria. Split

sample comparability criteria must be generated prior to sample collection and included 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-Laboratory 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	DHEC	Mitch Smith and Dennis Phillips , Proj Mgr	1 week before study begins	Mitch Smith and Donald Baer	Readiness Report	Dennis Phillips, Proj Mgr, and DHEC
Onsite TSA/E	Every 3 years, DW only	EPA Region 4	ABC, Upper Management	6 months	ABC, and Division Director	Response to the Audit	EPA Region 4
Onsite TSA/E	Every 3 yrs, due 8/2008	DHEC	Mitch Smith-QA Officer, Acme Labs	90 days	E. Slowinski, Acme Lab Director	Response to Audit	Susan Jackson, DHEC
Onsite TSA/I	1 is planned at approx. 6 months into the project. (7/2007)	Laboratory QA Office	Ellie Slowinski, Laboratory 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	DHEC QAM	1 month	Laboratory QA Officer, Field Manager	Memo to Project Director	DHEC QAM
ADQ/I	Monthly - beginning 2/2007	Laboratory QA Office	Ellie Slowinski, Laboratory Manager	1 week	Ellie Slowinski	Memo, plus corrected Data. Data Error Report and QA Narrative.	Mitch Smith QA Officer, Dennis Phillips, Project Manager

Table 19 Project Assessments and corrective Actions

*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. Note: In some cases EPA is the recipient.

Periodic QA Management Reports ensure that project staff is 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 19) 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.

3.4 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 from these reviews must also be defined in the QAPP. See Appendix F for EPA's Table of Qualifier Flags. This list is an example only. However, these are the flags that EPA has adopted.

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 review to determine that the samples were collected, transported, analyzed, and reported correctly. However, it is mostly a completeness check. See Table 20 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 performed by the laboratory (by the analyst and/or a QA Officer) prior to releasing the data to the client, but it is recommended that someone from the project also verify the data. It is

recommended that a checklist document the items that must be submitted to perform the verification. This checklist may include a list of the samples that were collected, the laboratory reports, the narrative report from the field and the laboratory concerning problems and quality control issues, actual raw data, etc. 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, and what QC will be performed. Table 20 gives examples of records that can be reviewed during verification. Not all of these records are submitted for verification for every project.

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
Laboratory name on the reports is the same as the Laboratory in the QAPP?
Chain-of-custody for each sample for field and Laboratory. A chain-of-custody is only needed for field analysis if the results are only documented on a chain-of-custody
Documentation of deviations from sampling methods or approved site 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 Appendix F)
Case narrative - Description of what happened to the sample from the field through the analysis in the laboratory to reporting. This may be in terms of only problems with the sample such as preservation or holding time issues.
Sample conditions upon receipt and storage records. (Examples: temperature, preservation pH issues)
Noted issues with QC
Evidence of Laboratory Certification for all parameters during the entire study. Sub-contracted Labs must also be certified. Issues with certification should be reported by the laboratory but the verifier may email labcerthelp@dhec.sc.gov to determine certification status. **Data from a non-certified Laboratory cannot be used for environmental decisions.**
Copies of internal or external assessments (Laboratory QA Office or DHEC Office of Environmental Laboratory Certification).
Copies of Laboratory notebook, records and prep sheets
Corrective Action reports
Reporting Limit standard analyzed (if required by the QAPP, SOP, and/or method)
Documentation of Corrective Action results
Documentation of method deviations for Laboratory
Instrument calibration results or reports
QC Summary report
Reporting forms, completed with actual results
Signatures for Laboratory sign-off (supervisor or Laboratory QA manager)

Table 20 Examples of Verification Records

Validation Review

Data validation is an examination of the entire data package including the raw data. Validation helps to ensure that the samples have been collected and analyzed properly according to the requirements in the QAPP. This includes a compliance check concerning preservation requirements, decontamination requirements for field sampling equipment, detection limit (sensitivity) requirements, SOP requirements, QC requirements, etc. were followed. In addition validation also includes the raw data from the instrument and a recalculation check. Validation also includes a review of the data set as a 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 validator 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

as well as other problems. Once the cause is found, data validation includes an assessment of whether the affected 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 streamline 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, the validation should not be so streamlined 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 streamlining 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.

In some cases, all the data and the raw data will be validated. This can easily be required of a simple field based project. A more difficult situation is when the data accuracy is absolutely critical for regulation development or will be used in a criminal case. This is very rare due to expense of obtaining the raw data and the time involved in a complete validation.

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 determines 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. At DHEC, the project manager is responsible for data validation or appointing staff to perform data validation. Data validation cannot be performed by the laboratory or staff producing the data.

As previously stated, validation looks at the specific samples and the entire sample set as a whole to determine if there are discrepancies, anomalies, and/or bias and if data integrity has been protected. There is also a general overview of the entire sample set to ensure that the data reflects 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 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 laboratory in 1 hour instead of the 3 hours it should have taken to reach the Columbia Laboratory. This sort of finding can be a simple mistake or it may be associated with fraud.

A validator discovers that the MDL documented in the laboratory report was 10µg/L. However he notices that the trigger or action limit in the QAPP is 5µg/L. The validator must determine if the laboratory 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.

A validator discovers in a raw data set that the identification and quantification of a target compound in a sample set was missed. The validator contacts the laboratory manager and determines that the instrument data system was not set up properly and that this target compound was not identified in each sample. The laboratory then issues an updated report for all impacted samples. The validator must also review a percentage of the new data to ensure that it is correct.

Table 21 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 specified in the QAPP and/or SOPs for the sampling site, sample frequency, sample documentation, sampling requirements (hold times, temperature on receipt), associated field and laboratory 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 in the laboratory 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 laboratory 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, and 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.
Reporting Limit information for each method/analysis	The validator would determine if the reporting limit requirement was met by the laboratory. If not, the validator would assess the impact of this on the study.
DHEC Laboratory Certification for the laboratory(ies) analyzing the samples and 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. 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 laboratory and an explanation for each.	Flags are a shorthand method of informing the data recipient that there was a problem with the sample and/or analysis. A flag may indicate a hold time exceeded, that a result was estimated, and other problems associated with the sample analysis. The validator would assess the impact of these flags.
Sample chronology (time of collection/receipt,	Will allow the validator to determine that the sample was within hold time when analyzed and to note anomalies.

QA Item	Comments/Purpose
extraction and analysis)	
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 laboratory. 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.
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 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 validator to ensure that the QC results were valid.
Calibration Data associated with each sample analysis	The validator will determine if the calibration data met the method specified criteria, was calculated properly, and analyzed at the correct frequency, as documented in either the SOP or QAPP.
Documentation of Laboratory Method/SOP Deviations	The laboratory may report this and the verifier will include it in the report. Or the verifier may 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 laboratory and/or 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.
Laboratory Assessment Reports	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 21 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 Laboratory 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/reporting limits were achieved as outlined in the QAPP and that the laboratory successfully analyzed a standard at the quantitation/reporting limit specified in the QAPP.

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

Performance Criteria: Evaluate QC data against project-specific performance criteria in the QAPP. For instance, did the laboratory fortified blanks meet the recovery criteria of ±20% as required by the QAPP?

Data Qualifiers: Determine that the data qualifier flags applied to samples in the data verification process were those specified and defined in the QAPP and that any deviations from specifications were justified. For example, if a sample result is qualified with a flag that indicates that the sample was not analyzed within the required holding time; did the QAPP specify if theses sample results were not acceptable for inclusion in the study results?

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 qualified with a flag of "M". The definition of the "M" flag (from a list that the validator supplies) reveals that the sample was used as a matrix spike and the matrix spike recovery did not meet the performance criteria of ±30% due to matrix effects. There may or may not be any corrective action, but the users are informed that the data may be erroneous because of noted matrix effects. Note: If the data is going to a CLP laboratory, all that needs to be stated in the validation section of the QAPP is that EPA will perform validation of CLP laboratory data.

D1 Data Review, Verification and Validation

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

This section is the final critical check to ensure that the data obtained will meet the requirements in Sections A and B. Prior to writing this section, a thorough review of the requirements in Section A7 and Section B should be performed.

As seen in Tables 20 and 21, many records will be reviewed to determine the quality of the data. The quality of the data is based upon concrete requirements established in Section B of the QAPP. For Section D1, a table or list will document the records that will be verified and validated with the criteria used to accept, reject or qualify (flag) the data.

Concerning sampling, the items to consider reviewing would include whether each data item met the quality objectives specified in Section B? This would include if 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 all of the QC data received or was some of it missing (verification)? Another item of importance to review would be sample holding times. For this

review, the chain-of-custody forms are needed to determine the date and time of collection and proper preservation. In addition the laboratory sample reports must be reviewed to determine the actual date and time of analysis. These reviews will allow the validation of meeting the required holding times for a specific analysis.

In Section A7 criteria is provided for acceptability based on laboratory results of the laboratory 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 qualified and define the qualifier flags in this section. Determine if the error for which the data is qualified substantially impacts the project that the data must be totally rejected 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 will be noted that the 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 20 and 21 for common verified/validated items. See Table 22 for examples of data acceptability criteria and associated flags. See Appendix F for EPA's Table of Qualifier Flags as examples. CLP laboratories are required to use these qualifiers.

Item	Criteria	If the criteria are not met is the sample flagged or rejected?	Flag (if applicable)	Comments
Holding Time Fecal Coliforms	Sample incubation must be started no later than 8 hours from time of collection.	Rejected	T-1	
Temperature upon Receipt-Fecal Coliforms	Samples must be <10ºC upon receipt at the Laboratory	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	Laboratory Fortified Blank (LFB) meets ±20% recovery	Rejected	Q-1	
LFM – VOCs	Laboratory Fortified Matrix meets ±30% recovery	The results of the sample used for the LFM is rejected	QM	
Laboratory loses their certification.	The laboratory must be certified by the DHEC Office of Environmental 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 22 Data Acceptance Criteria and Qualifier 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, sample receipt logs, calibration information, etc.
3. Identify the issue resolution process, method used, and individual responsible for conveying these results to data users.
4. Attach checklists, forms, and calculations utilized.

Note: If the data is going to a CLP laboratory, all that needs to be stated in the validation section of the QAPP is that EPA will perform validation of CLP laboratory data.

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 performed. The case narrative must include any deficiencies in field QC, laboratory QC, and procedures in the field or laboratory. Any data qualifier flags that the laboratory or verifier uses must be listed with the definition of the flag. Again verification is the check of completeness and correctness of the data.

As stated above, data 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 review of the project. A validator's job cannot be performed without knowledge of the specific project needs (the QAPP), access to all records, and the verification report. An experienced validator is required to perform an in depth review of the records. To review the laboratory records a chemist, aquatic biologist, microbiologist etc, should be used, in their area of expertise, since they are familiar with the 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 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 presented in Section B (and possibly the SOPs), and all of the data he is expected to validate.

Items 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 performed using a checklist or an SOP, with the name of the person performing the verification, and a description of the report concerning the verification process. Any software that is used (for example statistical analysis software) 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. At the end of the verification process, the verifier must provide a report to the project validator. The person validating the data must also be identified. The QAPP should include statements that the validator will review the verification report and then will review the data as a whole. This section should indicate that a validation report will be provided with a list of those to receive the report. This is especially important in large studies.

Item 3: For this requirement a plan must describe steps taken if issues arise from the validation and verification. The individual responsible for communicating these issues to the data users must be identified. For example, if the project requires that 75% of the data must be valid and this is not achieved, then the Project Manager will be responsible for contacting the data users, field sampling staff, and laboratory concerning the project extension to increase the amount of valid data.

Item 4: Checklists and forms used for verification and validation, as well as documenting the process must be attached. Any calculations and/or calculation formulas that will be used must be listed here or 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.

The purpose of this section is to identify that data which is usable and that which is not. This section formalizes the communication of this information to 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.

An example of a usability assessment would be the determination of which sample component results can be considered valid due to the contamination of the field blank from that sample collection batch. This could easily happen for a set of samples collected for volatiles in which the field blank is contaminated with methylene chloride. The raw data would have to be reviewed to determine which parameter results are impacted (false positive and false negatives) due to the presence of the contaminant in the trip blank and samples.

Items 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.

- 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 information on DQIs).

- Describe the procedure for reconciling the data to the project-specific DQOs.

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

Data Quality Indicators or DQIs will be part of the process for evaluating the usability of the data:

Precision: Assess the precision results to ensure that they meet the requirements in the QAPP. If not, identify and document how many results did not meet the requirements. 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 laboratory fortified blanks acceptable, and are blind PT or QC samples within the acceptable ranges? Document what was not within the specified 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. 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 meetings 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/Reporting Limits: The project data must meet the specified PQLs or other quantitation/reporting 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 23. **This is an**

example only. The project team works through the assessment instrument and assembles the report. The report can simply consist of each item on the assessment instrument and the team's findings for each item.

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.
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 laboratory be decertified?
SOP and Method Deviations	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 23 Example of a Usability Assessment Instrument

3.5 QAPP Updates and Revision History

If it is necessary to revise the QAPP, a revision history must be included (See Table 24). This revision history can be placed in an appendix to the QAPP.

Section/Page Changed	Change Made
A3 Page 4	Updated distribution list with new QA manager
B4 Page 24	Added method EPA 200.7

Table 24 Revision History

Appendixes

Appendix A - Acronyms/Definitions

Acronyms

ARESD	Analytical and Radiological Environmental Services Division. The main environmental laboratory in BEHS located in Northeast Columbia
BEHS	Bureau of Environmental Health Services
COC	Chain-of-custody
CWA	Clean Water Act
DHEC	South Carolina Department of Health and Environmental Control
DQA	Data Quality Assessment
DQIs	Data Quality Indicators
DQOs	Data Quality Objectives
EA	Environmental Affairs (formerly EQC)
EQC	Environmental Quality Control
EPA	U.S. Environmental Protection Agency
LOD	Limit of Detection
LFB	Laboratory Fortified Blank
LFM	Laboratory Fortified Matrix
LIMS	Laboratory Information Management System
LLOQ	Lower Limit of Quantitation
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
MDL	Method Detection Limit
MPN	Most Probable Number
MRL	Minimum Reporting Limit
MSR	Management System Review
PT	Proficiency Test/Testing
PQL	Practical Quantitation Limit, same as reporting limit
QAM	Quality Assurance Manager
SDWA	Safe Drinking Water Act
SOPs	Standard Operating Procedures
TIC	Tentatively Identified Compounds
TSA	Technical System Audit

Glossary of Quality Assurance and Related Terms from EPA Guidance for Quality Assurance Project Plans EPA QA/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 QAPP or regulatory requirements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

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

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 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 within the sample matrix. For instance, pH analysis when a probe is lowered into the effluent stream.

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.

Lower Limit of Quantitation (LLOQ) — 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. This is often the lowest standard of the calibration curve. See PQL.

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, 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.

Practical Quantitation Limit – 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. This is often the lowest standard of the calibration curve. See PQL.

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

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

Verification — the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual specifications. See also Section D.

Appendix B - EPA and DHEC Policy

EPA/DHEC 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 (DHEC) programs shall be implemented in accordance with a DHEC approved QAPP developed from a systematic planning process based on the "graded approach." **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.**

DHEC 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 QAPP is necessary and should be completed in accordance with the guidance documents and the Agency's Quality Management Plan (QMP)."

- Any laboratory producing data for a Program's direct utilization must have Standard Operating Procedures in accordance with approved 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 DHEC 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 laboratory must ensure the approved certification status of the subcontracted laboratory. 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/DHEC. 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 DHEC 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 DHEC office and available for referencing as needed.

Responsibilities

QAPPs may be prepared by DHEC 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-DHEC organizations must be approved by DHEC 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 (laboratory, sampling group, statisticians, etc.) and the QAM or designee 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 Quality Assurance Manager (QAM) 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 the QAPP are being resolved. The QAM or designee 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 DHEC and distributed to all participants in the project (see A3-Distribution List).**

If it is necessary to revise the QAPP, a revision history must be included in tabular form. See Section 3.5, Table 24.

Appendix C 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 intra-laboratory (within a laboratory) or interlaboratory (between laboratories) precision. Intra-laboratory 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. Intra-laboratory precision is more commonly reported; however, where available, both intra-laboratory 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, intra-laboratory 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 affect 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.

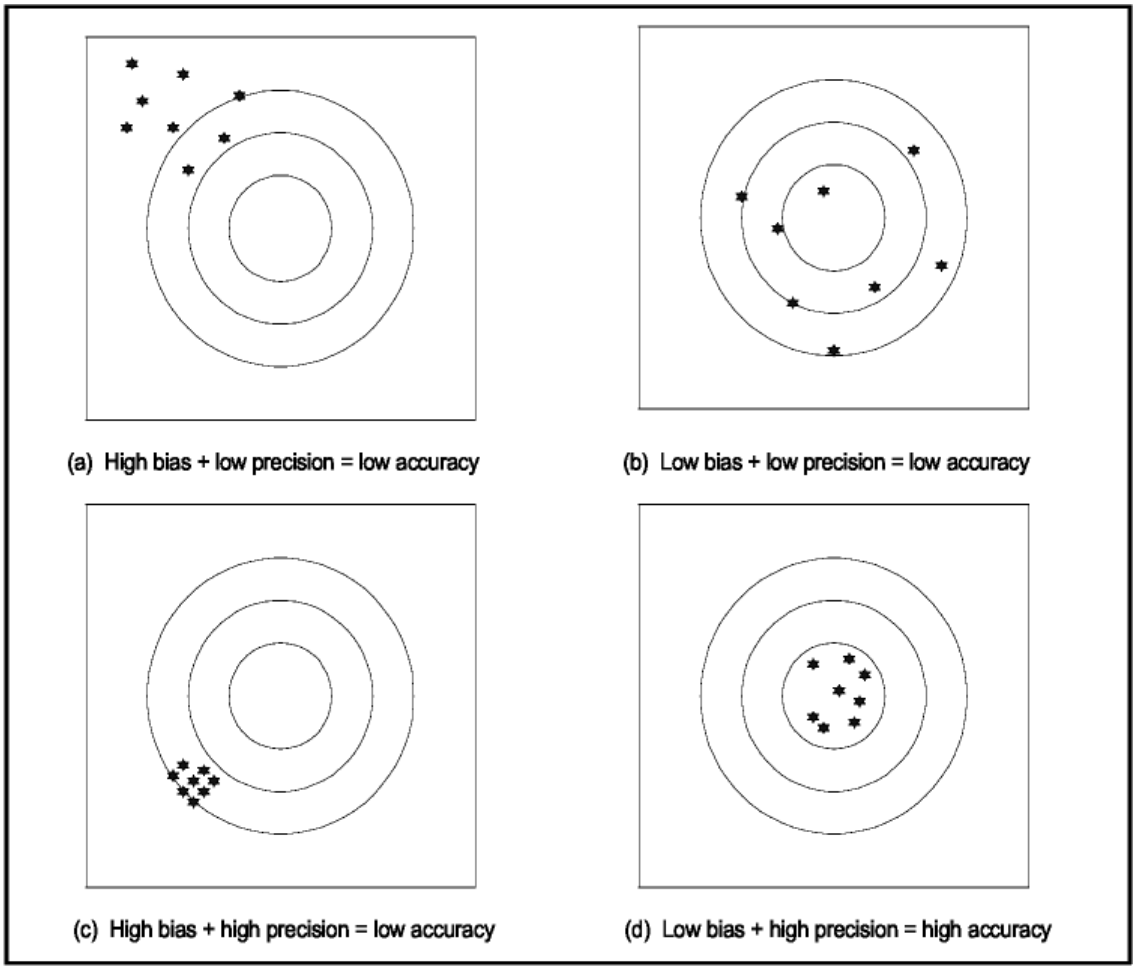

Figure AD1. Measurement Bias and Random Measurement Uncertainties: Shots at a Target

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, ppb	**Completeness**	**Outcome**
1	1.5 ppb ± 0.28	97%	Satisfies DQOs and study purpose
2	500 ppb ± 0.28	87%	Satisfies DQOs and study purpose
3	1.5 ppb ± 0.60	93%	Does not satisfy either
4	500 ppb ± 0.60	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 D - Preliminary Sampling Form

Request for Preliminary Sampling for QAPP Development

This form is to request sampling prior to QAPP approval 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 QAM or a new request is submitted.

Person making the request_____ Area/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 laboratory will perform the analysis?
Parameter _____Laboratory_____
Parameter _____Laboratory_____
Parameter _____Laboratory_____
Parameter _____Laboratory_____

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:

Area Director: _____Date:_____

Watershed Manager: _____Date: _____

QAM: _____Date: _____

Appendix E - QAPP Matrix – Internal DHEC 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 3 from an internal Class 2.

As it can be from the table, a project using 8 parameters and lasting for 6 months will fall under the Class 3 project, while a project with 11 parameters for 6 months will require a Class 2 QAPP.

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

Appendix F – EPA Example Qualifier Flags

Below are the data flags currently used by EPA.

* *Qualifiers in **blue** and flagged with an asterisk are Retained Qualifiers and will become your analytical result if used.*

A	The analyte was analyzed in replicate. Reported value is an average value of the replicates.
B-1	Analyte is found in the associated blank as well as in the sample (CLP B-flag).
B-2	Reporting level elevated due to trace amounts of analyte present in the method blank.
B-3	Level in blank does not impact data quality
B-4	Level in blank impacts MRLs.
B-5	Qualitative evidence of contamination in the blank at a concentration less than the MDL.
C-2	Improper sample container used
C-6	Sample aliquot taken from VOA vial with headspace (air bubble greater than 5-6 mm diameter).
C-7	Sample container leaked during transport.
C-8	Coring device sampler received by the laboratory unlocked
CL-1	BOD result estimated - Sample exhibited evidence of toxicity
CL-2	DOC result higher than TOC result
CLP01	Concentration reported is less than the lowest standard on calibration curve
CLP02	Concentration reported is greater than the highest standard on calibration curve
CLP03	Baseline instability in calibration or preparation blanks
CLP04	Analyte reported as potential false positive (% RSD > 20%, and result > MDL, but < CRQL)
CLP05	CLP ICP-MS method does not include: Al, Ca, Fe, Mg, K, & Na
CLP09	MRL elevated due to baseline instability.
CLP10	2,3,7,8-TCDF confirmed by second column.
CLP11	Storage blank contaminant
CLP12	Difference between GC columns above method warning limit
CLP13	Difference between GC columns above method action limit
CLP14	The analysis did not indicate the presence of the analyte. The data is rejected and the reported value is the Reporting Limit. Resampling and reanalysis are necessary to confirm or deny the presence of the analyte.
CLP15	TIC Results Reported as Identified by Lab - IDs Not Verified
CLP16	Initial Calibration Response Erratic
CLP17	Initial Calibration Relative Response Outside Method Control Limits
CLP18	Estimated Maximum Possible Concentration (EMPC) Reported
CLP20	Matrix Spike Recovery < 30%
CLP21	%RSD >20% for ICP Multiple Exposures
CLP22	Suspected interference from Al and/or Fe as noted in contractor ICSA solution
CLP23	Suspected over correction from Al and/or Fe as noted in contractor ICSA solution

CLP24	Result has not been confirmed by second column analysis.
CLP25	PE sample recovery scored as warning-low.
CLP26	PE sample recovery scored as warning-high.
CLP27	PE sample recovery scored as action low.
CLP28	PE sample recovery scored as action high.
CLP29	Matrix Spike recovery greater than 125%.
CLP30	Stage 4 validation consisting of electronic and manual review was performed for this data.
CLP31	Stage 4 validation consisting of full manual review was performed for this data.
CLP32	Continuing Calibration Relative Response Outside Method Control Limits
CLP33	Poor Chromatography - Split Peaks and/or Poor Peak Shape Present
CLP34	Percent recovery for the Post Digestion Spike was below the lower acceptance limit.
CLP35	Percent recovery for the Post Digestion Spike was above the upper acceptance limit.
CLP36	Identification/Concentration of analyte not confirmed by ICP-MS.
CLP37	ICP/MS tune not performed.
CLP38	ICP/MS tune not within required limits.
CLP39	Matrix Spike Recovery < 50%
CLP40	Samples received by laboratory above 6 C.
CLP41	Since 2,3,7,8-TCDD and 1,2,3,7,8-PeCDD both have Toxicity Equivalent Factors of 1.0 as assigned by the WHO, the R qualifier assigned to these two congeners following data validation were carried through to the TEQ calculated value at any concentration.
CLP42	Sample results are estimated "J" or "UJ" due to percent moisture content between 70%-89%, or sample results Rejected "R" due to moisture content greater than or equal to 90%.
CLP43	Per EPA Decision; Data is of unknown quality. Do Not Use.
CR	[Custom Value]
D-1	The analyte is determined to be present. The presence of the analyte was confirmed by GC/MS.
D-2	Due to Matrix Interference, the sample cannot be accurately quantified. The reported result is estimated.
D-3	Sample diluted due to the presence of high levels of non-target analytes resulting in elevated reporting limits.
D-4	MRL elevated due to interferences.
D-5	Estimated quantitation for one or more individual constituents comprising >10% of the total.
D-6	Presence of analyte confirmed by ICP-MS.
*EA-1	Skewness - [Custom Value] Right Skewed
*EA-2	Skewness - [Custom Value] Left Skewed
*EA-3	Kurtosis - [Custom Value] Mesokurtic
*EA-4	Kurtosis - [Custom Value] Leptokurtic
*EA-5	Kurtosis - [Custom Value] Platykurtic
*EA-6	Nitrogen
*EA-7	Phosphorus

*EA-8	Nitrogen + Phosphorus co-limited
*EA-9	Not Determined
*EA-A	Absent
*EA-P	Present
F-2	No flash detected up to 60°C (140°F).
H-1	Recommended holding time exceeded
H-2	PT or QC sample. Holding time met when calculated from preparation or analysis.
H-4	Holding time expired prior to receipt by laboratory.
H-5	ASB-defined holding time exceeded.
H-6	Sample originally analyzed within holding time; some QC requirements not met. The reported result is from a second analysis performed for confirmation which occurred after the holding time expired.
H-7	Recommended preparation holding time exceeded
H-8	Recommended analytical holding time exceeded
I-5	Mixture of Aroclors in sample; predominant Aroclors reported
J	The identification of the analyte is acceptable; the reported value is an estimate.
K	The identification of the analyte is acceptable; 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; the reported value may be biased low. The actual value is expected to be greater than the reported value.
MDL-U	The analyte was not detected at or above the method detection limit.
MRL-1	MRL verification for Potable Water matrix (Drinking Water)
MRL-2	MRL verification for Non-Potable Water matrix
MRL-3	MRL verification for Soil matrix
MRL-4	MRL verification for Tissue matrix
MRL-5	MRL verification for Air matrix
MRL-6	MRL verification for Waste matrix
MRL-7	MRL Verification for other matrices (bottle blanks, etc)
MRL-8	MRL verification result less than the LOD.
MRL-9	MRL verification for TCLP matrix
N	There is presumptive evidence that the analyte is present; the analyte is reported as a tentative identification.
NA	Not Analyzed.
NA-1	Not Analyzed. Sample lost during preparation or analysis.
NA-2	Not Analyzed. Canister received at 760mm pressure.
NA-3	Not Analyzed. Insufficient sample received for analysis.
NA-4	Not Analyzed or Reported due to Interferences.
NA-5	Not Analyzed. Cannot exceed TCLP regulatory levels based on Total Scan analyses.
NA-6	Not Analyzed. Sample did not flash. Percent Water and Percent Alcohol determinations not required.

NA-7 Not Analyzed. Sample is not aqueous. Percent Alcohol determination not required.

NA-8 Not Analyzed. Placeholder sample for DOC or other QC.

NA-9 Not Analyzed. No sample container received.

NA-10 Not Analyzed. Sample container broken when received.

NA-11 Not Analyzed. Sample container broken in laboratory.

NA-12 Sample has no measureable alkalinity. Original sample pH is less than 4.5.

NA-13 Not Analyzed. Screening indicates no possibility for a reportable acidity value.

NJ Presumptive evidence that analyte is present; reported as a tentative identification with an estimated value.

P-2 Sample at improper pH

P-3 Sample received unpreserved

P-4 Sample received at pH > 2.

P-5 Sample received at pH < 12.

P-6 Incorrect reagent or technique used to preserve sample.

P-7 Sample received at pH above preservation requirements.

P-8 Sample received at pH below preservation requirements.

P-9 Residual chlorine detected

Q-1 The original extraction of this sample yielded QC recoveries outside control limits. It was re-extracted after the recommended maximum holding time.

Q-2 Result greater than MDL but less than MRL.

Q-3 Instrument not calibrated for all constituents of the total concentration result.

Q-4 Greater than 40 % difference between primary and confirmatory GC columns

Q-5 Serial dilution precision outside method control limits

Q-6 Appropriate QC not prepared and/or analyzed with this sample.

QC-1 Analyte concentration low in continuing calibration verification standard

QC-2 Analyte concentration high in continuing calibration verification standard

QC-3 Analyte calibration criteria not met

QC-4 Result greater than the highest point on the calibration curve

QC-5 Calibration check standard less than method control limits.

QC-6 Calibration check standard greater than method control limits.

QI-1 Internal standard was outside of method control limits.

QI-2 Internal Standard Recovery less than 20%.

QL-1 Laboratory Control Spike Recovery less than method control limits

QL-2 Laboratory Control Spike Recovery greater than method control limits

QL-3 Laboratory Control Spike Precision outside method control limits

QL-4 Laboratory Control Sample recovery less than 10%

QM-1 Matrix Spike Recovery less than method control limits

QM-2 Matrix Spike Recovery greater than method control limits

QM-3	Matrix Spike Precision outside method control limits
QM-4	Matrix Precision outside method control limits
QM-6	Matrix Spike Recovery less than 10%
QR-1	MRL verification recovery less than lower control limits.
QR-2	MRL verification recovery greater than upper control limits.
QS-3	Surrogate recovery is lower than established control limits.
QS-4	Surrogate recovery less than 10%
QS-5	Surrogate recovery is higher than established control limits
R	The presence or absence of the analyte cannot be determined from the data due to severe quality control problems. The data are rejected and considered unusable.
SP-2	Elevated Reporting Limits due to limited sample volume.
T-0	No temperature blank present for cooler this sample was received in.
T-1	Sample received in cooler with temperature blank greater than 6 degrees C.
T-2	Sample received in cooler with temperature blank lower than recommended method limit.
T-3	Sample received unfrozen. Preservation requirement not met.
T-4	Samples received at ambient temperature.
T-5	Samples received in cooler with no temperature blank. Sample temperatures greater than 6 degrees C.
T-6	Sample storage temperature criteria not met.
TC-1	Cannot exceed TCLP regulatory levels based on Total Scan analyses
TC-6	Ambient lab temp. during TCLP dropped below method limits.
TC-7	Ambient lab temp. during TCLP exceeded method limits on the high side.
TC-8	Results for TCLP are greater than or equal to value reported. See Method 1311 Section 1.3.
U	The analyte was not detected at or above the reporting limit.
X-1	Non-target analyte
X-2	Matrix interference precludes recovery calculation
X-3	Co-eluting/interfering target analyte(s) preclude recovery calculation
X-4	Recovery not calculated due to CCV outside acceptance criteria
X-5	Spiked incorrectly.
X-6	Exclude value from QC data base. Refer to custom remark for details.
X-CH6	Sample is reducing in nature. Should not support hexavalent chromium
X-PDS	Post Digest Spike
XB-1	Carryover from high level sample
XD-1	Duplicate results less than MRL
XD-2	Duplicate results less than 5X MRL
XM-1	Sample background/spike ratio higher than method evaluation criteria
XS-1	Surrogate diluted out due to high analyte concentration
XS-2	Surrogate diluted out due to matrix interference
XS-3	Surrogate not reported due to matrix interference

Y-1	Data reported by memo
Y-2	Data should be limited to screening purposes only
*Z-01	[Custom Value]
pH-1	pH is equal to or less than reported result.
pH-13	pH is equal to or greater than reported result.

References

American Society for Quality Control. 1996. Definitions of Environmental Quality Assurance Terms. Milwaukee, WI: ASQC Press.

Gilbert, R.O. 1987. Statistical Methods for Environmental Pollution Monitoring. New York: Van Nostrand.

Ott, W.R. 1985. Environmental Statistics and Data Analysis. Boca Raton, FL: Lewis Publishers Inc.

Taylor, J.K. and T.W. Stanley. eds. 1985. Quality Assurance for Environmental Measurements. Philadelphia, PA: American Society for Testing and Materials.

Taylor, J.K. 1987. Quality Assurance of Chemical Measurements. Chelsea, MI: Lewis Publishers Inc.

U.S. Environmental Protection Agency. 1984. Chapter 5. Calculation of Precision, Bias, and Method Detection Limit for Chemical and Physical Measurements.

U.S. Environmental Protection Agency. 1994. AEERL Quality Assurance Procedures Manual for Contractors and Financial Assistance Recipients.

U.S. Environmental Protection Agency. 2002. EPA Guidance for Quality Assurance Project Plans. EPA QA/G-5, December.

U. S. Environmental Protection Agency. 2001. EPA Requirements for Quality Management Plans. EPA QA/R-2, March.

U.S. Environmental Protection Agency. 2001. EPA Requirements for Quality Assurance Project Plans. EPA QA/R-2, March.

Youden, W.J. 1967. Journal of the Association of Official Analytical Chemists. Vol. 50. p. 1007.

Revision History

Revision 2	**June 2018**
Portion Modified	**Modification**
Throughout	Took out all references to the Office of Quality Assurance. When needed, used the Quality Assurance Management Office. Changed State Quality Assurance Manager (SQAMO) to Quality Assurance Manager (QAM).
Throughout	Used both Reporting Limit (RL) and Practical Quantitation Limit (PQL) synonymously
Throughout	Changed the chapter numbers from Roman Numerals to English numerals.
Front pages	Changed the contact information and made it current
Throughout	Added the use of individual Bureau SOPs for field sampling and analysis.
Chapter 1 and 2	Moved EPA and DHEC policy information to Appendix B. Moved all QAPP Life Cycle information to Chapter 1. This removed what originally was in Chapter 2. So chapter 3 became chapter 2, etc.
Chapter 1	Chapter 1 became a frequently asked question section.
Chapter 1	Took the information about what is in the QAPP Guide and why it's important and consolidated this and put it into the Forward.
Chapter 1 and 3	Moved the information about the sections in a QAPP from Chapter 3 into Chapter 1.
Chapter 1	Added to the text of the life cycle of a QAPP that once the corrections to the QAPP are sent back to the team, the team must resubmit the corrected QAPP to the QAM/QAM designee for final approval. The designee will sign the QAPP and then the team must get the rest of the approval signatures.
Chapter 1	Updated Fig 1 Life Cycle of a QAPP
Chapter 1 Section 1.1	Changed the lead time for reviewing a QAPP from 15 to 20 days.
Chapter 1 Section 1.2	Add an Appendix Section to the QAPP organization to include a revision history and applicable SOPs.
Chapter 1 Section 1.4	Added information about the type of QAPPs.
Chapter 2 Table 1 and 2 and throughout	Removed the original Class 2 QAPP because this was essentially the same thing as a Class 1 (full QAPP). The original Class 3 QAPP became a Class 2 and the Original Class 4 QAPP became a Class 3. Removed all reference to a Class 4 QAPP.
Chapter 2	(formerly chapter 3) Became The Graded Approach in the Development of QAPPs
Chapter 2	Because of the preparation of separate Bureau Field SOP an addition was made that a Class 3 QAPP will reference either the EQC Field SOP or the Division/Bureau Field Sampling and Analysis SOPs.

Chapter 3	Became QAPP Preparation due to the removal of the information from the original chapter 2.
Throughout	Added numbered sections, for instance Section A in Chapter 3 is now 3.1 Section A.
Chapter 30, A3	Added an example validator and 2 verifiers to the distribution list example to make a point that these positions have to be chosen and they have to be on the distribution list.
Chapter 3, A4	Required the SC Laboratory Certification number here instead of A8
Chapter 3, A6	Added information about the types of items to include for critical dates for Section A6. Included dates set up from the date the QAPP is approved in the table.
Chapter 3,A7	Made Item 1 the DQO process and added the information previously in Item 3 to Item 1 (explaining the DQO process requirements for each class of QAPP). Item 2 is now the performance criteria. Added more information to each step of the DQO process. Simplified Table 5. Added more information to Table 5. Added a statement that said a table like Table 5 should be used for a programmatic QAPP, however, for simpler projects a reference (name of the SOP, page and section) of the applicable SOP may be referenced.
Chapter 3, A8	Changed the order of item 3 and 4. Added a note that EPA wants proof of certification. The laboratory's certificate must be included in the appendix of the QAPP.
Chapter 3, A9	Clarified that if major changes were made in a QAPP and it was in hardcopy form, then the entire QAPP should be sent. If few changes and in hardcopy format then just the changed pages could be sent. An electronic copy must be sent in entirety. In either case the Revision history must be included. Removed the comment that the Project Manager can include a signature page to be signed indicating that the updated QAPP has been received by each person it was sent to. This has not been done, so the comment was removed. In Table 6 changed the word "analyte" to "parameter" <u>Note:</u> CLP Samples for CERCLA will be validated by EPA. Only the data will be provided by the contracting laboratory
Chapter 3, B1	Added that the sampling schedule must include how the samples will be taken to the laboratory. Added clarification to sample site selection using a logical approach. Stated that if the sampling schedule was in A6 to reference that section. Table 8 changed the first column header to "Sample ID and location" and included GPS coordinates under the Sample ID, replaced analytical group with "parameter", removed concentration level and sampling SOP reference. Removed the note explaining that table 8 differentiates between analytical groups and concentrations and information about the SOP references. Added information about Items 4-7.
Chapter 3, B2	Added a note that continuous monitoring is for air samples only. Added emphasis that the methodology is different for drinking water and waste

	water. Table 9 was moved from B3 to B2. Table 9 is now "Sample Handling and Preservation" instead of sampling references and sample handling requirements. Added the word "wastewater" in table 9 to the column labeled "parameter". Removed the SOP identifier and the abbreviated name from Table 9 and replaced with Parameter and Matrix. In the Table 9 column headings- Removed Depth since this is in the previous table and added composite/grab. – Removed analytical group and replaced it with Split/Filtered or homogenized
Chapter 3, B4	Clarification of why non standard methods must be validated. For Table 10 changed the column "SOP ref" to "SOP ID" and removed the column labeled revision number and date.
Chapter 3, B5	Added that the acceptance criteria for QC must be include in the QAPP.
Chapter 3, B5 Table 11 and 12	Added a new column with the acceptance criteria and corrective action.
Chapter 3, B5 Item 3	Added an example equations used for calculating QC Statistics
Chapter 3,B5	Added a table entitled DQIs and QC requirements as Table 13, therefore the original Table 13 became 14, etc.
Chapter 3, B7	Added that this section could reference the SOP as long as the reference included the name, section and page. An example was also given.
Chapter 3 Page 52	Under Examples of Validation Output added an example where the validator discovers that an instrument missed a target compound.
Chapter 3, D1	Table 19: Removed this statement from the verification process: Evidence of QAPP Approval and that all revisions were approved. This is not part of the project verifier's job. Added that the verifier and validator needed a copy of the current QAPP. Removed Sampling Plan as this is part of the QAPP. Table 20 – removed items that would not be for verification (raw data for example). Added a note stating that EPA will validate CLP data.
Chapter 3 D2	Added a note stating that EPA will validate CLP data and that is all that needs to be written in this section.
Chapter 3, D3	Gave an example of a usability assessment.
Appendixes	App B was replaced with EPA and DHEC Policies, so the original App B became C and C became D, etc. Added references for EPA documents. Appendix F was updated with a complete list of EPA Flags

Note: Formatting has been changed throughout the documents. Minor changes such as moving spacing around, grammatical corrections and re-wording for clarification have not been included in the above table of revisions.