CHAPTER ONE
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CHAPTER ONE

Project Quality Assurance and Quality Control

For a summary of changes in this version from the previously published Chapter One, please see Appendix A at the end of this document.

1.0 INTRODUCTION

The goal of this chapter is to provide an understanding of environmental data and the need for quality. EPA has developed numerous guidance documents on quality assurance. This chapter is not intended to summarize the previously developed EPA guidance. Instead, this chapter will provide familiarity with regulations and guidance relating to QA and where to find them.

Regulations promulgated under the Resource Conservation and Recovery Act (RCRA) of 1976, as amended; require the collection and use of environmental data by regulated entities. In addition, organizations often collect and use environmental data for decision making. Given the significant decisions to be made based on environmental data, it is critical that the data are of sufficient quantity and quality for their intended use and can support decision-making based on sound science.

In response to the need for quality data, it is recommended that all parties follow a structured system of data quality assurance and quality control (QA/QC). In addition, some of the RCRA regulations include specific requirements for ensuring data quality.

This chapter provides general guidance intended to ensure data are of sufficient quality for their intended use. Its intended audience is any entity, government or private party that may be collecting environmental data. It is designed to support the efforts of those responsible for preparing and reviewing project planning documents such as Quality Assurance Project Plans (QAPPs), those involved in implementing and assessing data collection and generation activities in the field or laboratory, and those who use the data for decision-making.

Due to the diversity of data collection efforts, it is not possible to provide all details necessary to meet the needs of all members of the intended audience. However, EPA has developed a variety of detailed QA guidance documents that are incorporated into this Chapter by reference. This series of quality systems documents can be accessed on the EPA's Quality web site at: http://www.epa.gov/quality. These documents describe in detail EPA policies and procedures for planning, implementing and assessing the effectiveness of quality systems.

EPA's quality system comprises three structural levels: policy, organization/program, and project. This document addresses quality at the project level of the system, including technical aspects of analytical method quality assurance (QA) and quality control (QC). Entities which desire guidance on the other two structural levels (policy and organization/program levels) can access such guidance at the aforementioned EPA quality web site.

A project's life cycle under EPA's quality system has three phases: planning, implementation, and assessment. This chapter is organized into these three phases. Additionally, Figure 1 is provided, and illustrates this process.

Additionally, this chapter contains general project QC guidance to be used with the subsequent chapters and methods in this manual. It should be noted that several methods (e.g.,

Method 8000) also contain general QC criteria and guidance that pertain to the individual methods referenced therein (e.g., Methods 8081, 8082, 8260 and 8270). Individual methods may also contain QC criteria specific only to that method. The QC criteria in the general methods take precedence over chapter QC criteria. Method-specific QC criteria take precedence over general method QC criteria.

1.1 PLANNING

Planning, the first phase of a project's life cycle, involves the development of project objectives and acceptance or performance criteria using a systematic process. Data quality objectives (DQOs) and a sampling and analysis design are established to generate data of an appropriate type, quality and quantity to meet project objectives. The final output of this phase is a planning document, such as a QAPP, and/or a sampling and analysis plan (SAP) or a waste analysis plan (WAP).

This section provides guidance on activities and concepts that EPA recommends to be used or considered during the planning phase, when appropriate to a specific project.

1.1.1 Systematic Planning

Systematic planning is a process designed to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the availability of resources to accomplish it. The ultimate goal of systematic planning is to ensure collection of the appropriate type, quantity, and quality of data to support decisions with acceptable confidence. Following is a summary of EPA's Agency-wide guidance on systematic planning. More detail can be found in the *EPA Quality Manual for Environmental Programs (CIO-2105-P-01-0).*

The systematic planning process generally involves the following elements:

- Identification and involvement of data generators and users.
- Identification of project schedule, milestones, resources (including budget), and any applicable requirements.
- Description of the project goals and objectives (i.e., what is trying to be accomplished by performing this project)
- Identification of the type (e.g., individual data points to be used to estimate risk at a site, multi-point composites to be used to evaluate the average concentration in a decision unit), quantity and quality (e.g., screening for the presence/absence of an analyte, definitive data supported by all method specific QC results) of data needed. Be specific on what kind of analytical result will be needed to make a decision, whether the collected results need to be comprehensive and meet well defined DQOs or are merely for screening purposes to make a presence/absence decision?
- Specification of acceptance or performance criteria for ensuring the data collected meets the needs of the project.
- Description of how, when, and where the data will be obtained, and identification of any constraints on data collection.

- Specification of QA and QC activities needed to assess quality performance criteria (e.g., QC samples for the field and laboratory, audits, technical assessments, performance evaluations, etc.).

- Description of how acquired data will be analyzed (i.e., field and/or laboratory), evaluated, and assessed against performance criteria. If statistical assumptions are made as part of the planning process, the assessment must discuss how the assumptions will be verified as accurate, and what actions will be taken if the statistical assumptions are not supported by the data.

Planners should also recognize that existing data (i.e., secondary data) can be useful in supporting decision making. Secondary data can provide valuable information to help design a plan for collecting new data, while also lowering the cost of future data collection efforts. However, the limitations on using any secondary data must be clearly understood and documented. For example, secondary data must be examined to ensure that their quality is acceptable for a given application. Combining secondary data with current data can be a complex operation and should be undertaken with care. Sometimes, statistical expertise is necessary to evaluate both data sets before they can be combined. If combining data sets, make sure historical data use is appropriate in type and quality to the current project.

1.1.2 DQOs

The DQO process, discussed in detail in the *Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4*, is designed to produce scientific and resource-effective data collection designs that will support decision making with a defined level of confidence.

The DQO process can be applied to any study, regardless of its size. While there is no regulatory obligation to use the DQO process, it is the recommended planning approach for most EPA data collection activities. The depth and detail of DQO development will depend on the study objectives. The DQO process is particularly applicable to a study in which multiple decisions must be reached. By using the DQO process, the planning team can clearly separate and delineate data requirements for each decision to be made or question to be answered. It consists of seven planning steps that are summarized below.

1.1.2.1 Step 1: State the Problem

The purpose of Step 1 is to clearly define the problem that has created the need for the study. In describing the problem, especially for more complex sites, it is often useful to include a conceptual site model (CSM). The CSM is a three-dimensional "picture" of site conditions at a discrete point in time that conveys what is known or suspected about the facility, including releases, release mechanisms, contaminant fate and transport, exposure pathways, potential receptors, and risks.

1.1.2.2 Step 2: Identify the Goals of the Study

The purpose of Step 2 of the DQO process is to identify the key questions that need to be answered in order to resolve the problem(s) identified in Step 1. Step 2 should also identify any actions that may be taken based on study results. The goals of the study and the alternative actions are then combined to form decision statement(s) that will resolve the problem. A decision statement defines which of the identified alternative actions will be pursued depending on the outcomes of the study.

1.1.2.3 Step 3: Identify the Information Inputs

The purpose of Step 3 of the DQO process is to identify the information needed to resolve the decision statement. This may include, but is not limited to:

- Primary data, including sampling and analysis methods
- Secondary data, including the necessary information to ensure the data is of known and documented quality (e.g., sampling and analysis methods used as well as sufficient information to evaluate the quality of the data)
- Action limits to be considered
- Background information about the site or process, including known or anticipated variability of the study parameters that may help the planning team identify critical sampling locations

1.1.2.4 Step 4: Define the Boundaries of the Study

The purpose of Step 4 of the DQO process is to define the spatial and temporal boundaries for the data collection design, including where samples will be collected. Spatial boundaries describe the physical area (i.e., horizontal and vertical boundaries) of the study. They can include geographic area or volume of material. Temporal boundaries include both the period of time the data collection effort will represent and the timeframe to which the decision will apply.

1.1.2.5 Step 5: Develop the Analytic Approach

The purpose of Step 5 of the DQO process is to consider the outputs from Steps 1-4 and develop "If…, then…else" decision rules that unambiguously state which of the alternative actions identified in Step 2 will be pursued. These if/then/else decisions should be formulated to be dependent on how the results of the study compare to an established action level.

1.1.2.6 Step 6: Specify Performance or Acceptance Criteria

The purpose of Step 6 of the DQO process is to set limits on decision errors, and to document those limits. For judgmental and random samples, Step 6 should examine consequences of making incorrect decisions, and place acceptable limits on the likelihood of making decision errors. For random samples, Step 6 should specify any statistical hypothesis to be considered and all applicable statistical tests that will be used to assess the data.

1.1.2.7 Step 7: Develop the Plan for Obtaining Data

The purpose of Step 7 of the DQO process is to develop the data collection plan that will satisfy the objectives presented in Steps 1 through 6. *RCRA Waste Sampling Draft Technical Guidance*, dated August 2002, provides guidance that may be used during sampling design development. EPA also developed a guidance document called *Guidance for Choosing a Sampling Design for Environmental Data Collection (QA/G-5S)*, to specifically provide the information needed to carry out step 7 and develop a sampling design.

The proposed plan should be the most resource-effective data collection design that meets the previously identified performance or acceptance criteria. The plan for obtaining data is documented in detail by developing a project QAPP as per *EPA Requirements for*

Quality Assurance Project Plans (QA/R-5), which presents the requirements for QAPPs, and its companion document, *EPA Guidance for Quality Assurance Project Plans (QA/G-5)*.

1.1.3 Development of QAPPs, Waste Analysis Plans (WAPs) and Sampling and Analysis Plans (SAPs)

Documentation of planning processes and outcomes are critical to the:

- effective communication of planned activities to all participants in the process,
- reconstruction of completed events, and
- reconciliation of the analytical data with the project plans.

Two types of planning documents are discussed in this section. Section 1.1.3.1 discusses QAPPs, which are a key output of the systematic planning process. Section 1.1.3.2 discusses WAPs and SAPs.

1.1.3.1 QAPPs

All environmental data collection efforts performed by or funded by EPA (e.g., through an EPA contractor) must be supported by an approved QAPP. EPA also recommends the use of QAPPs for environmental data collection efforts by other entities (e.g., by other regulated entities in compliance with the RCRA regulations). EPA has issued several documents to aid in preparing QAPPs, including the documents noted in Section 1.1.2.7. These documents provide suggestions for both EPA and non-EPA organizations on preparing, reviewing, and implementing QAPPs.

The primary purpose of the QAPP is to present the data collection activities to be implemented, including all necessary QA and QC, to ensure that all data produced are of known and documented quality, and that the data will satisfy the stated performance criteria.

QAPPs, and any accompanying WAPs or SAPs, should be accessible to all participants throughout the life of the project. They should provide understandable instructions to those who must implement the QAPP, such as the field sampling team, the analytical laboratory, modelers, and the data reviewers.

When preparing a QAPP, a graded approach should be used to determine the level of detail needed. This will ensure that the level of information presented is consistent with the intended use of the results and the degree of confidence needed in the quality of the results. The QAPP should be detailed enough to provide a clear description of every aspect of the project, from site history through assessment of the planned data collection. At a minimum, the QAPP should provide sufficient detail to demonstrate that:

- the project technical and quality objectives are identified and agreed upon;
- the intended measurements and data generation or data acquisition methods are appropriate for achieving project objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

As described in QA/R-5 and QA/G-5, the QAPP should be composed of standardized, recognizable elements covering the entire project from planning through assessment. These elements may be divided into the following four general groups:

- Project Management - The elements in this group address project organization and management; site background and history; and project objectives. These elements ensure that project goals are clearly defined, that the participants understand the goals and the approach to be used, and that the planning process is documented.

- Data Generation and Acquisition - The elements in this group address all aspects of project design and implementation, including the numbers, types, and locations of all samples to be collected; the rationale for why the proposed data collection effort will be sufficient to address the study objectives; all sampling, subsampling and analytical procedures to be followed (i.e., both sample preparation as well as determinative procedures); QC requirements for all applicable field and laboratory procedures including the data quality indicators (DQIs) discussed below in Section 1.1.4; instrument calibration and maintenance for both field and laboratory equipment; use of secondary data; and data management. Implementation of these elements ensures that appropriate methods for sampling, analysis, data handling, and QC activities are employed and properly documented.

- Assessment and Oversight - The elements in this group address the activities for assessing the effectiveness of project implementation and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is properly implemented as prescribed.

- Data Validation and Usability - The elements in this group address the QA activities that occur after data collection or generation is completed. These elements address how data will be reviewed, verified and validated as well as how data will be assessed and reconciled with the project objectives.

While most QAPPs will describe project- or task- specific activities, there may be occasions when a *generic* QAPP may be more appropriate. A generic QAPP addresses the general, common activities of a program that are to be conducted at multiple locations or over a long period of time. For example, a generic QAPP may be useful for a large monitoring program that uses the same methodology at different locations. A generic QAPP describes, in a single document, the information that is not site or time-specific but applies throughout the program. Application-specific information is then added to the approved QAPP, either in the form of a site-specific QAPP, QAPP Addendum, or SAP.

1.1.3.2 WAPs and SAPs

In certain cases, WAPs or SAPs are required by a RCRA regulation. For example, WAPs are required as part of a permit application. Where WAPs or SAPs are required by regulation, the applicable regulations should be reviewed to ensure that the content and format requirements for the WAP or SAP are understood. Additionally, it should be noted that EPA has prepared various guidance documents to assist in preparing WAPs and SAPs that meet various regulatory requirements. Examples of these guidance documents include the following:

- EPA guidance on the preparation of WAPs can be found in the document entitled *Waste Analysis at Facilities that Generate, Treat, Store and Dispose of Hazardous Wastes* (ECDIC 2002-011), dated April 1994.
- EPA guidance on SAPs for delisting petitions can be found in the document entitled *EPA RCRA Delisting Program Guidance Manual for the Petitioner*, dated March 2000.
- General SAP guidance can be found in EPA's *RCRA Waste Sampling Draft Technical Guidance*, dated August 2002.
- Chapter 9 of this document (*Test Methods for Evaluating Solid Waste, Physical/Chemical Methods - SW-846*) presents additional discussion on sampling plans.

A QAPP may also be prepared, and required, as a supplement to any WAP or SAP. It should also be noted that if a WAP or SAP is not required by regulation, QAPPs can be prepared such that they present sufficient detail to cover both the QAPP and WAP or SAP in a single document. If a WAP or SAP is prepared along with a QAPP, it is common for these documents to reference one another for necessary information. To enhance the usability of QAPPs and WAPs/SAPs, references between the documents should be specific, providing the full document name, section number, subsection, and page number.

1.1.4 Data Quality Indicators

As part of systematic planning, measurement performance criteria for DQIs must be established and documented for each data collection effort. DQIs apply to both laboratory and field activities. At a minimum, DQIs should include precision, accuracy, representativeness, comparability, and completeness (PARCC). The following presents a discussion of PARCC and other DQIs.

1.1.4.1 Precision

Precision measures the agreement among a set of replicate measurements. Field precision is assessed through the collection and analysis of field duplicates. Analytical precision is estimated by duplicate/replicate analyses, usually on laboratory control samples, spiked samples and/or field samples. The most commonly used estimates of precision are the relative standard deviation (RSD) and, when only two samples are available, the relative percent difference (RPD).

1.1.4.2 Accuracy

Accuracy is the closeness of a measured result to an accepted reference value. Accuracy is usually measured as a percent recovery. QC analyses used to measure accuracy include standard recoveries, laboratory control samples, spiked samples, and surrogates.

1.1.4.3 Representativeness

Sample representativeness expresses the degree to which data accurately and precisely represents a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition. It is dependent on the proper design of the sampling program and will be satisfied by ensuring the approved plans were followed during sampling and analysis.

1.1.4.4 Comparability

Comparability expresses the degree of confidence with which one data set can be compared to another. It is dependent upon the proper design of the sampling program and will be satisfied by ensuring that the approved plans are followed and that proper sampling and analysis techniques are applied. Further, when assessing comparability, data sets should be of known and documented quality.

1.1.4.5 Completeness

Completeness is a measure of the amount of valid data collected compared to the amount planned. Measurements are considered to be valid if they are unqualified or qualified as estimated data during validation. Field completeness is a measure of the number of samples collected versus the number of samples planned. Laboratory completeness is a measure of the number of valid measurements compared to the total number of measurements planned.

1.1.4.6 Bias

Bias is the systematic or persistent distortion of a measurement process that causes error in one direction (e.g., the sample measurement is consistently lower than the sample's true value). Bias can be introduced during sampling, analysis, and data evaluation. Sampling bias is best addressed through the proper selection and use of sampling tools, uses of correct sampling and subsampling procedures to limit preferential selection or loss of sample media, use of random sampling designs, and use of sample handling procedures that limit the loss or gain of constituents to the sample media. Analytical bias refers to deviation in one direction (i.e., high, low or unknown) of the measured value from a known spiked amount. Analytical bias can be assessed by comparing a measured value in a sample of known concentration to an accepted reference value or by determining the recovery of a known amount of contaminant spiked into a sample (matrix spike). The planning team should specify qualitative criteria for sampling bias and quantitative criteria for analytical bias, typically expressed as "percent recovery."

1.1.4.7 Reproducibility

Analytical reproducibility is a quantitative indicator that is used when referring to the uncertainty associated with the use of multiple laboratories for a specific study. The ability of multiple laboratories to generate the same result for splits of the same sample can be expressed as a measure of interlaboratory precision and bias. Specific indicators of precision and bias (such as range or variance) are generated using data from replicate samples sent to multiple laboratories.

1.1.4.8 Repeatability

Repeatability is a quantitative indicator that in used within a single laboratory (i.e., intralaboratory precision). It is determined when the laboratory, analyst, test method and equipment remain constant and random aliquots of the same sample are analyzed within a short period of time.

1.1.4.9 Sensitivity

Sensitivity is an instrument's or method's minimum concentration that can be reliably measured or reported (i.e., or lower limit of quantitation [LLOQ]).

Please note the glossary section to this chapter includes further discussion of the DQIs.

1.2 IMPLEMENTATION

Implementation is the second phase of the project life cycle. The implementation phase includes the following steps:

1.2.1 Standard Operating Procedures (SOPs)

SOPs are written documents that describe, in detail, the routine procedures to be followed for a specific operation, analysis, or action. Please note, in most cases, referencing a given method or method number is not sufficient, unless the method is performed exactly as written (e.g., a method-defined parameter). Laboratories must have an SOP to demonstrate that their procedure meets the conditions of the referenced method. Information on how to prepare SOPs can be found in EPA's *Guidance for the Preparation of Standard Operating Procedures (QA/G-6)*, dated April 2007.

SOPs enable tasks to be accomplished reproducibly, even if there are changes in the personnel performing them. Consistent use of an approved SOP ensures conformance with organizational practices, reduction in the frequency of errors, and improved data comparability and defensibility. SOPs also serve as resources for training and for ready reference and documentation of proper procedures.

The SOPs, and/or procedures described in the QAPP, must be followed for all project activities from sample collection to validation. If project-specific modifications to SOPs are needed, they must also be presented in the QAPP. Field and laboratory SOPs should be provided for the areas discussed below, as applicable:

- Sample Custody SOPs that describe sample receipt and handling; sample storage; sample security and tracking; and holding times
- Sample collection
- Analytical Method SOPs, including subsampling, sample preparation/clean-up, calibration, QC, and analysis
- Reagent/Standard Preparation and Traceability SOPs
- Equipment Calibration and Maintenance SOPs
- Corrective Action SOPs
- Data Reduction SOPs
- Data Reporting SOPs
- Records Management SOPs
- Waste Disposal SOPs

As indicated above, the QC associated with each method may be provided in appropriate SOPs. The types of QC parameters to include in the SOPs and QAPP are defined in the glossary of this chapter. Since the QC acceptance limits are frequently adjusted more often than SOPs are revised, it may be impractical to update SOPs as these limits change. Therefore, field and laboratory QC limits may need to be presented in QAPP tables rather than SOPs.

1.2.2 Conducting the Study/Experiment

The data collection effort is performed in accordance with approved plans (e.g., QAPP). The QAPP will present all proposed methods (i.e., including sampling, subsampling, preservation, preparation, clean-up and determinative methods), as well as a rationale for why the proposed methods are sufficient to meet the project DQOs.

The QAPP should also indicate whether the proposed analyses include method-defined parameters and/or whether the flexible approach to methods will be utilized. For the flexible approach, the QAPP must also demonstrate that the proposed methods are adequate to reach the study goals outlined in the DQOs.

1.2.2.1 Method-defined parameters

Method-defined parameters (MDP), such as the Toxicity Characteristic Leaching Procedure (TCLP), have been written into regulations, the methods should be followed without deviation, and should not to be modified on a project basis. For a list of method-defined parameters, see Vol 40 CFR 260.11 references or the Methods Innovation Rule (MIR), in Volume 70, Number 113 of the Federal Register (70 FR 34537 Table 3). Some method-defined parameters are discussed in Chapter 8 of this manual.

1.2.2.2 Flexible Approach to Environmental Measurements

The Flexible Approach to Environmental Measurement was finalized in 2008 as EPA's preferred approach for environmental monitoring except in cases where methods are required by regulation.

The goals of the flexible approach are to:

- Provide method users flexibility when choosing sampling and analytical approaches to meet regulatory requirements for measurements
- Develop processes for validation to confirm measurements meeting quality requirements
- Increase collaboration with stakeholders to develop validation processes for new measurement technology
- Ensure timely assessment of new or modified technologies, methods, and procedures.

Chapter Two of this manual entitled, "Choosing the Correct Procedure" provides additional guidance regarding the selection of appropriate methods and method flexibility.

1.2.3 Technical Assessments

Technical Assessments (otherwise known as audits) are systematic and objective examinations of a program or project to determine whether environmental data generation activities and related results comply with planning documents. Technical assessments can be performed to evaluate all phases of a project including field sampling, laboratory analysis, validation and data handling/management.

The QAPP should identify all personnel responsible for performing technical assessments, the authority of the auditor (e.g., do they have the authority to stop work if significant deviations from planning documents are found), and the planned audit frequency. Additionally, if technical assessments are planned or required as part of a project, the QAPP should provide the applicable

technical assessment checklists. These checklists establish and document the scope of all proposed technical assessments. The development of these technical assessment checklists should overseen by an independent party (i.e., someone not involved in the day to day operations of a project), such as the organization's QA personnel. Further, the QAPP should establish a process for correcting technical assessment findings and confirming implementation of any corrective actions taken as a result of the findings.

While most technical assessments will be scheduled in advance with an organization, there may be occasions when unannounced technical assessments are needed. However, an unannounced audit may not reveal a representative picture of project activities if it occurs when the project is not active, or activities that are not within the scope of the technical assessment are occurring.

Technical assessments may be planned as part of the pre-award activities, or throughout the life of a project. For example, pre-award audits, including performance evaluation (PE) samples, are useful tools in determining the ability of a laboratory to perform the proposed analytical work. Additionally, technical assessments may also be used as an investigative tool where problems may be suspected. The EPA document Guidance on Technical Audits and Related Assessments for Environmental Data Operations (QA/G-7), dated January 2000, provides detailed information on various types of technical audits and includes an example checklist for a technical systems audit of a laboratory measurement system.

1.3 ASSESSMENT

Following planning (Sec. 1.1) and implementation (Sec. 1.2), assessment is the third and final phase of the project data generation life cycle. The purpose of this phase is to evaluate whether the data are of the type, quantity and quality needed to meet project DQOs. Assessment can involve many different complex activities, including the use of statistical tools. This section provides an introduction and overview of these data assessment activities.

1.3.1 Data Verification and Validation

Data verification and/or validation is the first step in the assessment process. Validation and verification are defined in the EPA Guidance on Environmental Data Verification and Data Validation (QA/G-8), dated November 2002. According to QA/G-8, verification is the process of evaluating the completeness, correctness, and conformance/compliance of a data set against a specified set of requirements. QA/G-8 defines validation as an analyte and sample specific process that extends the evaluation of data beyond data verification to determine its analytical quality. For the purposes of this chapter, it should be noted that the meaning of verification and validation is often program, organization and/or system specific. Further, these terms are used interchangeably at times, and in other cases have very different meanings. Therefore, it is critical that the procedures for verification and/or validation be clearly documented in the approved QAPP.

In general, data verification/validation involves the examination and review of project data (e.g., field and laboratory data for all applicable QC measurements) to confirm that the sampling and analysis protocols specified in the QAPP (and any other planning or contractual documents) were followed. Data verification/validation also involves examining whether the data met the method performance and acceptance criteria established in the project QAPP. When these criteria are not met, data verification/validation procedures should include qualification of the data (e.g., the *J* qualifier is commonly used to indicate *estimated* data and the *R* qualifier is commonly used to indicate *rejected* data). The reasons for any failure to meet performance criteria also

need to be documented during this phase of assessment (e.g., in a data verification/validation report).

In addition to QA/G-8, EPA has published several references which provide more detailed information on what should be included in data verification and validation procedures. These include EPA regional and programmatic validation guidance documents that may apply to particular projects. It is also common for EPA guidance from one program or region to be modified for use in another area. While this may be acceptable, any modifications or changes to the established validation procedures should be included in the approved QAPP.

Data verification/validation may be performed at various phases throughout a project. As such, the procedures for verifying and/or validating data may need to be described in laboratory SOPs and/or QA Plans, in addition to the project documents like the QAPP. Corrective action based on verification/validation findings may also need to be described in these documents.

Data verification/validation activities may be performed internally (e.g., when the laboratory or data collector review their own data), or externally by an independent entity (i.e., a party that is not associated with the data collection effort). Internal and external data verification/validation procedures should be defined in the QAPP or other project documents.

A data verification/validation report should be generated to document the procedures followed as well as the findings and qualifications applied during data verification/validation. The report should include a list of the samples collected, field information about how the samples were collected, the analyses performed on the samples, the results of the analysis and the quality of the reported data, at a minimum. The usability of this report can be enhanced by listing the samples and analytes affected by each QC criteria exceedance, as well as the extent of the exceedance, and any qualifiers applied. Any other observations noted by the data reviewer that may impact the usability of the data should also be documented.

1.3.2 Data Quality Assessment

Data quality assessment (DQA) is the second step in the assessment process. DQA is often needed because data verification/validation alone is generally not sufficient to determine whether a data set can be used for its intended purpose. Typically, the DQA follows the data verification and/or validation step.

In general, the DQA should include an evaluation of overall trends or biases in the data and associated QC results, as well as how the data may be affected. For random data sets, the DQA should evaluate the validity of any statistical assumptions made during the planning phase. If the statistical assumptions made during the planning phase are not supported by the data, recommendations for corrective action should be presented. All DQA findings should be summarized in a report.

Guidance documents available from EPA that discuss the DQA process include *Data Quality Assessment: A Reviewer's Guide* (QA/G-9R), dated February 2006, and *Data Quality Assessment: Statistical Tools for Practitioners* (QA/G-9S), dated February 2006.

The DQA process described in this guidance is a five-step process.

Step 1: Review the Data Quality Objectives and Sampling Design
Step 2: Conduct a Preliminary Data Review
Step 3: Select the Statistical Method
Step 4: Verify the Assumptions of the Statistical Method

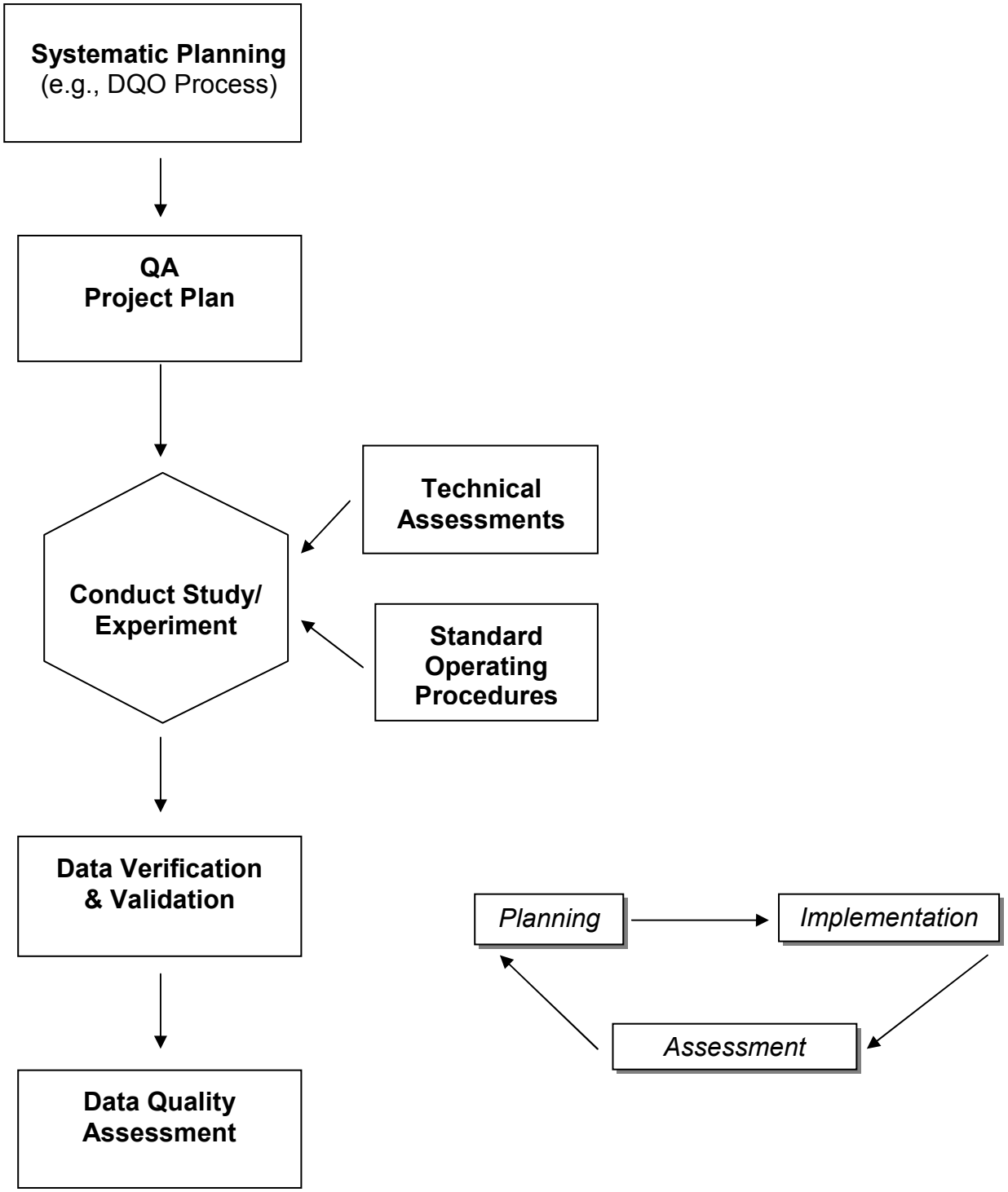
Step 5: Draw Conclusions from the Data

It is recommended that the data user refer to these guidance documents, because they provide extensive information about DQA and the statistical tools that can be employed.

Although the DQA process described in QA/G-9R and QA/G-9S includes a significant amount of statistical procedures, it should be noted that the DQA process is not only applicable to random data sets, where statistics can be used to assess the data. A DQA should also be performed on judgmental, or biased, data sets. The process for how any data set will be assessed should be determined during the planning phase, and documented in the QAPP or other site documents.

FIGURE 1-1

PROJECT LEVEL EPA QA SYSTEM



1.4. REFERENCES AND SOURCES FOR ADDITIONAL QA/QC INFORMATION

1. USEPA. *Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4*. Quality Staff, Office of Environmental Information, United States Environmental Protection Agency, Washington, D.C. February 2006.

2. USEPA. *EPA Quality Manual for Environmental Programs CIO 2105-P-01-0*. Office of Environmental Information Quality Staff, United States Environmental Protection Agency, Washington, D.C. May 5, 2000.

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1.5. GLOSSARY

Also see the following for a glossary of quality-related terms developed by EPA:

http://www.epa.gov/fem/pdfs/Env_Measurement_Glossary_Final_Jan_2010.pdf

ACCURACY — The degree of agreement between an observed value and an accepted reference value. When applied to a set of observed values, accuracy includes a combination of a random error (precision) and systematic error (bias) components.

ANALYTICAL BATCH — A group of samples, including quality control samples, which are processed together using the same method, the same lots of reagents, and at the same time or in continuous, sequential time periods. Samples in each batch should be of similar composition and share common internal quality control standards. For QC purposes, if the number of samples in a batch is limited to 20; laboratory QC samples are not included in the batch count.

Each batch should be uniquely identified within the laboratory for tracking purposes. Samples collected from the same site would normally be grouped together for batching purposes within the constraints imposed by the method holding times and batch size. Samples prepared in the same batch would normally be analyzed together on a single instrument. However, laboratories may find it necessary to group multiple clients' samples into a single batch. Under these circumstances, additional matrix QC samples (*i.e.*, duplicates, matrix spikes) may be needed to evaluate the effect of the matrix from each site on method performance.

BIAS — The constant or systematic distortion of a measurement process, different from random error, which manifests itself as a persistent positive or negative deviation from the known or true value. This can result from improper data collection, poorly calibrated analytical or sampling equipment, or limitations or errors in analytical methods and techniques.

Bias can be assessed by comparing a measured value to an accepted reference value in a sample of known concentration or by determining the recovery of a known amount of contaminant spiked into a sample (matrix spike). Thus, the bias (B) due to matrix effects based on a matrix spike is calculated as:

$$B = (x_s - x_u) - K$$

where:

x_s = measured value for spiked sample,
x_u = measured value for unspiked sample, and
K = known value of the spike in the sample.

Using the following equation yields the percent recovery (%R).

$$\%R = 100\,(x_s - x_u)/\,K$$

BLANK

Blanks are generally considered to be acceptable if target analyte concentrations are less than ½ the LLOQ or are less than project-specific requirements. Blanks may contain analyte concentrations greater than acceptance limits if the associated samples in the batch are unaffected (i.e. targets are not present in samples or sample concentrations are ≥10X the blank). Other criteria may be used depending on the needs of the project. For method specific details see methods 6010, 6020 for inorganics and Method 8000 for organics).

See also Calibration Blank, Equipment Blank, Method Blank, Reagent Blank and Trip Blank.

CALIBRATION BLANK

A calibration blank is a sample of analyte-free media that can be used along with prepared standards to calibrate the instrument. A calibration blank may also be used to verify absence of instrument contamination (e.g., initial calibration blank and continuing calibration blank).

CALIBRATION CHECKS

Calibration check analyses are used to assess calibration drift and memory effects over time for each analytical system. These analyses may include zero, span (low and high) to cover the full calibration range, and mid-range checks, depending on the method.

CALIBRATION CURVE

A plot of instrument response to an analyte versus known concentrations or amounts of analyte standards. Calibration standards are prepared by successively diluting a standard solution to produce working standards which cover the working range of the instrument. Standards should be prepared at the frequency specified in the appropriate method. The calibration standards should be prepared using the same type of acid or solvent and at the same concentration as the samples following sample preparation. This is applicable to organic and inorganic chemical analyses.

CO-LOCATED SAMPLES

A type of field duplicate where independent samples are collected as close as possible to the same point in space and time. They are two separate samples taken from the same source, stored in separate containers, and analyzed independently by the same method and laboratory. These duplicates are useful in documenting the precision of the sampling process.

COMPARABILITY

The degree to which different methods or data agree or can be represented as similar. Comparability describes the confidence that two data sets can contribute to a common analysis and interpolation.

COMPLETENESS

A measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under correct, normal conditions. Percent completeness is calculated as:

$$\% \text{ Completeness} = \frac{x}{y} \times 100$$

where:

x = amount of valid data obtained
y = amount of data expected to be obtained

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 indicators of data quality are precision, bias, accuracy, representativeness, comparability, completeness, and sensitivity.
DATA QUALITY OBJECTIVES (DQOs)	Qualitative and quantitative statements derived from the DQO Planning Process that clarify the purpose of the study, define the most appropriate type of information to collect, determine the most appropriate conditions from which to collect that information, and specify tolerable levels of potential decision errors.
DATA VALIDATION	The process of evaluating the available data against the project DQOs to make sure that the objectives are met. Data validation may be very rigorous, or cursory, depending on project DQOs. The available data reviewed will include analytical results, field QC data, laboratory QC data, and may also include field records.
DUPLICATE	See Co-located Samples, Laboratory Duplicate, Field Duplicate, Field Split Samples, and Matrix Spike Duplicate.
EQUIPMENT BLANK	A sample of analyte-free media which has been used to rinse the sampling equipment. It is collected after completion of decontamination and prior to sampling at a location. This blank is useful in documenting adequate decontamination of sampling equipment.
EQUIPMENT RINSATE	See Equipment Blank.
FIELD BLANK	Field blanks include any sample submitted from the field that is identified as a blank. These include trip blanks, rinsates, equipment blanks, etc. Field blanks may also be obtained by the sampling organization to measure ambient contamination in the field. If this type of field blank is requested, a container of reagent water or a solid blank material is opened in the field for a predefined period of time. The sample is then sent to the laboratory for analysis.
FIELD DUPLICATES	Field duplicates are useful in documenting the precision of the sampling process. Field duplicates are used to assess improper homogenization of the samples in the field; reproducibility of sample preparation and analysis; and, heterogeneity of the matrix. See also Co-located Samples and Field Split Samples.
FIELD SPLIT SAMPLES	A type of field duplicate where the sample is homogenized and then divided into two or more aliquots so that variability can be evaluated, (i.e., often between laboratories or methods). Homogenization may have an impact on sample integrity for some sample types (e.g., VOCs

in soil), and in these cases co-located samples may be more appropriate.

INITIAL DEMONSTRATION of PROFICIENCY (IDP)

Prior to the analysis of samples an initial demonstration of method proficiency is accomplished through the successful calibration of method-specific instruments according to project requirements and criteria set forth in the applicable analytical methodology. This initial demonstration should be performed prior to independently running an analytical method, and should be repeated if other changes occur (e.g., instrument repair, significant change in procedure).

Please see individual methods for additional guidance on IDP.

INTERNAL STANDARD

Internal standards may be spiked into prepared field samples and QC samples (or sample extracts). Their recovery is generally used to demonstrate the lack of severe matrix effect in the instrumental analysis by setting criteria for the internal standard response in comparison to a response in a sample with a known lack of matrix effect (*i.e.*, a standard). Internal standards are also used to account for matrix effects and/or variability in instrument response by normalizing the response of the target analytes and surrogates, thereby decreasing measurement bias to the extent that their behavior mimics that of the target analytes.

LABORATORY CONTROL SAMPLE

The Laboratory Control Sample (LCS) is analyzed to assess general method performance based on the ability of the laboratory to successfully recover target analytes from a control matrix. The LCS is similar in composition to the method blank in that it is an aliquot of analyte-free water or analyte-free solid (e.g., Ottawa sand, anhydrous sodium sulfate, or other purified solid) to which known amounts of the method analytes are added. LCS analyses help determine if the system is running properly (i.e., within pre-defined limits). Although the frequency of LCS analysis should be determined by the needs of a project, typically one LCS is prepared and analyzed for every analytical batch. The LCS sample is prepared and analyzed in the same analytical batch and in exactly the same manner as the other routine samples. The recovery of the target analytes in the LCS analysis demonstrates whether the methodology is in control and the laboratory is capable of making unbiased measurements. The results of the LCS are evaluated in conjunction with other QC information to determine the acceptability of the data generated for that batch of samples. Acceptance criteria for LCS recovery are calculated based on statistical treatment of historical LCS recovery data through the use of control charts.

LABORATORY DUPLICATE

The analysis or measurements of the variable of interest performed identically on two sub-samples of the same sample, usually taken from the same container. The results from duplicate analyses are used to evaluate analytical or measurement precision and include variability associated with sub-sampling and the matrix, but not the precision of field sampling, preservation, or storage internal to the laboratory.

Laboratory duplicate analysis entails removing two aliquots from the

same sample and taking them through the same preparative and analytical procedures to evaluate analytical precision. Laboratory duplicates are more commonly used to assess precision for inorganic and radiological constituents, while precision for organic analyses is usually assessed by determining the RPD between matrix spike and matrix spike duplicates. The frequency of laboratory duplicate analysis will depend on project requirements.

LOWER LIMIT OF QUANTITATION (LLOQ)

The lowest point of quantitation which, in most cases, is the lowest concentration in the calibration curve. The LLOQ is initially verified by spiking a clean control material (e.g., reagent water, method blanks, Ottawa sand, diatomaceous earth, etc.) at the LLOQ and processing through all preparation and determinative steps of the method. Laboratory-specific recovery limits should be established when sufficient data points exist. Individual methods may recommend procedures for verifying the LLOQ and acceptance limits for use until the laboratory has sufficient data to determine acceptance limits. LLOQs should be determined at a frequency established by the method, laboratory's quality system, or project.

Please see individual methods for additional guidance on implementing LLOQ (e.g., 8000, 6020).

MATRIX

The material of which the sample is composed or the substrate containing the analyte of interest, such as waste water, storm water and biosolids. Also called medium or media.

MATRIX SPIKE

Matrix spikes are aliquots of environmental samples to which known concentrations of certain target analytes have been added before sample preparation, cleanup, and determinative procedures have been implemented. Matrix spike analysis would normally be included with each preparation batch of samples processed. Under ideal circumstances, the original, unspiked, field sample will be analyzed first, to determine the concentration in the unspiked sample. However, if this approach is not practical, the samples may be spiked at the midpoint of the calibration range or at the same level as the LCS.

The matrix spike analysis is used to assess the performance of the method by measuring the effects of interferences caused by the sample matrix and reflects the bias of the method for the particular matrix in question.

MATRIX SPIKE DUPLICATES

Matrix spike duplicates are additional replicates of matrix spike samples that are subjected to the sample preparation and analytical scheme as the original sample. A matrix spike duplicate sample would normally be included with each preparation batch of samples processed. Analysis of spiked duplicate samples ensures a positive value, allowing for estimation of analytical precision.

Matrix spike duplicates are used to document the precision as well as bias of a method in a given sample matrix. When critical decisions are based on the matrix spike and matrix spike duplicate recoveries, the laboratory should maintain control charts for these samples to monitor

precision and bias for each particular matrix.

METHOD BLANK

Method blanks are analyzed to assess background interference or contamination that exists in the analytical system that might lead to the reporting of elevated concentration levels or false positive data. The method blank is defined as an interference-free blank matrix, similar to the sample matrix, to which all reagents are added in the same volumes or proportions as used in sample preparation and carried through the complete sample preparation, cleanup, and determinative procedures. For aqueous analyses, analyte-free reagent water would typically be used. For soil analyses, a purified solid matrix (e.g., sand) would typically be used, except for metals analyses. Method blank results are evaluated in conjunction with other QC information to determine the acceptability of the data generated for that batch of samples. The method blank results should be below the LLOQ for the target analytes being tested; otherwise, corrective action should be taken. A method blank is included with the analysis of every analytical batch of 20 samples or less or as stated in the QAPP or method, whichever is more frequent.

ORGANIC-FREE REAGENT WATER

All references to water in the methods refer to water in which an interferant is not observed at the LLOQ for the compounds of interest. Preparation of organic-free reagent water may depend on the types of interferants of concern for the analysis and may include boiling, sparging with an inert gas, reverse osmosis purification, distillation, particle filtration, activated carbon filtration, ion exchange filtration, etc.

POST-DIGESTION SPIKES

Post-digestion spike samples are typically prepared for inorganic analyses when pre-digestion/pre-distillation matrix spike recoveries are outside the required control limits. They are prepared by spiking a known amount of standard to the sample digestate. The recovery data from the post digestion spike analyses are used to further assess if matrix effects may be a source of measurement bias in sample quantitation.

PRECISION

The agreement among a set of replicate measurements without assumption of knowledge of the true value. Precision is estimated by means of duplicate/replicate analyses of separate aliquots of the same sample (not multiple runs of a single digestion/extraction). These samples should contain concentrations of analyte at or above the LLOQ, and may involve the use of matrix spikes. The most commonly used estimates of precision are:

Relative standard deviation (RSD), also known as the coefficient of variation (CV):

$$RSD = CV = (100)*(S/\bar{x})$$

where:

$\bar{x}$ = the arithmetic mean of the i measurements, and
S = the square root of the variance of i measurements; and,

Relative percent difference (RPD) when only two results are compared:

$$RPD = \frac{|X_1 - X_2|}{\left(\frac{X_1 + X_2}{2}\right)} * 100$$

where: x_1 and x_2 are measurements of independently prepared aliquots of the same sample or replicate samples.

PROJECT — Single or multiple data collection activities that are related through the same planning sequence.

QUALITY CONTROL SAMPLE — A sample made from standards or matrix and used to verify acceptability of the results from preparation and/or analysis of a batch of samples. Examples of laboratory quality control samples are method blanks, laboratory duplicates, and laboratory control samples; field quality control samples are field blanks, trip blanks, field duplicates, and matrix spikes.

QUALITY ASSURANCE PROJECT PLAN (QAPP) — A formal document describing in comprehensive detail the necessary quality assurance, quality control, and other technical activities that should be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

REAGENT BLANK — Reagent blanks are analyzed to assess background interference or contamination that exists in the analytical system that might lead to the reporting of elevated concentration levels or false positive data. The reagent blank is defined as an interference-free blank matrix, to which all reagents are added in the same volumes or proportions as used in sample preparation but are NOT carried through the complete sample preparation, cleanup, and determinative procedures. The purpose of a reagent blank is to gauge contamination from chemical inputs and instrumental factors only. A reagent blank is NOT run as part of a digestion or preparation method.

REAGENT GRADE — Analytical reagent (AR) grade, ACS reagent grade, and reagent grade are synonymous terms for reagents which conform to the current specifications of the Committee on Analytical Reagents of the American Chemical Society.

REAGENT WATER — Water that has been generated by any method which would achieve the performance specifications for ASTM Type II water. For organic analyses, see the definition of organic-free reagent water.

REFERENCE MATERIAL — A material containing known quantities of target analytes in solution or in a homogeneous matrix. It is used to document the bias of the analytical process.

REPEATABILITY — The degree of agreement between mutually 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

period of time.

REPRESENTATIVENESS — A measure of the degree to which data accurately represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition.

REPRODUCIBILITY — Reproducibility is defined as the closeness of the agreement between the results of measurements of the same analyte carried out under variable conditions of measurement.

STANDARD ADDITION — The addition of a known amount of analyte to the sample in order to determine the relative response of the detector to an analyte within the sample matrix. The relative response is then used to assess either an operative matrix effect or the sample analyte concentration.

SURROGATE — Surrogates are most commonly used to monitor the performance of organic analyses using methods such as high performance liquid chromatography (HPLC), gas chromatography (GC), and gas chromatography/mass spectrometry (GC/MS). Surrogate spikes are added to field samples and QC samples for organic analyses at known amounts, and their recoveries are used to assess matrix effects and, to some extent, verify proper processing and instrument performance for each sample. The analytes used as surrogates mimic the behavior of the target analyte(s) throughout sample preparation and instrument determination. Surrogates are organic compounds which are similar to the target analytes in chemical composition and behavior in the analytical process, but are not normally found in the environmental samples. Surrogates added to LCS samples and blanks are used to assess recovery in a matrix known to be free from interference. This information can be used to determine the magnitude of matrix interference effects on environmental sample results.

TRIP BLANK — A sample of analyte-free media taken from the laboratory to the sampling site and returned to the laboratory unopened. Trip blanks should be prepared at a frequency of one per day of sampling during which samples are collected for volatile organic constituents (VOCs). Trip blanks are prepared prior to the site visit at the time sample containers are shipped to the site. The trip blank should accompany the sampling kits throughout all the sample collection and transport operations. This blank will not be opened during the sampling activities and will be used to assess sample VOC contamination originating from sample transport, shipping, or site conditions. A trip blank is used to document contamination attributable to shipping and field handling procedures.

APPENDIX A

SUMMARY OF UPDATES/CHANGES IN CHAPTER 1

1. The entire Chapter has been rewritten and reorganized to reflect changes in the EPA data quality system approach.
2. The revision number was changed to two and the date published to July 2014.
3. This appendix was added to document changes made during the editorial process.
4. The document was updated to match the current SW-846 style guidelines.
5. Figure 1 was added based on information in EPA QA/G-8, November 2002, Figure 1.