8 Quality Assurance and Quality Control

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8.1 Introduction

Quality assurance and quality control (QA/QC) are commonly thought of as procedures used in the laboratory to ensure that all analytical measurements made are accurate. Yet QA/QC extends beyond the laboratory and includes a wide range of issues that nonpoint source (NPS) managers consider when addressing the challenges of developing a monitoring program (see chapters 2 and 3). When considered independently from monitoring program design, QA/QC may seem burdensome. Yet the purpose of QA/QC is the same as a well-intentioned NPS manager, which is to ensure that the monitoring data generated are complete, accurate, and suitable for the intended purpose. By integrating certain QA/QC aspects with monitoring program design, NPS managers can reduce repetition and ultimately reduce total costs by developing a more efficient monitoring design.

The remainder of this section defines QA/QC, discusses their value in NPS monitoring programs, and explains EPA's policy on these topics. Section 8.2 provides an overview of the Data Quality Objectives (DQO) process. EPA recommends that organizations use the DQO process to systematically plan their monitoring programs. Typically, written QA/QC documentation takes the form of a quality assurance project plan (QAPP). As discussed in section 8.3, a QAPP details the technical activities and QA/QC procedures that should be implemented to ensure the data meet the specified standards.

The QAPP should identify who will be involved in the project and their responsibilities; the nature of the study or monitoring program; the questions to be addressed or decisions to be made based on the data collected; where, how, and when samples will be taken and analyzed; the requirements for data quality; the specific activities and procedures to be performed to obtain the requisite level of quality (including QC checks and oversight); how the data will be managed, analyzed, and checked to ensure that they meet the project goals; and how the data will be reported. The QAPP should be implemented and maintained throughout a project.

Sections 8.4, 8.5, and 8.6 provide more specific information for preparing QAPPs with respect to field operations, laboratory operations, and data and reporting requirements, respectively. Although there are many commonalities, QAPP development to support modeling and secondary data usage is beyond the scope of this chapter. The reader is referred to CREM (2009) and USEPA (2002b) for guidance on the development and application of environmental models and related QAPPs. EPA also provides guidance about the evaluation of existing (secondary) data quality (USEPA 2012) and information needed to develop QAPPs for secondary data projects (USEPA 2008a).

8.1.1 Definitions of Quality Assurance and Quality Control

8.1.1.1 Quality assurance:

An integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client (USEPA 2001c).

8.1.1.2 Quality control:

The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality (USEPA 2001c).

In a laboratory setting, QC procedures include the regular inspection of equipment to ensure it is operating properly and the collection and analysis of blank, duplicate, and spiked samples and standard reference materials to ensure the accuracy and precision of analyses. QA activities are more managerial in nature and include assignment of roles and responsibilities to project staff, staff training, development of data quality objectives, data validation, and laboratory audits. Table 8-1 lists some common activities that fall under the heading of QA/QC. Such procedures and activities are planned and executed by diverse organizations through carefully designed quality management programs that reflect the importance of the work and the degree of confidence needed in the quality of the results.

Table 8-1. Common QA/QC activities

QA Activities
• Organization of the project into component parts • Assignment of roles and responsibilities to project staff • Determine the number of QC samples and sampling sites needed to obtain data of a required confidence level • Tracking of sample custody from field collection through final analysis • Development and use of data quality objectives to guide data collection efforts • Auditing of field and laboratory operations • Maintenance of accurate and complete records of all project activities • Training of personnel to ensure consistency of sample collection techniques and equipment use
QC Activities
• Collection of duplicate samples for analysis • Analysis of blank, duplicate, and spike samples • Regular inspection and calibration of analytical equipment • Regular inspection of reagents and water for contamination • Regular inspection of refrigerators, ovens, etc. for proper operation • Regular evaluation of data against QC objectives

Adapted from Drouse et al., 1986, and Erickson et al., 1991.

8.1.2 Importance of QA/QC Programs

While it is desirable to stay below 10 percent, development and implementation of a QA/QC program can require up to 10 to 20 percent of project resources (Cross-Smiecinski and Stetzenback 1994). This cost, however, can be recaptured in lower overall costs of a well-planned and executed project. Likely problems are anticipated and accounted for before they arise, eliminating the need to resample, reanalyze data, or revisit portions of the project to determine where an error was introduced. A QAPP can serve as a foundation for documenting standard operating procedures for all project activities, ensuring that project tasks are conducted consistently by all personnel and can support training for new personnel as the project moves forward. During a project, QA/QC information can provide essential feedback to ongoing project management. Most importantly, a QA/QC program helps ensure that project data are of known accuracy and precision, that errors are minimized, and that all critical project activities are conducted consistently. As long as the QA/QC procedures are followed, the data and information collected by the project will be adequate to support technical conclusions and choices from among alternative courses of action. These conclusions and actions will be defensible based on quality of the data and information collected. In short, QA/QC procedures and activities are cost-effective measures used to determine how to allocate project energies and resources toward improving the quality of research and the usefulness of project results (Erickson et al., 1991).

8.1.3 EPA Quality Policy

EPA has established a QA/QC program to ensure that data used in research and monitoring projects are of known and documented quality to satisfy project objectives. The use of different methods, lack of data comparability, unknown data quality, and poor coordination of sampling and analysis efforts can delay the progress of a project or render the data and information collected from it unsuited for decision making. QA/QC practices should be integral parts of the development, design, and implementation of an NPS monitoring project to minimize or eliminate these problems (Erikson et al. 1991; Pritt and Raese 1992; USEPA 2001b).

EPA Order CIO 2105.0 (formerly EPA Order 5360.1 A2), EPA's *Policy and Program Requirements for the Mandatory Agency-wide Quality System* (USEPA 2000b), provides requirements for the conduct of quality management practices, including QA/QC activities, for all environmental data collection and environmental technology programs performed by or for EPA. The *EPA Quality Manual for Environmental Programs* (USEPA 2000a) provides program requirements for implementing EPA's mandatory quality system. In accordance with EPA Order CIO 2105.0, EPA requires that environmental programs be supported by a quality system that complies with the quality system standard developed by the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC 1994). The ANSI/ASQC E4-1994 quality system standard was later updated as ANSI/ASQ E4-2004, *Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use* (ANSI/ASQ 2004).

EPA's mandatory agency-wide Quality System Policy (EPA Policy CIO 2106.0) requires each office or laboratory generating data to implement minimum procedures to ensure that precision, accuracy, completeness, comparability, and representativeness of data are known and documented (Erickson et al. 1991; USEPA 2008b). This policy is now based on the quality system standard developed by the American National Standards Institute and the American Society of Quality Control (ANSI/ASQ 2004). Each office or laboratory is required to specify the quality levels that data must meet to be acceptable and

satisfy project objectives. This requirement applies to all environmental monitoring and measurement efforts mandated or supported by EPA through regulations, grants, contracts, or other formal agreements. To ensure that this responsibility is met uniformly across EPA, each organization performing work for EPA must document in a Quality Management Plan (QMP) that is approved by its senior management how it will plan, implement, and assess the effectiveness of QA/QC operations applied to environmental programs (USEPA 2001b). In addition, each non-EPA organization must have an approved QAPP that covers each monitoring or measurement activity associated with a project (Erickson et al. 1991, USEPA 1983, 2008b). Additional implementation guidance is provided in *EPA Quality Manual for Environmental Programs* (USEPA 2000a).

The purpose of writing a QAPP prior to undertaking an NPS monitoring project is to establish clear objectives for the program, including the types of data needed and the quality of the data generated (accuracy, precision, completeness, representativeness, and comparability) in order to meet the project's water quality and land treatment objectives. See section 2.1 for a discussion of appropriate objectives for NPS monitoring projects.

The QAPP should specify the policies, organization, objectives, functional activities, QA procedures, and QC activities designed to achieve the data quality goals of the project. It should be distributed to all project personnel, and they should be familiar with the policies and objectives outlined in the QAPP to ensure proper interaction of the sampling and laboratory operations and data management. Although a QA/QC officer oversees major aspects of QAPP implementation, all persons involved in an NPS monitoring project who either perform or supervise the work done under the project are responsible for ensuring that the QA/QC procedures and activities established in the QAPP are adhered to.

The QMP and each QAPP must be submitted for review to the EPA organization responsible for the work to be performed, and they must be approved by EPA or its designee (e.g., federal or state agency) as part of the contracting or assistance agreement process before data collection can begin. In addition, it is important to note that the QMP and QAPP are "live" documents and programs in the sense that once they have been developed they cannot be placed on a shelf for the remainder of the project. All QA/QC procedures should be evaluated and plans updated as often as necessary during the course of a project to ensure that they are in accordance with the present project direction and efforts (Knapton and Nimick 1991, USEPA 2001c).

8.2 Data Quality Objectives

When monitoring data are being used to assess water quality and the effects of land-based activities on water quality or the effectiveness of best management practices, EPA recommends that states, tribes, and non-governmental organizations (NGOs) consider using the systematic planning tool called the Data Quality Objectives (DQO) Process. The DQO process should be part of project planning and development of a proposed monitoring strategy.

The DQO process is used to establish performance or acceptance criteria that serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the objectives of a study. The DQO process consists of seven iterative steps (USEPA 2006):

1) **State the problem:** define the problem that necessitates the study; identify the planning team, examine budget, schedule.

2) **Identify the goal of the monitoring program:** state how monitoring data will be used in meeting objectives and solving the problem, identify study questions, define alternative outcomes.
3) **Identify information inputs:** identify data and information needed to answer questions.
4) **Define the boundaries of the study:** specify the target population and characteristics of interest, define spatial and temporal limits, scale of inference.
5) **Develop the analytic approach:** define the parameters of interest, specify the type of inference, and develop the logic for drawing conclusions from findings.
6) **Specify performance or acceptance criteria:** develop performance criteria for new data being collected or acceptance criteria for existing data being considered for use.
7) **Develop the plan for obtaining data:** select the resource-effective monitoring plan that meets the performance criteria.

Several iterations of the process might be required to specify the DQOs for a monitoring program. Because DQOs are continually reviewed during data collection activities, any needed corrective action can be planned and executed to minimize problems before they become significant. General guidance and examples of planning for monitoring programs are also provided in related guidance (USEPA 2003a).

8.2.1 The Data Quality Objectives Process

The DQO process takes into consideration the factors that will depend on the data (most importantly, the decision(s) to be made) or that will influence the type and amount of data to be collected (e.g., the problem being addressed, existing information, information needed before a decision can be made, and available resources). From these factors the qualitative and quantitative data needs are determined. The purpose of the DQO process is to improve the effectiveness, efficiency, and defensibility of decisions made based on the data collected, and to do so in a resource-effective manner (USEPA 2006).

DQOs are qualitative and quantitative statements that clarify the study objective, define the most appropriate type of data to collect, and determine the most appropriate conditions under which to collect them. DQOs also specify the minimum quantity and quality of data needed by a decision maker to make any decisions that will be based on the results of the project. By using the DQO process, investigators can ensure that the type, quantity, and quality of data collected and used in decision making will be appropriate for the intended use. Similarly, efforts will not be expended to collect information that does not support defensible decisions. The products of the DQO process are criteria for data quality and a data collection design that ensures that data will meet the criteria.

A brief description of each step of the DQO process and a list of activities that are part of each step follow. For a detailed discussion of the DQO development process, refer to EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process* (USEPA 2006). This reference contains a case study example of the DQO process. A computer program, *Data Quality Objectives Decision Error Feasibility Trials* (USEPA 2001a), is also available to help the planning process by generating cost information about several simple sampling designs based on the DQO constraints before the sampling and analysis design team begins developing a final sampling design in the last step of the DQO process.

8.2.1.1 (1) State the problem

In this first step, concisely describe the problem to be studied . A review of prior studies and existing information is important during this step to gain a sufficient understanding of the problem in order to define it. The specific activities to be completed during this step (outputs) are:

- Identify members of the planning team.
- Identify the primary decision maker of the planning team and define each member's role and responsibilities during the DQO process.
- Develop a concise description of the problem.
- Specify the available resources and relevant deadlines for the study.

8.2.1.2 (2) Identify the goal of the monitoring program

Identify what questions the study will attempt to resolve and what actions might be taken based on the study. This information is used to prepare a "decision statement" or an objective that will link the principal study question to one or more possible actions that should solve the problem. Example NPS monitoring program objectives might be to "determine the sources of bacteria causing the water quality standard violation in Duck Creek" or "determine the effects of land treatment program xyz on phosphorus loads to Lake Eutrophy." Results from the monitoring program would then support management decisions to take action, modify an action, or take no action.

The specific activities to be completed during this step are:

- Identify the principal study question.
- Define the alternative actions that could result from resolution of the principal study question.
- Combine the principal study question and the alternative actions into a decision statement.
- If applicable, organize multiple decisions to be made by priority.

8.2.1.3 (3) Identify information inputs

Identify the information that needs to be obtained and the measurements that need to be taken to resolve the decision statement. The specific activities to be completed during this step are:

- Identify the information that will be required to resolve the decision statement.
- Determine the sources for each item of information identified above.
- Identify the information that is needed to establish the threshold value that will be the basis of choosing among alternative actions.
- Confirm that appropriate measurement methods exist to provide the necessary data.

8.2.1.4 (4) Define the boundaries of the study

Specify the time periods and spatial area to which decisions will apply and determine when and where data should be collected. This information is used to define the population(s) of interest. The term *population* refers to the total collection or universe of objects from which samples will be drawn. The population could be the concentration of a pollutant in sediment, a water quality variable, algae in the

river, or bass in the lake. It is important to define the study boundaries to ensure that data collected are representative of the population being studied (because every member of a population cannot be sampled) and will be collected during the time period and from the place that will be targeted in the decision to be made. The specific activities to be completed during this step are:

- Specify the characteristics that define the population of interest.
- Identify the geographic area to which the decision statement applies (such as a county) and any strata within that area that have homogeneous characteristics (e.g., recreational waters, dairy farms).
- Define the time frame to which the decision applies.
- Determine when to collect data.
- Define the scale of decision making, or the actual areas that will be affected by the decision (e.g., first-order streams, dairy farms with streams running through them, a county).
- Identify any practical constraints on data collection.

8.2.1.5 (5) Develop the analytic approach

Define the statistical parameter of interest, specify the threshold at which action will be taken, and integrate the previous DQO outputs into a single statement that describes the logical basis for choosing among alternative actions. This statement is known as a *decision rule*. It is often phrased as an "If...then..." statement. For example, "If septic systems are contributing to water quality standard violations, then failing septic systems will be remediated; otherwise, no action will be taken." The specific activities to be completed during this step are:

- Specify the statistical parameter that characterizes the population (the parameter of interest), such as the mean, median, or percentile.
- Specify the numerical value of the parameter of interest that would cause a decision maker to take action, i.e., the threshold value.
- Develop a decision rule in the form of an "if...then..." statement that incorporates the parameter of interest, the scale of decision making, the threshold level, and the actions that would be taken.

8.2.1.6 (6) Specify performance or acceptance criteria

Define the decision maker's tolerable limits of making an incorrect decision (or decision error) due to incorrect information (i.e., measurement and sampling error) introduced during the study. These limits are used to establish performance goals for the data collection design. Base the limits on a consideration of the consequences of making an incorrect decision. The decision maker cannot know the true value of a population parameter because the population of interest almost always varies over time and space and it is usually impractical or impossible to measure every point (sampling design error). In addition, analytical methods and instruments are never absolutely perfect (measurement error). Thus, although it is impossible to eliminate these two errors, the combined total study error can be controlled to reduce the probability of making a decision error. The specific activities to be completed during this step are:

- Determine the possible range (likely upper and lower bounds) of the parameter of interest.
- Identify the decision errors and choose the null hypothesis. Decision errors for NPS pollution problems might take the general form of deciding there is an impact when there is none [a false

positive, or type I error] or deciding there is no impact when there is [a false negative, or type II error].

- Specify the likely consequences of each decision error. Evaluate their potential severity in terms of ecological effects, human health, economic and social costs, political and legal ramifications, and other factors.
- Specify a range of possible parameter values where the consequences of decision errors are relatively minor (gray region). The boundaries of the gray region are the threshold level and the value of the parameter of interest where the consequences of making a false negative decision begin to be significant.
- Assign probability limits to points above and below the gray region that reflect the tolerable probability for the occurrence of decision errors.

8.2.1.7 (7) Develop the plan for obtaining data

Evaluate information from the previous steps and generate alternative data collection designs. Some aspects of this may be considered informally during the project planning process, and less attention can be given to some alternatives. The designs should specify in detail the monitoring that is required to meet the DQOs, including the types and quantity of samples to be collected; where, when, and under what conditions they should be collected; what variables will be measured; and the QA/QC procedures that will ensure that the DQOs are met. The QA/QC procedures are fully developed when the QAPP is written (see below). Choose the most resource-effective design that meets all of the DQOs. As resources dictate, it may be necessary to reduce or restate the DQOs. The specific activities to be completed during this step are:

- Review the DQO outputs and existing environmental data.
- Develop general data collection design alternatives.
- Formulate the mathematical expressions needed to solve the design problem for each data collection design alternative. This involves selecting a statistical test method (e.g., Student's *t* test), developing a statistical model that relates the measured value to the "true" value, and developing a cost function that relates the number of samples to the total cost of sampling and analysis.
- Select the optimal sample size that satisfies the DQOs for each data collection design alternative.
- Select the most resource-effective data collection design that satisfies all of the DQOs.
- Document the selected design's key features and the statistical assumptions of the selected design. It is particularly important that the statistical assumptions be documented to ensure that, if any changes in analytical methods or sampling procedures are introduced during the project, these assumptions are not violated.

The DQO process should be used during the planning stage of any study that requires data collection, and before the data are collected. EPA's policy is to use the DQO process to plan all data collection efforts that will require or result in a substantial commitment of resources. The DQO process is applicable to all studies, regardless of size; however, the depth and detail of the DQO development effort depends on the complexity of the study. In general, more complex studies benefit more from more detailed DQO development.

8.2.2 Data Quality Objectives and the QA/QC Program

The DQOs and the quality objectives for measurement data that will be specified in the QAPP are interdependent. The DQOs identify project objectives; evaluate the underlying hypotheses, experiments, and tests to be performed; and then establish guidelines for the data collection effort needed to obtain data of the quality necessary to achieve these objectives (Erickson et al. 1991, USEPA 2006). The QAPP presents the policies, organization, and objectives of the data collection effort and explains how particular QA/QC activities will be implemented to achieve the DQOs of the project, as well as to determine what future research directions might be taken (Erickson et al, 1991, USEPA 2006). At the completion of data collection and analysis, the data are validated according to the provisions of the QAPP and a Data Quality Assessment (DQA), using statistical tools, is conducted to determine:

- Whether the data meet the assumptions under which the DQOs and the data collection design were developed.
- Whether the total error in the data is small enough to allow the decision maker to use the data to support the decision within the tolerable decision error rates expressed by the decision maker (USEPA 2006).

Thus, the entire process is designed to assist the decision maker by planning and obtaining environmental data of sufficient quantity and quality to satisfy the project objectives and allow decisions to be made (USEPA 2001c, 2006). The DQO process is the part of the quality system that provides the basis for linking the intended use of the data to the QA/QC requirements for data collection and analysis (USEPA 2006).

8.3 Elements of A Quality Assurance Project Plan

QAPPs must be prepared in accordance with EPA Requirements for Quality Assurance Project Plans (USEPA, 2001b) and Guidance for Quality Assurance Project Plans (USEPA 2002a). EPA requires that four types of elements be discussed in a Quality Assurance Project Plan (QAPP): Project Management, Measurement and Acquisition, Assessment and Oversight, and Data Validation and Usability. These elements are listed in Table 8-2. For complete descriptions and requirements, see USEPA (2001b). Additional information on the contents of a QAPP is contained in Drouse et al. (1986), Erickson et al. (1991), and Cross-Smiecinski and Stetzenback (1994). Drouse et al. (1986) and Erickson et al. (1991) are examples of EPA QAPPs prepared under previous guidance.

The elements in Table 8-2 should always be addressed in the QAPP, unless otherwise directed by the overseeing or sponsoring EPA organization(s). Both laboratory and field operations should be included. The types, quantity, and quality of environmental data collected for each project could be quite different. The level of detail in each QAPP will vary according to the nature of the work being performed and the intended use of the data (USEPA 2001b). If an element is not applicable or required, then this should be stated in the QAPP. For some complex projects, it might be necessary to add special requirements to the QAPP. Again, the QAPP must be approved by the sponsoring EPA organization before data collection can begin.

Table 8-2. Elements required in an EPA Quality Assurance Project Plan. (USEPA, 2001b)

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

Standard Operating Procedures (SOPs) must be provided or referenced in the QAPP such that they are available to all participants. An SOP typically presents in detail the method for a given technical operation, analysis, or action in sequential steps and it includes specific facilities, equipment, materials and methods, QA/ QC procedures, and other factors necessary to perform the operation, analysis, or action for the particular project. By following the SOP, the operation should be performed the same way every time. Activities typically include field sampling, laboratory analysis, software development, and database management. EPA presents examples of the format and content of SOPs (USEPA, 2007). The format and content requirements for an SOP are flexible because the content and level of detail in SOPs vary according to the nature of the procedure. SOPs should be revised when new equipment is used, when comments by personnel indicate that the directions are not clear, or when a problem occurs. Organizations should ensure that current SOPs are used. SOPs are critical in the training of new personnel during the conduct of a long-term project.

Definitions of selected data quality terms

Precision (reproducibility) is an expression of mutual agreement of multiple measurements of the same property (e.g., duplicate field samples or duplicate lab samples) conducted under similar conditions. It is evaluated by recording and comparing multiple measurements of the same parameter on the same exact sample under the same conditions. Relative percent difference (RPD) is a measure of precision and is calculated with the following formula (Cross- Smiecinski and Stetzenback, 1994):

$$RPD = \frac{2(x_1 - x_2)}{x_1 + x_2}(100)$$

where

x_1 = analyte concentration of first duplicate and
x_2 = analyte concentration of second duplicate.

Accuracy (bias) is the degree of agreement of a measurement (or an average of measurements), *X*, with an accepted reference or true value, *T*. Accuracy is expressed as the percent difference from the true value {100 [(X-T)/T]} unless spiking materials are used and percent recovery is calculated (Erickson et al., 1991). Accuracy can be determined by analyzing a sample and its corresponding matrix spike. Accuracy can be expressed as percent recovery and calculated using the following formula (Air National Guard, 1993):

$$\%R = \frac{A - B}{C}(100)$$

where

A = spiked sample result;

B = sample result; and

C = spike added.

Comparability is defined as the confidence with which one data set can be compared to another (Erickson et al., 1991). Consistent sampling methodology, handling, and analyses are necessary to ensure comparability. Also, assurance that equipment has been calibrated properly and analytical solutions prepared identically is necessary to attain data comparability (Air National Guard, 1993).

Representativeness is a measure of how representative the data obtained for each parameter are compared with the values of the same parameter within the population being measured. Because the total population cannot be measured, sampling must be designed to ensure that the samples are representative of the population being sampled (Air National Guard, 1993). A relevant sampling design issue, for example, is to determine how a sample will be collected to ensure it is representative of the desired characteristic (Erickson et al., 1991).

Completeness is defined as the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under anticipated sampling/analytical conditions (Erickson et al., 1991). An assessment of the completeness of data is performed at the end of each sampling event, and if any omissions are apparent, an attempt is made to resample the parameter in question, if feasible. Data completeness should also be assessed prior to the preparation of data reports that check the correctness of all data. An example of a formula used for this purpose is

$$\%C = 100\left[\frac{V}{n}\right]$$

where

%C = percent complete;

V = number of measurements judged valid; and

n = total number of measurements necessary to achieve a specified level of confidence in decision making (Cross-Smiecinski and Stetzenback, 1994).

8.4 Field Operations

Field operations are an important activity in an NPS monitoring program. Field operations involve the organization and design of the field operation, selection of sampling sites, selection of sampling equipment, sample collection, sample handling and transport, and safety and training issues. For the purposes of QA/QC, the process of conducting field operations should be broken down into as many separate steps as are necessary to ensure complete consideration of all of the elements and processes that are a part of field activities. Field operations described in this section have been broken down into the phases mentioned above, but individual monitoring programs might require the use of more or fewer phases. For example, if the sample collection phase is very complex or if it is anticipated that sample collection will often be done under inclement weather conditions when field personnel might experience discomfort and feel rushed, it is advisable to break sample collection into separate preparation, sampling, and termination phases and discuss QA/QC for each of the phases separately. This will ensure that no details are omitted.

8.4.1 Field Design

Adherence to the procedures specified in the QAPP for field operations and documentation of their use for all aspects of field operations are extremely important if the data obtained from the project are to be useful for decision making, supportable if questioned, and comparable for use by future researchers (Knapton and Nimick 1991). Data sheets, for recording site visit information and field data, should be prepared beforehand. Where applicable data sheets should include data quality reminders to help ensure that all data are collected and QA/QC procedures are followed during all field activities.

General information that should be included in the documentation of the design for field operations includes the scale of the operations (laboratory, plot, hillslope, watershed); size of plots/data collection sites; designation of control sites; basin characteristics; soil and vegetation types; maps with the location of plots/data collection sites within the basin/catchment; weather conditions under which sampling is conducted; equipment and methods used; problems that might be encountered during sampling; dates of commencement and suspension of data collection; temporal gaps in data collection; frequency of data collection; intensity of data collection; and sources of any outside information (e.g., soil types, vegetation identifications) (Erickson et al., 1991). Some of these aspects are discussed in greater detail in the following sections.

8.4.2 Sampling Site Selection

The selection of sampling sites is important to the validity of the results. Sites must be selected to provide data to meet the goals/objectives of the project. The QAPP should provide detailed information on sampling site locations (e.g., latitude and longitude); characteristics that might be important to data interpretation (e.g., percent riparian cover, stream order); and the rationale for selecting the sites used (Knapton and Nimick, 1991). Sites from other studies can be convenient to use due to their familiarity and the availability of historical data, but such sites should be scrutinized carefully to be certain that data obtained from them will serve the objectives of the project. If during the course of the project it is found that one or more sampling sites are not providing quality data, alternative sites might be selected and the project schedule adjusted accordingly. The adequacy of the sampling locations and the sampling program should be reviewed periodically by project managers, as determined by data needs (Knapton and Nimick, 1991).

Sampling sites should be visited before sampling begins. It is important to verify that the sites are accessible and are suitable for collection of the data needed. Consideration should be given to accessibility in wet or inclement weather if samples will be taken during such conditions. The sites should be visited, if possible, in the type(s) of weather during which sampling will occur.

Plastic-laminated pictures of each sampling site with an arrow pointing to each monitoring location can assist field personnel in finding the sites during inclement weather when the sites might appear different.

If permission to access a site is needed (for instance, if one or more sites are on or require passage through private property), such permission must be obtained before sampling begins. The person(s) granting the permission should be fully informed about the number of persons who will be visiting during each sampling event, frequency of sampling, equipment that will have to be transported to the sampling site(s), any hazardous or dangerous materials that will be used during sampling, and any other details that might affect the decision of the person(s) to grant access permission. A lack of full disclosure of information to gain access permission creates a risk of the permission's being revoked at some point during the project. A copy of the site entry permission letter or document should be taken to the site at the time of field visit.

8.4.3 Sampling Equipment

Equipment for field operations includes field-resident equipment such as automatic samplers and stage-level recorders and nonresident sampling equipment such as flow, pH, and conductivity meters; equipment needed to gain access to sampling sites such as boats; and equipment for field personnel health and safety, such as waders, gloves, and life vests. The condition and manner of use of the field equipment determines the reliability of the collected data and the success of each sampling event. Therefore, operation and maintenance of the equipment are important elements of field QA/QC. All measurement equipment must be routinely checked and calibrated to verify that it is operating properly and generating reliable results, and all access and health and safety equipment should be routinely checked to be certain that it will function properly under all expected field conditions.

A manual with complete descriptions of all field equipment to be used should be available to all field personnel. The manual should include such information as model numbers for all measurement equipment, operating instructions, routine repair and adjustment instructions, decontamination techniques, sampling preparation instructions (e.g., washing with deionized water), and use limitations (e.g., operating temperature range). If any samples are to be analyzed in the field, the techniques to be used should be thoroughly described in the manual.

8.4.4 Sample Collection

A Sampling Plan should be developed and approved prior to sampling. The process of sample collection should be described with the same amount of detail as the equipment descriptions. A thorough description of the sample collection process includes when the sampling is to be done (e.g., time of day, month, or year; before and/or after storms); the frequency with which each type of sample will be collected; the location at which samples are to be taken (i.e., depth, distance from shore, etc.); the time between samples (if sampling is done repetitively during a single sampling site visit); and how samples are to be labeled. Each field person must be thoroughly familiar with the sampling techniques (and equipment) prior to the first sampling event. Holding practice sampling events prior to the commencement of actual sampling is an excellent way to prepare all field personnel and will help to identify potential problems with the

sampling sites (access, difficulty under different weather conditions), sampling equipment, and sampling techniques.

Quality control activities for field operations must ensure that all field operations are conducted so that sampling is done in a consistent manner and that all generated information is traceable and of known and comparable quality. Each field activity should be standardized. Standard operating procedures (SOPs) for field sampling have been developed and might be required depending on the agency for which the sampling is being conducted. Elements of the field operations section of a QAPP should include clear statements of the regulatory requirements applicable to the project. Any SOPs that are part of regulatory requirements should be followed precisely. The pictures taken of each sampling site to aid in locating the sampling sites also help ensure consistency of field monitoring across time and personnel by ensuring that the same spot is used at each sampling event.

Depending on the DQOs and data requirements of the program (type of data and frequency of collection), additional quality control samples might be needed to monitor the performance of various field (as well as laboratory) operations including sampling, sample handling, transportation, and storage.

As the samples are collected, they must be labeled and packaged for transport to a laboratory for analysis (or other facility for nonchemical analyses). Computer-generated sample bottle labels prepared before the sampling event and securely attached to each bottle help minimize mistakes. Sampling location and preservation, filtration, and laboratory procedures to be used for each sample should be recorded on each label. Be sure these labels are printed with waterproof ink on waterproof paper, and use a No. 2 pencil or waterproof/solvent-resistant marker to record information.

8.4.5 Sample Handling and Transport

Once samples have been collected, they must be analyzed, usually in a laboratory. Handling and transport of sampling containers and custody of sample suites is also a part of field operations. Sample transport, handling, and preservation must be performed according to well-defined procedures. The various persons involved in sample handling and transport should follow SOPs for this phase of the project. This will help ensure that samples are handled properly, comply with holding time and preservation requirements, and are not subject to potential spoilage, cross-contamination, or misidentification.

The chain of custody and communication between the field operations and other units such as the analytical laboratory also need to be established so that the status of the samples is always known and can be checked by project personnel at any time. The chain of custody states who the person(s) responsible for the samples are at all times. It is important that chain of custody be established and adhered to so that if any problem with the samples occurs, such as loss, the occurrence can be traced and possibly rectified, or it can be determined how serious the problem is and what corrective action needs to be taken. Field data custody sheets are essential for this effort (Cross-Smiecinski and Stetzenback, 1994). Chain-of-custody seals must be applied to sample containers and shipping containers.

8.4.6 Safety and Training

When dealing with NPS monitoring, sampling activities often occur during difficult weather and field conditions. It is necessary to assess these difficulties and establish a program to ensure the safety of the sampling personnel. The following types of safety issues, at a minimum, should be considered and included in training and preparation activities for sampling: exposure, flood waters, debris in rivers and

streams, nighttime collecting, criminal activity, and first aid for minor injuries. The trade-off between the need for data quality and the safety of personnel is a factor that project staff should consider collectively.

Finally, the QAPP for the field operations should include provisions for dealing with any foreseeable problems such as droughts, floods, frozen water, missing samples, replacement personnel during sickness or vacation, lost samples, broken sample containers, need for equipment spare parts, and other concerns.

8.5 Laboratory Operations

Laboratory operations should be conducted with great care and attention to detail. Often, an independent laboratory conducts sample analyses, so QA/QC for the laboratory are not under the direct control of project personnel. However, it is important that project personnel are certain that the laboratory chosen to do analyses follows acceptable QA/QC procedures so that the data produced meet the DQOs established for the project. Laboratories should be selected based on quality assurance criteria established early in the project. The Quality Assurance Officer for the project should be certain that these criteria are used for selecting a laboratory to perform any necessary analyses for the project and that any laboratories selected meet all criteria. Laboratories can be evaluated through the following measures (Air National Guard, 1993):

- Performing proficiency testing through analysis of samples similar to those which will be collected during the project.
- Performing inspections and audits.
- Reviewing laboratory QA/QC plans.
- One or more of these measures should be used by the project manager, and the laboratories should be visited before entering into a contract for sample analyses.

8.5.1 General Laboratory QA/QC

EPA recommends using an accredited laboratory with an established QA/QC policy to ensure that results will be defensible. The National Environmental Laboratory Accreditation Conference (NELAC) Institute provides accreditation of environmental testing laboratories. Numerous references are available on laboratory QA/QC procedures, and one or more should be consulted to gain an understanding of laboratory QA/QC requirements if project personnel are not familiar with them already. The details of a laboratory's QA/QC procedures must be included in the QAPP for the NPS monitoring project. Some elements to look for in a laboratory QA/QC plan include (Cross-Smiecinski and Stetzenback, 1994):

- How samples are received
- Proper documentation of their receipt
- Sample handling
- Sample analysis
- QC requirements (procedures and frequencies of QC checks, criteria for reference materials, types of QC samples analyzed and frequencies)
- Waste disposal
- Cleanliness and contamination

- Staff training and safety
- Data entry and reporting
- Confidentiality

This section provides some information on laboratory QA/QC procedures to which managers of monitoring programs should pay particular attention when deciding to use a particular laboratory for sample analysis.

8.5.2 Instrumentation and Materials for Laboratory Operations

The laboratory chosen to do chemical analyses should have all equipment necessary to perform the analyses required, including organic analysis, inorganic analysis, and assessments of precision and accuracy. If any specialized analyses are required (e.g., microbiology, histopathology, toxicology), be certain that the laboratory has the appropriate equipment and that laboratory staff are adequately trained to perform the desired analyses. As noted in the elements of the QAPP, periodic calibration checks that are conducted to ensure that measurement systems (instruments, devices, techniques) are operating properly should be described in the QAPP, including procedures and frequency (Cross-Smiecinski and Stetzenback, 1994).

8.5.3 Analytical Methods

The laboratory chosen for sample analysis should use analytical methods approved by the agency for which the sampling is being conducted or by project personnel, as appropriate. Standard methods include those published by the U.S. Geological Survey (USGS), the USEPA, and the American Society for Testing and Materials (ASTM), or those published in *Standard Methods for Examination of Water and Wastewater* (Rice et al., 2012). A compendium of methods for environmental analysis is maintained by the National Environmental Methods Index (NEMI), supported by both USGS and USEPA. If any methods to be used are not published, they should first be validated and verified as acceptable for the project. Each approved and published method should be accompanied by an SOP that is followed rigorously by the laboratory (Pritt and Raese 1992).

8.5.4 Method Validation

The laboratory chosen for sample analysis should have well-developed procedures for method validation. Method validation should account for and document the following (at a minimum): Known and possible interferences; method precision; method accuracy, bias, and recovery; method detection level; and method comparability to superseded methods, if applicable (Pritt and Raese 1992).

8.5.5 Training and Safety

An analytical laboratory should be able to ensure its customers that its personnel are adequately trained to perform the necessary analyses. Individual laboratory staff should be independently certified for each of the analyses they will be allowed to perform in the laboratory. Selection of a laboratory for sample analysis should be based on queries about how often training is conducted, whether employees are limited to using equipment for which they have been adequately trained, whether the training program is

independently certified, who conducts the training, how the staff's competence with individual instruments is measured, and other factors (Pritt and Raese 1992).

Safety for staff is an important consideration when choosing a laboratory because, aside from the paramount concern for human well-being, accidents can seriously delay sample analyses or create a need for resampling. Prospective laboratories should be inspected for their attention to safety procedures, including the availability of safety equipment such as fire extinguishers, safety showers and eyewashes, fume hoods, and ventilation systems; use and disposal practices for hazardous materials; and compliance with environmental regulations. Safety equipment should be tested on a regular basis (Pritt and Raese 1992).

Additionally, laboratory safety includes procedures for ensuring that the laboratory is accessible only to authorized personnel to ensure confidentiality of the data. The laboratory should have a system for accounting for and limiting (or denying) laboratory access to all visitors, including persons affiliated with projects for which the laboratory is analyzing samples (Pritt and Raese 1992).

8.5.6 Procedural Checks and Audits

A laboratory should have established procedures (SOPs) for conducting internal checks on its analyses and taking corrective action when necessary. If more than one laboratory is used for sample analyses, it will be important to know that the data obtained from the two are of the same quality and consistency. A protocol for conducting interlaboratory comparisons should also be an element of a laboratory's QA/QC plan. For many projects occasional samples are analyzed by a second laboratory to determine whether there is any bias in the data associated with the primary laboratory's analyses.

Laboratory audits by independent auditors are normally conducted on a prescribed basis to ensure that laboratory operations are conducted according to accepted and acceptable procedures (Cross- Smiecinski and Stetzenback, 1994). Determination that a laboratory undergoes such audits and reviews audit results might be sufficient to determine that a laboratory will be adequate for conducting analyses of samples generated by the NPS monitoring project.

8.6 Data and Reports

It is essential during the conduct of an NPS monitoring project to document all data collected and used, to document all methods and procedures followed, and to produce clear, concise, and readable reports that will provide decision makers with the information they need to choose among alternative actions, as described in the DQOs. See sections 3.9 and 3.10 for additional details on data management, reporting, and presentation.

8.6.1 Generation of New Data

All data generated during the project, whether in the field, laboratory, or some other facility, should be recorded. Include with the data any reference materials or citations to materials used for data analyses. These include computer programs, and all computer programs used for data reduction should be validated prior to use and verified on a regular basis. Calculations should be detailed enough to allow for their reconstruction at a later date if they need to be verified (Cross-Smiecinski and Stetzenback 1994). Data generated by a laboratory should be accompanied by pertinent information about the laboratory, such as its name, address, and phone number, and names of the staff who worked directly with the project samples.

8.6.2 Use of Historical Data

Historical data are data collected for previous projects that concerned the same resource in the same area as the project to be implemented. Historical data sometimes contain valuable information, and their use can save time and effort in the implementation and/or data analysis phases of a new project. Before new data are collected, all historical data available should be obtained and their validity and usability should be assessed. *Data validity* implies that individual data points are considered accurate and precise because the field and laboratory methods used to generate the data points are known. *Data usability* implies that a database demonstrates an overall temporal or spatial pattern, though no judgment of the accuracy or precision of any individual data point is made (Spreizer et al., 1992). The validity of historical data can be difficult to ascertain, but data usability can be assessed through a combination of graphical and statistical techniques (Spreizer et al. 1992).

Specifically, historical data that can be shown to be either valid or usable can be applied to a new project in the following ways (Coffey 1993, Spreizer et al. 1992, USEPA 2001c):

- If the quality (i.e., accuracy and precision) of historical data is sufficiently documented, the data can be used alone or in combination with new data. The quality of historical data should be evaluated relative to the project requirements.
- Characteristics derived from the historical data, such as the variability or mean of data, can be used in the development or selection of a data collection design. Knowledge of expected variability assists in determining the number of samples needed to attain a desired confidence level, the length of monitoring program necessary to obtain the necessary data, and the required sampling frequency (see section 3.4.2).
- Spatial analysis of historical data can indicate which sampling locations are most likely to provide the desired data.
- Historical data can provide insights about past impacts and water quality that can be useful in defining an NPS pollution problem.
- Past trends can be ascertained, and the present tendency of water quality characteristics (degrading, stable, or improving) can be established for trend analysis (see section 7.8.2.4).

8.6.3 Documentation, Record Keeping, and Data Management

- All information and records related to the NPS monitoring project should be kept on file and kept current. This documentation should include:
- A record of decisions made regarding the monitoring project design
- Records of all personnel, with their qualifications, who participated in the project
- Intended and actual implementation schedules, and explanations for any differences
- A description of all sampling sites
- Field records of all sampling events, including any sampling problems and corrective actions taken
- Copies of all field and laboratory SOPs
- Equipment manuals and maintenance schedules (intended and actual, with explanations for any discrepancies)

- Printouts from any equipment
- Sample management and custody records
- Laboratory procedures
- Copy of the laboratory QA/QC plan
- Personnel training sessions and procedures, including any training manuals or other materials
- All data generated during the project in hard copy and electronic forms
- All correspondence related to the project
- Project interim and final reports

One aspect that merits further discussion is documentation and management of data, from the collection process through the data analysis. Data management activities include documenting the nature of the data and subsequent analyses so that the data from different sites are comparable. Data management also includes handling and storing both hard copies and electronic files containing field and laboratory data. A data management system that addresses project needs should be selected at the beginning of the monitoring program (see section 3.9). It is also important to understand and comply with applicable state agency and/or grant policies and standards regarding data collection and generation.

Some grants might require local NPS and water resources managers to add their data to EPA's storage and retrieval (STORET) database (https://www.epa.gov/waterdata/storage-and-retrieval-and-water-quality-exchange). STORET contains raw biological, chemical, and physical data on surface water and ground water collected by federal, state, and local agencies; tribes; volunteer groups; academics; and others. Each sampling result in STORET is accompanied by information on where the sample was taken (latitude, longitude, state, county, hydrologic unit code, and brief site identification), when the sample was gathered, the medium sampled (e.g., water, sediment, fish tissue), and the name of the organization that sponsored the monitoring. Staff working with the database should have expertise and training in the software and in the procedures for data transport, file transfer, and system maintenance.

The operation of the data management system should include QA oversight and QC procedures. If changes in hardware or software become necessary during the course of the project, the data manager should obtain the most appropriate equipment and test it to verify that the equipment can perform the necessary jobs. Appropriate user instructions and system documentation should be available to all staff using the database system. Developing spreadsheet, database, and other software applications involves performing QC reviews of input data to ensure the validity of computed data.

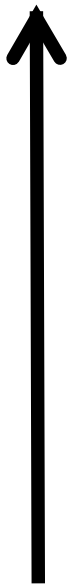
8.6.4 Report Preparation

The original project description should include a schedule and format for required reports, including the final report. Adherence to this schedule is important to provide information and documentation of project progress, problems encountered, and corrective actions taken. Reports are also valuable for supporting continuation of a project if at any point during the project its continuation is scrutinized or if additional funding must be secured to ensure its completion. Reports can also become the primary sources of historical information on projects if there are changes in project personnel during the project. Project managers should decide on the necessary content and format of all reports prior to commencement of the project, and these will differ depending on funding and intended audience.

8.7 Geospatial Data

Projects should incorporate procedures for documenting geospatial data appropriately. Geospatial Information System (GIS) data can vary from relatively simple site locations to complex with many overlapping contextual boundaries. For example, the development of a watershed implementation plan may involve analyzing water samples from industrial dischargers, developing water quality models, creation of new geospatial data, or even updating existing geospatial data. Use of geospatial data from external sources may require the development of a secondary data QAPP. QAPPs also apply to geospatial data (USEPA 2001b), but should vary with the complexity of the project (see Table 8-3). The project planning phase should determine the scope and complexity of the project that will inform the complexity of the QAPP (USEPA, 2003b).

Table 8-3. Continuum of Geospatial Projects with Differing Intended Uses

Purpose of Project	Typical Quality Assurance Issues	Level of QA
Regulatory compliance Litigation Congressional testimony	Legal defensibility of data sources Compliance with laws and regulatory mandates applicable to data gathering Legal defensibility of methodology	
…	…	
Regulatory development Spatial data development (Agency infrastructure development)	Compliance with regulatory guidelines Existing data obtained under suitable QA program Audits and data reviews	
…	…	
Trends monitoring (non-regulatory) Reporting guidelines (e.g., Clean Water Act) “Proof of principle”	Use of accepted data-gathering methods Use of accepted models/analysis techniques Use of standardized geospatial data models Compliance with reporting guidelines	
…	…	
Screening analyses Hypothesis testing Data display	QA planning and documentation as appropriate Use of accepted data sources Peer review of products	

Source: USEPA, 2003b.

8.7.1 Performance Criteria for a Geospatial Data Project

Projects with geospatial components will likely follow the same DQO process described in section 8.2 of this chapter. In decision-making programs taking the form of the DQO process, data quality to achieve a desired level of confidence in the decision takes a number of typical forms as listed below (USEPA 2003b):

- A description of the resolution and accuracy needed in input data sources
- Statements regarding the speed of applications programs written to perform data processing (e.g., sampling at least “n” points in “m” minutes)
- Criteria for choosing among several existing data sources for a particular geospatial theme (e.g., land use); geospatial data needs are often expressed in terms of using the “best available” data, but different criteria—such as scale, content, time period represented, quality, and format—

may need to be assessed to decide which are the "best available" (when more than one is available) to use on the project

- Specifications regarding the accuracy needs of coordinates collected from GPS receivers
- Criteria for aerial photography or satellite imagery geo-referencing quality, such as specifications as to how closely these data sources need to match spatially with ground-based reference points or coordinates
- Criteria for minimum overall match rate, tolerances including whether or not spatial offsets are to be supplied in the resulting coordinates procedures, and if so, the offset factor in address matching
- Topology, label errors, attribute accuracy, overlaps and gaps, and other processing quality indicators for map digitizing
- Criteria to be met in ground-truthing classified satellite imagery

8.7.2 Spatial Data Quality Indicators for Geospatial Data

The most comprehensive way to track the quality and applicability of a geospatial data set is through the use of metadata. EPA requires that appropriate metadata accompany every data set, in accordance with Federal Geographic Data Committee standards (FGDC 1998). There are five components applicable to the Federal Geographic Data Committee metadata requirements (FGDC 1998, USEPA 2003b):

- **Accuracy – positional:** The closeness of the locations of the geospatial features to their true position.
- **Accuracy – attribute:** The closeness of attribute values (characteristics at the location) to their true values.
- **Completeness:** The degree to which the entity objects and their attributes in a data set represent all entity instances of the abstract universe (defined by what is specified by the project's data use in systematic planning). It is in the metadata where the user may define the abstract universe with criteria for selecting features to include in the data set. The information is relevant to any user who wishes to independently replicate geospatial procedures. Missing, or incomplete data can affect logical consistency needed for correct processing of data by software.
- **Logical consistency:** The data in any spatial data set is logically consistent when it complies with the structural characteristics of the data model and is compatible with attribute constraints defined for the system.
- **Lineage:** The description of the origin and processing history of a data set.

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