5. QUALITY ASSURANCE AND QUALITY CONTROL

5.1 INTRODUCTION

Quality assurance (QA) and quality control (QC) are commonly thought of as procedures used in the laboratory to ensure that all analytical measurements made are accurate. Yet QA and QC extend beyond the laboratory and are essential components of all phases and all activities within each phase of a nonpoint source (NPS) monitoring project. This section defines QA and QC, discusses their value in NPS monitoring programs, and explains EPA's policy on these topics. The following sections provide detailed information and recent references for planning and ensuring quality data and deliverables that can be used to support specific decisions involving nonpoint source pollution.

5.1.1 Definitions of Quality Assurance and Quality Control

Quality assurance:

An integrated system of management procedures and activities used to verify that the quality control system is operating within acceptable limits and to evaluate the quality of data (Taylor, 1993; USEPA, 1994c).

Quality control:

A system of technical procedures and activities developed and implemented to produce measurements of requisite quality (Taylor, 1993; USEPA, 1994c).

QC procedures include the collection and analysis of blank, duplicate, and spiked samples and standard reference materials to ensure the integrity of analyses and regular inspection of equipment to ensure it is operating properly. 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 5-1 lists some common activities that fall under the headings of QA and 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.

5.1.2 Importance of QA/QC Programs

Although the value of a QA/QC program might seem questionable while a project is under way, its value should be quite clear after a project is completed. If the objectives of the project were used to design an appropriate data collection and analysis plan, all QA/QC procedures were followed for all project activities, and accurate and complete records were kept throughout the project, the data and information collected from the project will be adequate to support a choice from among alternative courses of action. In addition, the course of action chosen will be defensible based on the data and information collected. Development and implementation of a QA/QC program can require up to 10 to 20 percent of project resources (Cross-Smiecinski and Stetzenback, 1994), but this cost can be recaptured in lower overall costs due to the project's being well planned and executed. Likely problems are anticipated and accounted for before they arise, eliminating the need to spend countless hours and dollars resampling, reanalyzing data, or mentally reconstructing portions of the project to determine where an error was introduced. 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).

Table 5-1. Common QA and QC activities.

QA Activities

- Organization of project into component parts
- Assignment of roles and responsibilities to project staff
- Use of statistics to determine the number of 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
- Audits of field and laboratory operations
- Maintenance of accurate and complete records of all project activities
- Personnel training to ensure consistency of sample collection techniques and equipment use

QC Activities

- Collection of duplicate samples for analysis
- Analysis of blank and spike samples
- Replicate sample analysis
- Regular inspection and calibration of analytical equipment
- Regular inspection of reagents and water for contamination
- Regular inspection of refrigerators, ovens, etc. for proper operation

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

This chapter discusses many elements and aspects of QA/QC programs that do not differ significantly from one type of program to another—for instance, from a point source permit compliance sampling program to an NPS best management practice effectiveness monitoring program. Therefore, much of the following discussion is not specific to NPS projects. This does not, however, mean that a well-designed and well-implemented QA/QC program is not necessary for an NPS project. It is hoped that the following discussion will convey to the reader the importance of QA and QC to the success of every project involving the collection and analysis of environmental data.

5.1.3 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 methodologies, 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 insufficient for decision making. QA/QC practices should be used as an integral part 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, 1994d).

EPA's mandatory agency-wide Quality System policy 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, 1984c). This policy is now based on the quality system standard developed by the American Society of Quality Control (ASQC, 1994). 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 and QC operations applied to environmental programs (USEPA, 1994d). In addition, each non-EPA organization must have a well-documented Quality Assurance Project Plan (QAPP) that covers each monitoring or measurement activity associated with a project (Erickson et al., 1991; USEPA, 1983c, 1994).

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). This information is used to design the program to meet these objectives. Developing a QAPP prior to undertaking the NPS monitoring project also establishes the boundaries of the project, in terms of the time allotted to it and the decisions that can realistically be made from the data and information that will be collected.

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. 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 the work 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, 1994c).

5.2 DATA QUALITY OBJECTIVES (DQOS)

Before collecting environmental data in support of an NPS project, it is important to determine the type, quantity, and quality of data needed to meet the project objectives and support a specific decision based on the results of the project. Not doing so creates the risk of expending too much effort on data collection (i.e., more data are collected than necessary), not expending enough effort on data collection (i.e., more data are necessary than were collected), or expending the wrong effort (i.e., the wrong data were collected).

Proper planning and execution of a data collection effort can prevent these problems. EPA has developed the Data Quality Objectives Process as a flexible planning tool that should be used to prepare for a data collection activity. The information compiled in this effort is then used to develop the QAPP (USEPA, 1994e).

5.2.1 The Data Quality Objectives Process

The Data Quality Objectives (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, 1994e).

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.

The DQO process consists of seven steps, described below. The process is iterative. As one step of the process is completed, its outputs might lead to reconsideration of previous steps. The previous steps should then be repeated. Optimization of the design (the last step) should begin only when all previous steps have been completed. When the optimization step is reached, as at any time during the DQO process, it might be necessary to reconsider earlier steps (i.e., to reiterate part or all of the process) to determine the optimum design.

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 for the Data Quality Objectives Process* (USEPA, 1994e), from which the following information was taken. This reference contains a case study example of the DQO process. A computer program, *Data Quality Objectives Decision Error Feasibility Trials* (EPA QA/G-4D), 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. (Contact EPA's Quality Assurance Management Staff, 202 260-9464).

(1) State the problem

In this first step the problem to be studied is described concisely. 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.

(2) Identify the decision

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" that will link the principal study question to one or more possible actions that should solve the problem. Possible options include take no action, take action, or modify an action. A decision statement might be phrased as follows: *Determine whether [or which] NPS impacts require taking [one of the alternative actions]*. For example, if the question to be addressed is "Are nutrients from agricultural runoff contributing to the growth of algal mats in the river?" and the alternative actions are "require vegetation buffers along streams" or "take no action," the decision statement is "Determine whether nutrients from agricultural runoff are contributing to algal growth and require regulation." 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.

(3) Identify the inputs to the decision

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.

(4) Define the study boundaries

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 parameter, 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 (since 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.

(5) Develop a decision rule

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 the mean concentration of contaminant X in the water downstream from farm Y exceeds 0.5 µg/L, then vegetation will be planted; 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.

(6) Specify limits on decision errors

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 no impact when there is [a false positive, or type I error], or deciding there is an impact when there is none [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 point above and below the gray region that reflect the tolerable probability for the occurrence of decision errors.

(7) Optimize the design

Evaluate information from the previous steps and generate alternative data collection designs. 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. 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.

5.2.2 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, 1994e). The QAPP presents the policies, organization, and objectives of the data collection effort and explains how particular QA and 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, 1994e). 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, 1994e).

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, 1994c, 1994e). 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, 1994e).

5.3 Elements of a Quality Assurance Project Plan

QAPPs must be prepared according to guidance provided in *EPA Requirements for Quality Assurance Project Plans for Environmental Data Objectives* (USEPA, 1994c). EPA requires that four types of elements be discussed in a Quality Assurance Project Plan (QAPP). These elements are listed in Table 5-2 and discussed briefly below. (For complete descriptions and requirements, be sure to see USEPA (1994c)). 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 described below should always be addressed in the QAPP, unless otherwise directed by the overseeing or sponsoring EPA organization(s). The types, quantity, and quality of environmental data collected for each project could be quite different. As noted in USEPA (1994c), "the content and level of detail in each QAPP will vary according to the nature of the work being performed and the intended use of the data." 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 work can begin, and it should be reviewed annually (for multiyear projects) and updated and reapproved as often as necessary during the project.

5.3.1 Group A: Project Management

These elements cover basic project management, including project history and objectives, roles and responsibilities of participants, and other factors to ensure that the project has a defined goal understood by all the participants and that all planning activities have been documented.

A1 Title and Approval Sheet

Provide the title of the plan; name of organization(s) implementing the project; and names, titles, and signatures of the appropriate approving officials and their approval dates.

A2 Table of Contents

List sections, figures, tables, references, and appendices. If document control format is required, see Cross-Smiecinski and Stetzenback (1994) and USEPA (1994e).

Table 5-2. Elements required in an EPA Quality Assurance Project Plan. (USEPA, 1994b)

	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 for Measurement Data
A8	Project Narrative (ORD only)
A9	Special Training Requirements/Certification
B1	Sampling Process Design
B2	Sampling Methods Requirements
B3	Sampling Handling and Custody Requirements
B4	Analytical Methods Requirements
B5	Quality Control Requirements
B6	Instrument/Equipment Testing, Inspection, Maintenance Requirements
B7	Instrument Calibration and Frequency
B8	Inspection/Acceptance Requirements for Supplies and Consumables
B9	Data Acquisition Requirements (Nondirect Measurements)
B10	Data Management
C1	Assessments and Response Action
C2	Reports to Management
D1	Data Review, Validation, and Verification Requirements
D2	Validation and Verification Methods
D3	Reconciliation and User Requirements

A3 Distribution List

List all individuals and organizations who will receive copies of the approved QAPP and subsequent revisions.

A4 Project/Task Organization

Discuss the specific roles and responsibilities of all individuals or organizations participating in the project.

A flow chart or box diagram is useful for depicting project organization and responsibilities (Figure 5-1). Using the diagram, explain the rationale for the organization (e.g., to maximize the interaction of site and task leaders). This section provides details on the division of the project into teams, support teams, review committees, and other groups and identifies the persons and entities that will be involved in the project. All members of each project team should be listed along with their

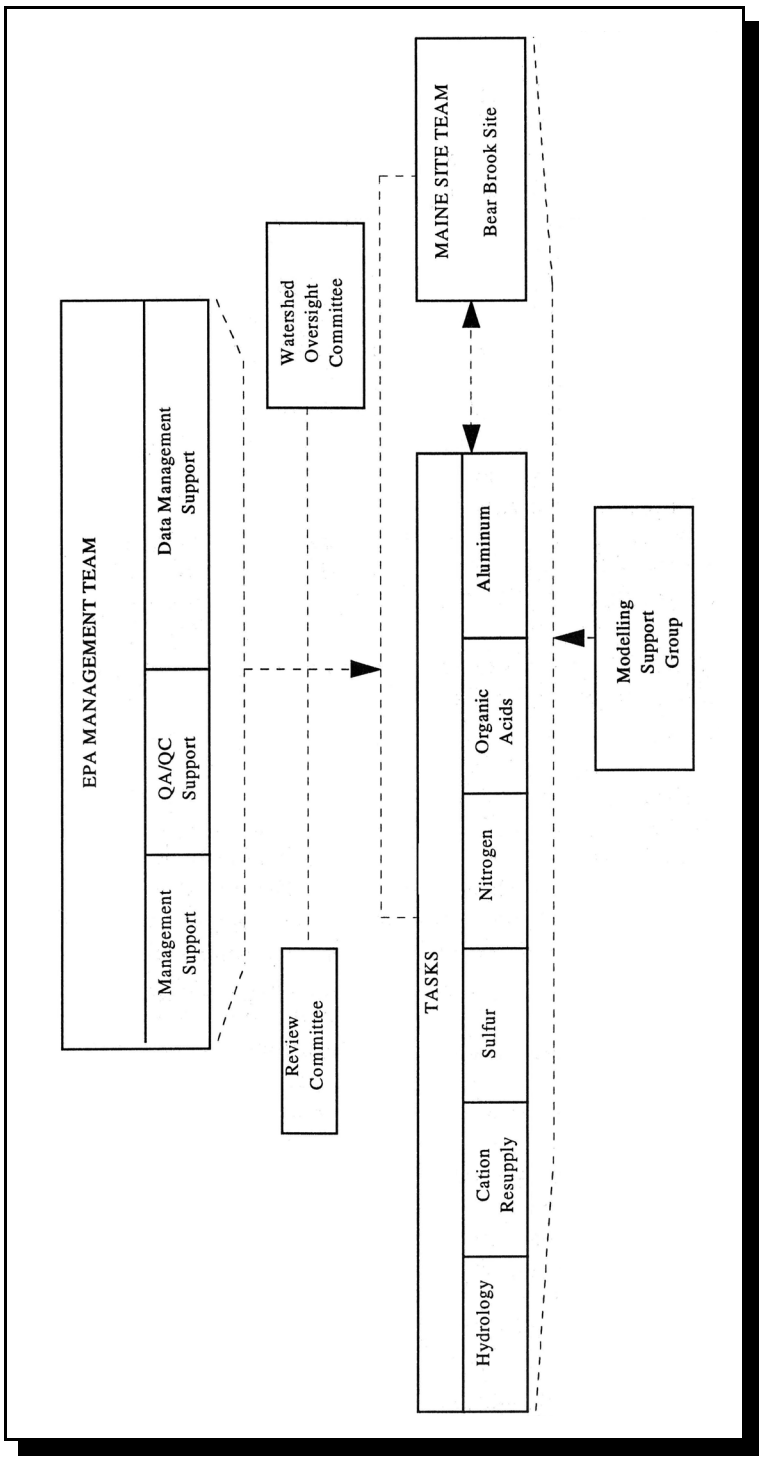

Figure 5-1. Sample organization chart for a quality assurance project plan. (Erickson et al., 1991)

affiliations with participating organizations. The program manager, managers or coordinators of any specific tasks, directors of technical tasks to be conducted, and any organizations or agencies that will be involved in the project should be identified. Also identify the specific roles and responsibilities (such as field sampling, laboratory analyses, and report preparation) that will be conducted by each person and organization involved in the project.

A5 Problem Definition/Background

State the problem to be solved or the decision to be made and describe its history for this particular project.

A6 Project/Task Description

Describe the work to be performed (measurements to be made, applicable quality standards, any special personnel or equipment requirements, assessment tools needed, records and reports needed) and the schedule for its implementation.

A7 Quality Objectives and Criteria for Measurement Data

The DQO process will provide this information, or state the project quality objectives and measurement performance criteria that are necessary to support the management decision(s) to be made based on the result(s) of the project. State quality objectives in terms of project requirements, preferably in quantitative terms, rather than in terms of analytical or sampling method capabilities. Then, with the quality objectives stated, select the appropriate methods to achieve the requirements (Cross-Smiecinski and Stetzenback, 1994). The quality of data should be expressed in terms of precision, accuracy, comparability, representativeness, and completeness (defined below). A table of quality objectives, like that in Figure 5-2, is helpful.

Definitions of data quality terms

Precision (reproducibility)

(a) Precision is a measure of mutual agreement among individual measurements of the same property. The coefficient of variation (CV), also known as the percent relative standard deviation (RSD), is used to express precision (Erickson et al., 1991).

$$CV = \left(\frac{s}{\bar{x}}\right) 100$$

where

s = sample standard deviation and
x = arithmetic mean.

(b) Precision is an expression of mutual agreement of multiple measurement values of the same property conducted under prescribed 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.

Parameter	Units	Expected Range	Accuracy	Precision	Completeness
Particulate NO_3/SO_4					
SSI[a]	$\mu g/m^3$	10-1000	10%	20%	70%
47 mm TF/PC[b]	$\mu g/m^3$	10-1000	10%	20%	90%
NO_3					
47 mm TF/PC	$\mu g/m^3$	1 to 25	20%	20%	90%
SO_2					
47 mm TF/PC	$\mu g/m^3$	1 to 75	20%	20%	90%
Meteorological					
Wind speed	m/s	0 to 75	2%	2%	90%
Wind direction	deg	0 to 360	2%	2%	90%
Dew point	0°C	-30 to 70	2%	5%	90%
Solar radiation	watts/m^2	-	-	-	-
Ambient temperature	°C	-20 to 50	1°C	2°C	90%

[a] PM_{10} Size Selective Inlet High Volume Sampler
[b] Teflon/Polycarbonate Filter

Figure 5-2. Sample quality assurance objectives. (Erickson et al., 1991).

Accuracy (bias)

(a) Accuracy 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).

(b) Accuracy is the correctness of the value obtained from analysis of a sample. It is 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

(a) Comparability is defined as the confidence with which one data set can be compared to another (Erickson et al., 1991).

(b) Comparability is the quality that makes data obtained from one study comparable to data from other studies. 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

(a) Representativeness can be defined both qualitatively and quantitatively; it depends on the experimental design and choice of sampling methods. The desired degree of representativeness is important in planning for the collection of samples and the subsequent uses of the data. 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).

(b) Representativeness is a measure of how representative the data obtained for each parameter is compared with the value the same parameter has within the population being measured. Since 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).

Completeness

(a) 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).

(b) Completeness is the amount of valid data obtained from the measurement system (field and laboratory) versus the amount of data expected from the system. 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).

A8 Project Narrative

This is a narrative description of work to be performed that will demonstrate to technical or QA reviewers that the project or task will achieve its quality objectives. See USEPA (1994e) for complete details of what should be included in a project narrative.

A9 Special Training Requirements/Certification

If personnel will require any specialized training or certification to successfully complete the project, discuss how this training will be obtained and documented.

A10 Documentation and Records

Itemize all of the information and records (e.g., raw data, field logs, instrument printouts, results of calibration and QC checks, analytical laboratory case narratives) that must be included in a data report package, and describe the desired report format and final disposition of records and documents.

5.3.2 Group B: Measurements and Acquisition

The Project/Task Description element (A6) contains a summary of this information, which should be provided in detail in this section. Methods that have been well documented and are available to all participants can merely be cited; for those not well documented, detailed copies of the methods and/or Standard Operating Procedures (SOPs) must be provided in the QAPP.

B1 Sampling Process Design (Experimental Design)

Explain the experimental design or data collection design, including types and numbers of samples required, sampling locations and frequencies, sampling screening criteria (if applicable), sample matrices, measurement parameters of interest, and the rationale for the design. As with all information contained in a QAPP, recording information such as the reasoning behind decisions will make the data more defensible in the future. Statistics can play an important part in determining the sampling strategy. Therefore, record all statistical procedures that will be used to determine the sampling strategy. Two basic sampling decisions that must be made are the types and numbers of quality control samples to be collected (Keith, 1988). See USEPA (1994e) for additional details on what to include in this element of the QAPP.

B2 Sampling Methods Requirements

Identify and describe all procedures for collecting samples for each sampling method, as well as what should be done when a sampling or measuring failure occurs and who is responsible for taking corrective action. Other aspects pertinent to sampling, such as record keeping, sample storage, and transport to laboratories, should also be described in this section (Cross-Smiecinski and Stetzenback, 1994).

B3 Sample Handling and Custody Requirements

Describe all aspects of sample handling and custody. Sample custody is a documentation of where and with whom samples are at all times from the moment they are collected in the field to when they are analyzed in the laboratory. A sample is considered to be under custody if (1) it is in your actual possession; (2) it is in your view, after being in your physical possession; (3) it was in your physical possession and then you locked it up to prevent tampering; or (4) it is in a designated and identified secure area (Air National Guard, 1993). Special tracking procedures called "chain-of-custody" procedures are used whenever samples are collected for use in an enforcement action or when demonstrating compliance with a regulatory requirement (e.g., NPDES). Chain-of-custody forms should be printed on multipart carbonless paper for tracking custody and should have, at a minimum, space for recording date, time, name of person accepting samples, sample numbers, and remarks (Figure 5-3). Copies of the form must be completed in the field, and signed by the fieldteam when they transfer custody of the samples to the shipper. Upon receipt in the laboratory, the laboratory signs the remaining copies, indicating they have accepted custody of the samples. Each time the form is signed, the person signing the form retains the bottom copy and passes the remaining copies along with the samples. The

CHAIN-OF-CUSTODY RECORD

PROJ NO	PROJECT NAME		No. of Containers	TAG NUMBERS	PARAMETERS				REMARKS
SAMPLERS (*Signature*)									
DATE	TIME	DESCRIPTION							

Relinquished by: (*Signature*)	Date	Time	Received by: (*Sign.*)	Relinquished by (*Sign.*)	Date	Time	Received by (*Sign.*)
Print Name:			Print Name	Print Name			Print Name

Relinquished by: (*Signature*)	Date	Time	Received by: (*Sign.*)	Date	Time	Remarks
Print Name:			Print Name			

Figure 5-3. Sample custody chart. (After Cross-Smiecinski and Stetzenback, 1994)

laboratory should return at least one copy of the completed chain-of-custody record to the client, or proceed as directed in the QAPP.

B4 Analytical Methods Requirements

Describe the analytical methods and equipment required for both field and laboratory activities, waste disposal requirements, and specific performance requirements, as well as what should be done when a failure in the analytical system occurs and who is responsible for taking the corrective action. Also include information on any supporting methods or documents used to collect field or laboratory data. For instance, if identifications of benthic invertebrates are made, include information on the source(s) used to verify identifications; if the amount of riparian vegetation cover is estimated, describe the method used to arrive at the estimate.

Analytical methods: Describe the methods that will be used for the project. If the methods to be used are published (e.g., by the U.S. Geological Survey, EPA, or ASTM) it is sufficient to indicate what methods will be used and where descriptions of them can be found. If the best methods to be used cannot be completely ascertained until some samples have been analyzed, indicate the order of preference for use of the methods. Any modifications to published or standard methods or variations of them must be documented, and the variations must be verified as providing data of acceptable quality.

Method validation: Method validation accounts for and documents, at a minimum, the following characteristics: known and possible interferences; method precision; method accuracy, bias, and recovery; method detection level, and method comparability to superseded methods, if any (Pritt and Raese, 1992). All methods chosen for use in the project must be validated.

Generally, laboratories with their own QA/QC procedures will be used for sample analyses. The methods to be used in the laboratory must be acceptable to project managers. All potential laboratory facilities to be used in the project should be extensively evaluated before their selection and throughout their participation in the project.

B5 Quality Control Requirements

Identify the QC procedures (types, frequency, and control limits of QC checks) needed for each sampling, analysis, or measurement technique. (They might have to be modified to suit each project.) Also state what corrective action is required when control limits are exceeded. Data collected as part of field sampling and laboratory measurements must be verified as accurate. Thus, some samples are taken or measurements made to check for accuracy rather than to collect additional data. Specify what means will be used to check the accuracy of samples and measurements. Field blanks, duplicate samples, replicate samples, spiked samples, and spiked blanks are commonly used methods. Describe precisely how these control samples will be prepared for analysis.

Standard reference materials (SRMs) should be used periodically in any measurement system to monitor for changes to the system that might go unnoticed. SRMs should be used when a measurement change is noted to verify that the change is not due to a change in the measurement system. The optimum frequency of use of SRMs and also of replicates of actual test samples depends on the integrity of the measurement system and the magnitude of the errors involved when the system ceases to give predictable results. All measurements from last-known-in-control sample to first-known-out-of-control sample are suspect, so the length of the period between these two samples must be calibrated to be appropriate to the measurements being made (Taylor, 1993).

B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements

This section should include descriptions of the types of preventive maintenance for equipment that will be used to ensure that research schedules are adhered to and project objectives are completed on schedule. The section should include the following: a schedule of preventive maintenance, an inventory of critical spare parts and supplies, maintenance contract information, location of important manuals and instructions, record keeping requirements, and training of instrument and equipment operators (Cross-Smiecinski and Stetzenback, 1994). Some aspects of training can be considered a part of preventive maintenance. Describe in this section general safety precautions that will be part of project operations. Examples include materials handling, transportation of chemicals, hazardous waste disposal procedures, emergency procedures, standard safety operations,

chemical hygiene, hazard communication, hazardous waste management, waste disposal, location of safety equipment, tour of facilities, and annual classes in cardiopulmonary resuscitation and standard first aid (Pritt and Raese, 1992).

B7 Instrument Calibration and Frequency

Describe the procedures used for equipment calibration, the frequency of calibration of each piece of equipment, and the results of calibration procedures. Record any problems encountered and corrective actions taken. This section should identify each tool, gauge, instrument, or other sampling, measuring, and test equipment used for data collection activities for which quality must be controlled and which must be calibrated to maintain performance within specified limits.

B8 Inspection/Acceptance Requirements for Supplies and Consumables

Supplies and consumables to be used in the project must be inspected and accepted, according to specified criteria, for use in the project. Identify who will perform the inspections and how they will be conducted.

B9 Data Acquisition Requirements (Nondirect Measurement)

Data obtained from noninstrument sources such as computer databases, spreadsheets, and programs and literature files need to be identified and acceptance criteria established for the use of the data. Also discuss any limitations resulting from uncertainty in the quality of the data and the impact of adding more error to the results.

B10 Data Management

This section should describe all aspects of data management, from their generation in the field or laboratory to final use or storage. Discuss the control mechanisms (and provide examples of forms or checklists) for detecting and correcting errors and for preventing loss of data during data reduction. This discussion should also include all data handling equipment and procedures that will be used to process, compile, and analyze the data (hardware and software).

5.3.3 Group C: Assessment/Oversight

The purpose of these elements is to ensure that the QAPP will be implemented as prescribed; they describe the activities for assessing the effectiveness of the implementation of the QAPP and its associated QA/QC program.

C1 Assessments and Response Actions

Assessments can include a variety of activities, such as surveillence, peer review, management systems review, technical systems audit, or performance evaluation. Audits are assessments of the extent to which QA procedures and QC activities are being adhered to. They may be performed by an internal (i.e., within the project structure) but independent audit team or by an external audit team. Audits may be performed before, during, and/or after the project is performed. Audit frequency, intensity, and type should be determined, and the audit(s) should be scheduled as part of the overall program QA effort. This section of the QAPP should describe the audits to be performed and the process and procedures for responding to problems raised during audits (Cross-Smiecinski and Stetzenback, 1994).

This section should also describe actions to be taken if and when unexpected problems arise during the course of the study. Problems that can be foreseen, such as running low on commonly used laboratory supplies, should be addressed as SOPs. Many problems, however, are encountered so infrequently or are unpredictable enough that

SOPs will not be prepared for them. Special or emergency procedures address these types of problems. It is difficult to address unanticipated problems before they arise, but the QAPP should specify who is responsible for handling problems that arise from different aspects of the project (e.g., field sampling, laboratory analysis, audits). It is helpful to categorize problems based on their impact on the project (e.g., critical, important, noncritical, unimportant) and to specify the type of corrective action necessary based on the problem's category. A critical problem, for instance, would be one that would affect obtaining data of the necessary quality or quantity. If a critical problem arises, a critical-problem response by project staff would be required. This should be specified in the QAPP.

C2 Reports to Management

This section specifies the type and frequency of reports to be prepared and submitted to project management, as well as the chain of responsibility for ensuring that reports are prepared and submitted. The preparer of the reports and recipients of each report should be identified. Any required report contents and format should also be specified.

5.3.4 Group D: Data Validation and Usability

After the data collection has been completed, the data must be examined to determine whether they conform to the specified criteria and will satisfy project objectives.

D1 Data Review, Validation, and Verification Requirements

The requirements used to review and accept, reject, or qualify data should be identified, including any project-specific calculations or algorithms.

D2 Validation and Verification Methods

This section should describe each of the elements defined below in enough detail to support use of the data for their intended purpose and for comparability to past, present, and future studies (Cross-Smiecinski and Stetzenback, 1994). If computer software is used in data manipulations, record which software is to be used. Software that performs complex manipulations might have to be verified before its use to ensure that it functions properly (Cross-Smiecinski and Stetzenback, 1994).

Data reduction: The transformation of raw data into a more useful form, calculations.

Data verification: A routine activity conducted by technical, laboratory, and clerical personnel on small sets of the data to determine whether data have been accurately quantified, recorded, and transcribed; whether data have been collected and analyzed in accordance with prescribed, approved procedures; whether the data appear suitably complete; and whether the data appear to be reasonable and consistent, based on prior knowledge of the research.

For example, it is a good practice to enter data into the database twice and scan them for outlying values. This helps to detect and eliminate transcription errors. Range checks, internal consistency checks, and quality assurance evaluations should also be included for data certification (Drouse et al., 1986).

Data validation: The process by which a sample, measurement method, or datum is deemed useful for a specified purpose; an independent, timely review of a body of verified data against a predetermined set of qualitative and quantitative criteria to evaluate their adequacy for their intended use.

Data reporting: Specify any special forms or formats (e.g., tables and figures) that are to be used, as well as who is responsible for data reporting, due dates, etc.

D3 Reconciliation with User Requirements

The precision, accuracy, completeness, representativenesss, and comparability of data must be assessed using appropriate techniques. This section should give details of the formulas, statistical techniques, and procedures that will be used to assess the data. The methods used to assess the data must be in agreement with the DQOs. The terms *precision, accuracy, completeness, representativeness*, and *comparability* are defined on page 5-11, and some sample data assessment formulas are given.

The following sections provide more specific information for preparing QAPPs with respect to field and laboratory operations, and data and reporting requirements.

5.4 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 and 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 and QC for each of the phases separately. This will ensure that no details are omitted. Table 5-3 summarizes many important items that should be considered in the field operations portion of a QA/QC program.

5.4.1 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 prepared beforehand, with quality reminders included where appropriate, will 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.

Table 5-3. Checklist of items that should be considered in the field operations section of a QA/QC program.

Field Operations			
Element	**Specifics**	**Check-off**	**Responsibility**
Organization	Field organization chart created . . . . . _____ Staff duties and responsibilities defined . . . . . _____ Communication lines within and with other units established . . . . . _____ Project documents made available to all staff . . . . . _____ Staff qualifications established . . . . . _____		
Field Logistics	Sampling sites investigated and selected . . . . . _____ Means of access to sampling sites determined . . . . . _____ Sample transport and shipping procedures specified . . . . _____ Field sample handling areas selected . . . . . _____ Chain-of-custody for samples established . . . . . _____ Field equipment selected and supplied . . . . . _____ Procedures for decontamination of sampling equipment established . . . . . _____		
Monitoring Equipment	Equipment installation procedures specified . . . . . _____ Equipment maintenance and control schedules established . . . . . _____ Equipment maintenance manual updated and distributed Trouble shooting and corrective action manual updated and distributed . . . . . _____		
Quality Control Samples	Type(s) of control samples (blanks, duplicates, spikes, analytical standards, reference materials) to be used have been determined . . . . . _____ Frequency of control sample use has been determined . . . . . _____		
Field Audits	QA field auditor designated . . . . . _____ Aspects of field operations that will undergo quality assessments as part of field audits have been determined Acceptance criteria for compliance with SOPs and the QAP set for field events and activities . . . . . _____ Field audit forms, with investigations to be conducted and data to be collected, prepared . . . . . _____ Person(s) to review field audit records designated . . . . . _____ _____		

Table 5-3. (continued)

Health and Safety	Field personnel properly trained	_____	
	Proper field gear and clothing issued to field personnel	_____	
SOPs	Sample management	_____	
	Sample collection procedures	_____	
	Reagent preparation	_____	
	Decontamination	_____	
	Equipment calibration and maintenance	_____	
	Corrective action	_____	
	Waste disposal	_____	
	Health and safety	_____	
	Field measurements	_____	
	Reagent/standard preparation	_____	
	Equipment calibration and maintenance	_____	
	Data reduction and validation	_____	
	Reporting	_____	
	Corrective action	_____	
	Waste disposal	_____	
	Health and safety	_____	
	Records management	_____	
	Project-specific records	_____	
	Field operations records	_____	

Source: USEPA, 1990b.

5.4.2 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.

5.4.3 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 and QC. All measurement equipment must be routinely checked and calibrated to verify that it is operating properly and generating reliable results (Spooner, 1994), 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.

5.4.4 Sample Collection

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 (Spooner, 1994). 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 (Spooner, 1994).

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 (Spooner, 1994). 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.

5.4.5 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; Spooner, 1994). Chain-of-custody seals must be applied to sample containers and shipping containers.

5.4.6 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 (Spooner, 1994).

5.5 LABORATORY OPERATIONS

Laboratory operations should be conducted with the same attention to detail as field operations. Often, an independent laboratory conducts sample analyses, so QA and 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.

5.5.1 General Laboratory QA and QC

Numerous references are available on laboratory QA/QC procedures, and one or more should be consulted to gain an understanding of laboratory QA and 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 (Table 5-4). More detailed references on laboratory QA and QC should be consulted for further information.

Table 5-4. Checklist of items that should be considered in the laboratory operations section of a QA/QC program.

Laboratory Operations			
Element	**Specifics**	**Check-off**	**Responsibility**
Sample Management	Sample receipt . . . . . _____ Sample storage . . . . . _____ Sample handling . . . . . _____ Sample scheduling . . . . . _____		
Equipment	Equipment calibration and maintenance . . . . . _____		
SOPs	Sample management . . . . . _____ Analytical methods . . . . . _____ Sample preparation and analysis procedures . . . . _____ Reagent/standard preparation . . . . . _____ Raw data requirements . . . . . _____ Data reduction and validation . . . . . _____ Precision, accuracy, and method detection/reporting limits . . . . . _____ Reporting . . . . . _____ Corrective actions . . . . . _____		
Records Management	Project-specific records . . . . . _____ Laboratory operations records . . . . . _____		
QC Procedures	Control samples . . . . . _____ Method blanks . . . . . _____ Matrix spikes . . . . . _____ Matrix duplication/matrix spike duplicates . . . . . _____		
Audits	Laboratory audits schedule . . . . . _____		
Health and Safety	Fire and emergency equipment . . . . . _____ Fire and emergency equipment inspection . . . . . _____ Health equipment (masks, gloves, ...) . . . . . _____ Waste disposal . . . . . _____		

Source: USEPA, 1990b.

5.5.2 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).

5.5.3 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, the U.S. Environmental Protection Agency, and the American Society for Testing and Materials, or those published in *Standard Methods for the Analysis of Water and Wastes* (Clesceri et al., 1989). 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).

5.5.4 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).

5.5.5 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).

5.5.6 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.

5.6 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.

5.6.1 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.

5.6.2 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, 1994c):

- 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 must be determined absolutely, generally with the help of a statistician.
- 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.
- 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.

5.6.3 Documentation and Record Keeping

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

5.6.4 Report Preparation

The original project description should include a schedule and required 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.