U.S. Department of the Interior
U.S. Geological Survey

Prepared in cooperation with the
FEDERAL HIGHWAY ADMINISTRATION

Principles and Practices for Quality Assurance and Quality Control

Open-File Report 98-636

A Contribution to the
NATIONAL HIGHWAY RUNOFF DATA AND METHODOLOGY SYNTHESIS

U.S. Department of the Interior
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Principles and Practices for Quality Assurance and Quality Control

By Berwyn E. Jones

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Marlborough, Massachusetts
1999

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PREFACE

Knowledge of the characteristics of highway runoff (concentrations and loads of constituents and the physical and chemical processes which produce this runoff) is important for decision makers, planners, and highway engineers to assess and mitigate possible adverse-impacts of highway runoff on the Nation's receiving waters. In October, 1996, the Federal Highway Administration and the U.S. Geological Survey began the National Highway Runoff Data and Methodology Synthesis to provide a catalog of the pertinent information available; to define the necessary documentation to determine if data are valid (useful for intended purposes), current, and technically supportable; and to evaluate available sources in terms of current and foreseeable information needs. This paper is one contribution to the National Highway Runoff Data and Methodology Synthesis and is being made available as a U.S. Geological Survey Open-File Report pending its inclusion in a volume or series to be published by the Federal Highway Administration. More information about this project is available on the World Wide Web at http://mass1.er.usgs.gov/fhwa/runwater.htm

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APPROXIMATE CONVERSIONS TO SI UNITS

Symbol	When You Know	Multiply By	To Find	Symbol
	LENGTH			
in	inches	25.4	millimeters	mm
ft	feet	0.305	meters	m
yd	yards	0.914	meters	m
mi	miles	1.61	kilometers	km
	AREA			
in^2	square inches	645.2	square millimeters	mm^2
ft^2	square feet	0.093	square meters	m^2
yd^2	square yards	0.836	square meters	m^2
ac	acres	0.405	hectares	ha
mi^2	square miles	2.59	square kilometers	km^2
	VOLUME			
fl oz	fluid ounces	29.57	milliliters	mL
gal	gallons	3.785	liters	L
ft^3	cubic feet	0.028	cubic meters	m^3
yd^3	cubic yards	0.765	cubic meters	m^3
NOTE: Volumes greater than 1000 l shall be shown in m^3.				
	MASS			
oz	ounces	28.35	grams	g
lb	pounds	0.454	kilograms	kg
T	short tons (2000 lb)	0.907	megagrams (or "metric ton")	Mg (or "t")
	TEMPERATURE (exact)			
°F	Fahrenheit temperature	5(F-32)/9 or (F-32)/1.8	Celcius temperature	°C
	ILLUMINATION			
fc	foot-candles	10.76	lux	lx
fl	foot-Lamberts	3.426	candela/m^2	cd/m^2
	FORCE and PRESSURE or STRESS			
lbf	poundforce	4.45	newtons	N
lbf/in^2	poundforce per square inch	6.89	kilopascals	kPa

APPROXIMATE CONVERSIONS FROM SI UNITS

Symbol	When You Know	Multiply By	To Find	Symbol
	LENGTH			
mm	millimeters	0.039	inches	in
m	meters	3.28	feet	ft
m	meters	1.09	yards	yd
km	kilometers	0.621	miles	mi
	AREA			
mm^2	square millimeters	0.0016	square inches	in^2
m^2	square meters	10.764	square feet	ft^2
m^2	square meters	1.195	square yards	yd^2
ha	hectares	2.47	acres	ac
km^2	square kilometers	0.386	square miles	mi^2
	VOLUME			
mL	milliliters	0.034	fluid ounces	fl oz
L	liters	0.264	gallons	gal
m^3	cubic meters	35.71	cubic feet	ft^3
m^3	cubic meters	1.307	cubic yards	yd^3
	MASS			
g	grams	0.035	ounces	oz
kg	kilograms	2.202	pounds	lb
Mg (or "t")	megagrams (or "metric ton")	1.103	short tons (2000 lb)	T
	TEMPERATURE (exact)			
°C	Celcius temperature	1.8C + 32	Fahrenheit temperature	°F
	ILLUMINATION			
lx	lux	0.0929	foot-candles	fc
cd/m^2	candela/m^2	0.2919	foot-Lamberts	fl
	FORCE and PRESSURE or STRESS			
N	newtons	0.225	poundforce	lbf
kPa	kilopascals	0.145	poundforce per square inch	lbf/in^2

* SI is the symbol for the International System of Units. Appropriate rounding should be made to comply with Section 4 of ASTM E380.

(Revised September 1993)

Principles and Practices for Quality Assurance and Quality Control

By Berwyn E. Jones

Abstract

Quality assurance and quality control are vital parts of highway runoff water-quality monitoring projects. To be effective, project quality assurance must address all aspects of the project, including project management responsibilities and resources, data quality objectives, sampling and analysis plans, data-collection protocols, data quality-control plans, data-assessment procedures and requirements, and project outputs. Quality control ensures that the data quality objectives are achieved as planned. The historical development and current state of the art of quality assurance and quality control concepts described in this report can be applied to evaluation of data from prior projects.

INTRODUCTION

Water-quality monitoring is a resource-intensive activity. A rigorous quality-assurance and quality-control (QA/QC) program within each project ensures that government resources are responsibly expended, so that the results of water-quality monitoring projects satisfy the needs of State departments of transportation, the Federal Highway Administration (FHWA) and other customers such as regulatory agencies and property owners. QA/QC ensures that project conclusions are based on precisely drawn project goals, appropriate data, and technically defensible interpretations; that is to say, QA/QC documents that the information produced by water-quality monitoring projects is as accurate and precise as possible. No other kind is worth the cost! According to a statement by Clark and Whitfield (1993), "Bad data for half the price of good data is a fool's investment."

The Federal Highway Administration and the U.S. Geological Survey (USGS) have undertaken the National Highway Runoff Data and Methodology Synthesis to catalog the pertinent available information, define the documentation that is needed to validate the data, and evaluate data sources for current and future information needs. This paper is a contribution to that synthesis, and is made available as a U.S. Geological Survey Open-File Report pending its inclusion in publication by the Federal Highway Administration.

The concept of quality systems encompassing and managing QA and QC activities is not new to the transportation community. In 1963, the Public Roads Director of Research and Development appointed a task force to study the problem of quality systems in highway construction (McMahon and others, 1990). Federal, State, and local transportation agencies have long been expected to incorporate quality systems in planning, design, construction plans and specifications, construction activities, and maintenance of highway systems (Maslin and others, 1983). Just as responsible transportation agencies would not purchase materials or contract for construction without proper assurances of quality, they cannot responsibly purchase water-quality information without the same kinds of assurance. Many of the same principles that apply to quality assurance in construction also apply to quality assurance in environmental information. As stated in the FHWA water-quality training course student workbook (Federal Highway Administration, 1986), "Quality assurance programs document field and laboratory methods used for a monitoring program, to ensure that the monitoring program will yield data that is [sic]:

- meaningful
- representative
- complete
- precise
- accurate
- comparable, and
- admissible as legal evidence”

Data collected for regulatory purposes must be substantiated by documentation of QA and QC activities. For example, the U.S. Environmental Protection Agency (USEPA) (1984) requires that,

" ...environmental data collected by and on behalf of the agency be supported by a mandatory quality system...," including project quality assurance.

Although QA is a necessary part of any scientific research or data-gathering project, it is even more important in environmental sciences than in traditional laboratory sciences. In laboratory research, the experimental system is carefully isolated from its surroundings, and experimental conditions are carefully controlled and documented so that an independent experimenter can repeat the observations to verify them. In environmental sciences, conditions are observed and described as thoroughly as possible, but they seldom are subject to the experimenter's control, nor can they be reproduced at will. Even a complete description of the significant influences on the system may be difficult or impossible to achieve. Therefore, the best assurance that a researcher's data and interpretations are valid depends on the ability to document that (1) the project design was adequate to achieve the stated goal of the project, (2) valid protocols were used to collect and interpret data, and (3) the protocols were properly executed. Data obtained by the use of valid protocols provide a basis for making sound management decisions, whereas unvalidated data serve merely to cast suspicion and create argument. Well-documented protocols allow one to compare data collected at different times and places, in order to identify trends, similarities, and differences. In this way, scientists can generalize their observations and make predictions about the future behavior of systems, which is the goal of all science and the basis for sound management and engineering decisions.

Documented QA/QC data that validate protocols describe the bias and variability of the data, which allows the user to assess its statistical significance. Data of known bias and variability have validity not only for the current investigation, but for future investigations as well. Therefore the cost of providing QA/QC, which can be substantial, is more than repaid by the value added to the data as a result.

Purpose and Scope

This report describes the history and current state of QA/QC concepts and practices that are used in water-quality monitoring. It is intended to assist the user in evaluating data from prior highway runoff water-quality monitoring projects.

It is not possible to prescribe a single set of QA practices to be used in all projects. The QA issues are different for every activity, based on the risks of error associated with each activity of the project and the likelihood and consequences of each type of error. There are, however, consistent principles that apply to evaluating these risks and constructing a QA program that will minimize them in a cost-effective way. The currently accepted approach to project QA design is to

- Define project goals and the quality and quantity of data required to meet them,
- Design a set of data-collecting and data-analysis activities to generate the required data,
- Assess the data-quality risks associated with these activities, and
- Develop project-specific QA requirements that address the more significant risks

This report describes the basic principles of QA for water-quality monitoring and provides guidelines for selecting appropriate practices for monitoring the specific quality risks identified in a project.

Terms Used to Describe Quality and Their Application to Water-Quality Monitoring

Terms that are used to describe quality are commonly confusing and must be carefully defined. The international authority for these definitions is the International Organization for Standardization (ISO). In the United States, ISO standards are sponsored by the American National Standards institute (ANSI), and published as American National Standards by the American Society for Quality (1998), formerly the American Society for Quality Control (ASQC). The appropriate standard for definitions in the field of quality is American National Standard A8402-1994,

"Quality Management and Quality Assurance-Vocabulary" (American National Standards Institute and others, 1994).

The ISO definition of the word "quality" is as follows: "Quality is the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs." The assessment of quality in environmental data, then, depends on the ability to define the needs of the intended user(s) of project results. To determine these needs, it is necessary to define the goals of the project in some detail. Thus, environmental project planning begins with an exact description of the problem to be addressed, and an analysis of the specific quality, quantity, and types of data required to address the problem.

Quality assurance is defined (American National Standards Institute and others, 1994) as: "...all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality." Once the requirements for quality in environmental data have been defined, QA activities are implemented to provide confidence in the data to be collected. QA activities generally fall into three categories:

- Documentation of the project plans to produce quality (project QA plan),
- Records that demonstrate that the project quality plans have been followed (QA Records), and
- Audits by internal or external personnel to assure that the QA activities are being carried out according to the plan. (QA audits)

Confidence in the data and data interpretations depends on the availability and completeness of these kinds of QA information.

The purpose of QA is to demonstrate to the customer and other readers of project reports that valid data and justifiable conclusions have been produced during the project. The project manager and staff, however, are usually the greatest beneficiaries of their own project QA plan, because it provides a framework for rigorous planning for project activities. Frequently, the cost of QA is repaid by eliminating unnecessary activities in the project, the need to repeat imperfectly planned or executed activities, or the consequences of wrong management decisions based on incorrect information.

QA records consist of various logs certifying that project activities were conducted according to the project QA plan, and QC data that demonstrate that project activities were successfully performed. The requirement to maintain QA records is a deterrent to "cutting corners" when time is short or conditions in the field are unpleasant. It is less tempting to violate protocols when the scientist has to sign a log certifying that the job was done "by the book." QC data provide quantitative evidence that protocols were effective in producing useable results.

QA audits provide internal or external scrutiny of process execution, project planning documents, and QA records. Auditing the project plans ensures that they meet organizational standards, and auditing quality records ensures that the specified practices were performed during periods when no auditor was on-site. Auditing the way processes are actually carried out guards against "protocol drift," which occurs when instructions are miscommunicated or misunderstood, or when processes are incorrectly recalled as the project wears on.

Quality control is defined (American National Standards Institute and others, 1994) as: "...operational techniques and activities that are used to fulfill requirements for quality," with the following explanatory NOTE: "Quality control involves operational activities aimed both at monitoring a process and at eliminating causes of unsatisfactory performance at all stages of the quality loop in order to result in economic effectiveness." In environmental monitoring, the concept of 'economic effectiveness' is interpreted to mean confidence in the data and in data interpretation. Thus, environmental QC includes activities that (1) monitor the sampling processes, including equipment function and cleanliness, instrument test and calibration, and sample preservation, shipping and analysis, and (2) document that the data meet all requirements for quality. QC also is applied to data interpretation protocols, as well as data transmission, storage, and retrieval.

Environmental QC also includes the corrective and preventive actions taken to eliminate causes of unsatisfactory performances that are identified by the monitoring activities. It should go without saying that all instances of corrective and preventive actions must be logged as part of the project's quality records.

Quality management (QM) is defined (American National Standards Institute and others, 1994) as "...all activities of the overall management function that determine the quality policy, objectives, and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement, within the overall quality system." In water-quality monitoring work, quality management occurs above the project level and provides the framework within which the project manager works.

Taken together, QM, QA, and QC represent the quality system for a water-quality monitoring project. The essence of this system can be summarized in terse and simple terms as:

- Say what you are going to do.
- Do what you said you would.
- Prove that you did it.

The project planning activities covered by Granato and others (1998) represents the first item in this list. QM and QA plans describe how the second item is accomplished, and the third item is satisfied by QC data, QA records, and quality audits.

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DEVELOPMENT AND EVOLUTION OF ENVIRONMENTAL QUALITY ASSURANCE

Although quality control through product inspection existed earlier than this, the scientific study of quality is usually dated from the publication of "Economic control of quality of manufactured product" (Shewhart, 1931), in which statistical quality-control charts were first described. This book was the outgrowth of the 1926-31 experiments with statistical studies at the Western Electric Hawthorne Works, the manufacturing facility of the Bell Telephone System. From this beginning, the science of statistical quality control has gradually expanded into comprehensive quality systems, and has spread to many types of process-oriented work, including water-quality monitoring (Juran, 1995).

A decade or more after producers introduced quality control, customers of manufactured products developed the idea of quality assurance. The first kind of QA activity was "acceptance testing" of statistically sampled product, using a decision rule in which a certain fraction defective product was considered acceptable. The U.S. Army's Rock Island (Ill.) Arsenal developed many of these concepts, culminating in the MIL-STD-105 series of acceptance sampling tables (Dodge and Romig, 1959). Much later, purchasers of manufactured goods realized that QA by inspection is wasteful, and gradually shifted to the present type of QA, which is based on ensuring quality by requiring that proper processes be used to make and quality control products. This methodology-based concept of QA, codified in the ISO 9000 series of international standard for QA (American National Standards Institute and American Society for Quality Control, 1994), has been carried over into non-manufacturing activities, including environmental monitoring.

The transfer of QA/QC concepts to environmental analytical laboratories was pioneered in 1965, when the USGS developed a system of interlaboratory QC that is based on Standard Reference Water Samples for its network of water-quality laboratories around the country (Skougstad and Fishman, 1974; Schroder and others, 1981). The

USEPA was primarily responsible for extending the concepts of QA/QC nationwide into other environmental laboratories, and ultimately into all environmental monitoring activities (Kulkarni and Bertoni, 1996). In the 1970s, the USEPA required use of USEPA-approved methods in contract laboratories, and evaluated laboratory data quality on the basis of blind analyses of reference samples. In the 1980s, the USEPA added a requirement for Quality Assurance Project Plans (U.S. Environmental Protection Agency, 1980, 1984) that addressed both field and laboratory processes. About the same time, the American Chemical Society's Committee on Environmental Improvement published comprehensive guidelines for environmental project QA (American Chemical Society Committee on Environmental Improvement, 1980; Keith and others, 1983). Introduction in the 1990s of the concept of designing project QA around well-designed data quality objectives (DQO) (U.S. Environmental Protection Agency, 1994a) extended the QA concept by providing results to which specific confidence limits on decisions could be assigned, as described by Granato and others (1998).

The American National Standards Institute (ANSI) and the American Society for Quality Control extended the QA concept into an overarching quality system for environmental investigations and remediation (American National Standards Institute and American Society for Quality Control,1994). The quality system includes organization-level quality management, project-level quality assurance, and quality control of environmental measurements. Together, these elements form an information product that is both reliable and self-improving over time. The quality system concept defines the current state-of-the-art in quality of environmental monitoring programs and projects.

THE QUALITY MANAGEMENT PLAN AND RELATED ACTIVITIES

The ANSI/ASQC comprehensive environmental quality system begins a quality management plan (QMP) that provides the project manager with a clear and reasonable set of expectations for quality, and the resources with which to meet them. In addition, it provides the organization with a means of managing the quality of multiple projects effectively. The QMP assures that the project will have personnel, equipment and supplies, and records and computer systems that meet stated quality standards, and a solid framework of documented and tested protocols for project activities. The QMP assures management that adequate information will emanate from the project to ensure that organizational standards are met. Thus, both parties have a common set of expectations and a system for achieving them. Responsibility for the QMP should reside with a quality manager who reports directly (and regularly) to top management. The QMP should be audited on a regular basis. Audits may be performed by first-party (in-house), second-party (customer) or third-party (outside expert) auditors. The values of external audits are manifold - they (1) provide a neutral, expert assessment of the QMP and its execution, which assures that sound management practices are in place and are being followed, (2) emphasize the importance that management gives to quality, and (3) are invariably learning experiences for all concerned. The QMP may be audited to certify compliance with ISO 9000 standards, if desired. Certification to ISO 9000 provides public confirmation of management's commitment to quality, to employees and customers, as well as to other information users such as regulators. The Quality Management Plan (QMP) covers the fundamental management responsibilities for quality, as defined by ANSI/ASQ Standard E-4 (1994b). Ten elements of a Quality Management Plan are required by that Standard:

- a quality policy for the organization,
- a quality system that ensures that the policy is implemented,
- a system to ensure the quality of equipment and supplies procured externally,
- personnel hiring and development systems to provide quality staff,
- documents and records systems to ensure that information is accurately preserved in a retrievable form,
- a quality system for computing systems,

- a systematic process for planning projects,
- a work-process documentation system,
- a system for assessing quality and responding to deficiencies, and
- a continuous improvement system

The QMP represents management's responsibilities to provide the project chief with the resources required to produce a quality information product. Because this report is directed primarily toward project-level QA/QC, the interested reader is referred to ANSI/ASQC Standard E-4 for detail about preparation of the QMP.

THE PROJECT QUALITY ASSURANCE PLAN AND RELATED ACTIVITIES

The second phase of the quality system, the Project QA Plan, describes project-level QA/QC. QA/QC for a water-quality monitoring project begins with the planning and staffing of the project, and continues through sample design, data collection, data assessment, data interpretation, reporting, and data archiving. Each of these steps is subject to quality assurance in its planning, and quality control in its execution. Clearly, the credibility of the project's findings can be no stronger than the weakest link in the system that produces them. Omitting or slighting QA/QC in any step of this process decreases the credibility of the project's results and conclusions. It is ironic that in the past, environmental QA/QC was commonly focused primarily on laboratory analysis, even though studies have shown that environmental laboratories typically make a relatively small contribution to the overall error in environmental monitoring data (see, for example, Helsel and Koltun, 1986). A whole-system approach to QA/QC is necessary for the production of credible results.

A modern comprehensive project QA/QC plan requires that the last step of the project be a self-critique, identifying "Lessons Learned" to improve the next project or, in the words of Peter Senge (1990), to create a "Learning Organization." The project QA process is shown in figure 1 in the form of a cycle, in which self-evaluation closes the loop by providing input for improving processes for the next project.

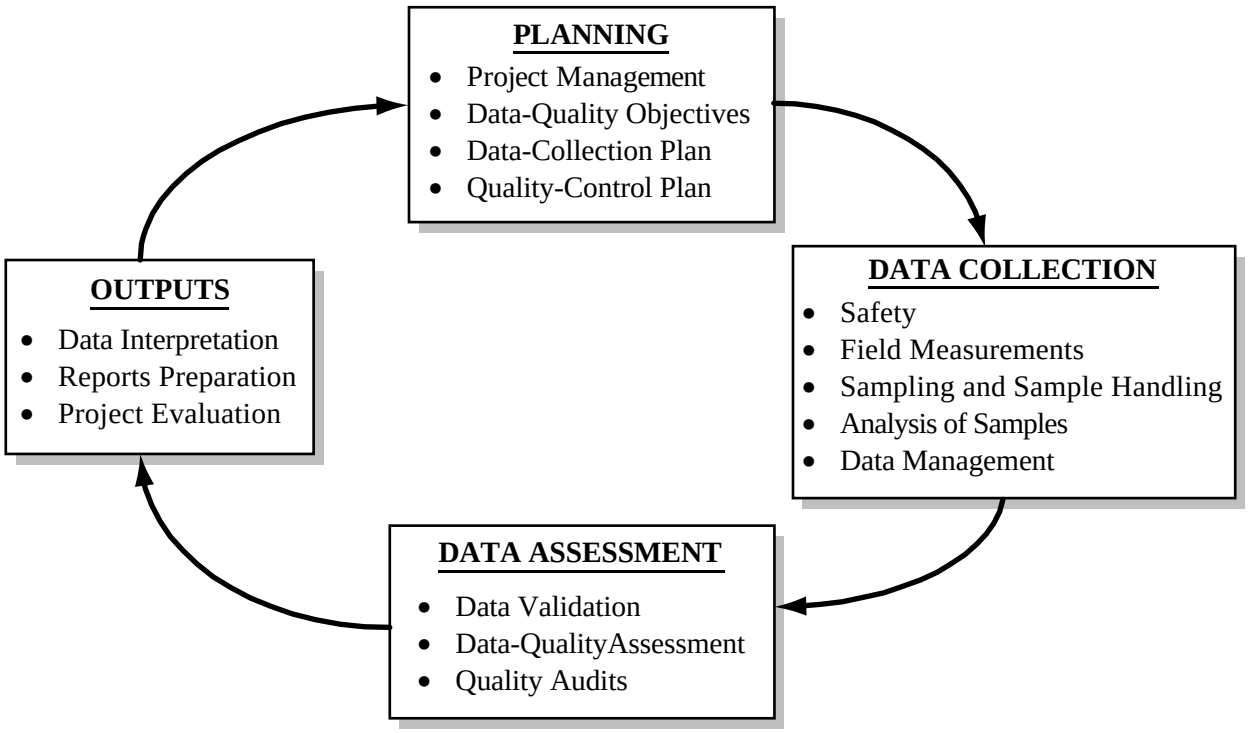

Figure 1. Project quality assurance cycle (adapted from Kulkarni and Bertoni, 1996).

PROJECT PLANNING

Although it is easy to skimp on efforts in the planning process, nothing is more important to developing the user's confidence in project data and conclusions than clear and full documentation of a valid planning process for use in developing the project. Elements of this planning process include a description of (1) how and by whom the project is to be managed, (2) the goals of the project and corresponding data-quality objectives, (3) detailed plans for defining and collecting the data required to meet these objectives, and (4) a plan for monitoring the quality of the data and correcting data-quality problems.

Project Management

The first element of the QA plan is to identify the persons responsible for carrying out the project, and delineating their responsibilities. An organizational chart showing the lines of responsibility and communication is desirable where more than a very few persons are involved. The credentials and, if appropriate, certifications of the persons who will perform all project tasks must be included, along with plans for training to rectify any deficiencies. The QA manager for the project must be organizationally independent of (that is, not reporting to) the project manager, to ensure objectivity. The organizational quality management plan should be incorporated in this plan, usually by reference, to provide a description of how the organization will oversee and provide resources to the project management.

A project schedule, including intermediate checkpoints and contingency plans in case the schedule is not being met, must be provided. All required and optional products and outputs must be listed. A detailed budget for the project also may be required.

Data-Quality Objectives

All too frequently, the most neglected steps in environmental projects are (A) Documenting the problem that led to the formation of the project, (B) Articulating specific, quantitative project goals, and (C) Designing a data-collection system that is tailored to meet these specific goals. Whitfield (1988) classifies the goals of environmental monitoring projects under five headings: (1) assessment of trends in some variable, (2) compliance with standards, (3) estimation of mass transport, (4) assessment of environmental impact, and (5) surveillance to determine the general level of environmental quality in an area. Highway runoff studies may fall into any or all of these categories. Data collection must be tailored to support the specific goal of the project. Data that are valid to support one goal may be inadequate for another. Worse yet, data gathered with no well-defined goal in mind may have no real usefulness at all. Each type of project and, indeed, each project within a type will require different data-quality characteristics to meet varying project goals (Shampine and others, 1992).

Once the goals of the project are clearly defined, the quality, quantity, and type of data required to fulfill them can be determined. The USEPA's DQO approach (U.S. Environmental Protection Agency, 1994a) is a useful way of addressing the issue of how much precision and accuracy are needed in the data. In this approach, which has been discussed by Granato and others (1998), the objective of the project is stated in the form of an hypothesis, which is tested at a defined level of uncertainty; that is, in terms of the acceptable risk of reaching an erroneous conclusion. Each risk can be translated into the required degree of certainty with which the data must be defined and, therefore, the number and types of QC and environmental samples of defined quality that are required.

A software program (DEFT) has been developed to simplify the statistical computations for computing the number of samples required to achieve the desired degree of certainty in the data. (U.S. Environmental Protection Agency, 1994b). A downloadable version of this software is available from the USEPA on the World Wide Web (U.S. Environmental Protection Agency, 1994b). The current software package addresses only comparison of the concentration of a constituent to a defined standard. Future versions are anticipated to address other types of decisions. In the ideal case, the DQOs will be used as input for a statistical calculation of numbers and types of samples that are required to meet project data requirements. Even when the quantitative statistical method is not used, however, developing qualitative DQOs is useful in planning for efficient and effective sampling design. (U.S. Environmental Protection Agency, 1994b, p. 7). The Intergovernmental Task Force on Monitoring Water Quality (ITFM) also has embraced the DQO concept

for water-quality monitoring projects by all government agencies (Intergovernmental Task Force on Monitoring Water Quality, 1995).

The five attributes of data quality are often summarized by the acronym PARCC, which stands for Precision (variability), Accuracy (bias), Representativeness, Completeness, and Comparability. Descriptions of these terms, adapted from the USEPA (1998a), are as follows:

Precision: The extent of random differences among replicate measurements of the same property, such as the concentration of a specific pollutant in a water-quality sample. The precision of many environmental measurement systems is not constant over their range of utility, but is relative to the value measured. Precision is, therefore, often best represented as relative standard deviation, the standard deviation of the measurement divided by the concentration at which it is measured. The relative standard deviations of many analytical methods are more or less constant over much of their useful ranges, although this relationship tends to break down at the lowest concentration. Therefore, almost every analytical method is assigned a "limit of detection." This is the lowest concentration that can reliably be distinguished from a blank containing none of the substance being measured, usually defined to be three times the standard deviation of the blank. A "limit of quantitation" is then set at 10 times the standard deviation of the blank. Variability is an alternative term for precision.

Accuracy: The degree to which a measured value (or mean of measured values) agrees with the true value of the measured property. The measure of accuracy is bias, the degree to which the measured value differs from the true value of the measured property. Bias is the inverse of accuracy; as accuracy decreases, bias increases.

Representativeness: The extent to which a sample or set of samples possesses the same properties as the body from which it is derived. The representativeness of a sample is dependent upon scientific and statistical sample design; no single computed value measures it. If the body that is sampled (river, lake, streambed, etc.) were perfectly homogeneous, obtaining a representative sample of it would not be a problem. Every part of it would be identical to every other part, and any portion of it would have the same properties. Unfortunately, sampling is almost never that simple. Environmental materials are almost never homogeneous; many are extremely heterogeneous. Therefore, the body to be represented must be sampled in a statistically valid way to obtain a representative sample.

Completeness: The percent of the planned data that was actually obtained. Unforeseen circumstances, such as the breakdown of automatic samplers, recorders, or monitors in the field, or accidental loss of a sample in shipping or in the laboratory, often prevent collection of 100 percent of the planned data. A standard of 95- to 98 percent completeness is commonly targeted in water-quality monitoring projects.

Comparability: The degree to which different data sets represent environmental conditions in the same way and, thus, can be compared to determine changes in environmental conditions over space or time. Commonly, data obtained by widely-differing methods produce data that are not directly comparable. It also must be realized that data may be comparable for testing one hypothesis but not for another.

Each type of project has general requirements for these data-quality characteristics. When, for example, a trend is to be studied, the data must be precise enough to distinguish reliably between the expected initial and final conditions of the system. As long as the bias is the same in the before and after measurements, however, it is not a critical factor in trend analysis. If a 10 percent difference is expected between initial and final states of the system, single before-and-after measurements with 10 percent relative standard deviation are not adequately precise to confirm the existence, let alone the magnitude, of the trend. In this situation, the data collector has two choices: (1) change to a more precise measuring technique, or (2) make enough replicate measurements to reduce the uncertainty in the mean value of the measurement, so that the trend can be defined with the required degree of certainty. The worst situation of all would be failure to determine the precision of the data, resulting in random variation being interpreted as a trend. Without due attention to data-quality characteristics, this situation can easily occur.

If the goal of the project is to assess compliance with a regulatory standard, it is critical that the measurement method have a high degree of accuracy

(low bias) and a limit of quantitation sufficiently below the standard to provide precise measurements in the vicinity of the standard level. The more precise the measurement, the fewer data will be required to determine with the desired level of confidence that the regulatory limit has or has not been exceeded.

The question of representativeness is addressed in project planning by the selection of a suitable sampling frame; that is, the portion of the system that will be chosen to represent the entire system. If the system to be studied is a certain river, it is obviously not possible to sample the entire river in all time and space. One must select a certain number of sites and a certain number of times each site will be measured, to provide data that adequately represent the condition of the entire river with respect to the goal of the project. For example, a project goal of describing the annual sediment load carried by a certain river cannot be answered without detailed knowledge of the variation of river stage throughout multiple years and knowledge of how the concentration of sediment varies with river stage. Valid measures cannot be obtained upstream from any tributary inlet that contributes significant amounts of sediment to the river. For the purpose of computing total load, a tributary that merely adds volume to the stream would have no effect on the outcome except to dilute the sediment concentrations, thereby making its measurement more difficult. On the other hand, a different project goal relating to sediment concentrations rather than loads would have a different sampling requirement; dilution would be a significant issue. Additional considerations might include whether data collected on one river are representative of other rivers as well, or whether several different kinds of river systems must be sampled to understand the sedimentation process in rivers in general.

In summary, data-quality objectives and plans for meeting them are very important considerations in project design and must be addressed carefully and completely in the earliest stages of the project by the project manager in consultation with field and laboratory personnel. Documentation of data-quality considerations is critical to the evaluation of the project data by potential subsequent users; therefore this documentation is a necessary part of the permanent project record.

Data-Collection Plan

Once the sampling frame is established, a sampling plan must be developed that represents the constituents of interest within that sampling frame. The sampling plan outlines all measurements to be made in the field, as well as all samples to be removed from the hydrologic system for laboratory analysis. A discussion of the hydrologic considerations that must be taken into account in developing sampling plans is beyond the scope of this report; however, the interested reader is referred to Averett and Schroder (1994) and Keith (1996), and the references therein. The project QA plan must demonstrate that the samples will represent the system accurately and will meet the DQOs. To avoid needless repetitive sampling, a literature search of the sampling area should always be a part of project planning. The quality of historical data must be assessed, and data gaps must be addressed as part of the current project. An understanding of the hydrologic system being sampled is also prerequisite to formulating the project-sampling plan. In developing the data-collection plan, the project manager should always keep in mind that project data might have uses beyond current project goals. Potential needs of other scientists and decision-makers in the future always should be considered when planning sampling and measurements for a project.

An area frequently overlooked in sample design is the collection of ambient control samples taken from sites not affected by the pollution source being studied. Another example of a control sample is the "before" sample in an environmental impact study. Not all of a contaminant found at a study site can necessarily be attributed to the source being studied; some may be natural or non-point source background. Failure to document the background concentration of contaminants can invalidate an entire study.

The development of the sampling plan requires a high level of professional judgment. This portion of the project QA plan must demonstrate that good judgment has been exercised in planning the project. Records that document the logic behind the design of the sampling plan are an integral part of project records, because later users of the data must evaluate that logic.

All sample-collection and analysis activities must be conducted according to well-defined protocols, such as those described in the FHWA Student

Workbook (Federal Highway Administration, 1986), or more recent publications from agencies such as the USEPA or the USGS. Written standardized protocols, when properly designed, selected, and executed, ensure the validity and repeatability of data-collection processes, and therefore of the data produced by these processes. Protocols must be written for two reasons - to make certain that all personnel who will carry out sampling or analysis know exactly how it is to be done, and to provide documentation for current and potential future users who must evaluate data usability. Also, without written documentation there is a tendency for methods to "creep" toward less and less rigorous processing. If the appropriate methods for data collection are not covered by documented and accepted protocols, extra effort is required to document and validate the procedures.

Sample preservation, packaging, shipment to the analyzing laboratory, and storage before and after shipment must be specified for every kind of sample that will be collected. Often the basic requirements for these operations are specified in either the sample-collection or analysis protocol. The plan for meeting these requirements, however, is a necessary part of project quality planning. The means by which holding time limitations between the time of sampling and the time of analysis will be met is often one of the most critical parts of this planning process. In addition, protocols for documenting continuous custody of samples throughout this handling process is required whenever there is a possibility that data will need to be admissible in court.

The analysis plan begins with selection of the laboratory to be used. This selection should be based on the laboratory's proven capability in the types of analyses required by the project, acceptance of the laboratory's QA plan and staff credentials, and adequacy (kinds and numbers) of instrumentation and facilities. Where prior experience does not provide proof of capabilities, performance testing or on-site inspection is necessary. Erdmann (1991a, 1991b) has described a set of QA requirements for analytical laboratories and a process for conducting an inspection. Alternatively, ISO 9000 or the USEPA's National Environmental Laboratory Accreditation Program certification is excellent evidence that a laboratory delivers data of acceptable quality. These selection criteria should become part of the project record, because they provide information that helps the user assess the validity of the results.

The choice of analytical protocols must be based on the DQOs of the project in terms of accuracy, precision and limit of detection, comparability with data from other studies, and consideration of any interferences to which the method may be subject. The need to select the most appropriate analytical method, rather than the least expensive one, cannot be overemphasized. Laboratory costs are usually a fairly small percentage of the actual total project cost, yet a small saving on laboratory costs may have disastrous consequences on the real value of the data. Because highway runoff water may be subject to regulation, the protocols selected should meet the requirements of the USEPA. During federal fiscal year 1999, the USEPA is moving away from requiring the use of specific analytical methods to specifying a performance based measurement system (PBMS). This new philosophy allows more flexibility in choice of protocol, but also requires that the protocols be backed up with performance data in the circumstances in which they are used. The project manager will need to be in touch with the appropriate USEPA Program Office and Regional Office to stay abreast of evolving requirements for PBMS. (Federal Register, 1997).

A clear agreement must be made with the laboratory concerning the content of the analytical data package. The data package must contain enough information to identify the sample unambiguously and to allow the reviewer to determine that the project DQO's were met. A sample list of data that each report should contain is given below:

- Project name and unique project ID number
- Field sample ID number
- Laboratory sample ID number
- Preparation and analysis batch numbers
- Time and date sample was collected
- Time and date sample was received at the laboratory
- Time and date sample was prepared for analysis
- Time and date sample was analyzed
- Identifiers for all preparation and analysis protocols
- Parameter or analyte being tested
- Laboratory detection limit
- Detection limit adjusted for sample-specific factors (dilution, preconcentration aliquot size, moisture content of soil, etc.) -Laboratory quantitation limit
- Concentration reporting units
- Dilution or concentration factor, if any
- Percent moisture or percent solids
- Sample aliquot size
- Final extract volume, if appropriate
- Sample preservation

- Laboratory batch-specific QC information
- Raw and interpreted analytical instrument output, as appropriate, and
- Original chain of custody documents, if any.

This list is adapted from the U.S. Army Corps of Engineers (1997) manual. Different lists may be appropriate for other organizations or purposes. Regulatory agencies, such as the USEPA, may place specific requirements on the content of data packages for some projects. All applicable regulations must be consulted before a final list of data specification can be made.

Protocols must be distributed to all members of the project staff who are required to use them. Protocol documents are usually issued to staff under a system of document control, in which copies are serially numbered, dated, and given revision numbers so that updates can be delivered to the qualified holders and outdated versions can be removed and destroyed. An archive of outdated protocols provides documentation of changes in procedures and the effective date of every change and must be maintained for use in later data evaluation. It is important to know what version of a protocol was used to collect data at any point in time. The project QA plan will provide for controlled document distribution unless it is handled by the parent organization's QMP.

Quality-Control Plan

Once the environmental data-collection plan is determined, the plan for QC samples must be developed. The QC plan is based on the principle of risk analysis. In this approach, the risks of error in each field-measurement, sample-collection, or analysis activity is estimated to be high, moderate, or low, considering both the likelihood and the seriousness of each error. Appropriate measures are developed to detect the errors that represent the higher risk factors. A lower level of QC may be directed at moderate risks, and even lower levels of QC would be directed at low-risk factors.

An example of this kind of risk analysis is in the handling of samples for analysis of volatile organic compounds (VOCs). There is a significant risk of sample contamination by absorption of airborne VOCs during shipment to the laboratory. The consequences of this contamination would be very serious, so a trip blank is usually included with each shipment of VOC samples. If the trip blank is contaminated, it is reasonable to assume that the samples also are contaminated, and the data from the shipment must be rejected. By contrast, there is relatively little risk of airborne contamination by major inorganic ions, such as calcium and chloride, so trip blanks are not necessary for these samples. There is some risk of chloride contamination from the sampling equipment, however, so an equipment blank may be sent to the laboratory to verify the cleanliness of the sampling equipment.

The most commonly used types of QC samples include: blanks, spikes, replicate samples, split samples, and reference materials. Each of these types of QC samples has many variations, but each has a single basic purpose. Blanks are used to detect and document possible contamination. Spikes are used to ensure that each constituent, if present, is being detected and accurately measured in the actual sample matrix. Replicates monitor the reproducibility of the overall sampling and analysis process. Split samples monitor just the reproducibility of the analysis process. By combining information from replicates and splits, the variability in the sampling process can be estimated. Reference materials are used to ensure that the analysis process is capable of giving accurate results. When based on a thorough understanding of the needs of the individual project, the right combination and number of QC sample types can provide the desired level of protection against the principal risks of accepting bad data.

It is not possible to specify a percentage of samples that should be devoted to QC samples in every project. The DQOs for the project must always guide this decision. When the quantitative DQO approach that was described previously is used, the number of each type of QC samples will be based on firm statistical computations. When the quantitative DQO approach is not feasible, the professional judgment of the project manager is crucial. Evaluating this judgment after the fact is difficult for subsequent users of the data. The project manager should, therefore, document fully the reasoning used in deciding which and how many QC samples to use. Common QC sample types and their uses are summarized in table 1.

Blanks are QC samples that are reliably free from detectable amounts of any of the constituents to be measured. They are used to detect contamination of the samples. The composition of the blank should mirror the matrix of the environmental samples.

Table 1. Common types of quality control samples used in water-quality monitoring investigations

Type	Description	Purpose	Alternative	Comments
Replicate samples	Multiple samples are collected from the environment at the same time and place, using the same method.	Evaluate the variability in sampling and analysis processes.	No other good way to estimate the reproducibility of environmental sampling.	Estimate sampling process variability, by using in conjunction with split samples
Split samples	One sample collected from the environment is divided into two or more equivalent parts. May be done in field or at lab.	Evaluate analysis variability, if sent to the same lab. Evaluate interlaboratory bias if sent to different laboratories.	Many other ways of determining laboratory variability or interlab bias are possible. This method has the advantage of being matrix-specific.	Sample-splitting process may not produce exact replicates. Also, splitting procedure may introduce contamination, or allow loss of analyte through volatilization or sorption.
Spiked samples	Measured amounts of analytes are added to known volumes of sample. Analyses are compared to those of unspiked sample, identically treated.	Evaluate recovery of the analyte(s) from the specific sample matrix by the analytical method.	Laboratories usually have recovery data for normal sample matrices. Spikes are useful for unusual matrices.	Recovery of spikes may not accurately represent recovery of native materials.
Surrogate-spiked samples	Measured amounts of surrogate compounds are added to known volume of sample.	Evaluate the recovery of analytes by monitoring recovery of a chemically similar compound.	Analyte spike provides similar data, but requires two analyses.	Typically used with multi-analyte organic methods.
Synthetic samples	A known concentration of analyte(s) is added to a matrix (commonly source water; occasionally a synthetic matrix such as seawater).	Document the bias of a laboratory's analyses.	Reference samples, spiked samples may also be used to test bias.	Unless a synthetic matrix is created, results do not take matrix effects on bias into account and therefore tend to give optimistic results.
Reference samples	An actual environmental sample in which the "true" concentration of analytes is known, through multiple analyses by multiple laboratories, using multiple methods.	Document the bias of a laboratory's analysis.	Synthetic samples, Spiked samples may also be used to test bias. Reference samples provide an absolute standard, not prepared by the user.	Matrix-specific reference materials may be difficult or impossible to obtain. Non-matrix specific reference samples may provide misleading results. Reference samples are used sparingly because they are expensive.

For example, if the samples for trace metals analysis are acidified, the corresponding blanks should be acidified also. Several types of blanks are commonly used. Field equipment blanks are passed through the sampling and (or) processing devices to document that these devices are free from contamination. Travel or trip blanks are used to ensure that samples are not contaminated during transportation from the field site to the laboratory. Preservative blanks are used to check the purity of the preservative that is added to each

sample[1]. Laboratory blanks originate in the analytical facility and are used to document that none of the constituents of interest are being introduced into environmental samples during their processing in the laboratory. An overview of types of blanks is presented in table 2.

Spiked samples are used to assess the bias in an analytical method. By comparing the results of spiked and unspiked samples, one determines the percent of the spike that is recovered by the method. If it is assumed that the native concentration of the analyte is recovered to the same extent as the spike, one can infer the percent of the native concentration of analyte that is recovered by the analytical method. This assumption, although usually made, is somewhat questionable because the spiked constituent may not be bound to the matrix in the same way and to the same extent as the environmental constituent. The amount of the spike should be great enough to provide an accurate recovery figure when the concentration in the unspiked sample is subtracted from that in the spiked sample, but not so great as to swamp the very matrix effects that are being studied. A spike approximately equal to the concentration of the natural material in the sample is usually best. Ambient background samples are usually spiked at about the same concentration found in the contaminated samples. Samples may be spiked in the laboratory to evaluate the analytical process alone. Most laboratories routinely spike samples for multi-analyte organic analyses with one or more "surrogate" compounds, the recovery of which mimics that of the analytes, to monitor the effectiveness of sample preparation and analysis processes. Samples also may be spiked in the field to document that the constituent survives the process of shipping to the laboratory. This is a valuable but difficult field operation, demanding precise quantitative techniques under difficult circumstances. If field spiking is called for, the protocol will address the problem of getting the spiking solution and micropipets to the field site. A protocol and training and performance evaluation programs for spiking techniques also should be developed. For comprehensive treatments of performing and calculating spike recoveries, consult Mueller and others (1997) and ASTM (1996).

Replicate samples can be used to test the reproducibility of the sampling and analysis processes. The sampling process is often the least reproducible part of the entire data-gathering system. Replication of water samples is relatively straightforward, although it becomes more difficult when the suspended sediment load is high. Bed-sediment samples are even more problematic to replicate, because a single large particle or a few moderate-sized particles can bias the result significantly. Particle-size separation is usually employed for analysis of bed sediment. Environmentally important substances usually are associated primarily with the smaller-particle fractions, which are also the fractions that are most accurately replicated (Helsel and Koltun, 1986). Replicate samples should be collected and analyzed very close together in time to get the best information, unless one is studying the long-term reproducibility of the measurement process.

Split samples are used to assess the variability of the analysis process. Their use is often confused with that of replicate samples; however, they are in fact very different. Split samples are obtained by dividing a single sample into multiple, presumably identical portions, but replicate samples are obtained by performing the sampling operation multiple times. Results of analyses on replicate samples include both sampling and analytical variability, whereas split sample analyses contain only the variability of the analysis process. Several devices are available for accurately splitting whole-water samples (that is, water-suspended sediment mixtures). As in replication, bed sediment samples offer the greatest difficulty in splitting, but if particle size separation is employed and only the smallest size fraction is used, the difficulty can be reduced. Samples may be split at various points in the analytical preparation and measurement process, to assess the variability at different stages in the process. By combining results from replicate samples with those from a series of split samples, one can assess the contribution of each step in the overall sampling and analysis process (see, for example, Helsel and Koltun, 1986).

[1] The author has personal experience with a case of contamination from paint that had been placed on the outside of vials of acid used to preserve trace metal samples. Because preservation blanks were not used, contamination was not detected in a timely manner, and a number of trace metal analyses were invalidated

Table 2. Common types of quality control blank samples used in water-quality monitoring investigations

Type	Description	Purpose	Alternative	Comments
Source water blank	A portion of the water that is used as the source of all blanks, and as the matrix for all QC samples, is analyzed.	Document that the source water is free of contamination.	Buy certified source water from the laboratory or a commercial supplier, and accept their analysis. Use water from a deionizer in the field laboratory.	Field-lab deionizers may be a significant source of contamination, and should be monitored with conductance meters, using a safe cutoff value. The value chosen will depend on the detection limit of the analyses being performed.
Field blank	Source water is taken to the sampling site and, as nearly as possible, sampled, preserved, and bottled in the same way as the environmental samples.	Document that the field sample handling process is not introducing contamination.	No reasonable alternative. Necessary for all but the roughest reconnaissance studies.	If contamination is found in the analysis of the field blank, it gives no indication of the source, only that it has occurred. Also, it is often not possible to sample the source water exactly the same way as the environmental samples.
Ambient atmosphere blank	A sample container of source water is exposed to the atmosphere at the sampling site for the same amount of time required to handle a sample.	Document that the atmosphere of the sampling site is not introducing contamination.	Test the atmosphere for analytes to be determined in the samples.	Especially important for relatively "clean" ground water samples collected in surface environments that are highly contaminated, either by volatile constituents or air borne particulates.
Equipment blank	A source water sample is passed through the sampling, splitting, or filtration equipment, then bottled and preserved like a sample and sent to the lab.	Document that the sampling equipment is not introducing contamination.	Super-clean the equipment before coming to the field, seal it in a protective container, and use it only once per trip, to ensure that no contamination is introduced.	Separate blanks for sampler, splitter, pump, filter, etc., may be used to identify individual sources of contamination. Analyze total equipment blank first. If it is blank, no further tests needed.
Preservation blank	A source water sample that has been preserved exactly as the environmental samples, is analyzed.	Document that the preservative, and the act of adding it to the sample, is not introducing contamination.	Use pretested preservative supplied by the lab, and assume that the operation of introducing preservative in the field isn't causing contamination.	If preservation blanks show no contamination, there is no need to analyze separate source blanks.

Table 2. Common types of quality control blank samples used in water-quality monitoring investigations—*Continued*

Type	Description	Purpose	Alternative	Comments
Trip blank	A sample of source water, preserved and contained identically to the samples, is shipped with environmental samples.	Document that contaminants are not introduced during shipping.	Detect contamination during shipping, from atmospheric or container/closure sources, or from other samples.	Most necessary when volatile analytes will be determined. Cross contamination may occur between "clean" and "loaded" samples shipped together.
Laboratory blank	A source of water sample is prepared at the laboratory, and analyzed along with the environmental samples.	Document that contamination has not occured during lab storage, subsampling, and analysis.	If the blank shows no contamination thoughout the entire sampling and analysis process, the absence of contamination in both field and lab is documented, and separate lab blanks are unnecessary.	If the field blank shows contamination, the laboratory blank helps identify its source as being in the field or in the laboratory.

Reference materials are indispensable in assessing the absolute accuracy of an analytical method and the laboratory that is performing it. Methods development researchers almost invariably use reference materials to validate new methods. Reference samples also are used to qualify and monitor laboratories and to define the bias in data that are used to make important environmental management decisions. It is important that the matrix of the reference material be as similar as possible to that of the environmental samples for which the method is to be used. Pronounced matrix-dependent biases exist in some analytical methods. When reference materials are used to qualify or monitor a working laboratory, they generally are submitted "blind" - that is, with the true values unknown to the analyst.

DATA COLLECTION

In this section of the project QA plan, the practicalities of carrying out the field measurement, sampling, analysis, and QC plans will be addressed. The critical parts of the project QA plan for the data-collection process are procedures to ensure the safety of field and laboratory personnel, and specifications for the exact protocols, equipment, and materials to be used in field measurements, sample collection and shipping, sample analysis, and data handling.

Safety

No portion of the water-quality monitoring investigation is as important as ensuring the safety of project personnel. Safety hazards unique to the project, such as the collection and analysis of hazardous, toxic, or radioactive samples, must be cited, and plans to protect personnel from these hazards must be developed and documented. The availability of safety equipment must be ensured, and all personnel must be informed of its location and availability and trained in its use. The project QA plan will provide information about how these responsibilities are to be organized and implemented, and how their implementation is to be documented.

Field Measurement

The project QA plan specifies what information must be collected concerning the selection and description of sampling sites, and how and by whom it is to be collected and recorded. This will include information related to site location and instrumentation as well as conditions observed at each site visit.

The exact make, model, and serial number of instruments to be used in making field measurements must be specified, and the processes and scheduled frequency for its calibration, testing, use, and maintenance must be described. The documents that contain this information are distinct from the protocols, or "standard methods," and are sometimes called standard operating procedures, or SOPs. Protocols, which are described in the planning portion of the project QA plan, document what project personnel are to do. SOPs describe how to carry out the protocols under actual field conditions. Protocols are often national standard methods; SOPs are invariably local documents, specific to the project time and place.

When possible, every instrument should be calibrated against standard reference materials traceable to the National Institute of Science and Technology (formerly National Bureau of Standards). Instruments should be tested before each use whenever feasible. Most instruments should have a plan for regular preventive maintenance. All calibration, testing, and maintenance activities for each instrument must be recorded in a signed, dated, permanent project record, which is archived so that data users and evaluators can ascertain that these procedures were carried out as specified and scheduled.

The USGS has demonstrated the advisability of regular proficiency testing of field personnel for their ability to perform accurate field measurements (Stanley and others, 1992). It is advisable to perform proficiency tests for all critical field measurement techniques and other difficult operations, such as field spiking, and include the results in project data archives. The USGS protocols for conducting proficiency testing of field personnel are described by Stanley (1995). Each project QA plan should provide for this vital function.

Sampling and Sample Handling

The type of equipment and the techniques to be used to collect samples for analysis must be specified, and processes for any required calibration, testing, and maintenance of sampling equipment must be described. Procedures for cleaning sampling equipment between uses are of critical importance and must be developed, tested, written, and distributed to field personnel. If cleaning takes place in the laboratory before going to the field site, provisions for maintaining cleanliness to the point of use must be specified. If QC blanks are to be used to ensure and document the cleanliness of sampling equipment between uses, the project QA plan will specify the nature and frequency of these blanks. The number, type, and means of preparation of other QC samples also must be specified in the sampling and shipping plan.

Availability of contaminant-free source water for the preparation of blanks and other QC samples is often problematic. Some analytical laboratories supply blank source water to their clients to ensure quality and consistency. Chemical supply houses also offer certified contaminant-free water, preservatives, and other sampling supplies in one-use quantities to maintain purity. Even when a laboratory or chemical supplier certifies the source water, its purity must be verified by testing, and the data included in project records. When field spikes are indicated in the sampling plan, provisions must be made for obtaining and verifying the spiking solutions and volumetric ware needed. Spiking procedures must be provided, and field personnel must be trained and tested in their use. The same is true for split samples, duplicates, and any other QC that the sampling plan may call for.

The type of container to be used for delivering each kind of sample to the analytical laboratory must be specified, along with the logistics for obtaining the containers and procedures for cleaning them and maintaining cleanliness until they are used. Preservatives that may be required for some types of samples must be specified, along with procedures for obtaining the materials and testing them for impurities that may affect the analyses. Frequently, the analytical laboratory will supply and test the necessary containers and preservatives. If this is the case, the project QA plan must indicate this source and reference the procedures used to ensure against contamination.

Quality-control samples, including blank, spike, duplicate, reference material, and split samples, must be prepared and shipped with the environmental samples for analysis. A detailed plan for the frequency of each type of QC sample and tested procedures for preparing or obtaining these samples are a critical part of the project QA plan. QC samples should be prepared and handled exactly like the environmental samples. Where differences are necessary in the preparation and handling QC samples they must be documented. The project QA plan will include instructions to field personnel in how QC samples are to be prepared and documented. When field personnel are expected to produce the QC samples in the field, provision for training and periodic proficiency testing of field personnel is highly advisable.

The project QA plan must specify the protocol for shipping samples to the laboratory, including shipping containers, the designated shipper, labels, invoices, and paperwork identifying the samples and the analyses requested for each. If samples are time-dependent, the means of meeting the required holding times should be described. If samples are temperature-sensitive, the project QA plan should specify the means for documenting how the required temperature is to be maintained.

The project QA plan specifies the nature of logs and data files that document how all these requirements are met. In general, these records are part of the laboratory's data file, which is delivered with each batch of analytical reports.

Analysis of Samples

The project typically has little responsibility for laboratory operation, except to select a capable laboratory and to record the results of the laboratory's in-house QC as well as the results of QC samples shipped from the field for the project. The laboratory QA plan, certifications, and QC records can be included, either by reference, or by including copies in the project archive. The existence and availability of these archived records should be indicated in published reports.

The project manager must negotiate a firm agreement on the method to be used for each analysis to ensure that project DQOs will be met. Project records must document this agreement before sampling begins, and data assessments (covered later in this report) will confirm that the laboratory uses the methods agreed upon.

The project QA plan must provide for prompt feedback to the laboratory in case data quality proves unacceptable. This necessitates prompt review of all laboratory results, including QC reports. The project QA plan should provide for carrying out and documenting the review process. The project data review must include (1) the review of laboratory batch-specific QC data, (2) verification that the requested analyses are complete, and (3) comparison to prior data to verify that data make sense in context. The project QA plan also must specify a process for resampling, reanalysis, or other corrective actions when data are not acceptable. The project chief should require preventive action reports when field or laboratory errors are responsible for data failing the project review.

Shipping reports from the laboratory should be reviewed promptly to ensure that samples were received within the required time and in the required condition (such as temperature control, leakage and breakage). These shipping reports then become part of the project data archive to document shipping conditions.

Data Management

The project QA plan must specify the requirements for collecting, archiving, and handling project data. Provisions include requirements for preserving the original data records such as field notebooks, or laboratory instrument output. As more and more field and laboratory instruments incorporate computers that process data before reporting it, the definition of "original record" may be problematic; such problems must be addressed so that records are consistent. As a rule of thumb, the original record is the signed and dated first available written or printed output from a measuring instrument that can be converted mathematically into a finished datum. Field notes are increasingly being entered in laptop computers. In this case, the original record is a signed and dated paper copy of the first data entry, before transfer to a central database. Electronic records that are stored on magnetic media are unsatisfactory as original records because of their inherent

impermanence, danger of being accidentally erased or altered, and inevitable inaccessibility when the devices that generated them become obsolete and unavailable.

Ancillary data (sometimes called 'metadata') that describe the circumstances of the data collection are an extremely important part of the record. These data may include the name of the collector, the methods and equipment used to generate the results, and the conditions at the sampling site (for example, high or low flow, ice cover or open water, rain or fair weather, industrial discharge, highway runoff, or background site, etc.). Data records generated to satisfy regulatory requirements must contain specific and usually extensive ancillary data. The project QA plan should specify what ancillary data must be recorded, and the justification for doing so.

QA of the data-management system, whether it be a filing cabinet or an electronic database, must be specified in the project QA plan. Electronic data systems are highly advisable for all but the smallest data-collection efforts. It is not trivial to ensure that the current data in a computerized system accurately and completely represent the data that were entered at the time of the study. In most instances, at least some of these rules are determined at a higher organizational level than that of the project manager and may be handled by citation of the appropriate documents.

DATA ASSESSMENT

Data assessment is conducted at three levels: (1) the review and validation of each set of measurements and observations from one field visit, or from a set of laboratory samples from one field sampling event; (2) overall data-quality assessments that occur when specified percentages or all of the project data have been collected; and (3) a site audit of field and laboratory processes. The project QA assessment plan will determine when and by whom these assessments are to be done. Validation of sets of data should always be done as soon as the data are available, in order to catch and correct errors before they affect more data. An overall data quality assessment at the end of the data-collection phase is needed to determine whether the body of data meets the project data quality objectives. Process audits may be required, and are usually very worthwhile as learning experiences.

Data Validation

The project QA plan must specify the criteria for accepting reviewed data, the process and time requirements for reviewing data, and corrective actions required if data do not meet data quality objectives. Environmental data are usually internally consistent and logical. Deviations from these conditions generally signal problems within the data. For example, a value of 300 for a constituent that has previously yielded values of around 30 at that site would be suspect unless some extreme change in conditions at the site can be identified. Likewise, the balance between milliequivalents of cations and milliequivalents of anions can be used to identify gross errors. A discussion of how to evaluate environmental data, with real-world examples, is provided by Brown and others (1991). The time interval within which it is possible for the laboratory to reanalyze the sample or the time interval within which the field site can be resampled may govern time limits for reviews. Names of persons responsible for performing the initial data review should be included in the plan. Corrective actions may involve resampling, reanalysis, or checking of original records for computational or transcription errors. In cases in which the data cannot be recovered, the project QA plan will address the possibility of compensating for missing data.

Data Quality Assessment

The entire set of data is evaluated periodically and at the end of the data-collection phase, to ensure that data quality objectives are met. The project QA plan defines when, how, and by whom this assessment is to be made, and what corrective action will be undertaken if the DQOs are not fully achieved. Because precision and accuracy of data were evaluated during the initial data review, this assessment concentrates on completeness, comparability, and representativeness of data. All five data quality attributes, plus the defensibility of the data in court, if this is a goal of the project, must pass assessment in order to consider the project QA successful.

Beyond the assessment of PARCC data quality factors, however, the data must be evaluated for scientific sense in the context in which it is to be used. For this kind of data assessment, the USEPA's document, Guidance for Data Quality Assessment

(U.S. Environmental Protection Agency, 1998b), provides a veritable textbook of ways to analyze data statistically for good sense in context. A very productive approach to assessing data in context is that of exploratory data analysis, pioneered by Tukey (1977). Using these techniques, it is easy to discern general patterns in the data and identify particular pieces of data that seem not to fit. Often, once attention is focused on these outliers, the record can be scrutinized, and the reasons for anomalies can be found. In fortunate cases, transcription errors can be corrected, or malfunctions in measuring devices can be detected by patterns in the data.

Quality Audits

When all of the above QA/QC requirements have been met, assessment of data quality by project personnel, the customer (second party assessment), or an independent auditor (third party assessment) is readily accomplished, and the project manager will have few unpleasant surprises from the auditors. In addition, a potential subsequent data user will find all the information needed to assess the usability of data for other purposes.

Project audits are specified in the project QA plan, unless they are provided for in the sponsoring organization's quality-management plan. Audits may include

- Whole-system audits, in which the project is reviewed for conformance with the project QA plan,
- Data-collection process audits in the field and in the laboratory, and
- Audits of the data, including QC data.

An audit of the data-management systems is also an obligation, and is usually addressed by the parent organization in the quality management plan.

System audits focus on the adequacy of quality management and project QA plans and whether they are being carried out as written. A process audit focuses on the adequacy of the protocols and SOPs to meet project and legal requirements, and whether they are being performed as written. A data audit looks at the project records, both paper and electronic, to determine whether they are complete and in good order as required by the project plans. Electronic data-management system audits will verify that the systems are being managed according to good professional practices, including QA of the data in the database.

Audits may be done by first-, second-, or third-party auditors. First-party audits should be a required part of an agency or corporate quality management plan. Many organizations routinely review the progress of each project according to a schedule, such as at 20-, 50-, and 80-percent completion. Second party, or customer, audits assure the customers that they are receiving what they paid for, or that regulations are being met. Third party audits may take the place of a customer audit and are increasingly replacing duplicative audits by multiple customers. Particularly in analytical laboratories that handle samples from many different customers, third-party audits by accrediting organizations are gaining credence. The project QA plan must describe the required audits and the corrective action plans for any deficiencies discovered by auditors.

Management Accountability

The information acquired in project record keeping and in reviews and audits is typically required by management of both the producing and receiving organizations. The project QA plan should include a description of the nature and frequency of these reports to management.

PROJECT OUTPUTS

The fourth and final section of the project QA plan describes the processes to be used for interpretation of data, the production and distribution of reports, including how they will be reviewed and approved, and a project self-evaluation for the purpose of continuous quality improvement in subsequent projects.

Data Interpretation

Statistical tools for the analysis and interpretation of water-quality data abound. The problem is less one of finding the tools than of selecting the most appropriate one for a given task. The selection of tools for data interpretation requires considerable professional judgement on the part of the

project chief. The choices and the reasoning behind them should be documented in the project QA plan, so that others who must evaluate the information and the conclusions that are reached by the project personnel can access them. Helsel and Hirsch (1992) provide an overview of the tools for hydrologic data interpretation and their applications.

The conversion of raw chemical, biological, and physical data into useful environmental information, scientific conclusions, and support for management decisions increasingly involves complex computations and modeling using highly specialized computer software. The selection and quality assurance of these pieces of software is a necessary component of the project QA plan. Selection of software should be based on the appropriateness of the conceptual model that it implements. Care is taken that the process the software performs is appropriate to the task and that the process is accurately performed.

Quality assurance of software is a difficult process because commercial software providers usually do not disclose the source code for the software. Substantive errors in software for data interpretation are not unknown. Test data sets may provide the only QA evidence available. It is highly advisable to run a test data set before using any new software package and when a new version or a new operator comes online. Quality assurance of all software used in data interpretation should be given the most serious consideration in the project QA plan.

Reports Preparation

The project QA plan should specify the form in which information and conclusions are to be reported, by whom they are to be prepared, when they will be delivered, and how those reports will receive technical, editorial, and policy review by the publishing organization. Moore and others (1990) suggest that an outline of all anticipated reports in the project be made and reviewed by technical management in the first month of the project, and that an annotated outline of each report be prepared within the first several months of the project. This practice helps to ensure that planning for the report is thorough and that the necessary data are being collected and interpreted. Reports should include estimations of the uncertainty of data based on project QA/QC activities, and of the resulting uncertainty in interpreted results and conclusions made on the basis of the data.

Project Evaluation

It is advisable for all organizations to practice self-evaluation and strive for continuous improvement in all their processes. The final process in any project should be an examination of project plans and processes for opportunities for improvement. Sometimes this evaluation produces new techniques that benefit the entire field of water-quality monitoring. In such cases, the investigating organization has an obligation to publish their discoveries. More frequently, the examination results in incremental improvements in project plans, protocols, and SOP's that make subsequent projects more efficient and effective.

CONCLUSION

Planning for quality assurance and quality control (QA/QC) should be documented in a comprehensive project QA plan. QA/QC should be carried out as part of a comprehensive corporate (or agency) quality system that is centered in a quality management plan. No single QA/QC plan is likely to require all the elements described herein, but each of these elements is needed in some situation. The project manager and project QA officer must identify the elements required by the goals of the individual project or type of project and design a plan around the QA/QC elements that address those goals. Because the concepts of modern QA/QC are quite recent in origin, it should not be expected that projects conducted a decade or more ago will possess all or even many of the kinds of records and data described here. The lack of QA/QC data will, however, decrease the usefulness of much older environmental data for incorporation in future projects without extensive reverification.

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GLOSSARY

This glossary contains definitions of terms as they are used in this paper. The following references were consulted in developing these definitions: Shampine and others (1992); American National Standards Institute, International Organization for Standards, and American Society for Quality Control (1994).

Accuracy: the degree to which a measured value agrees with the true value of the measured property.

Bias: the extent to which a measured value differs from the true value of the measured property.

Blank: a synthetic sample that is free of the analyte(s) of interest.

Chain-of-custody: unbroken record of accountability that ensures the physical security of samples.

Comparability: the degree to which two pieces or sets of data represent environmental conditions in the same way, so that the difference between the data or sets of data accurately represents the change in environmental conditions over time or space.

Completeness: the percentage of the planned data that was actually obtained in a project.

Corrective action: action taken to eliminate the cause of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

Data quality objectives: qualitative and quantitative statements that clarify the goals of the study, define the appropriate data to be collected, determine the most appropriate conditions from which to collect the data, and specify tolerance limits on decision errors that will be used to establish the quality and quantity of data needed to support the decision.

Limit of detection: the lowest concentration of an analyte that can reliably be distinguished from a blank by a given analytical method or measurement. Generally computed as three times the standard deviation of the blank.

Limit of quantitation: The lowest concentration that can be measured quantitatively by a given analytical method. Generally computed as 10 times the standard deviation of the blank.

Precision: the extent of random variability among replicate measurements of the same property.

Protocol: a set of instructions that describes a way to carry out an activity, such as sampling or measuring an environmental system. Standard protocols have been thoroughly investigated and have known and documented quality characteristics. Protocols are sufficiently general to be applicable in many organizations, where a variety of instrument and equipment models are used.

Quality: total characteristics of an entity that bear on its ability to satisfy stated and implied needs.

Quality audit: systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Quality Assurance: all of the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality.

Quality control: operational techniques and activities that are used to fulfill requirements for quality.

Quality Management: all activities of the management function that determine the quality policy, objectives, and responsibilities, and implement them by such means as quality planning, quality control, quality assurance, and quality improvement within the quality system.

Quality system: organizational structure, procedures, processes, and resources needed to implement quality management.

Reference material: a substance that has been extensively analyzed to arrive at a consensus or best value of the concentration of one or more of its constituents. Used to assess measuring systems: protocols, instruments, laboratories, or analysts.

Replicate samples: two or more samples taken from the environment at the same time and place, by using the same protocols. Used to estimate the random variability of the material sampled.

Representativeness: the extent to which a sample represents the population from which it is withdrawn.

Sample: a portion of a population (environmental entity) that is measured and assumed to represent the entire population.

Spiked sample: an aliquot of an environmental sample to which a measured amount of analyte has been added. When the analysis of the spiked sample is compared to an otherwise identical unspiked sample, the percent of the spike that is recovered can be computed. This quantity is assumed to represent the percent of the analyte recovered in the analysis.

Split sample: a single sample which, after removal from the population, is divided into two or more parts believed to be identical. Used to estimate variability in sample handling or measurement processes.

Standard operating procedure: the exact description of how to carry out a protocol under project conditions. Includes organization-, equipment-, and site-specific instructions that are more detailed than a protocol.

Variability: the extent to which results from multiple results of the same measurement yield differing results. Variability may be inherent in a measuring instrument or in the sampled material.