CHAPTER 7 Quality Assurance and Quality Control

7.1 General Procedures

Quality assurance activities provide a formalized system for evaluating the technical adequacy of sample collection and laboratory analysis activities. These quality assurance activities begin before samples are collected and continue after laboratory analyses are completed, requiring ongoing coordination and oversight. The quality assurance program should integrate management and technical practices into a single system to provide data that are sufficient, appropriate, and of known and documented quality.

Checklist

QA practices within a laboratory should address all activities that affect the quality of the final data, such as

- ✓ sediment sampling and handling
- ✓ condition and operation of equipment
- ✓ instrument calibration
- ✓ replication
- ✓ use of standards
- ✓ record keeping
- ✓ data evaluation

Developing and maintaining a quality assurance (QA) program requires an ongoing commitment by project management and also includes the following: (1) appointment of a quality assurance officer with the responsibility and authority to develop and maintain a QA program, (2) preparation of a Quality Assurance Project Plan with Data Quality Objectives, (3) preparation of written descriptions of Standard Operating Procedures (SOPs) for sediment sampling and manipulations, instrument calibration, sample chain-of-custody, laboratory sample tracking system, and (4) provision of adequate, qualified technical staff and suitable space and equipment to assure reliable data. Program specific guidance for developing and maintaining a QA program should be followed as appropriate. Examples of program guidance for developing a quality assurance program can be found in USEPA (1994; 1995; 2000d), PSEP (1997a), WDE (1995), and USEPA/ACOE (1991, 1998).

Quality control (QC) practices consist of more focused, routine, day-to-day activities carried out within the scope of the overall QA program. QC is the routine application of procedures for obtaining data that are accurate (precise and unbiased), representative, comparable, and complete. QC procedures include activities such as identification of sampling and analytical methods, calibration and standardization, and sample custody and record keeping. Audits, reviews, and complete and thorough documentation are used to verify compliance with predefined QC procedures. Project-specific QA plans (QAPP; see Section 7.3 below) provide a detailed plan for activities performed at each stage of the study and outline the data quality objectives that should be achieved. Through periodic reporting, QA activities provide a means to track progress and milestones, performance of measurement systems, and data quality. A complete project-specific QA/QC effort has two major components: a QA program implemented by the responsible agency (i.e., the data

user) and QC programs implements by the parties responsible for collection and analyses (i.e., the data generators).

7.2 QA/QC Procedures for Sediment Collection and Manipulation

To ensure the appropriateness of the sample collection protocol for sample integrity and data of suitable quality, a program of scheduled field QC samples, such as field replicates (duplicates, splits, field spikes), field blanks (rinsate equipment), bottle, trip, and background (upgradient) samples is critical. All field QC samples should be handled exactly as the sediment samples and should be treated as blind samples so as to minimize bias in the analysis. A random portion of the samples should also be analyzed by a third party to evaluate the primary laboratory's performance. QC replicates (duplicates, splits) should be collected for analysis by the primary laboratory to determine analytical variability (USEPA 1995).

Checklist

QA/QC procedures for sample collection should include the following principal elements:

- ✓ implementing a sound sampling approach based on the intended use of the data.
- ✓ use of sampling methodologies which allow the collection of representative samples based upon data needs.
- ✓ use of sampling devices that minimize the disturbance or alteration to the media's chemical composition.
- ✓ employing decontamination procedures which reduce cross-contamination potential between sampling points.
- ✓ use of proper sample containers and preservation techniques that maximize the integrity of samples.

The procedures for sediment manipulations described in Chapter 4 should maintain the sample in a chemical condition as similar as possible to that at the time of collection. QA procedures are established to assure that SOPs are followed and that contamination is neither introduced to nor lost from the manipulated sample. For example, samples to be analyzed for trace metals should not come in contact with metal surfaces (except stainless steel). Sample tracking sheets should document date, time, and investigator related to removal and replacement of samples from storage. Specific manipulation procedures should follow established SOPs that minimize chemical alteration of the sample (excepting chemical spiking), maintain sediment physical properties, and include replication and blank samples.

7.3 The Quality Assurance Project Plan (QAPP)

The Quality Assurance Project Plan (QAPP) is a project-specific document that specifies the data quality and quantity requirements needed for the study as well as all procedures that will be used to collect, analyze, and report those data.

The QAPP uses input from the sampling design derived from the Data Quality Objectives Process (see Chapter 2 specifically Measurement Quality Objectives discussion, Section 2.4, and USEPA, 2000a) to specify the above elements. This Plan should be reviewed by an independent person (e.g., quality assurance officer or staff member not involved in the project directly) for accuracy and completeness. A key element of a QAPP is Standard Operating Procedures (see Section 7.4). Further information on preparing a QAPP and resources necessary can be found in USEPA (2000e).

7.4 Standard Operating Procedures

Standard operating procedures are written descriptions of routine methods and should be provided for all methods used. A large number of field and laboratory operations can be standardized and presented as standard operating procedures. General types of procedures that benefit from standard operating procedures include field measurements ancillary to sample collection (e.g., water quality measurements or mixing model input measurements); chain-of-custody, sample handling, and shipment; and routine analytical methods for chemical analyses and toxicological analyses. Standard operating procedures ensure that all persons conducting work are following the same procedures and that the procedures do not change over time. All personnel should be thoroughly familiar with the standard operating procedures before work is initiated. Deviations from standard operating procedures might affect data quality and integrity. If it is necessary to deviate from approved standard operating procedures, these deviations must be documented and approved through an appropriate chain-of-command.

7.5 Sediment Sample Documentation

Bound field logbooks should be used for the maintenance of field records. All entries should be dated and time of entry recorded. All aspects of sample collection and handling as well as visual observations should be documented in the field logbooks. Documentation should be recorded in pre-numbered bound notebooks using indelible ink pens in sufficient detail so that decision logic may be traced back, once reviewed.

Checklist

Quality Assurance Project Plans vary in content depending on program needs, but should address the following elements:

- ✓ a description of the project organization and responsibilities
- ✓ definition of data quality objectives (see Section 2.1)
- ✓ sampling, analysis, and measurement procedures
- ✓ instrument calibration procedures
- ✓ procedures for recording, reducing, validating, and reporting data
- ✓ procedures for performing quality assurance verification and internal quality control checks
- ✓ preventive maintenance schedules
- ✓ specific routine procedures to evaluate precision, accuracy, and completeness
- ✓ definitions of deviations and appropriate corrective actions
- ✓ information on appropriate training

Proper field sheet, sample labeling, chain-of-custody, and sample tracking documentation should be maintained as appropriate. Specific details concerning sample documentation and sample management should be included in planning documents and reviewed by the sampling team prior to initializing the sampling program.

7.6 Sample Tracking Documentation

Samples delivered to the laboratory should be accompanied by a chain-of-custody record that includes the name of the study, location of collection, date and time of collection, type of sample, sample name or number, number of containers, analysis required, and the collector's signatures. When turning over possession of samples, the relinquisher and the receiver sign, date and record the time on the record sheet. The record sheet allows the transfer of a group of samples at one time. When the laboratory takes possession of the samples, each should be assigned a unique laboratory identification designation. This assures a consistent system for tracking within the laboratory. If the samples arrive at the laboratory when designated personnel are not there to receive them, the samples are put into a secure location and the transfer is conducted when the appropriate personnel are present.

Upon arrival at the laboratory, samples are inspected for condition and temperature, and sample container labels are verified against the chain-of-custody record or sample tracking form. Sample information is entered on a laboratory log-in data sheets used to maintain information regarding sample: receipt, shipping, collection date, and storage. To allow for accurate identification of samples, information contained on sample tracking forms must match identically with information contained on the sample container labels. The tracking form lists both the collector's and the laboratory's identification designations. Verified tracking forms are signed by the laboratory personnel with date and time in ink. Missing and/or compromised samples (e.g., inappropriate preservation to maintain integrity, inappropriate containers, and unlabeled or mislabeled containers) are documented on the tracking forms.

When samples are removed from storage, the sample tracking form accompanies it and documents data, time, and investigator associated with any manipulations. The manipulation type is noted on the form in detail or by reference to an approved laboratory SOP. Any deviation from the SOP are also noted. Should the sample be

Checklist
Sample documentation should include:

- ✓ project name, and analysis or test to be performed
- ✓ sampling locations
- ✓ dates and times
- ✓ sampling personnel present
- ✓ level of personal protective equipment worn
- ✓ weather or any environmental condition that might affect samples
- ✓ equipment used to collect samples, and sample container preparation
- ✓ calibration data
- ✓ deviations from approved work plans or SOPs
- ✓ sketch of sampling area
- ✓ notation of the system identifying and tracking samples
- ✓ notation of any visitors to the site
- ✓ initials and date on each page

modified in such a way that additional subsamples are created, additional tracking forms must also be created.

7.7 Record Keeping

Proper record keeping is essential to the scientific defensibility of a sediment sampling and manipulation program. A separate file should be maintained for each sampling/manipulation event or closely related events. This file should contain field logs, chain-of-custody forms, sample tracking forms, storage records, and any QA/QC documentation and records. Original documentation should be signed and dated by the originator.

7.8 QA Audits

In addition to the QA/QC procedures conducted on a routine basis, quality audits (i.e., performance and quality systems audits) might be conducted. Performance audits refer to independent checks to evaluate the quality of data produced during testing. There are three types of performance audits: sampling; test; and data processing. These audits are independent of normal quality control checks performed by the operator.

A systems audit is an on-site inspection and review of the quality assurance system. The systems audit is performed to verify that the organization is following the policies and procedures described in its QA/QC plan and in appropriate SOPs. Systems audits are performed by an auditor typically from an accrediting body.

Checklist
Performance auditing procedures are:

- ✓ sample auditing - the auditor uses a separate set of calibrated standards to check the sample collection system.
- ✓ test auditing - the auditor is provided with set of a duplicate sample or split portion.
- ✓ data processing audit - the auditor spot checks calculations or a dummy set of raw data is inserted followed by review of validated data.

7.9 Corrective Action (Management of Non-conformance Events)

The QA Officer and the responsible manager are responsible for reviewing the circumstances of all instances of occurrence of nonconformities, to determine whether corrective action should be taken. The manager is responsible for determining if new samples are required, if the customer should be notified, if additional testing is necessary, or whether the results should be confirmed. A good communication plan is invaluable in helping to identify interactions among labs, clients, and agencies during corrective actions.

Corrective action might take two forms: that of addressing technical problems associated with project activities and that of addressing QA/QC infractions based upon performance. Technical problems in meeting project objectives may range in magnitude from failure to meet minor procedural requirements, to major problems associated with inappropriate methods or data loss.

Established procedures for corrective action of minor technical problems are often included in the SOPs for cases where performance limits or acceptance criteria have been exceeded. On-the-spot corrective actions are noted on data sheets. Major or recurrent QA/QC problems which require long-term corrective action, such as modification of SOPs, are reported. Depending upon the nature and

severity of the problem, an approach might be developed. Any corrective action is documented by management.

Infractions of QA/QC policies by staff are identified and addressed by the management. Minor infractions are corrected through additional training and/or closer supervision. Major or recurrent infractions are corrected through re-assignment of technical personnel.

Corrective actions relative to sample collection and manipulation may include, but are not limited to, review of the data and calculations, flagging and/or qualification of suspect data, or possible re-sampling. A review that provides a preliminary check of all "out of limit" events is performed as soon as the data for a given parameter or test is tabulated and verified for accuracy. "Out of limit" events are flagged to determine whether new samples are required.

7.10 Data Reporting

In addition to reporting the raw data from a given sediment quality study or analysis, the data report should include additional quality assurance information to ensure the data user that sample handling and analyses are in accordance with the project plan. The quality assurance information also documents procedures taken to ensure accurate data collection. Data are to be presented electronically as well as in hardcopy for many regulatory programs. Required electronic format should be explicitly outlined as a data quality objective during the planning process.

Checklist
Quality Assurance Reporting

- ✓ A copy of the sample chain of custody record, including documentation of sample collection date and time
- ✓ Documentation of the laboratory certification number
- ✓ Documentation of the analysis method used
- ✓ Documentation of analysis date and time (or testing period in the case of toxicity tests)
- ✓ Documentation that data for spikes, duplicates, standards, etc meets laboratory QA/QC requirements for chemical analytes
- ✓ Documentation that reference toxicant test data meets laboratory QA/QC requirements for toxicity tests.
- ✓ Documentation of any deviations in sample preparation or analysis protocols