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A PROGRAMMATIC APPROACH TO ACHIEVING DATA QUALITY OBJECTIVES

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INTRODUCTION

The U.S. Environmental Protection Agency (EPA) requires that all EPA-sponsored programs follow the Quality Assurance (QA) Plan preparation guidelines of the QAMS-005/80, "Guidelines and Specifications for Preparing Quality Assurance Project Plans." The QAMS-005/80 format requires the preparer of the QA Project Plan to develop a set of "objectives for measurement data in terms of precision, accuracy, completeness, representativeness and comparability," better known as Data Quality Objectives (DQOs).

"Data Quality Objectives (DQOs) are quantitative and qualitative statements describing the quality of data needed to support a specific environmental decision or action" (RQAMO 1988). Usually expressed in terms of precision, accuracy, completeness, representativeness, and comparability, DQOs "are the attributes of the data we produce that make it suitable for reiterating into the decision making and planning process and provide for defensibility if challenged either in litigation or as to professional credibility" (RQAMO 1988).

Once a project manager has established DQOs that are both valid and verifiable, steps should be undertaken before and during the life of a project to determine whether or not the DQOs are being achieved.

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ACHIEVING DATA QUALITY OBJECTIVES

The ability of a project to achieve its DQOs does not hinge on any single component of the project's QA program but on the implementation and adherence to a comprehensive QA program. To concentrate on only one aspect of a QA program to achieve DQOs implies that the rest of the program is unnecessary and ignores problems that may be generated elsewhere in the project. For example, what value are precision and accuracy DQOs of ± 10% when untrained individuals may be taking the field samples or measuring and test equipment (M&TE) is not calibrated, possibly introducing as much as 50% uncertainty into the sample? All the components of a project-specific QA Plan interact to reinforce each other and to ensure that the final product is legally defensible and reproducible.

In order to achieve the DQOs established by the project, a project-specific QA Plan that addresses, as a minimum, the following items must be prepared, implemented, and maintained:

- the use of standardized procedures, where possible
- a system for calibrating and maintaining M&TE
- the use of Quality Control (QC) samples, where applicable
- control of purchased items and/or services
- training
- a system for maintaining project records
- the use of verified and validated software, where applicable
- a system of audits to provide project oversight
- a method for determining and implementing corrective actions.

QUALITY ASSURANCE PLANS

The heart of any QA program lies in the preparation of a project-specific QA Plan before starting work. Such preparation requires the project manager to anticipate the goals, needs, and potential problems of a project in advance. It establishes the approach that a project will take toward the work to be performed, within the constraints of time and available funds, and thus serves as a guidance document for all project participants. As a

guidance document, each QA Plan should consider, at least, the following questions:

- What type(s) and how many samples should I collect?
- What methods should I use to collect my samples?
- What type of data do I want to collect?
- What analytical methods will I use to collect the data?
- What is the intended use of my data?
- What level of confidence must I have in my data?
- What type of QA/QC activities will I use to verify that my results have a high probability of being correct?

"Good planning is an essential principle of environmental analysis" (ACS 1983). The development and use of a project-specific QA Plan helps assure that all aspects of the project will be aimed at achieving the DQOs.

STANDARDIZED PROCEDURES

Approved, standardized procedures should be used whenever possible to promote consistency among the various project participants and techniques. Examples of situations that lend themselves to the use of standardized procedures include sample collection, equipment calibration and operation, record-keeping, laboratory measurements, data reduction, data validation, and data reporting.

The use of standardized procedures ensures that routine tasks are performed in a consistent manner, are documented and that the results are reproducible. Standard procedures may either be developed internally by the organization or adopted from outside the organization. Examples of time-tested national standards include the American Society for Testing and Metals (ASTM) methods and the protocols of the EPA SW-846, Methods for Evaluating Solid Waste.

MEASURING & TEST EQUIPMENT

A system for ensuring that M&TE is periodically calibrated and maintained is critical to the integrity of the analytical results. This applies to equipment that is calibrated by the user, an onsite specialist, or

an offsite manufacturer's representative. Analytical results from uncalibrated equipment cast doubt on the validity of the data. All routine calibration and maintenance activities should be standardized and documented to ensure that these activities are performed in the same manner each time the activity is performed. A log should be kept of all calibration and maintenance activities performed on each piece of equipment.

All M&TE should be uniquely identified, usually by a serial number or property account number. This will allow for the identification of all equipment used to collect, transfer, process or analyze samples and/or data. The identification of all equipment is critical in order to establish the traceability of data from the final print-out back through the analytical process to the actual date and time of sample collection.

An M&TE Control Listing, a record document listing all M&TE used on a specific project, along with a description of each piece of M&TE, the M&TE location, calibration interval, equipment custodian, the last date of calibration, and the date of next calibration, provides a single location for most of the information needed to provide sample traceability. Records of calibration/maintenance activities should also be traceable to the individual who performed the work.

QUALITY CONTROL SAMPLES

Quality Control (QC) check samples are used to validate both the analytical data and the methods used to collect the data, and to provide specific information on the level of confidence that can be assigned to each data point. QC check samples can be divided into two groups: QC samples for field activities and QC samples for laboratory operations. Within each group, two basic types of QC samples exist: blanks and standards.

A blank is a sample of a matrix, either solid, liquid, or gas, similar to the matrix being analyzed, but free of any of the analytes being sampled for in the sample collection--analysis process. Blanks are used to establish a baseline or background value that can be used to determine the existence and magnitude of contamination problems. Blank data results can be used to adjust or correct routine analytical results.

Blanks used to evaluate sampling conditions can be divided into several types, each measuring the quality of a different phase of sampling. For example, equipment and trip blanks are prepared, handled, and analyzed in the same manner as the normal carrying agents but are not exposed to the medium being sampled, and are thus designed to sample ambient equipment, handling, and transport conditions.

The use of National Institute of Standards and Technology (NIST)-traceable Standard Reference Materials (SRMs) to assess the precision and accuracy of laboratory instruments is a critical step in the validation of the data. Standard Reference Materials are materials for which certain properties, such as composition, have been certified by the NIST or other agency to the extent possible to satisfy its intended use (EPA 1984). The material used as a standard should be in a matrix similar to the matrix of the actual samples to be analyzed. In addition to being used to determine the precision and accuracy of laboratory measurements, NIST-traceable SRMs are used to calibrate field and laboratory equipment (e.g., pH and Conductivity Meters).

PROCUREMENT CONTROL

Quality assurance is not internal to the project, it extends beyond the project to suppliers of goods and/or services. The quality of many facets of environmental projects depends, either directly or indirectly, on the quality of goods and services procured from outside the company. A rigorous program of Procurement Quality Assurance (PQA) helps ensure that the requesting project will receive the quality of goods and services required.

If the requested item is "off-the-shelf," quality restrictions can be placed on the procurement of the item. For example, at Pacific Northwest Laboratory (PNL), sample collection containers for use on Resource Conservation and Recovery Act (RCRA) ground-water monitoring projects are required to be cleaned to specific EPA protocols to reduce the potential for sample contamination. This requirement is passed to prospective vendors. If this requirement cannot be met, the sample containers are purchased

elsewhere. Additionally, some M&TE, such as digital thermometers, is required to be calibrated to an NIST-traceable standard by the manufacturer before shipment to the project.

If services are to be procured (e.g. analytical laboratory services), the prospective vendor's QA program and capability to perform the required work should be evaluated using the same standards the project must maintain.

TRAINING

The use of trained and qualified personnel to perform project tasks is imperative to the credibility of the project's product. Analytical laboratory personnel must be appropriately trained to calibrate and operate complex analytical instrument systems. To ensure that results are repeatable, personnel must be trained using standardized procedures. This pertains to someone taking a ground-water sample from a well, to someone operating a hydrogen peroxide sampler on a bouncing aircraft in a thunderstorm at 17,000 feet, or to a lab technician who operates a GC/MS in an analytical lab.

In addition, all training that is pertinent to the project should be documented and maintained as a permanent project record. A copy of these records should be kept by the project manager in a central location.

PROJECT RECORDS

A system for controlling project records must be developed. This system should be documented in a way that will allow the project's work to be reviewed and, if necessary, reconstructed. Project records include the maintenance of project-client communications, all data, training records, procedures, laboratory record books, and data sheets necessary to reproduce the project work.

COMPUTER SOFTWARE

More often than not, computers are used to aid in the reduction of extremely large quantities of data collected by more advanced environmental monitoring systems. Computer codes used to evaluate large quantities of data

or to generate a "model" must be tested and documented. Because of space constraints, this discussion shall only touch on the rudiments of Software Quality Assurance (SQA).

All computational and analytical software should be documented. This documentation, as a minimum, should include the name and a brief description of each code to be used, its intended use by the project, and the computer system to be used. A Code Custodian should be assigned to maintain the documentation for each code, to make any necessary changes to the code, and to keep records of specific versions of the code used to produce specific results.

All computer codes used to produce results should be verified and, if possible, validated. Verification is the process of testing a code to ensure that it correctly solves mathematical equations and performs the data processing functions it was designed to perform. This is done by applying several test cases to the code, the results of which are known in advance and are compared to the test output. Validation is the process of determining how well the code describes reality over the range of variables of interest. Code validation is done by inputting test data and comparing the code results to observed data.

The "application" of a computer code (i.e., the use of a code to perform calculations or to manipulate data and produce reportable results) requires documentation of which version of the code was used to generate, or process, which results. It is imperative that data results be traceable to the version of the code that produced the results. If a problem is discovered with a particular version of a code, this "traceability" allows a reviewer to determine which data were processed with which code version so that corrections can be made to all results generated by the problem version.
The testing and documentation of computer codes ensures that a knowledgeable person can reconstruct the input and that errors are not being artificially introduced into the data.

AUDITS

At PNL, the use of an established system of internal audits and surveillances, coupled with a system for requiring and evaluating corrective

action(s), ensures that when problems are discovered a mechanism is in place to deal with, and help prevent the reoccurrence of, the discovered problem. Internal auditors are tasked with performing internal audits on programs or projects. The frequency and extent of an internal audit should be dependent upon client requirements, the importance of the project activity, and/or project visibility. Internal audits are "systems audits" and are conducted to determine how effectively the various aspects of a project's QA program are being implemented.

Surveillances are usually performed by the project's quality engineer. A surveillance is, in effect, a focused mini-audit. Surveillances performed on environmental projects can be placed into three basic groups: compliance, real-time, and data traceability surveillances. Compliance surveillances are performed to ensure that a specific requirement, or set of requirements, is being implemented. Real-time surveillances are performed during the work or analysis process to ensure that specific standardized procedures are being followed. Data traceability surveillances are performed to ensure that the resultant project data are traceable back through the analysis process, through sample handling and transportation, back to the actual date, time, location, individual, and technique used to collect the sample. Of the three different types of surveillances, data traceability surveillances tend to be the most effective at uncovering potential problems.

CORRECTIVE ACTION

At PNL, corrective actions to problems uncovered during audits, during surveillances, or by project personnel during the course of the project are tracked via audit reports, surveillance reports, deficiency reports (for noncompliance to established procedures), or nonconformance reports (for materials that do not meet quality specifications, such as an SRM that does not have an NIST-traceable certification). All findings, observations, deficiencies, and nonconformances are given an alpha-numeric deficiency code. Each deficiency code is weighted depending upon the degree of deviation from the QA program and placed into the Trend Analysis/Severity Classification (Trend) System.

PNL's Trend system is a simple computer data base that systematically quantifies all deficiencies according to severity. Deficencies are further categorized by a three-element numerical rating scale that is used to determine the severity (low, minor, significant, or major) of the deficiency. Deficiency information can be sorted by any of several factors using a three-dimensional model: severity, deficiency-type, program, project, or organization. Frequent evaluation of the Trend data base allows management personnel to monitor all reported deficiencies for trends. Information in the Trend system is available to project and line managers as well as to Quality Assurance Department personnel.

SUMMARY

The use of Data Quality Objectives (DQOs) represents an attempt to define and standardize repetitive measurements in order to promote data quality and to provide for data comparability. To achieve predetermined DQOs, a comprehensive QA/QC program for the project or program must be implemented. Any QA/QC program must be well thought out and must consider and document all aspects of the project including training, procurements, field sampling, sample transportation, actual laboratory analysis, data reduction, and data reporting.

There is no certainty that the implementation of the controls previously discussed will achieve all of the DQOs. However, by using such controls a project will be in a much better position to systematically determine why it may not be achieving its DQOs and to pinpoint potential sources of the problem. Additionally, the inability of a researcher to validate his/her data by such means as documented data traceability, calibrated equipment, the use of Standard Reference Materials, and trained personnel, casts doubt on the resultant data regardless of how precise and accurate the laboratory measurements were or whether the DQOs were achieved or not.

Note: Any number of QA program models are available in the open literature. Among them are ANSI/ASME NQA-1, ASTM Method C 1009-83, and the EPA's QAMS-004/80 and QAMS-005/80. A recent paper compares and contrasts the requirements of several of these models (English and Dahl 1988).

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