

9. Quality Assurance

The overall goal of a well-designed and well-implemented sampling and analysis program is to measure accurately what is really there. Environmental decisions are made on the assumption that analytical results are, within known limits of accuracy and precision, representative of site conditions. Many sources of error exist that could affect the analytical results. Factors to consider as sources of error include improper sample collection, handling, preservation, and transport; inadequate personnel training; and inappropriate analytical methods, data reporting, and record keeping. A quality assurance program is designed to minimize these sources of error and to control all phases of the monitoring process.

9.1 INTRODUCTION

The application of a quality assurance/quality control (QA/QC) program for environmental monitoring activities at the ORR is essential for generating data of known and defensible quality. Each aspect of the environmental monitoring program, from sample collection to data management, must address and meet applicable quality standards.

9.2 FIELD SAMPLING QUALITY ASSURANCE

Field sampling QA encompasses many practices that minimize error and evaluate sampling performance. Some key quality practices include the following:

- use of standard operating procedures for sample collection and analysis;
- use of chain-of-custody and sample-identification procedures;
- instrument standardization, calibration, and verification;
- technician and analyst training;
- sample preservation, handling, and decontamination; and
- use of QC samples, such as field and trip blanks, duplicates, and equipment rinses.

Because of changing technologies and regulatory protocols, training of field personnel is a continuing process. To ensure that qualified personnel are available for the array of sampling tasks to be accomplished, training programs by the EPA and by private contractors have been used to supplement internal training. Examples of topics addressed include the following:

- planning, preparation, and record keeping for field sampling;
- well construction and groundwater sampling;
- surface water, leachate, and sediment sampling;
- soil sampling;
- stack sampling;
- decontamination procedures; and
- health and safety considerations.

9.3 ANALYTICAL QUALITY ASSURANCE

The contract analytical laboratories have well-established QA/QC programs, well-trained and highly qualified staff, and excellent equipment and facilities. Current, approved analytical methodologies employing good laboratory and measurement control practices are used routinely to ensure analytical reliability. The analytical laboratories conduct extensive internal QC programs with a high degree of accuracy, participate in several external QA programs, and use statistics to evaluate and continuously improve performance. Thus, QA and QC are daily responsibilities of all employees.

9.3.1 Internal Quality Control

Analytical activities are supported by the use of standard materials or reference materials (e.g., materials of known composition that are used in the calibration of instruments, methods standardization, spike additions for recovery tests, and other practices). Certified standards traceable to the National Institute of Standards and Technology (NIST), other DOE sources, or EPA are used for such work. The laboratories operate

under specific QA/QC criteria. Additionally, separate QA/QC documents relating to analysis of environmental samples associated with regulatory requirements are developed.

QA/QC measurement control programs external to the sample analysis groups have single-blind control samples submitted to the analytical laboratories to monitor performance. The results of such periodic measurement programs are statistically evaluated and reported to the laboratories and their customers. Most reports are issued quarterly, and some laboratories compile annual summary reports. These reports assist in evaluating the adequacy of analytical support programs and procedures. If serious deviations are noted by the QA/QC groups, the operating laboratories are promptly notified so that corrective actions can be initiated and problems can be resolved. QC data are stored in an easily retrievable manner so that they can be related to the analytical results they support.

9.3.2 External Quality Assurance

In addition to the internal programs, all contract analytical laboratories participate in external QA programs. The QA programs generate data that are readily recognizable as objective packets of results. The external QA programs typically consist of the contract laboratories analyzing a sample of unknown composition provided by various DOE- or EPA-approved proficiency-testing supplier organizations. The organizations know the true composition of the sample and provide the contract laboratories with a data report on their analytical performance. The sources of these programs are laboratories within DOE and the commercial sector. The following sections describe the external QA programs in which contract analytical laboratories may be required to participate.

9.3.2.1 EPA Water Pollution and Water Supply Performance Studies

Participation in the Water Pollution Program and the Water Supply Program studies is required

by most states for laboratories performing analyses of water samples for regulatory programs. The Water Supply Program is used by the state of Tennessee to certify laboratories for drinking water analysis. To maintain a certification, a laboratory must meet a specified set of criteria relating to technical personnel, equipment, work areas, QA/QC operating procedures, and successful analysis of QA samples. This program is also used by other states as part of their certification programs. Participation in the Water Pollution program satisfies the EPA and NPDES program requirement for laboratories performing Clean Water Act analyses to participate in a Discharge Monitoring Report Quality Assurance Program.

Since October 24, 1999, all water pollution and water supply studies except for whole effluent toxicity testing have been performed by private companies. NIST certifies non-EPA proficiency testing providers to prepare performance evaluation samples and to evaluate laboratory performance. EPA continues to issue standard operating procedures for use in the water supply and water pollution programs.

9.3.2.2 American Industrial Hygiene Association Proficiency Analytical Testing Program

The American Industrial Hygiene Association (AIHA) administers the Proficiency Analytical Testing Program as part of its AIHA accreditation process for laboratories performing analyses of industrial hygiene air samples.

9.3.2.3 Intercomparison Radionuclide Control Program

The EPA Intercomparison Radionuclide Control Program administered by the National Exposure Research Laboratory at Las Vegas has been replaced by a vendor-supplied program approved by EPA. Samples are composed of a water matrix. The state of Tennessee requires participation for drinking water certification of radionuclide analysis. This program is also used by other states as part of their laboratory certification process.

9.3.2.4 AIHA Environmental Lead Proficiency Analytical Testing Program

The Environmental Lead Proficiency Analytical Testing Program is administered by AIHA. This program was established in 1992 to evaluate analysis of environmental lead samples in paint, soil, and dust wipes. The participating laboratory can analyze each matrix at four levels. In addition, a laboratory may request to become accredited for lead analysis in this program.

9.3.2.5 DOE Mixed Analyte Performance Evaluation Program

The Mixed Analyte Performance Evaluation Program is a program set up by the DOE Radiological and Environmental Sciences Laboratory in conjunction with the Laboratory Management Division of the Office of Technology Development to evaluate analysis of mixed-waste samples. Participation is required by DOE for laboratories that perform environmental analytical measurements in support of environmental management activities.

9.3.2.6 DOE Environmental Measurements Laboratory Quality Assessment Program

The Radionuclide Quality Assessment Program is administered by the DOE Environmental Measurements Laboratory in New York. Various matrices, such as soil, water, air filters, and vegetation, are submitted semiannually for analysis of a variety of radioactive isotopes. All matrices, except air filters, are actual materials obtained from the environment at a DOE facility. A statistical report is issued by Environmental Measurements Laboratory for each study.

9.3.2.7 Proficiency Environmental Testing Program

The Proficiency Environmental Testing Program is a service purchased from an outside vendor and is used by some contract analytical

laboratories to meet the need for a QA program for environmental analyses. The samples are supplied by the commercial company at concentrations that meet the EPA-established guidelines. Data from the laboratory are reported to the supplier. The commercial supplier provides a report on the evaluated data to the laboratory. The report includes a percentage recovery of the referenced value, deviation from the mean of all reported data, specific problems in a laboratory, and other statistical information.

9.3.3 Quality Assessment Program for Subcontracted Laboratories

A competitive award system has been established by the BJC Sample Management Office to place analytical work that is required by BJC. The Sample Management Office provides single-point sample management for BJC projects/programs and BJC subcontractors. Commercial laboratories approved by the Sample Management Office are required to comply with the requirements set forth in the Integrated Contractor Procurement Team Basic Ordering Agreement terms and conditions. Oversight of subcontracted commercial laboratories is performed by the DOE Environmental Management Consolidated Audit Program, which is supported by the Sample Management Office. DOE, the Sample Management Office, and other subcontractors from across the DOE complex work together in the Environmental Management Consolidated Audit Program to conduct on-site laboratory reviews and to monitor the performance of all subcontracted laboratories. Awards are made to laboratories to provide analytical support to BJC projects based on the best value added to the project. Best value is a graded approach that comprises price and performance history.

BJC manages the Integrated Performance Indicator Program to report quality indicators that will assess trends for commercial analytical laboratories used to support BJC projects (and their subcontractors) within the DOE-ORO. The objective of the Integrated Performance Indicator Program is to evaluate all analytical laboratories

based on a set of standardized performance criteria that can then be quantitatively tracked and trended. BJC management uses these performance indicators to develop performance indicator factors, which are used as modifier factors when evaluating cost bids. In this approach, the low bidder may not win the work unless they have a favorable performance indicator factor score.

A limited basic order agreement with commercial laboratories has been established by UT-Battelle for the procurement of analytical services to characterize environmental and waste samples. Laboratories included in the agreement are required to comply with the terms and conditions of the Integrated Contractor Procurement Team Contract, Basic Order Agreement. A statement of work for each project specifies any additional QA/QC requirements and includes detailed information data deliverables, turnaround times, and required methods.

9.3.3.1 Single-Blind PE Program

If applicable, laboratories participate in several external single-blind performance evaluation programs. All results that are officially reported by the responsible agency (EPA or DOE) during the period of evaluation are used in computing the single-blind performance evaluation score. Single-blind performance evaluation program results are categorized into radiochemistry, organic, and inorganic methodology areas.

9.3.3.2 Double-Blind Performance Evaluation Program

Double-blind performance evaluation programs are employed to quantitatively evaluate the total laboratory process. Performance samples are submitted to laboratories with batches of actual field samples in order to ensure that the laboratory is not able to distinguish them as QA samples. Once the project data have been received, the performance evaluation results are evaluated and scored. Double-blind performance evaluation program results are categorized into

radiological, organic, and inorganic methodology areas.

The BJC SMO combines single- and double-blind performance evaluation scores to obtain a total Integrated Performance Indicator Program performance evaluation score. A laboratory must score 80% or better to remain in good standing. A score of 64 to 79% would result in a laboratory being placed on probation.

9.4 DATA MANAGEMENT, VERIFICATION, AND VALIDATION

Verification and validation of environmental data are performed as components of the data collection process, which includes planning, sampling, analysis, and data review. Verification and validation of field and analytical data collected for environmental monitoring and restoration programs are necessary to ensure that data conform with applicable regulatory and contractual requirements. Validation of field and analytical data is a technical review performed to compare data with established quality criteria to ensure that data are adequate for the intended use. The extent of project data verification and validation activities is based on project-specific requirements.

Over the years, the environmental data verification and data validation processes used by ORR environmental programs have evolved to meet continuing regulatory changes and monitoring objectives. For routine environmental effluent monitoring and surveillance monitoring, data verification activities may include processes of checking whether (1) data have been accurately transcribed and recorded, (2) appropriate procedures have been followed, (3) electronic and hard-copy data show one-to-one correspondence, and (4) data are consistent with expected trends. For example, the requirements for self-monitoring of surface-water and wastewater effluents under the terms of an NPDES permit require the permittee to conduct the analyses as defined in 40 CFR 136 and to certify that the data reported in the monthly discharge monitoring report are true and accurate.

Typically, routine data verification actions alone are sufficient to document the truthfulness

and accuracy of the discharge monitoring report. For restoration projects, routine verification activities are more contractually oriented and include checks for data completeness, consistency, and compliance against a predetermined standard or contract.

Certain projects may perform a more thorough technical validation of the data as mandated by the project's data quality objectives. For example, sampling and analyses conducted as part of a remedial investigation to support the CERCLA process may generate data that are needed to evaluate risk to human health and the environment, to document that no further remediation is necessary, or to support a multimillion-dollar construction activity and treatment alternative. In that case, the data quality objectives of the project may mandate a more thorough technical evaluation of the data against predetermined criteria. For example, EPA has established functional guidelines for validation of organic and inorganic data collected under the protocol of the EPA's Contract Laboratory Program. These guidelines are used to offer assistance to the data user in evaluating and interpreting the data generated from monitoring activities that require Contract Laboratory Program performance.

The validation process may result in identifying data that do not meet predetermined QC criteria (in flagging quantitative data that must be considered qualitative only) or in the ultimate rejection of data from its intended use. Typical criteria evaluated in the validation of Contract Laboratory Program data include the percentage of surrogate recoveries, spike recoveries, method blanks, instrument tuning, instrument calibration, continuing calibration verifications, internal standard response, comparison of duplicate samples, and sample-holding times.

Integration of compliance-monitoring data for the ORR with sampling and analysis results from remedial investigations is a function of the Oak Ridge Environmental Information System (OREIS). OREIS is necessary to fulfill requirements prescribed in both the Federal Facility Agreement and the Tennessee Oversight Agreement and to support data management activities for DOE. The Federal Facility Agreement, a tripartite agreement among DOE, EPA Region 4, and the state of Tennessee, requires DOE to maintain one consolidated database for environmental

data generated at DOE facilities on the ORR. According to the Federal Facility Agreement, the consolidated database is to include data generated pursuant to the agreement as well as data generated under federal and state environmental permits. The Tennessee Oversight Agreement further defines DOE staff obligations to develop a quality-assured, consolidated database of monitoring information that will be shared electronically on a near-real-time basis with the state staff.

OREIS is the primary component of the data management program for restoration projects, providing consolidated, consistent, and well-documented environmental data and data products to support planning, decision-making, and reporting activities. OREIS provides a direct electronic link of ORR monitoring and remedial investigation results to EPA Region 4 and the TDEC/DOE Oversight Division.