

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, including sample collection methods; sample handling, preservation, and transport; personnel training; analytical methods; data reporting; and record keeping. Quality assurance programs are designed to minimize these sources of error and to control all phases of the monitoring process.

9.1 Introduction

The application of quality assurance/quality control (QA/QC) programs for environmental monitoring activities on the ORR is essential for generating data of known and defensible quality. Each aspect of an 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 work planning and control and 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.

9.3 Analytical Quality Assurance

The contract analytical laboratories that perform the analyses of environmental samples from the ORR environmental monitoring programs are required to have documented QA/QC programs, well-trained and qualified staff, and appropriately maintained equipment and facili-

ties and applicable certifications. The analytical laboratories conduct extensive internal QC programs, participate in external QA programs, and use statistics to evaluate and continuously improve performance.

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), DOE sources, or EPA are used (when available) for such work. The laboratories operate under specific QA/QC criteria.

QA/QC measurement control programs external to the sample analysis groups include the submission of single- and double-blind control samples to monitor performance. The results of such periodic measurement programs are statistically evaluated and reported to the laboratories and their customers. Reports are issued routinely, 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.

9.3.2 External Quality Assurance

In addition to the internal programs, all contract analytical laboratories participate in external QA programs. The external QA programs typically consist of the contract laboratories analyzing samples of unknown composition sup-

plied by various DOE- or EPA-approved proficiency-testing supplier organizations. The supplying organizations know the true composition of the samples and provide the contract laboratories with data reports on their analytical performance. The following sections describe 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 National Pollutant Discharge Elimination System (NPDES) program requirement that laboratories performing Clean Water Act analyses participate in a Discharge Monitoring Report Quality Assurance Program.

Since October 24, 1999, all water pollution and water supply studies except whole effluent toxicity testing have been performed by commercial vendors. 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. A sample is 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 processes.

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. 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 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. Various matrices, such as soil, water, air filters, and vegetation, are submitted semiannually for analysis of a variety of radioactive isotopes as well as metals and organic parameters. A statistical report is issued for each study.

9.3.2.6 DOE Environmental Measurements Laboratory Quality Assessment Program

The Radionuclide Quality Assessment Program (QAP) was administered by the DOE En-

Environmental Measurements Laboratory (EML) in New York and was funded by the Energy Research and Development Administration and DOE. The program was an external, independent, performance evaluation program designed to test the quality of environmental radiological measurements. This program was terminated in 2004, and no more reports will be issued. In its place, DOE has expanded the Mixed Analyte Performance Evaluation Program to include the matrices previously provided via the EML QAP, such as soil, water, air, and vegetation.

9.3.2.7 Proficiency Evaluation Testing Programs

The Proficiency Evaluation Testing Programs are services purchased from outside vendors. They are required for many contract analytical laboratories to meet the need for a QA program for environmental analyses. The samples are supplied by commercial companies at concentrations that meet EPA-established guidelines. The analytical data are reported to the supplier, and a report on the precision and accuracy of the results is provided to the laboratory. This 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. Matrices can include water as well as soils. In addition, program participation via some vendors may satisfy requirements for participating in discharge monitoring report QA studies for the NPDES program and/or meet other certification program requirements imposed on laboratories.

9.3.3 Y-12 Analytical Chemistry Organization Scores on FY 2005 Performance Evaluation Programs

The BWXT Y-12 Analytical Chemistry Organization subscribes to a number of independent, external QC programs that submit blind samples and score the quality of the results. This is necessary to retain numerous certifications required by customers and to ensure the quality of the analyses. The Analytical Chemistry labs achieved an overall FY 2005 score of 98.02% from 68 different studies. This compares with a national average of 94.4% among programs for which data are available. On 53 of the studies,

the Analytical Chemistry Organization labs received a score of 100%.

9.3.4 Quality Assessment Programs for Subcontracted Laboratories

Competitive award systems are used by UT-Battelle and by DOE's Sample Management Office to select laboratories that are contracted under Basic Ordering Agreements to perform analytical work. 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 projects based on the best value added to the project. Best value is a graded approach that comprises price and performance history.

The Sample Management Office contractor manages the Integrated Performance Indicator Program to report quality indicators that will assess trends for commercial analytical laboratories used to support Sample Management Office projects (and their subcontractors) within 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. The Sample Management Office contractor uses these performance indicators to monitor the labs' performance.

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.

9.3.4.1 Single-Blind Performance Evaluation Program

If applicable, laboratories participate in 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.

9.3.4.2 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 Sample Management Office 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's 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. Some level of verification and validation of field and analytical data collected for environmental monitoring and restoration programs is necessary to ensure that data conform with applicable regula-

tory 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 validity and accuracy of environmental reports. 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 Comprehensive Environmental Response, Compensation, and Liability Act 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 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 the identification of 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 for their 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 Tennessee Department of Environment and Conservation/DOE Oversight Division.

