
QUALITY ASSURANCE

The quality assurance (QA) program at the West Valley Demonstration Project (WVDP) provides for and documents consistency, precision, and accuracy in collecting and analyzing environmental samples and in interpreting and reporting environmental monitoring data.

Organizational Responsibilities

West Valley Nuclear Services Co., Inc. (WVNS) Quality Assurance is responsible for monitoring the quality of site activities, including the environmental monitoring program. Laboratory management and staff are directly responsible for carrying out sampling and analytical activities in a manner consistent with good quality assurance practices and for following approved procedures.

Program Design

The quality assurance program for environmental monitoring activities at the Western New York Nuclear Service Center (WNYNSC) is consistent with 10 CFR 830.120, Quality Assurance, and the WVDP's

Environmental Quality Assurance Plan (West Valley Nuclear Services 1994) and is based directly upon the eighteen-element program outlined in Quality Assurance Program Requirements for Nuclear Facilities (American Society of Mechanical Engineers 1989), which describes the major aspects of a good quality assurance program. The program focuses upon assigning responsibilities and upon thorough planning, specification, control, and documentation of all aspects of an activity:

√ *Responsibility.* Responsibilities involved in overseeing, managing, and conducting an activity must be clearly defined. Personnel who check and verify that the activity has been completed correctly must be independent of those who performed it.

√ *Planning.* An activity must be planned beforehand and the plan followed. All activities must be documented. Similarly, purchases of any equipment or items must be planned, specified precisely, and verified for correctness upon receipt.

√ *Control of design, procedures, items, and documents.* Any activity, equipment, or construction must be clearly described or defined and tested,

and changes in the design must be tested and documented. Procedures must clearly state how activities will be conducted. Only approved procedures may be used. Any equipment or particular items affecting the quality of environmental data must be identified, inspected, calibrated, and tested before use. Calibration status must be clearly indicated. Items that do not conform to requirements must be identified and separated from other items and the nonconformity documented.

√ *Documentation.* Records must be kept of all activities in order to verify what was done and by whom. Records must be clearly traceable to an item or activity.

√ *Corrective action.* If a problem should arise the cause of the problem must be identified, a corrective action planned, responsibility assigned, and the problem remedied.

√ *Audits.* Scheduled audits and self-assessments must be conducted to verify compliance with all aspects of the quality assurance program and determine its effectiveness.

Subcontractor laboratories providing analytical services for the environmental monitoring program are contractually required to maintain a quality assurance program consistent with WVNS requirements with respect to the above elements.

Procedures

Activities affecting the quality of environmental monitoring data are conducted according to approved procedures that clearly describe how the activity should be performed and what precautions are to be taken in connection with the activity. Any person performing an activity that could affect the quality of environmental monitoring data is trained in that procedure and must demonstrate proficiency.

New procedures are developed each time an activity is added to the monitoring program. Procedures are reviewed periodically and updated when necessary. Documents are controlled so that only current procedures are used.

Quality Control in the Field

Quality control (QC), an integral component of environmental monitoring quality assurance, is a way of verifying that samples are being collected and analyzed according to established quality assurance procedures: Quality control ensures that sample collection and analysis is consistent and repeatable; it is a means of tracking down possible sources of error. For example, sample locations are clearly marked in the field to ensure that future samples are collected in the same locations; collection equipment in place in the field is routinely inspected, calibrated, and maintained; and automated sampling stations are kept locked to prevent tampering and ensure sample integrity.

Samples are collected into appropriate containers and labeled immediately with pertinent information. Date, time, person doing the collecting, and special field sampling conditions are recorded and kept as part of the record for that sample. If necessary, samples are preserved as soon as possible after collection.

In order to monitor quality problems that might be introduced by the sampling process, duplicate field samples, field blank samples, and trip blank samples are collected. Background samples are collected for baseline environmental information.

Field Duplicates

Field duplicates are samples collected simultaneously for the same analyte at one location, after which they are treated as separate samples. If the sampling matrix is homogenous, field duplicates provide a means of assessing the precision of

collection methods. Field duplicates are collected at a minimum rate of one per twenty analyses.

Field Blanks

A field blank is a sample of laboratory-distilled water that is put into a sample container at a field collection site and is processed from that point as a routine sample. Field blanks are used to detect contamination introduced by the sampling procedure. They are processed at a minimum rate of one per twenty analyses.

If the same collection equipment is used for more than one site, a special form of field blank known as an equipment blank may be collected by pouring laboratory-distilled water through cleaned collecting equipment and into a sample container. Equipment blanks are collected to detect any cross-contamination that may be passed from one sampling location to another by the equipment. Many wells and surface water collection stations have dedicated collecting equipment that remains at that location; equipment blanks are not necessary at these locations.

Trip Blanks

Trip blanks are prepared by pouring laboratory-distilled water into sample bottles in the laboratory. The bottles are then placed into sample coolers where they remain throughout the sampling event. Trip blanks are collected in order to detect any volatile organic contamination from the containers, coolers, or from handling during collection, storage, or shipping. Trip blanks are collected only when volatile organic samples are being collected.

Environmental Background Samples

To monitor each pathway for possible radiological contamination, samples of air, water, vegetation, meat, and milk are taken from locations remote from the site. Samples that are clearly outside site influence show natural radiological concentrations

and serve as backgrounds or "controls," another form of field quality control sample. Background samples provide baseline information to compare with information from near-site or on-site samples so that any possible influence from the site can be determined.

Quality Control in the Laboratory

More than 12,000 samples were handled as part of site monitoring in 1995. Samples for routine radiological analysis were analyzed on-site, with the rest being sent to subcontract laboratories. Off-site laboratories must maintain a level of quality control as specified in contracts between WVNS and the subcontract laboratories. Subcontract laboratories are required to participate in all applicable crosscheck programs and to maintain all relevant certifications.

In order to monitor the accuracy and precision of data, laboratory quality control practices specific to each analytical method are clearly described in approved references or procedures. Laboratory quality control consists of proper training of analysts, maintenance and calibration of measuring equipment and instrumentation, and specific methods of processing samples as a means of monitoring laboratory performance.

Analytical instruments and counting systems are calibrated at specified frequencies and logs of instrument calibration and maintenance are kept. Calibration methods for each instrument are specified in procedures or in manufacturers' directions. Standards traceable to the National Institute of Standards and Technology (NIST) are used to calibrate counting and test instrumentation.

Laboratory quality control samples consist of three general types: standards (including spikes), used to assess accuracy; blanks, to assess the possibility of contamination; and duplicates, to assess precision.

Standards

Laboratory standards are materials containing a known concentration of an analyte of interest such as a pH buffer or a plutonium-239 counting standard. Standards are either NIST-traceable or reference materials from other nationally recognized sources. At a minimum, one reference standard is analyzed for every twenty sample analyses, or one per day. The results of the analyses are plotted on control charts, which specify acceptable limits. If the results lie within these limits, then analysis of actual environmental samples may proceed and the results deemed usable.

Laboratory Spikes

Another form of standard analysis is a laboratory spike. In a laboratory spike, a known amount of analyte is added to a sample or blank before the sample is analyzed. The percent recovery of the analyte indicates how much of the analyte of interest is being detected in the analysis of actual samples; hence, a spike also is an assessment of the accuracy of the method. Spike recoveries are recorded on control charts with documented acceptance limits.

Laboratory Blanks

Laboratory blanks are prepared from a matrix similar to that of the sample but known to contain none of the analyte of interest. For instance, distilled water, taken through the same preparatory procedure as a sample, serves as a laboratory blank for both radiological and chemical analyses of water samples. A positive result for an analyte in a blank indicates that something is wrong with the analysis and that corrective action should be taken. In general, one laboratory blank is processed daily or with each batch of samples for a given analyte.

A special form of laboratory blank for radiological samples is an instrument background count, which is a count taken of a planchet or vial

containing no sample. The count serves three purposes:

- 1) to determine if contamination is present in the counting instrument
- 2) to determine if the instrument is responding in an acceptable manner
- 3) to determine the background correction that should be applied in calculations of radiological activity.

An instrument background count is taken before each day's counting. Background counts are recorded on control charts with defined acceptance limits. An unacceptable count requires corrective action before analyses can proceed.

Laboratory Duplicates

Duplicates are analyzed to assess precision in the analytical process. Laboratory duplicates are created by splitting existing samples before analysis; each split is treated as a separate sample. If the analytical process is in control, results for each split should be within documented acceptance criteria.

Crosschecks

WVNS participates in formal radiological cross-check programs conducted by the U.S. Department of Energy (DOE) and the U.S. Environmental Protection Agency (EPA). The DOE requires all organizations performing effluent or environmental monitoring to participate in the semiannual Environmental Measurements Laboratory (EML) Quality Assessment Program (QAP), which is designed to test the quality of environmental measurements being reported to the DOE by its contractors. WVNS also participates in crosscheck programs from the EPA's National Exposure Research Laboratory Characterization Research Division (NERL-CRD), formerly the Environmental Monitoring Systems Laboratory (EMSL). Crosscheck samples for ra-

diological analyses are analyzed by both the Environmental Laboratory on-site and by the subcontract laboratories.

Results from radiological crosschecks are summarized in *Appendix D*, Tables D-1 through D-3 (pp. D-1 through D-6). A total of 141 radiological crosscheck analyses were performed by or for WVNS and reported in 1995. One hundred thirty-five results (95.7%) were within control limits. Forty-six of the results were produced by the on-site Environmental Laboratory; 97.8% were within control limits. Out-of-control results were followed up through formal corrective action procedures.

No nonradiological crosschecks were performed by WVNS in 1995.

By contract, subcontract laboratories are required to perform satisfactorily on crosschecks, defined as 80% of results falling within control limits. Crosscheck results that fall outside control limits are addressed by formal corrective actions in order to determine any conditions that could adversely affect sample data and to ensure that actual sample results are reliable.

WVDP environmental thermoluminescent dosimeters (TLDs) were analyzed by WVNS for the first three quarters of 1995. Analysis was transferred to the independent off-site subcontractor for the final three quarters of 1995, allowing two quarters of overlap. Table D-4 (p. D-7) summarizes environmental TLD analytical results from WVNS and the off-site subcontractor compared to results from U.S. Nuclear Regulatory Commission (NRC) TLDs placed in the same locations but collected and analyzed by the NRC. Although not a formal crosscheck, the agreement of these sets of results demonstrates the precision of these measurements and substantiates confidence in results from the remainder of the environmental TLD locations.

Personnel Training

Anyone performing environmental monitoring program activities must be trained in the appropriate procedures and qualified accordingly before carrying out the activity as part of the site environmental monitoring program.

Record Keeping

Control of records is an integral part of the environmental monitoring program. Field data sheets, chain-of-custody forms, requests for analysis, sample-shipping documents, sample logs, bench logs, laboratory data sheets, equipment maintenance logs, calibration logs, training records, crosscheck performance records, data packages, and weather measurements, in addition to other records, are maintained as documentation of the environmental monitoring program. All records pertaining to the program are routinely reviewed and securely stored.

A Laboratory Information Management System (LIMS) is used to log samples, print labels, store and process data, track quality control samples, track samples, produce sampling and analytical worklists, and generate reports. Subcontract laboratories, where possible, provide data in electronic form for direct entry into the LIMS.

Chain-of-Custody Procedures

Chain-of-custody records begin with sample collection. Samples brought in from the field are transferred under signature from the sampler to the sample custodian and are logged at the sample receiving station, after which they are stored in a sample lock-up before analysis or shipping.

Samples sent off-site for analysis are accompanied by an additional chain-of-custody/analytical request form. Signature control must be maintained by the agent transporting the samples. Subcontract laboratories are required by contract to maintain internal chain-of-custody records and to store the samples under secure conditions.

Audits and Appraisals

WVNS Quality Assurance conducted several surveillances in 1995 of various aspects of specific environmental programs at the WVDP, comparing them with requirements of the WVDP Environmental Quality Assurance Plan (WVDP-099). The environmental monitoring program, which was included in the scope of the surveillances, met the requirements of WVDP-099.

The NRC visited the WVDP site in June 1995 in order to assess the status of WVNS' program for the operation of the vitrification facility. As a result of this review it was determined that a viable program for protecting public health and safety was in place. The NRC included five recommendations for program enhancement in their report.

Later in 1995 WVNS Project Appraisals assessed environmental monitoring program compliance with DOE Orders. This assessment was part of the line-management self-assessment supporting the operational readiness review and included environmental monitoring. Project Appraisals reported one observation and one noteworthy practice. (For more information on site audits and assessments see the *Environmental Compliance Summary: Calendar Year 1995* [p. lviii].)

Self-Assessments

Areas of inquiry from two prescheduled self-assessments were combined into one self-assessment of the environmental monitoring program, conducted in calendar year 1995. In the course of the self-assessment, three observations were noted. Deficiencies have been addressed through formal corrective action procedures. In addition, several comments regarding possible program improvements were noted and commendable practices were identified.

Nothing was found during the course of the self-assessment that would compromise data in this report or in the program in general.

Data Management and Data Validation

Information on environmental monitoring program samples is maintained and tracked in the LIMS and includes collection, chain-of-custody transfer, shipping information, analytical results, and final validation status.

All analytical data produced in the Environmental Laboratory at the bench level must be reviewed and signed off by a qualified person other than the one who performed the analysis. A similar in-house review is contractually required from subcontractor laboratories.

All software used to generate data is subjected to verification and validation before use.

Analytical data from both on- and off-site laboratories are formally validated by the data validation group. As part of the validation procedure, quality control samples analyzed in conjunction with a batch of samples are checked for acceptability. After validation is complete and transcription between hard copy and the LIMS is

verified, the sample result is formally approved and released for use in reports.

The data are then evaluated and reports are prepared. Before each technical report can be issued it must undergo a peer review in which the document, including the data, is comprehensively reviewed by one or more persons who are knowledgeable in the necessary field of work.

The multiple levels of scrutiny built into data generation, validation, and reporting ensure that reliable and accurate data are reported from the environmental monitoring program.

Data Reporting

Radiological measurements require that analytical or instrumental background counts be subtracted from sample counts to obtain net values. If background counts are equal to or greater than the sample count, an individual sample result can be zero or negative. Therefore, sometimes a result will be lower than the minimum detection limit of an analytical technique.

Although a negative value does not represent a physical reality, a reliable long-term average of many measurements can be obtained only if the very small and negative values are included in the population calculations.

For individual measurements, uncertainties are reported as two times the standard deviation, which approximates a 95% confidence level or interval around the measurement. (See also “confidence coefficient” in the *Glossary*.) Positive means for which the 95% confidence interval does not include zero may be assumed to indicate detectable amounts of activity.

Averages from measurements from a particular sampling location are calculated by taking a simple arithmetic mean. What is not so clear, even

as a professional consensus, is how to represent the uncertainty associated with an average from data collected from a given sample point throughout a set period of time, such as weekly samples collected over a year.

One method in use by other facilities is to represent an average of a set of samples by using an arithmetic mean of the central values and then using the standard error of the mean to represent the range of variation in the sample values alone. This method does not consider the relative value of the uncertainties associated with the measurements.

Thus, in situations where the analytical results of a group of samples are near the minimum detectable concentration and may all include zero within their confidence interval, the 95% confidence interval for the mean may not include zero; therefore, the average may appear to be statistically greater than zero even though it is doubtful that any individual sample contained detectable radioactivity.

In this report we have opted to express the confidence interval of the average of repeated independent samples collected at a sample location periodically over the year by pooling the error terms from the individual measurements going into the average, given that the standard deviations of the samples are relatively comparable. In this manner, we are expressing a reasonable and representative estimate of the uncertainty term for the (annual, monthly) average value, as follows:

$$e_m = \frac{\sqrt{e_1^2 + e_2^2 + \dots + e_n^2}}{\sqrt{n}}$$

where e_1 through e_n represent the confidence interval or error terms for each of n measurements, and e_m equals the confidence interval for the mean.

In previous years samples for which the confidence interval was larger than the result were reported with “less than” values. This year, to allow the readers to perform similar calculations with data groups, as has been the past practice of the report preparers, the actual calculated value, whether positive, negative, or zero, is being reported. The associated confidence interval will be expressed as e_m , above.