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

Managers of programs, projects, and tasks are responsible for determining and documenting the applicability of quality assurance requirements to their activities and for implementing those requirements. For example, Environmental 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 rule 10 CFR Part 830.120, Quality Assurance, and DOE Order 5700.6C, Quality Assurance (U.S. Department of Energy 1991) provide the quality assurance program policies and requirements applicable to activities at the WVDP. The integrated quality assurance program applicable to environmental monitoring at the WVDP also incorporates requirements from Quality Assurance Program Requirements for Nuclear Facilities (American Society of Mechanical Engineers 1989) and Quality Systems Requirements for Environmental Programs (American National Standards Institute and American Society for Quality Control 1994).

The quality assurance program focuses upon assigning responsibilities and upon thorough planning, specification, control, and documentation of all aspects of an activity in order to ensure the quality of both radiological and nonradiological monitoring data. The quality assurance program includes requirements in the following areas:

√ *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 of all activities must be kept 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 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.

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 are 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 certified pre-cleaned containers made of an appropriate material and capacity and are labeled immediately with the 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 assess 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 that may be introduced 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 11,000 samples were handled as part of site monitoring in 1996. 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 with WVNS. 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. Examples of laboratory quality control activities include proper training of analysts, maintaining and calibrating measuring equipment and instrumentation, and processing samples in accordance with specific methods 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. 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, may serve 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 when calculating radiological activity in certain samples.

An instrument background count is taken before each day's counting or with each batch of twenty samples. 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 crosscheck 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). Crosscheck samples for radiological 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-8). A total of 139 radiological crosscheck analyses were performed by or for WVNS and reported in 1996. One hundred and twenty-nine results (92.8%) were within control limits. Forty-six of the results were produced by the on-site Environmental Laboratory; 100% were within control limits. Out-of-control results were followed up through formal corrective action processes.

Results for nonradiological EPA crosschecks are summarized in Table D-5 (p. D-10). Twenty-one parameters were analyzed by Recra Environmental, Inc. and two by WVNS. All twenty-three results (100%) were within control limits.

By contract with WVNS, 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.

Table D-4 (p. D-9) summarizes environmental TLD results and the 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. Subcontract laboratories are required by contract to maintain internal chain-of-custody records and to store the samples under secure conditions.

Audits and Appraisals

The WVNS Quality Assurance Department assesses compliance with and the effectiveness of WVNS programs by performing audits, assessments, surveillances, and/or inspections of processes.

In 1996 WVNS Quality Assurance (QA) conducted several surveillances of various aspects of specific environmental programs at the WVDP. Topics addressed were shipping hazardous and radioactive materials, measuring air emission and liquid effluent discharge concentrations, calibrating and operating the meteorological system, sampling groundwater monitoring wells that contain radioactive contamination, calibrating and operating main stack air monitoring and sampling equipment, packaging and shipping crosscheck samples, inspecting groundwater monitoring well screens, collecting liquid effluent samples for analysis and comparison with the SPDES permit, collecting ambient air samples, and calibrating equipment for collecting routine air samples.

Activities were assessed against applicable regulations, safety requirements, or procedures. Results of all surveillances were satisfactory.

No formal audits of the environmental monitoring program by either WVNS Quality Assurance or by external agencies were conducted in 1996. (For more information on site audits and assessments see the *Environmental Compliance Summary: Calendar Year 1996* [p. lix]).

Self-Assessments

One self-assessment of the environmental monitoring program was conducted in 1996. The focus of this self-assessment was the adequacy of environmental monitoring program components that address new systems and processes associated with the start-up of vitrification.

Areas of inquiry were:

- liquid effluent monitoring
- airborne effluent monitoring
- meteorological monitoring
- environmental surveillance
- laboratory procedures
- data analysis and statistical treatment of data
- dose assessment
- records and reports
- quality assurance.

One finding and seven observations were noted. Deficiencies were addressed through formal corrective action procedures. In addition, several comments regarding possible program improvements were noted and commendable practices identified.

Nothing was found during the course of the self-assessment that would compromise the 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 date and time of 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 technical aspects of the field of work.

While evaluating 1996 data it was found that some values for iodine-129 in effluent air were not correct. The vendor laboratory corrected the procedures that had caused the problem and a different method was used to calculate the iodine-129 values that had been reported during the time that the incorrect analyses had occurred.

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

There is inherent uncertainty associated with all environmental radioactivity measurements. The uncertainty that is associated with individual measurements is expressed as a *confidence interval*, i.e., the range of measurement values above and below the test result within which the "true" value is expected to lie. This interval is derived mathematically using statistical concepts. The width of the interval is based primarily on a predetermined level of confidence that the "true" value lies within the interval. This *confidence level* is expressed in terms of a probability that the confidence interval actually encompasses the "true" value. For example, the WVDP environmental monitoring program uses a 95% confidence level for all radioactivity measurements and calculates confidence intervals accordingly.

Radiological measurements require that analytical or instrumental background counts be subtracted from sample measurement values to obtain net values. If background values are equal to or greater than the gross sample measurement value, then the net sample measurement value can be zero or negative. 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 calculations.

Averages of radioactivity 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 confidence interval that is associated with an average of many measurements.

One method in use by other facilities is to represent an average of a set of samples by using an arithmetic mean of the values and then using the standard error of the mean to represent the confidence interval. This method does not consider the value of the confidence interval for each of the individual measurements. Thus, in situations where the measurements are near the minimum detectable concentration and may all include zero within their confidence interval, the confidence interval for the average may not include zero; therefore, even though it is doubtful that any individual sample contained detectable radioactivity the confidence interval for the average may not include zero.

For this reason, in this report we have opted to express the confidence interval of the average of repeated measurements of independent samples by pooling the confidence intervals from the individual measurements. In this manner, we are expressing a reasonable and representative estimate of the confidence interval for the average as follows:

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

where e_1 through e_n represent the confidence intervals for each of *n* measurements, and e_m equals the confidence interval for the mean.

Up until 1992, samples for which the confidence interval included zero were reported as "less than" values. Since then, to allow 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 pooled confidence interval will be expressed as e_m, above.