QUALITY ASSURANCE

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

Organizational Responsibilities

WVNS Quality Assurance is responsible for ensuring 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.

Program Design

The quality assurance program for environmental monitoring at the WNYNSC is consistent with DOE Order 5700.6C, Quality Assurance, and the WVDP's Environmental Quality Assurance Plan (West Valley Nuclear Services 1991) 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 and managing an activity must be clearly defined. Personnel who check and verify the activity must be independent of those who perform the activity.

√ *Planning*. The 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 tested and documented. Procedures must clearly state how activities will be conducted. Only approved procedures may be used. Any equipment or particular items must be clearly identified, inspected, calibrated, and tested before use. Calibration status must be clearly labeled. Items that do not conform 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. 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.

Vendors providing analytical services for the environmental monitoring program are contractually required to maintain a quality assurance program consistent with these elements.

Procedures

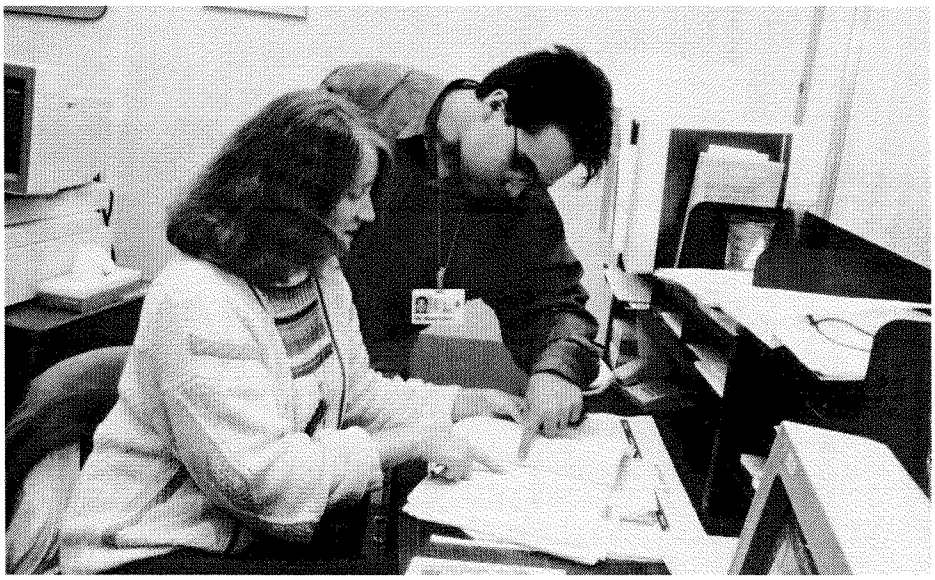
Activities affecting the quality of environmental monitoring data are conducted according to approved procedures that clearly describe how the activity should be performed and what precautions are to be taken in connection with the activity. Any person performing an activity that could affect the quality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

Samples are collected into appropriate containers and labeled immediately with pertinent information. Date, time, person doing the



Review of Regulatory Requirements

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 for the same analyte at the same location at the same time, 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 and 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. Special equipment blanks are not necessary at these locations because the equipment is used exclusively at that station.

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. Trip blanks are collected only when volatile organics are being monitored in order to detect any volatile organic contamination from the containers, coolers, or from handling during collection, storage, or shipping.

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 of 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 15,000 samples were handled as part of site monitoring in 1993. Approximately 60% of these samples were analyzed on-site, with the rest being sent to vendor laboratories. Samples analyzed by laboratories off-site must maintain a level of quality control similar to on-site laboratories, as specified in contracts between the site and the vendor laboratories. Vendor laboratories are required to participate in all relevant crosschecks 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 the analyte of interest, such as a pH buffer or a plutonium-239 counting standard, and are either NIST-traceable standards or standard reference materials from other nationally recognized sources. At a minimum, one reference standard is analyzed for every ten sample analyses, or one per day, to determine if the method is producing results within acceptable limits.

The results from analyses of standards are plotted on control charts, which specify acceptable limits. If the analysis produces results within acceptable limits, then analysis of actual environmental samples may proceed and the results are deemed usable.

Laboratory Spikes

Another form of standard analysis is a laboratory spike in which a known amount of analyte is added to a sample or blank before the sample is analyzed. The percent recovery of the analyte is an indication of 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. Acceptance limits are documented for spike recovery and spike results are recorded on control charts.

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 water analyses. 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 "run" 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.

A 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 criteria of acceptability.

Crosschecks

WVNS participates in formal radiological crosscheck programs conducted by the DOE and the EPA. The DOE requires participation in the semiannual EML Quality Assessment Program (QAP) by any laboratory analyzing samples for environmental monitoring at DOE sites. WVNS also participates in crosschecks from the EPA's Environmental Monitoring Systems Laboratory (EMSL). Crosscheck samples for radiological analyses are analyzed by both the Environmental Laboratory on-site and by the vendor laboratories and are reported by WVNS.

Ninety-seven radiological crosscheck analyses were performed by or for WVNS and reported by WVNS in 1993. Results from radiological crosschecks are summarized in *Appendix D*, Tables D-1, D-2, and D-3. Eighty-one results (83.5%) were within control limits. Most out-of-control results were part of QAP-39, which is summarized in Table D-2. Excluding the QAP-39 results, the percentage in control for 1993 was 94.0% (63 of 67 results.) The performance on QAP-39 is being followed up by formal corrective action.

WVNS also participates in nonradiological crosschecks as submitted by the EPA and by NYSDOH. Successful completion of NYSDOH performance evaluation samples is necessary to maintain laboratory certification. Results from nonradiological crosschecks are summarized in *Appendix D*, Tables D-4 and D-5. Forty-nine analyses were performed, and forty-six were within control limits (93.9%).

By contract, vendor laboratories are required to perform satisfactorily on crosschecks, defined as 80% of results falling within control limits. Crosscheck results outside of control limits for both radiological and nonradiological analyses 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-6 summarizes environmental thermoluminescent dosimeter (TLD) analytic results from WVNS and results from NRC TLDs placed in the same locations but collected and analyzed by the NRC. Although not a formal crosscheck, the agreement of these two 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 all 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. Vendor laboratories, where possible, provide data in electronic form for direct entry into the LIMS.

Chain-of-Custody Procedures

Field data sheets, completed when samples are collected, serve as chain-of-custody records for routine samples. Samples are brought in from the field and logged at the sample receiving station, after which they are stored in a sample lock-up before analysis or shipping.

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

Audits and Appraisals

During 1993 NYSDEC conducted a comprehensive groundwater monitoring evaluation and the NRC conducted an extensive audit of the WVDP radiological monitoring program. While formal reports have not yet been issued, preliminary results do not indicate any significant findings. (See *Environmental Compliance Summary: Calendar Year 1993.*)

Self-Assessments

Four routine quarterly internal appraisals (self-assessments) of the environmental monitoring program and the Environmental Laboratory were conducted in 1993.

During the course of these appraisals, thirteen findings requiring corrective action and fourteen observations requiring preventive action were identified. In general, findings and observations were largely due to lapses in documentation or to transfer of responsibilities for components of the program when environmental monitoring and laboratory functions were reorganized in 1993. These deficiencies have been or are being addressed through formal corrective action procedures. In addition, several comments regarding possible program improvements were noted and several commendable practices were identified.

Along with the findings and observations, nothing was found during the course of the self-assessments 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 vendor laboratories.

All software used to generate data is subjected to a verification procedure before use.

All data, from both on- and off-site laboratories, is formally validated by the data validation group. As part of the validation procedure,

quality control samples analyzed in conjunction with the sample calculations are checked. After validation is complete and transcription between hardcopy 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 thoroughly grounded 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. Therefore, sometimes a result will be lower than the minimum detection limit of an analytical technique. Consequently, individual sample measurements can result in values of zero and negative numbers.

Although a negative value does not represent a physical reality, a valid 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 represents a 95% confidence interval around the measurement. Means for which the 95% confidence interval does not include zero may be assumed to indicate detectable amounts of activity.

The calculation of averages from measurements from a particular sampling location is straightforward 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:

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

where e_1 through e_n represent the confidence interval or error terms for each of n measure-

ments, 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.