



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 24, 1997

Mr. Ronald A. Milner, Director
Program Management and Integration
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, D.C. 20585

SUBJECT: OBSERVATION AUDIT OF THE WEST VALLEY DEMONSTRATION PROJECT

Dear Mr. Milner:

I have enclosed the U.S. Nuclear Regulatory Commission Observation Audit Report OA-97-02 of the U.S. Department of Energy (DOE), Environmental Management, Office of Waste Management, Office of Technical Services (EM-37) compliance based audit of the quality assurance (QA) program of the West Valley Demonstration Project (WVDP). This audit, 97VP-WV-AU-01, was conducted on January 27-30, 1997, at the WVDP facilities in West Valley, New York. The audit evaluated the adequacy and effectiveness of the WVDP QA program as applied to the WVDP activities related to high-level radioactive waste form production. The audit took place while WVDP personnel were completing the fill of the 69th of some planned 300 canisters with the high-level radioactive waste slurry at the West Valley site. DOE's Office of Civilian Radioactive Waste Management Office of Quality Assurance had an observer at this audit; the State of Nevada did not.

Overall, the EM-37 audit team concluded that the high-level radioactive waste form production and associated processes of the WVDP met QA program requirements and were acceptable. The NRC staff agrees with this conclusion. One deficiency was noted in that one software program was not identified as "Quality Effecting Software" as it should have been.

Based on the observation of this audit, the NRC staff has determined that EM-37 Audit 97VP-WV-AU-01 was useful and effective and that the QA program for high-level waste form production is being effectively implemented at the WVDP. The audit was organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited, they were well qualified in their disciplines, and their assignments and checklist items were adequately described in the audit plan.

DOE should continue to closely monitor implementation of the WVDP QA program to ensure that the deficiency identified during this audit is corrected in a timely manner and that future QA program implementation is effective. The NRC staff may participate in this monitoring as observers and may perform its own independent audits at a later date to assess WVDP implementation of its QA program.

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A written response to this letter is not required. If you have any questions, please call Bill Belke of my staff on (702) 388-6125.

Sincerely,

[Original signed by:]

John H. Austin, Chief

Performance Assessment and High-Level Waste Integration Branch
Division of Waste Management
Office of Nuclear Material Safety and Safeguards

Enclosure: As stated

- cc: R. Loux, State of Nevada
- C. Johnson, State of Nevada
- S. Zimmerman, State of Nevada
- B. Price, Nevada Legislative Committee
- J. Meder, Nevada Legislative Counsel Bureau
- M. Murphy, Nye County, NV
- M. Baughman, Lincoln County, NV
- D. Bechtel, Clark County, NV
- P. Niedzielski-Eichner, Nye County, NV
- B. Mettam, Inyo County, CA
- V. Poe, Mineral County, NV
- W. Cameron, White Pine County, NV
- R. Williams, Lander County, NV
- L. Fiorenzi, Eureka County, NV
- J. Hoffman, Esmeralda County, NV
- J. Regan, Churchill County, NV
- L. Bradshaw, Nye County, NV
- W. Barnard, NWTRB
- R. Holden, NCAI
- T. Burton, NIEC
- R. Arnold, Pahrump, NV
- N. Stellavato, Nye County, NV
- R. Milner, YMPO
- S. Brocoum, YMPO
- W. Barnes, YMPO
- D. Horton, YMPO
- C. Einberg ~~OR~~ F. Rodgers, DOE/Wash, DC

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U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT OA-97-02
OF THE DEPARTMENT OF ENERGY
OFFICE OF TECHNICAL SERVICES
AUDIT NUMBER 97VP-WV-AU-01
OF THE WEST VALLEY DEMONSTRATION PROJECT

Prepared by:


02/07/97
John G. Spraul
Tank Waste Remediation Section
Special Projects Branch
Division of Fuel Cycle Safety
and Safeguards

Reviewed and approved by:


02/11/97
Michael Tokar, Section Leader ^{Chief}
Tank Waste Remediation Section
Special Projects Branch
Division of Fuel Cycle Safety
and Safeguards

Enclosure

~~9702-130-001~~

MANAGEMENT SUMMARY

This U.S. Department of Energy (DOE), Environmental Management, Office of Waste Management, Office of Technical Services (EM-37) compliance audit of the quality assurance (QA) program of the West Valley Demonstration Project (WVDP) evaluated the adequacy and effectiveness of the WVDP QA program as applied to the WVDP activities related to high-level radioactive waste form production. The audit took place while WVDP personnel were completing the fill of the 69th of some planned 300 canisters with the high-level radioactive waste slurry at the West Valley site.

Overall, the EM-37 audit team concluded that the high-level radioactive waste form production and associated processes of the WVDP met QA program requirements and were acceptable. The NRC staff agrees with this conclusion. One deficiency was noted in that one software program was not identified as "Quality Effecting Software" as it should have been.

Based on the observation of this audit, the NRC staff has determined that EM-37 Audit 97VP-WV-AU-01 was useful and effective and that the QA program for high-level waste form production is being effectively implemented at the WVDP. The audit was organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited, they were well qualified in their disciplines, and their assignments and checklist items were adequately described in the audit plan.

1.0 INTRODUCTION

A member of the Nuclear Regulatory Commission Division of Fuel Cycle Safety and Safeguards QA staff observed the Department of Energy (DOE), Environmental Management, Office of Waste Management, Office of Technical Services (EM-37) compliance audit of the QA program of the West Valley Demonstration Project (WVDP). This audit, 97VP-WV-AU-01, was conducted on January 27-30, 1997, at the WVDP facilities in West Valley, New York. The audit evaluated the adequacy and effectiveness of the WVDP QA program as applied to the WVDP activities related to high-level radioactive waste form production. DOE's Office of Civilian Radioactive Waste Management (OCRWM) Office of Quality Assurance had an observer at this audit; the State of Nevada did not.

The principal participants in the WVDP are (1) the DOE West Valley Project Office, responsible for the project, and (2) West Valley Nuclear Services (a subsidiary of Westinghouse Electric Company), the management and operating contractor for the project. The NRC's interest in the WVDP stems primarily from the possibility that the radioactive waste may eventually be stored in an NRC-licensed facility and from the NRC's current involvement in the Hanford tank waste remediation system which may use a vitrification process similar to that being used at West Valley.

The objectives of this audit by EM-37 were to assess the processes and procedures applied by WVDP to high-level waste form production and to determine whether the WVDP QA program and its implementation met the applicable requirements of the OCRWM Quality Assurance Requirements and Description document (QARD: DOE/RW-0333P) and associated WVDP implementing procedures.

The primary objective of the NRC staff was to gain confidence that OCRWM, EM-37, WVDP, and their contractor/subcontractor personnel are properly implementing the requirements of their organizations' QA programs in accordance with the OCRWM QARD and Title 10 of the Code of Federal Regulations (10 CFR), Part 70 - Subpart 70.22(f), and Part 60 - Subpart G. (Both subparts reference Appendix B of 10 CFR Part 50). A second objective of the NRC staff was to become familiar with the WVDP processes and procedures for vitrification of high-level radioactive waste and its associated QA program.

This report addresses the effectiveness of the EM-37 audit and the adequacy of implementation of WVDP QA controls for its activities related to high-level radioactive waste form production.

2.0 AUDIT PARTICIPANTS

2.1 NRC

John G. Spraul Observer

2.2 DOE

Jim Conway	Audit Team Leader (ATL)	EM-37
Bryan Bower	Auditor	WVDP

Jim Flaherty	Technical Specialist	BDM/Science Applications International Corporation (SAIC)
Kriss Grisham	Auditor	EM-32
Bob Hartstern	Auditor	MACTEC
Dick Lynch	Auditor	Savannah River
Ed Martinez	Auditor	WVDP
Andria Mellon	Technical Specialist	New York Energy Research and Development Authority
Norm Moreau	Auditor	MACTEC
Jim George	Observer	OCRWM Office of Quality Assurance/Quality Assurance Technical Support Services/CER

3.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

3.1 Auditing Procedures

This audit of the WVDP was conducted in accordance with EM-37's Standard Practice Procedure (SPP-) 4.02, "Administration and Conduct of Quality Assurance Audits," and SPP-5.01, "Deviations and Corrective Actions."

The NRC staff observation of this audit was based on the procedure, "Conduct of Observation Audits," issued by NRC's Division of High-Level Waste Management on October 6, 1989.

3.2 Scope of Audit

The audit plan identified this as an audit to examine the adequacy and effectiveness of implementation of the WVDP QA program and procedures as applied to the waste acceptance activities associated with high-level radioactive waste form production at WVDP.

The potentially applicable QA programmatic elements (from the QARD and listed below) were audited during this audit. The audit team ascertained whether the QA program elements met the requirements imposed by DOE and commitments made by WVDP. This was done by determining, for these elements, the adequacy of the WVDP QA program, its implementation, and its effectiveness as well as verifying compliance with requirements as regards to the process for vitrification of high-level radioactive waste.

<u>Reference</u>	<u>Programmatic Element</u>
1.0	Organization
2.0	Quality Assurance Program
3.0	Design Control
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
8.0	Identification and Control of Items
9.0	Control of Special Processes

10.0	Inspection
11.0	Test Control
12.0	Control of Measuring and Test Equipment
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test, and Operating Status
15.0	Nonconformances
16.0	Corrective Action
17.0	QA Records
18.0	Audits
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigations
Appendix A	High-Level Waste Form Production (The checklist for Design Control addressed Appendix A as well.)

The NRC staff found this approach to be acceptable in light of the fact that EM-37 had previously performed performance-based audits to verify product quality.

3.3 Conduct of Audit

The EM-37 audit team had prepared an 81 page checklist prior to the audit. The checklist was used by the ATL and auditors as they performed their interviews, reviewed pertinent documents, and made the QA evaluations.

The EM-37 audit team and the observers caucused at the end of each day's audit. The ATL did not hold formal daily meetings with WVDP management to discuss the then-current audit status and preliminary findings of the audit team. Rather, the audit team maintained a "status board" readily available to interested WVDP personnel and discussed potential problems with WVDP personnel when such problems surfaced. This method of keeping WVDP management informed of the audit status was effective during this audit.

The audit was performed in a professional manner. The members of the audit team were well prepared and demonstrated a sound knowledge of their assigned audit areas.

3.4 Timing of Audit

In lieu of an audit of WVDP in 1996, EM-37 had conducted a surveillance in May of 1996 and participated in the "Readiness Validation" during the Spring of 1996. The "Readiness Validation" investigated personnel qualification and training, whether the QA program for operations was in place, and whether the other prerequisites for start-up given in the Waste Qualification Report had been met.

The audit took place while WVDP personnel were completing the fill of the 69th of some planned 300 canisters with the high-level radioactive waste slurry at the West Valley site. The audit was timely.

3.5 Examination of Audited Areas

Appropriate WVDP personnel and documents were made available to the audit team during the audit. The WVDP personnel were questioned by audit team members as they reviewed the objective evidence. The interview method of auditing, conducted simultaneously with the checking of objective evidence, was effective.

Audit team members received thorough responses to the checklist questions. The checklist contained questions regarding the programmatic elements listed in Section 3.2, above. The auditors posed numerous questions beyond the checklist during the audit as necessary to investigate further into the QA program and its implementation. This probing by the auditors indicated that they were familiar with the subject matter and were well prepared for the audit. Pertinent documents were reviewed to verify audit results. The audit team findings are presented in Section 3.8 of this report.

The audit team performed an acceptable audit.

3.6 Audit Team Qualifications and Independence

The qualifications of the ATL and auditor were found to be acceptable in that each met the requirements of SPP-3.03, "Qualification and Certification Requirements for Audit Personnel."

The audit team members did not have prior responsibility for performing the activities they audited. Two of the auditors on the audit team are WVDP employees who were familiar with the activities audited. However, they had no responsibility or involvement for the activities they audited. During the audit, the nature and depth of the objectivity of the questions substantiated the independence of these auditors. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence. The audit team was qualified in the QA discipline, and the assignments and checklist items were adequately described in the audit plan.

3.7 Review of Previous DOE Audit Findings

Earlier audits and surveillances of WVDP conducted by DOE had identified deficiencies. The corrective actions for these deficiencies were generally verified previously by DOE, but one had not been verified at the time of this audit. Therefore, this audit reviewed the status of this deficiency and determined that it could not be closed. This is shown as the fifth concern listed in Section 3.8, below, as presented by the ATL at the post-audit meeting with WVDP management.

3.8 EM-37 Audit Team Findings

The EM-37 audit team's overall finding was that WVDP's QA performance was satisfactory. Specific findings reported by the audit team at the post-audit meeting are shown below.

Deficiency: The RS/1 software program was not identified as "Quality Effecting Software" as it should have been.

Concerns:

- **Matrices in WVDP-074 and WVDP-212 need to be updated.**
- **WVDP needs to evaluate making Development Vitrification Procedure 63-57 an SOP.**
- **Two Analytical Chemistry Procedures (4.1 and 9.1) and one Program Requirements Document (9.0) need to be updated/revise.**
- **The Priority Assessment Matrix needs to address the QARD basis of product quality.**
- **Deviation and Corrective Action Report 96VP-WV-S-01-D01 needs to be closed.**
- **The Analytical and Process Chemistry conditional data release process for slurry samples and glass shard samples needs to be reviewed and evaluated.**
- **Sample inputs to the SPECIES RANGE program need to be clearly identified.**
- **Sample outliers in PCT CHECK program need to be identified.**
- **Software test cases need to be periodically rerun.**
- **Sample identification field in SAMPSTAT program output needs to show actual sample numbers.**
- **Comments on Production Records made April 16, 1996, need to be dispositioned.**

Positive Findings:

- **Analytical and Process Chemistry plans to begin trending the conditional data release process as part of its independent internal assessment program.**
- **Appendix F of SOP 63-28 has been by Field Change 1 to Revision 3 to identify the slurry batch glass yield.**

3.9 NRC Staff Findings

The WVDP process for vitrification of high-level radioactive waste appears to be conducted in an effective and well documented manner. The processes and procedures are subjected to a review process by WVDP which appears to be effective in eliminating errors. The EM-37 audit team's overall finding was that WVDP's QA performance was satisfactory. NRC staff agrees with this finding.

The audit was conducted in a professional manner, and the audit team adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the WVDP QA program as applied to high-level waste form production.

The initial checklist questions provided an adequate basis to conduct a thorough audit of the WVDP QA program for vitrification of high-level radioactive waste. The auditors went into sufficient detail during the audit to examine the QA activities related to the WVDP process for vitrification of high-level radioactive waste performed by WVDP. Based on the discussions, it appeared that the WVDP personnel audited were knowledgeable in their respective fields. The method used by the audit team to perform the audit was an appropriate combination of discussions with the involved WVDP personnel, review of the data sources and production records, and reviews of project files and other reference material requested by the audit team and provided by WVDP. Previously recognized good auditing practices were followed by the ATL and the audit team, and the NRC staff did not observe any deficiencies in the audit process.