

**U. S. DEPARTMENT OF ENERGY
ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT
OFFICE OF WASTE MANAGEMENT**

VITRIFICATION PROJECTS DIVISION

AUDIT NUMBER 92EA-WV-AU-001

**DOE-WEST VALLEY PROJECT OFFICE
QUALITY ASSURANCE PROGRAM IMPLEMENTATION
WEST VALLEY DEMONSTRATION PROJECT**

AUDIT REPORT

WEST VALLEY, NEW YORK

JULY 27-31, 1992

EXECUTIVE SUMMARY

**U. S. DOE AUDIT
NO. 92EA-WV-AU-001
WEST VALLEY DEMONSTRATION PROJECT
QUALITY ASSURANCE PROGRAM**

The Vitrification Projects Division (EM-343) conducted an audit on July 27-31, 1992 of the West Valley Demonstration Project (WVDP) to determine the adequacy, effectiveness, and implementation of the WVDP Quality Assurance (QA) Program for the waste acceptance activities related to the high-level canistered waste form production. The audit was performed in accordance with line organization responsibilities described in the Secretary of Energy Notice 6E-92, "Departmental Organizational and Management Arrangements" and implemented to meet the requirements of the Office of Civilian Radioactive Waste Management (OCRWM), "Quality Assurance Requirements Document (RW-0214)."

The audit team commends the DOE-West Valley Project Office (WVPO) and the West Valley Nuclear Services (WVNS) for their utmost cooperation and professionalism displayed during the conduct of this audit. Interaction with WVPO and WVNS personnel demonstrates their comprehensive understanding of the applicable QA requirements. In addition, the immediate and increased level of WVPO and WVNS management attention to the audit team's concerns and observations was noteworthy.

The major concerns identified by the audit process were in the areas of design control and control of purchased items and services. In the area of design control only one System Description (SD) has been issued to date, though many other SDs have been prepared but have not been approved and issued, as required by implementing procedures.

In the area of control of purchased items and services, a nonconforming item was not documented on a Nonconformance Report (NR). Dimensions recorded on an Inspection and Instruction Data Sheet (IIDS) differed from the dimensions noted on the drawing. A number of discrepancies were also noted regarding the WVNS Acceptable Supplier List (ASL) and supporting qualification files: three suppliers of quality-related items and services are not shown on the ASL; the Annual Supplier Assessment, the Supplier Quality Surveys, and audit reports were not in the vendor QA file; and the ASL does not reflect additional restrictions on a supplier which was on a restricted status.

The audit team would like to express sincere appreciation for the positive attitudes of all personnel contacted and the assistance provided by WVPO and WVNS personnel. This assistance contributed to the success of the audit. It was obvious to the team that personnel displayed ownership and exhibited great pride in their QA program.

EM-343 was unable to declare the WVDP QA program fully qualified. The program was determined to be effective for criteria 1, 2, 4, 6, 7 (Receiving Inspection), 10, 13, 15, and 18. The remaining criteria will be the subject of a future audit to be conducted during the first half of fiscal year 1993.

Overall adequacy and implementation of the WVDP QA Program was deemed marginally effective by the audit team.

A description of audit activities, results, and observations is presented in the following audit report. Specific details of audit findings are provided in Deviation and Corrective Action Reports (DCARs) which are enclosed with this report.

AUDIT REPORT

**DOE/EM-343 QUALITY ASSURANCE AUDIT
NO. 92EA-WV-AU-001**

**DOE WEST VALLEY DEMONSTRATION PROJECT
QUALITY ASSURANCE PROGRAM**

**WEST VALLEY PROJECT OFFICE
WEST VALLEY, NEW YORK
JULY 27-31, 1992**

I. AUDIT SCOPE

The audit determined the adequacy, effectiveness, and implementation of the WVDP QA Program for the waste acceptance activities related to the high-level canistered waste form production in accordance with line organization responsibilities described in the Secretary of Energy Notice 6E-92, "Departmental Organizational and Management Arrangements" and implemented to meet the requirements of OCRWM's RW-0214.

A. PROGRAMMATIC REQUIREMENTS:

The QA Program elements reviewed to assess the adequacy and effectiveness of WVDP Program implementation included the following:

- (1) Organization
- (2) QA Program
- (3) Design Control
- (4) Procurement Document Control
- (5) Instructions, Procedures, and Drawings
- (6) Document Control
- (7) Control of Purchased Items and Services
- (8) Identification and Control of Items
- (9) Control of Processes
- (10) Inspection
- (11) Test Control
- (12) Control of Measuring and Test Equipment
- (13) Handling, Storage, and Shipping
- (14) Inspection, Test and Operating Status
- (15) Control of Nonconforming Items
- (16) Corrective Action
- (17) QA Records
- (18) Audits
- (19) Software QA

WVPO and WVNS personnel were interviewed, and applicable records and documents pertinent to the above program elements were reviewed by the audit team members to verify implementation of QA program requirements.

3. PROGRAM DEFINING DOCUMENTS:

The basis for the audit is contained in the applicable requirements and criteria identified in the following documents:

- (1) WVDP Quality Assurance Program Description No. WVDP-074, QAPD-2 and QAPD-3
- (2) WVPO Quality Procedures (QPs)
WVNS Quality Assurance Procedures (QAPs)
- (3) Department of Energy Orders: (as applicable to QA Program provisions)
 - 5820.2A, "Radioactive Waste Management"
 - 4700.1, "Project Management System"
- (4) DOE/EM/WO/02, Rev. 1, VPD High Level Waste "Quality Assurance Program Description"
- (5) DOE/RW-0214, Rev. 4 and ICN 4.1, "Quality Assurance Requirements Document (QARD)"
- (6) American Society for Mechanical Engineers, NQA-1-1989 Edition, "Quality Assurance Requirements for Nuclear Facilities" (including applicable Supplements and Appendices)

II. AUDIT PARTICIPANTS

A. Audit Team Members:

J. E. Hennessey, EM-343, Audit Team Leader (ATL)
J. T. Conway, EM-343
S. L. Crawford, BDM/SAIC —
R. A. Toro, BDM/SAIC
D. E. Miller, BDM/SAIC
L. R. Wade, MACTEC
C. B. McKee, MACTEC
J. F. LeVea, Jr., BDM/SAIC

B. Observers:

C. D. Morell, CER Corporation (RW-3)
W. E. Belke, U.S. Nuclear Regulatory Commission (NRC)
R. S. Brient, NRC

C. Attendees at the pre-audit and post-audit conferences and personnel contacted during the audit are identified in Attachment 1.

III. PRE-AUDIT CONFERENCE

A pre-audit conference was held on July 27, 1992 at 8:00 a.m. T. Rowland, WVPO Director, presented the opening remarks and reviewed the DOE and operating contractor's organizational structures. R. Provencner, Environment, Safety, Health (ESH) and Quality Verification Program Manager, presented the WVPO overview and status of the QA Program. D. Shugars, WVNS QA Manager, presented the status of their QA Program as well as the WVDP facility, QA Program milestones, and the results of a qualification survey. J. Hennessey, EM-343 ATL, presented the audit scope, objectives, method of qualification, schedule of daily activities, observer protocol, and interfaces. Remarks were invited from representatives of the NRC and the OCRWM. Identification of escorts and audit contacts were noted, and the meeting adjourned at 9:30 a.m.

IV. CONDUCT OF AUDIT

The audit was conducted according to the requirements of the EM-343 Standard Practice Procedure No. 4.02., "Administration and Conduct of Quality Assurance Audits," Revision 2, dated 6/5/92. Using checklists developed specifically to correspond to the scope of the audit, lines of inquiry were pursued by the audit team to evaluate the adequacy and effectiveness of the DOE-WVPO's implementation of the WVDP Quality Assurance Program Description, WVDP-074, QAPD-2 and QAPD-3, and its compliance with DOE/RW-0214, "QARD" and DOE/EM/WO/02, Vitrification Projects Division High-Level Waste "Quality Assurance Program Description."

A daily briefing for WVPO and WVNS management was conducted by the ATL at 8:00 a.m. to discuss audit concerns and observations noted from the previous day.

A brief tour of the WVDP facilities was conducted by WVNS representatives for the benefit of interested audit team personnel and observers.

V. SUMMARY OF AUDIT RESULTS

Using the checklists developed specifically to correspond to the audit scope, the following information was obtained through review of pertinent documents and interviews conducted with cognizant WVPO and WVNS personnel for each QA Program element. The deviations and/or observations noted for the appropriate criteria are discussed in detail in Section VI, Deviations and Observations.

Organization (Criterion 1)

Evaluation of Criterion 1 was conducted by interviews with DOE/WVPO personnel in the Regulatory Compliance Office (RCO) and Quality Verification Manager (QVM). A review of the Program documents for WVPO/WVNS organizational interfaces, arrangements, and responsibilities definition was also conducted including delegations to WVNS. Systems for quality verification, stop work process, quality concerns program, and provisions for dispute resolution, and the knowledge and experience of QA management personnel were also performed.

Implementation of Criterion 1 is considered to be effective.

Quality Assurance Program/Training (Criterion 2)

Evaluation of the QA Program was conducted by interviews with cognizant personnel in the WVPO Program Integration Office (PIO) and WVNS Project Office Documents Department. A review of the Program Execution Guidance document, QAPD-2, and QAPD-3 was conducted. Records were reviewed to determine compliance with the requirements contained in these documents and pertinent procedures.

Evaluation of QA Training was conducted by interviews with cognizant personnel in the WVPO PIO and WVNS Training and Development Department. A review of personnel training and qualification records was also conducted. A sample of selected courses and personnel training records was selected and reviewed to determine compliance with the requirements contained in the pertinent procedures.

WVPO staff typically have received a significant amount of classroom training on topics that include but are not necessarily limited to:

1. NQA-1 and DOE/RW-0214
2. Performance of Surveillances
3. Conduct of Operations
4. Hazardous Waste Training
5. DOE Order 5000.3A

One readiness review by WVPO (Phase I for the Integrated Radwaste Treatment System) was reviewed and was found to be satisfactory. WVPO used a conservative approach in that they performed an independent readiness review rather than observe the WVNS review process. WVPO is in the process of determining what future readiness reviews will be performed. These determinations will be timely because the next readiness reviews are well in the future.

WVPO and WVNS have a graded QA Program that satisfies the requirements of DOE/RW-0214. It provides for classifying items as quality level A, B, C, or N, with N being not quality-related. Procedures generally do not specify different controls for A vs. B vs. C items. The differentiation is between A, B, and C on the one hand and N on the other.

Thus, although WVPD has a four level system on paper, in reality it has a two level system. There is nothing wrong with this system, but WVPO and WVNS may wish to clarify this matter.

ME
The audit team identified four observations for Criterion 2. Implementation of Criterion 2 is considered to be effective, while QA training is considered to be marginally effective.

Design Control (Criterion 3)

Evaluation of this criterion was conducted by interviews with cognizant personnel in the WVPO Technical Program Office (TPO) and WVNS Site and Vitrification Engineering Department. A review of design control documents was also conducted. Records were reviewed to determine compliance with the requirements contained in the WVNS Engineering Procedures.

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ME
The audit team identified one deviation and one observation for Criterion 3. This QA Program element is considered to be marginally effective.

Procurement Document Control (Criterion 4)

Evaluation of this criterion was conducted by interviews with cognizant personnel in the WVPO PIO and WVNS Construction and Project Administration Department. A review of procurement documents was also conducted. A system is in place to monitor this process, and records were reviewed to determine compliance with the requirements contained in the WVPO and WVNS procedures.

E
No deviation or observation was noted for Criterion 4. This QA Program element is considered to be effective.

Instructions, Procedures, and Drawings (Criterion 5)

Evaluation of Criterion 5 was conducted by interviews with WVPO and WVNS personnel. A review of records was undertaken to determine compliance with the requirements contained in pertinent procedures.

ME ?
No deviation or observation was noted for Criterion 5. This QA Program element is considered to be marginally effective.

Document Control (Criterion 6)

Evaluation of Criterion 6 was conducted by interviews with the WVPO QVM and the WVNS Records Management (RM) Department. WVNS has established a centralized document control system (also used by WVPO) which provides for a thorough inspection of documents delivered for publication. Procedures and supporting documents were reviewed.

WVNS has established a centralized document control system which provides for a thorough inspection of documents delivered for publication, as well as document control lists and distribution control. This system is also used by WVPO. It is an excellent system in both its design and implementation. As noted in Observation No. 6, several minor problems were noted, indicating that some further improvements can be made.

cbS
The audit team noted one observation for Criterion 6. This QA Program element is considered to be effective.

Control of Purchased Items and Services (Criterion 7)

Evaluation of Criterion 7 was conducted by interviews with WVNS personnel in its QA and Quality Services Management (QSM) Departments. A review was conducted of procedures, purchase orders (POs), document packages for QRs, inspection personnel certification warehouse POs, and the Acceptable Supplier List (ASL) and supporting vendor qualification files. A sample of these documents was selected, and records were reviewed to determine compliance with the requirements contained in the pertinent WVNS procedures.

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The receiving inspection element was evaluated under Criterion 10 (Inspection) and was deemed to be effective, while the supplier evaluation element was considered to be marginally effective.

Identification and Control of Items (Criterion 8)

Evaluation of this criterion was conducted by interviews with cognizant personnel in the WVNS Quality Services (QS) and Quality Engineering (QE) Operations Planning Departments. A sample of POs and work orders was selected, and records were reviewed to determine compliance with the requirements contained in the pertinent procedures.

1 chs
ED
The audit team noted one observation for Criterion 8. The audit team did not have sufficient time to thoroughly verify implementation of this criterion. Therefore, this QA Program element is considered to be indeterminate upon evaluation of the adequacy and effectiveness of implementing this criterion.

Control of Processes (Criterion 9)

This criterion was evaluated through the review of procedures, interviews with personnel from WVNS Vitrification Process Development (VPD) and QS Departments, and review of personnel certifications. Bell Power Corporation has been delegated to perform the special processes. Currently, there are no special processes being performed that are within the waste acceptance envelope. Processes requiring special controls will be defined in the distant future. A review of welding and nondestructive examination (NDE) documentation was also conducted. A sample of surveillance reports, work orders, IIDSs, certifications for NDE personnel, welding and NDE procedures were selected, and records were reviewed to determine compliance with the requirements contained in QAPs 9-1, 9-2, and 9-3.

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The audit team noted one observation for Criterion 9. Due to the lack of activity in this area, this QA Program element is considered to be indeterminate upon evaluation of the adequacy and effectiveness of implementing this criterion.

Inspection (Criterion 10)

Evaluation of this criterion was conducted by interviews with WVNS personnel in the QSM and QE Departments. A review of Construction Inspection Program Plan, Revision 2 and Construction Inspection Plan CIP-VIT-033, Revision 1, 7/24/92, was also conducted.

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No deviation or observation was noted for Criterion 10. Implementation of this QA Program element is considered to be effective.

Test Control (Criterion 11)

Evaluation of this criterion was conducted by interviews with WVNS QA, QS, QE, and VPD Departments. A review of WVNS procedures, test plans, and contracts was also conducted. As a result of the interviews, the audit team concluded that no systems have been turned over to WVNS and testing has not been completed.

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No deviation or observation was noted for Criterion 11. This QA Program element is considered to be indeterminate because test data was not available for review.

Control of Measuring and Test Equipment (Criterion 12)

Evaluation of the control of measuring and test equipment (M&TE) was performed by interviews with cognizant personnel in the QS Department, Work Control Center, and Instrument Shop. A review of storage practices for standards and equipment, M&TE log book, calibration records, and procurement packages and records (e.g. certifications, receipt inspection records) for calibrations performed by outside vendors was also conducted. A sample of ten M&TE was selected, and records were reviewed to determine compliance with the requirements (e.g. calibration frequency, labeling of equipment) contained in procedures Quality Management QM 12 "Measuring and Test Equipment Control" and QAPD 12-1 "Control and Calibration of Standards and Measuring and Test Equipment."

A potential finding was identified, and it contained the following elements:

- Vendor indicated out of calibration condition for gage block set (TG-013) on certificate, but Receiving Inspection did not write an NR.
- Thermometer (TG-107) did not have a calibration sticker, and there was no evidence of calibration.
- M&TE log book for 1991 was not transferred to the Master Records Center in a timely manner.
- Megger (TG-068) was not calibrated in September 1991 as scheduled.
- M&TE log book did not contain information for a missing immersion thermometer (TG-077).
- Primary standard THC-1 was identified in calibration procedure SOP 41-21, but it was not the standard being used for calibrating thermometers.

In response to the potential deviation, WVNS initiated a Request for Corrective Action (RCA) No. 92-022, 7/31/92, and a Recommended Change Form to revise SOP No. 41-21, "Calibration Procedure for Thermometers." EM-343 will verify the implementation of the corrective action during a future audit or surveillance of WVPO and WVNS.

This QA Program element is considered to be marginally effective.

Handling, Storage, and Shipping (Criterion 13)

Evaluation of this criterion was conducted by interviews with WVNS personnel in the QE, QS, Environmental Operations and Transportation Departments. A review of WVPO and WVNS procedures (WV-660, SOP-300, QM-13-1, and QAP-13-1) was also conducted. A sample of radioactive materials shipped and rigging inspections was selected, and records were reviewed to determine compliance with the requirements contained in referenced procedures.

- No deviation or observation was noted for Criterion 13. This QA Program element is considered to be effective.

Inspection, Test, and Operating Status (Criterion 14)

Evaluation of this criterion was conducted by interviews with WVNS personnel in the QA, QS, and RM Departments. As a result of these interviews, the audit team concluded that no systems have been turned over to WVNS.

- No deviation or observation was noted for Criterion 14. Due to lack of activity in this area, this QA Program element is considered to be indeterminate.

Control of Nonconforming Items (Criterion 15)

Evaluation of this criterion was conducted by interviews with WVPO personnel in the RCO and QVM. A review of Qualification Clarification Reports (QCRs) and NRs, both open and closed, for 1992 were reviewed. A sample review of disposition approval, technical justification and disposition verification was performed to determine compliance with the requirements contained in the pertinent procedures.

- 2 obs
○ The audit team identified two observations for Criterion 15. This QA Program element is considered to be effective.

Corrective Action (Criterion 16)

Interviews were conducted with WVPO RCO and QVM to evaluate Criterion 16. The current WVPO Request for Immediate Corrective Action (RICA) tracking database and files which lists several WVNS RCAs were reviewed to determine compliance with the requirements contained in pertinent procedures.

- 1 obs
○ The audit team identified one observation for Criterion 16. This QA Program element is considered to be marginally effective.

Quality Assurance Records (Criterion 17)

Evaluation of Criterion 17 was conducted by interviews with WVPO PIO and WVNS Information Services Records Management personnel. WVPO has delegated records storage to WVNS. During the conduct of the audit, the records retrieval system was evaluated. A sample of records was selected and processing of the records into the records system was observed. All records were retrievable.

CRS
The audit team identified one observation for Criterion 17. This QA Program element is considered to be marginally effective.

Audits (Criterion 18)

Evaluation of this criterion was conducted by interviews with WVPO and WVNS personnel. A review of Lead Auditor certifications was performed to determine compliance with the requirements contained in pertinent procedures.

No deviation or observation was noted for Criterion 18. This QA Program element is considered to be effective.

Software Quality Assurance (Criterion 19)

CRS
Evaluation of this criterion was conducted by interviews with WVPO RCO and QVM. The audit team identified an observation for Criterion 19. This QA Program element is considered to be marginally effective.

A summary chart of the effectivity for each Program element is shown in Attachment 2.

VI. DEVIATIONS AND OBSERVATIONS

DEVIATIONS

Deviation No. 1 (Criterion 3):

WVNS Engineering Procedure EP-3-025, Revision 0, 7/5/91, identifies 28 vitrification systems which will have System Descriptions (SDs) prepared. The SDs are defined as "a comprehensive technical document that includes the complete description of the system design features, such as flow path and performance, operating and design parameters, arrangements, subsystems, or component design features, systems interfaces, and system safety, quality, operating, and maintenance requirements."

EP-3-025 further states: "SDs should be prepared as early as feasible during the conceptual design as a means of enabling project participants to reach agreement on system design. As the design work progresses, more detailed design should be provided by the system designer through timely updates to the SDs." ".....The SDs need not be complete at first release, because all details will not be established at the same time in the execution of design work. In such cases a complete outline of the document should be identified at the initial release."

Only one SD, WVNS-SD-011, Revision 0, 7/20/92, "Off-gas Vessel and Vent System" has been issued to date. (Note: Many other SDs are in preparation, but have not been approved and issued.)

System Descriptions that have not been issued yet include the following:

<u>System</u>	<u>Description</u>
55	Sludge Mobilization System
63I	Primary Process System
63J	Canister Decontamination
63IA	Instrument Air System
65	Cold Chemical System
67	Vitrification Facility HVAC System
68	HLW Interim Storage System
69A	Vitrification Facility Sampling System
69B	Vitrification Facility Sample Transfer System
200A	Instrumentation and Control Hardware
200B	Instrumentation and Control Hardware

Some of the above systems, including the Sludge Mobilization System, have been exercised through test programs.

Deviation No. 2 (Criterion 7):

Paragraph 5.2.3 of WVPO Quality Assurance Procedure QAP 10-2, Revision 6, 2/27/92, requires an NR to be prepared and processed when nonconforming items are found during receipt inspection.

During receipt inspection of an impact wrench component (P.O. 19-56732) dimensions were found as not meeting requirements on drawing no. 900d-2889 (Revision 3, Sheet 2 of 2). The condition was reported on an IIDS No. 92-384 and was accepted by a Quality Engineer without benefit of evaluation by the cognizant engineer. An NR was not prepared and processed as required by the procedures.

Deviation No. 3 (Criterion 7):

Numerous discrepancies were noted regarding the WVNS ASL and supporting vendor qualification files. (WVNS maintains that the vendor QA files are working files; the record copies of documents are maintained in audit, surveillance, and procurement files.)

- Three suppliers of quality-related items and services were not shown on the ASL
 - Hellier - NDE Level III services (training, examination, and procedures)
 - Ledco - HLW glass canisters
 - Gage Lab - Calibration
- Annual Supplier Assessment, WV-001, not in vendor QA file (Commercial Archives - record storage)
- Supplier Quality Surveys, WV 1249, not in vendor QA file (Commercial Archives - record storage)
- Audit reports (including annual assessment references) not in vendor QA file or referenced to alternate file location
 - Catholic University (EA-91-06, EA-92-04)
 - Alfred University (EA-91-05)
- Supplier Assessment for Catholic University, 3/15/92, recommended "maintain on ASL" without comment on restrictions: the ASL identified a restricted status for Catholic University. A subsequent audit of Catholic University, EA-92-04, indicated significant program deficiencies exist, but the ASL does not reflect any additional restrictions on Catholic University.

These three deviations are documented in detail in Attachment 3.

OBSERVATIONS

Observation No. 1 (Criterion 2):

Contrary to the requirements identified in the Federal Register Notice (Vol. 55, No. 153, pg. 32288), the Director and Quality Verification Manager were the only personnel on the DOE/WVPO staff required to meet the requirements of DOE-80, "Quality Assurance Training and Qualification Records." A response to this observation is requested.

Observation No. 2 (Criterion 2):

The following errors were noted during an examination of two files of input documents for the WVPO Correspondence Tracking System:

- Record Number 20149 was entered as an open (tracked) item. It should have been entered as a closed (historical) item.
- For Record Number 17954, the WVPO Concurrence Sheet (which contains input for the tracking system) did not indicate that the record should be entered as a closed item. In addition, an "N/A" (Not Applicable) which should have been in the "Closed Record No." blank was omitted. These errors made it very difficult to determine and to verify the correct status of this record.

WVPO has a system for tracking open items until resolution. As described in Observation No. 2, problems were noted in its implementation. A management assessment was performed in November 1991, and results showed that it met the requirements of the applicable procedure. No deficiencies were identified requiring followup corrective action.

A study should have been undertaken to determine the prevalence of similar errors, their impact on report accuracy, the root cause, and the corrective action needed. No response to this observation is required.

Observation No. 3 (Criterion 2):

QAPD-3, Sections 2.3 and 2.4 require a number of actions to be performed by WVNS QA Group. Applicable procedures do not address two of these requirements, such as

- The requirement to assist in problem resolution
- The requirement to assist in identifying the specific scientific or technical information to be collected, analyzed, or used.

The establishment and maintenance of the QA Program have been well conducted. A minor concern, as noted in this observation, indicates that the QAPD-3 requires the WVNS QA to assist in problem resolution and in identifying specific technical or scientific information to be collected, etc. This requirement makes QA partly responsible for quality achievement. This has not been reflected in the implementing procedures. WVNS should determine whether the problem pertains to deficiencies in the procedures or incorrect requirements in the QAPD, and implement the appropriate corrective action. No response to this observation is required.

Observation No. 4 (Criterion 2):

WVPO-QP-643, Revision 5, and Training Plan (WVPO-TR-101, Revision 0, issued 5/7/91) require that specific training courses be determined and provided. It was found that WVPO has substituted other training for that specified by approved training plans, but determinations of equivalency have not been documented. WVPO, however, has substituted other training for that specified course. No response to this observation is requested.

Observation No. 5 (Criterion 3):

The Waste Compliance Plan (WCP), WVNS-WCP-001, Revision 3, 12/3/91, submitted to EM-343 for the Technical Review Group (TRG) review, was prepared to meet the draft Waste Acceptance Preliminary Specifications (WAPS) dated June 1991. Although the draft WAPS was used as the basis for the WCP, with EM-30 direction, the WAPS was withdrawn at DOE/RW's request dated 4/16/92. The current approved WAPS is DOE/RW-0261 (PE-04), Revision 1; January 1990.

Differences between the January 1990 and June 1991 WAPS include:

- Product Consistency Test not in January 1990
- Weight and heat loads lower in January 1990
- Leak rate increased by three orders of magnitude in June 1991
- Minimum wall thickness not specified in June 1991

A response to this observation is requested.

Observation No. 6 (Criterion 6):

Although the centralized document control system for WVDP is exemplary, several minor deficiencies were noted which indicate that improvement is needed in the system and its implementation:

- The final resolution of a "Nonconformance" by the Quality Engineer on Engineering Procedure EP-3-002, Revision 7 was unclear. The "Concur with Comments" box was checked but not initialed and dated.
- The meaning of procedure dates is unclear as to whether it indicated the date of approval, issuance, or effectivity. It is understood that a clarification is in process.
- For ACP 7.9, Revision 7, the second delinquency notice (for receipt acknowledgement) was not issued on the due date of 7/20/92.
- Contrary to WVPO-EP-647, Revision 4, paragraph 6.4, the release date for QAPD-2, Revision 2 is not indicated on the first page.

No response is required for this observation.

Observation No. 7 (Criterion 7):

The following suppliers have not been identified as high level waste related activity on audit schedules:

- Battelle Pacific Northwest Laboratories (PNL)
- Commercial Archives

These suppliers perform activities within the scope of DOE/RW-0214. A response is required for this observation.

Observation No. 8 (Criterion 7):

Recent audits (EA-91-06 and EA-92-04) of Catholic University identified substantial and recurring problems in the implementation of required QA Program controls. A detailed review, documentation, and resolution of actual and potential impact to waste form qualification is being prepared. WVPO had identified the need to perform the impact analysis and a corrective action recovery plan during the qualification survey of WVNS which was conducted on April 29-30, 1992. Nonetheless, EM-343 should maintain an oversight of the resolution process to assure the integrity of glass test data collected and analyzed by Catholic University. No response is required for this observation.

Observation No. 9 (Criterion 8):

NQA-1 Criterion 8 requires that "Identification shall be maintained on the item or in documents traceable to the item, or in a manner which assures that identification is established and maintained." Supplement 8S-1, 2.1 Item Identification requires that "Items of production shall be identified from the initial receipt and fabrication of the item up to and including installation and use." Paragraph 2.2 indicates that "Physical Identification shall be used to the maximum extent possible."

Contrary to this requirement, WVPO procedures do not require identification to be placed on an item until it is installed. The specific item which was traced during the audit was the 69-DV-008 Diverter Valve (Assembly Drawing No. 900-D-2890, Revision 0). A response is requested for this observation.

Observation No. 10 (Criterion 9):

Contrary to the requirements of Bell Power Corporation NDE-QP-01, the method of verification, date, and the initials of the Level III inspector have not been recorded on the education and employment records for the Non-Destructive Examination (NDE) personnel.

Since no special processes are being conducted which affect the waste acceptance process, this QA Program element is considered to be indeterminate upon evaluation of the adequacy and effectiveness of implementing this criterion. Special processes requiring special controls are to be defined and implementing procedures will be developed at a later date. No response is required for this observation.

Observation No. 11 (Criterion 15):

QAP 15-3 is not specific in defining what conditions can be addressed on a QCR. It is feasible that a nonconforming condition could be addressed via a QCR instead of an NR. Consideration should be given to include a descriptive list of activities/conditions that could be dispositioned using the QCR. Also, provisions should be added to the procedure requiring a nonconformance determination review by appropriate organizations.

Examples include:

- QCR 90-072 identified deficiencies during an electrical inspection. These conditions were ultimately identified on NR 90-0065.
- QCR 90-012 identified deficiencies during inspection Jumper J-212 (unacceptable welds). No NR has addressed this item.

A response is requested for this observation.

Observation No. 12 (Criterion 15):

QAP 15-1 does not have any specified timeframe identified for item nos. 5 or 15 of the instructions for completing the NRs. Review of NRs revealed times for item 5 ranged from one week to one month. This is subjective and is totally at the discretion of the initiator.

NR 92-021 did not have the commitment date of Block 15 completed. The NR was written on 3/20/92 and was not closed until 7/30/92. Action required for disposition was completed on 5/27/92.

NR 92-015 was initiated on 2/7/92 and was not closed until 7/30/92. Disposition action (use-as-is) and supporting documentation was dated 2/13/92.

NR 92-018 was initiated on 2/18/92. There was no objective evidence of further processing to date.

The absence of required timeframes for response and action to be taken provides inadequate controls for timely resolution of nonconformances. A response is requested for this observation.

Observation No. 13 (Criterion 16):

WVPO RICAs have not been uniquely identified. WVPO intends to identify RICAs individually by a unique document number to improve the RICA tracking system and RICA files.

Some problems were noted which could be improved by the use of specific RICA identification numbers:

- The current WVPO tracking database lists several WVNS Requests for Corrective Action (RCA) as a part of the RICA which are not related to any RICA.
- Three RICAs dated 5/14/92 are tracked and filed under a single action item number because all three RICAs were covered by a single WVNS RCA (92-015).

A response is requested for this observation.

Observation No. 14 (Criterion 17):

The SF-12 test package revealed a number of conditions which jeopardize records retrievability, including numerous record identifications, various configurations of records packages, records shipment offsite, and no method to supplement records. The assurance that all records on a particular subject are retrieved depends on the personal knowledge of records specialists.

There is a lack of consistency among the departments in how records are collected, packaged, and identified. This makes the retrievability of records arduous. Complete retrieval depends primarily on the knowledge and experience of the records specialists, rather than on a simple, well understood system.

A response is requested for this observation.

Observation No. 15 (Criterion 19):

The ORIGIN 2 computer code used to support the Waste Form Qualification Report (WQR) submittals has not been validated by the developer. The code is an ORNL-developed code; a previous DOE/RW audit of Oak Ridge had identified that there were no formal QA controls in place at Oak Ridge to validate the code and to maintain the version configuration of the code.

A response is requested for this observation.

SUMMARY:

Evaluation of the deviations and observations described previously indicate that the overall effectiveness of the WVDP QA Program was deemed marginally effective. The program was determined to be effective for criteria 1, 2, 4, 6, 7 (Receiving Inspection), 10, 13, 15, and 18. The remaining criteria will be the subject of a future audit to be conducted during the first quarter of fiscal year 1993.

VII. POST-AUDIT CONFERENCE

The audit team held a post-audit conference on July 31, 1992, at 11:30 a.m. The ATL presented a summary of the audit team's concerns and observations to the WVPO and WVNS management, including the positive program elements and the audit team's approach for categorizing the audit results and qualifying the WVDP QA Program. Comments on the conduct and results of the audit were provided by representatives from NRC and RW. Closing comments were given by R. Provencher.

VII. AUDIT TEAM LEADER/SUB-TEAM LEADERS CONCURRENCE:

J. E. Hennessey
J. E. Hennessey, AUDIT TEAM LEADER

9-10-92
Date

S. L. Craxford
S. L. Craxford, SUB-TEAM LEADER

9/10/92
Date

C. B. McKee
C. B. McKee, SUB-TEAM LEADER

9/11/92
Date

J. E. Miller
J. E. Miller, SUB-TEAM LEADER

9/10/92
Date

ATTACHMENT 1

AUDIT MEETING ATTENDEES AND CONTACTS

ATTACHMENT 1
LIST OF AUDIT MEETING ATTENDEES AND CONTACTS

A = ATTENDED PRE-AUDIT CONFERENCE
B = ATTENDED POST-AUDIT CONFERENCE
C = CONTACTED DURING AUDIT

<u>NAME</u>	<u>ORGANIZATION</u>	<u>A</u>	<u>B</u>	<u>C</u>
T. Rowland	DOE/WVPO	X		
R. Provencher	DOE/WVPO	X	X	X
B. Mazurowski	DOE/WVPO	X	X	X
D. Sullivan	DOE/WVPO	X	X	X
W. Hunt	DOE/WVPO	X		
S. Metzger	DOE/WVPO	X	X	X
P. Van Loan	DOE/WVPO	X	X	X
W. Ketola	DOE/WVPO	X	X	X
J. Yeazel	DOE/WVPO	X		X
H. Moore	DOE/WVPO		X	
D. Cook	DOE/WVPO		X	
A. Lengyel	DOE/WVPO		X	
E. Hagaman	DOE/WVPO		X	
P. Abrams	DOE/WVPO		X	X
E. Matthews	DOE/WVPO		X	
D. Sullivan	DOE/WVPO			X
E. Riley	Riley & Associates (WVPO)			X
R. Hinds	WSRC	X		
D. Shugars	WVNS	X	X	X
R. Humpnrey	WVNS	X	X	
J. Marek	WVNS	X	X	X
R. Farchmin	WVNS	X	X	X
D. Bonenberger	WVNS	X	X	X
C. Schiffhauer	WVNS	X	X	X
R. Lawrence	WVNS	X	X	
J. Volpe	WVNS	X	X	
J. Hummel	WVNS	X	X	X
J. Berg	WVNS	X		
R. Werchowski	WVNS	X	X	X
P. Keel	WVNS	X		
G. Centrich	WVNS	X		
R. Gessner	WVNS	X		
D. Crouthamel	WVNS		X	X
W. Poulson	WVNS		X	
B. Gray	WVNS			X

**ATTACHMENT 1
(CONTINUED)
LIST OF AUDIT MEETING ATTENDEES AND CONTACTS**

**A = ATTENDED PRE-AUDIT CONFERENCE
B = ATTENDED POST-AUDIT CONFERENCE
C = CONTACTED DURING AUDIT**

<u>NAME</u>	<u>ORGANIZATION</u>	<u>A</u>	<u>B</u>	<u>C</u>
V. DesCamp	WVNS			X
S. McKenzie	WVNS		X	X
D. Kuhns	WVNS		X	X
L. Domes	WVNS			X
J. Greenquist	WVNS			X
J. Bacnman	WVNS			X
G. Reed	WVNS			X
D. Demoster	WVNS			X
J. Abbott	WVNS			X
S. Barnes	WVNS			X
L. Wichman	WVNS			X
S. Schweichart	WVNS			X
C. Fenuz	WVNS			X
J. Nesselbush	WVNS			X
J. Mahoney	WVNS			X
V. Riggi	WVNS			X
P. Nowicki	WVNS			X
L. Donovan	WVNS			X
H. Farmer	WVNS			X
M. Elliott	WVNS			X
G. Robbins	WVNS			X
P. Burn	WVNS			X
G. Jones	WVNS			X
M. Ciaramella	WVNS			X
H. Payne	WVNS-PA		X	
J. Gerber	WVNS-PA		X	
P. Piciulo	NYSERDA	X	X	
C. Morrell	CER (RW-3)	X	X	
W. Belke	USNRC	X	X	
T. McIntosh	EM-343		X	
J. Hennessey	EM-343	X	X	
J. Conway	EM-343	X	X	
S. Crawford	BDM/SAIC (EM-343)	X	X	

**ATTACHMENT 1
(CONTINUED)
LIST OF AUDIT MEETING ATTENDEES AND CONTACTS**

**A = ATTENDED PRE-AUDIT CONFERENCE
B = ATTENDED POST-AUDIT CONFERENCE
C = CONTACTED DURING AUDIT**

<u>NAME</u>	<u>ORGANIZATION</u>	<u>A</u>	<u>B</u>	<u>C</u>
D. Miller	BDM/SAIC (EM-343)	X	X	
J. LeVeae, Jr.	BDM/SAIC (EM-343)	X	X	
R. Toro	BDM/SAIC (EM-343)	X	X	
C. McKee	MACTEC (EM-343)	X	X	
L. Wade	MACTEC (EM-343)	X	X	

ATTACHMENT 3

**DEVIATION AND CORRECTIVE ACTION REPORTS
(DCARs)**

Deviation and Corrective Action Report (DCAR)

DCAR No.: 92EA-WV-AU-001-01 Revision: 0 Page 1 of 1
 Date of discovery: 7/27/92 Evaluated Organization: WVNS
 Evaluated Organization Representative: V. A. DesCamp
 Corrective Action taken immediately: No
 Activity: Design Control (Criterion 3) Location: WVPO

Requirement(s) not met: WVNS Engineering Procedure EP-3-025, Revision 0, 7/5/91, identifies 28
verification systems which will have System Descriptions (SDs) prepared.

Deviation description: Only one SD, WVNS-SD-011, Revision 0, 7/20/92, "Off-gas Vessel and Vent
System" has been issued to date. (Note: Many other SDs are in preparation,
but have not been approved and issued.)

Corrective Actions Required:

	Yes	No
- Root cause analysis	<u>x</u>	_____
- Action to prevent recurrence	<u>x</u>	_____
- Action regarding similar work	<u>x</u>	_____

Provide Response by: Within 30 days upon receipt of this report

Initiator: <u>S. L. Crawford, BDM/SAIC</u>	Date: <u>9/18/92</u>
QA Program Manager: <u>J. T. Conway, EM-343</u>	Date: <u>9-11-92</u>
Program Manager: <u>T. W. McIntosh, EM-343</u>	Date: <u>9/11/92</u>
Division Director: <u>R. E. Erickson, EM-343</u>	Date: <u>9/11/92</u>

Proposed Corrective Actions: _____

Scheduled completion date: _____

Evaluated Organization Representative: _____ Date: _____

Evaluation of Proposed Corrective Actions: _____

Acceptable	_____
Unacceptable	_____

Evaluator: _____ Date: _____
 Program Manager: _____ Date: _____
 QA Program Manager: _____ Date: _____

Corrective Actions Complete:
 Verified by: _____ Date: _____
 Program Manager: _____ Date: _____
 Verification Approved
 Division Director: _____ Date: _____

Deviation and Corrective Action Report (DCAR)

DCAR No.: 92EA-WV-AU-001-02 Revision: 0 Page 1 of 1
 Date of discovery: 7/28/92 Evaluated Organization: WVNS
 Evaluated Organization Representative: D. Croutname/J. Abbott
 Corrective Action taken immediately: No
 Activity: Control of Purchased Items & Services Location: WVPO
 (Criterion 7)

Requirement(s) not met: Paragraph 5.2.3 of WVPO Quality Assurance Procedure QAP 10-2, Revision 6, 2/27/92, requires an NR to be prepared and processed when nonconforming items are found during receipt inspection.

Deviation description: During receipt inspection of an impact wrench component (P.O. 19-56732) dimensions were found as not meeting requirements on drawing no. 900d-2889 (Revision 3, Sheet 2 of 2). The condition was reported on an IIDS No. 92-384 and was accepted by the Quality Engineer without benefit of evaluation by the cognizant engineer. An NR was not prepared and processed as required by the procedures.

Corrective Actions Required:	Yes	No
- Root cause analysis	<u>x</u>	<u> </u>
- Action to prevent recurrence	<u>x</u>	<u> </u>
- Action regarding similar work	<u>x</u>	<u> </u>

Provide Response by: Within 30 days upon receipt of this report

Initiator: <u>L. Wade, MACTEC</u>	Date: <u>9-11-92</u>
QA Program Manager: <u>I. T. Conway, EM-343</u>	Date: <u>9-11-92</u>
Program Manager: <u>T. W. McIntosh, EM-343</u>	Date: <u>9/11/92</u>
Division Director: <u>R. E. Erickson, EM-343</u>	Date: <u>9/11/92</u>

Proposed Corrective Actions: _____

Scheduled completion date: _____

Evaluated Organization Representative: _____ Date: _____

Evaluation of Proposed Corrective Actions: _____

Acceptable
 Unacceptable

Evaluator: _____ Date: _____
 Program Manager: _____ Date: _____
 QA Program Manager: _____ Date: _____

Corrective Actions Complete:
 Verified by: _____ Date: _____
 Program Manager: _____ Date: _____
 Verification Approved
 Division Director: _____ Date: _____

Deviation and Corrective Action Report (DCAR)

DCAR No.: 92EA-WV-AU-001-03 Revision: 0 Page 1 of 1
 Date of discovery: 7/28/92 Evaluated Organization: WVNS
 Evaluated Organization Representative: R. F. Farnmin
 Corrective Action taken immediately: No
 Activity: Control of Purchased Items & Services Location: WVPO
 (Criterion 7)

Requirement(s) not met: QAP 7-1, para. 4.2 "Suppliers are placed on the Acceptable Suppliers List as a result of an acceptable or acceptable with restrictions evaluation."

Deviation description: A number of discrepancies were noted regarding the WVNS Acceptable Supplier List (ASL) and supporting qualification files: three suppliers of quality-related items and services are not shown on the ASL; the annual Supplier Assessment, the Supplier Quality Surveys, and audit reports were not in the vendor QA file; and an annual Supplier Assessment does not reflect restrictions on the supplier which is on a restricted status.

Corrective Actions Required:	Yes	No
- Root cause analysis	<u>x</u>	_____
- Action to prevent recurrence	<u>x</u>	_____
- Action regarding similar work	<u>x</u>	_____

Provide Response by: Within 30 days upon receipt of this report
 Initiator: S. L. Crawford, BDM/SAIC Date: 9/10/92
 QA Program Manager: J. T. Conway, EM-343 Date: 9-11-92
 Program Manager: T. W. McIntosh, EM-343 Date: 9/11/92
 Division Director: R. E. Erickson, EM-343 Date: 9/11/92

Proposed Corrective Actions: _____

 Scheduled completion date: _____
 Evaluated Organization Representative: _____ Date: _____

Evaluation of Proposed Corrective Actions: _____

Acceptable	_____
Unacceptable	_____

Evaluator: _____ Date: _____
 Program Manager: _____ Date: _____
 QA Program Manager: _____ Date: _____

Corrective Actions Complete:
 Verified by: _____ Date: _____
 Program Manager: _____ Date: _____
 Verification Approved
 Division Director: _____ Date: _____