

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT

OF

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

WASHINGTON, D.C.

AUDIT YMP-94-07

JULY 18 THROUGH 22, 1994

Prepared by: Thomas E. Rodgers Date: 8/29/94
Thomas E. Rodgers
Audit Team Leader
Yucca Mountain Quality Assurance Division

Approved by: Donald G. Horton Date: 8/31/94
Donald G. Horton
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit YMP-94-07, the audit team determined that the Office of Civilian Radioactive Waste Management (OCRWM) is satisfactorily implementing an effective QA program in accordance with the U.S. Department of Energy (DOE) OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 0, and OCRWM implementing procedures for QA Program Elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 16.0, 17.0, 18.0, and QARD Appendices A and B. The effectiveness of QARD Supplement I was determined to be unsatisfactory, since the documentation and approval processes required by the Energy Information Administration (EIA) standards do not meet with OCRWM QARD, Supplement I requirements. Significant Corrective Action Requests (CAR), resulting from the previous audit of EIA, remain open documenting these conditions.

The audit team identified one deficiency during the audit that resulted in the issuance of one CAR, YM-94-060, which identified that the qualifications of personnel performing quality-affecting work had not been adequately documented. The audit team identified three deficiencies that were corrected prior to the postaudit meeting. These deficiencies are described in Section 5.5.2 of this report. Additionally, there were five recommendations resulting from the audit which are detailed in Section 6.0 of this report.

It should be noted that during the conduct of this Audit, the OCRWM Quality Records Center (QRC) staff demonstrated that they are very capable and effectively practice, with much enthusiasm and pride, their duties to implement the procedures associated with QA Records Management. These individuals are a great asset to this activity and their capable efforts were very much appreciated by the audit team.

2.0 SCOPE

The audit was conducted to evaluate compliance to, and the effectiveness of the OCRWM QA Program as described in the QARD and OCRWM implementing quality documents. Quality-affecting activities performed by the EIA in direct support of OCRWM Headquarters (HQ) were also evaluated within the scope of the audit.

The QA program elements/requirements evaluated during the audit, in accordance with the published audit plan, are as follows:

QA PROGRAM ELEMENTS

- 1.0 Organization
- 2.0 Quality Assurance Program
- 4.0 Procurement Document Control
- 5.0 Implementing Documents

6.0 Document Control
7.0 Control of Purchased Items and Services
16.0 Corrective Action
17.0 Quality Assurance Records
18.0 Audits
Supplement I, Software
Appendix A, High Level Radioactive Waste Form Production
Appendix B, Transportation

The following QA program elements were not evaluated since they are not included in the OCRWM QA Program at this time:

3.0 Design Control
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
Supplement II, Sample Control
Supplement III, Scientific Investigation
Supplement IV, Field Surveying
Appendix C, Mined Geologic Disposal System

TECHNICAL AREAS

The technical areas audited consisted of the following quality-affecting computer programs being developed by the EIA as direct support to OCRWM HQ:

Data Collection System, Radioactive Waste (RW)-859, Nuclear Fuel Data Survey; and Automatic Data Model, Personal Computer International Nuclear Model (PC-INM).

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members, their assigned areas of responsibility, and observers:

<u>Individual</u>	<u>QA Program Element/Requirement</u>
Thomas E. Rodgers, Audit Team Leader (ATL), Yucca Mountain Quality Assurance Division (YMQAD)	

Vance A. Cannaday, Technical Specialist, Headquarters Quality Assurance Division (HQAD)	Supplement I (EIA)
Walter R. Coutier, Auditor, HQAD	1.0, 2.0, 4.0 and 7.0
Norman C. Frank, Auditor, HQAD	1.0, 2.0, 5.0, 6.0, 16.0, and 17.0 (EIA)
Raul A. Hinojosa, Auditor, YMQAD	2.0, 5.0 and 6.0
Robert L. Holliday, Auditor, HQAD	17.0, App. A and B
Richard L. Maudlin, Auditor, YMQAD	2.0, 16.0 and 18.0
Mario R. Diaz, DOE Representative, YMQAD	
Robert D. Brient, Observer, U.S. Nuclear Regulatory Commission (NRC)	
John G. Spraul, Observer, NRC	
William T. Farmer, Observer, Management and Operating Contractor (M&O)	

4.0 AUDIT MEETINGS

The preaudit meeting was held at OCRWM HQ facilities in Washington, D.C., on July 18, 1994. A daily debriefing and coordination meeting was held with OCRWM management and staff, and daily audit team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at the OCRWM HQ facilities in Washington, D.C., on July 22, 1994. Personnel contacted during the audit are listed in Attachment 1 of this report. This list includes an indication of those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, in general, the OCRWM QA Program is adequate and is being effectively implemented for the scope of this audit. Individually, QA Program Elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 16.0, 17.0, 18.0, and Appendices A and B are satisfactorily implemented. Implementation of Supplement I, Software, was unsatisfactory since significant CARs remain open in the area of computer software that were identified during the previous audit of EIA.

5.2 Stop Work or Immediate Corrective Actions or Additional Actions

There were no Stop Work Orders, immediate corrective actions, or related additional items resulting from this audit.

5.3 QA Program Audit Activities

Details of the QA program audit activities are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3.

5.4 Technical Audit Activities

Details of the technical activities audited are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3.

5.5 Summary of Deficiencies

The audit team identified one deficiency during the audit for which one CAR was issued. In addition, the audit team identified three deficiencies that were corrected during the course of the audit related to training, corrective action, and audits.

A synopsis of the deficiency documented as a CAR is contained in Section 5.5.1 of this report and an information copy is included in Attachment 4.

A synopsis of the deficiencies corrected during the audit is contained in Section 5.5.2 of this report.

5.5.1 Corrective Action Request

CAR YM-94-060

Contrary to Quality Assurance Administrative Procedure (QAAP) 2.2, Revision 1, Sections 6.6.1 through 6.3.3, the qualification records of three Quality Assurance Technical Support Services (QATSS) personnel performing quality-affecting are incomplete.

5.5.2 Deficiencies Corrected During the Audit

Deficiencies which are considered isolated in nature and require only remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit.

1. QAAP 2.1, Revision 2, Paragraphs 5.4.1 and 5.4.2 state in part: "Personnel shall receive training to achieve and maintain proficiency for their position; Individuals may perform a given activity subject to quality program controls provided that documentary evidence exists of training to applicable procedures governing the activity; and personnel shall receive training

necessary to maintain proficiency and to accommodate changes in procedures." Contrary to these requirements, four individuals were found to have performed quality-affecting activities without documented evidence in the form of a training matrix sign off indicating that they had read and understood the applicable procedure prior to performing the activity. This was resolved during the audit by verifying that the required training had been conducted prior to the performance of work and updating the individual quarterly training matrices to accurately reflect that fact.

2. Quality Assurance Procedure (QAP) 16.1, Revision 6, Paragraph 5.4.b states in part: "The Responsible Individual: transmits, prior to the due date, a written request for extension of the corrective action completion dates if it becomes evident that the actions will not be completed as scheduled. The request shall include appropriate justification for the delay...." Contrary to this requirement, there was no objective evidence to support the extension of the corrective action due dates for CARs HQ-92-022, -023, and -029 beyond December 31, 1993. Corrective action extension requests for each of the subject CARs were submitted and approved during the audit. It should be noted that all of these CARs were related to the same activity and were written during the same period. Subsequently, this does not represent a trend.
3. QAAP 18.1, Revision 3, Section 6.4 states in part: "Technical Specialists who are not qualified as auditors shall receive training identified in QAAP 2.1, Indoctrination and Training, and shall read and sign Attachment IV, 'Audit Guide for Technical Specialists' prior to the QA audit." Contrary to this requirement, there was no objective evidence in the form of signed Attachment IVs that training had been conducted in accordance with QAAP 2.1 for two technical specialists that participated in OCRWM QA Audit HQ-94-01. This was corrected during the audit by verifying that the required training had been conducted prior to audit performance. Completed Attachment IVs for the two individuals were placed in the QA records package for the subject audit.

None of the aforementioned deficiencies have an impact on the quality of the work being performed.

5.5.3 Follow-up of Previously Identified CARs

CARs HQ-92-022, -023 and -029

The above CARs were issued as a result of OCRWM QA Audit HQ-92-04 of the EIA in September 1992. The subject CARs document the adverse condition that EIA has not adequately addressed the requirements of the QARD Supplement I for the development of the Data Collection System, RW-859, Nuclear Fuel Data Survey; and Automatic Data Model, PC-INM. These CARs remain open and are awaiting the completion of corrective action.

A CAR follow-up, performed during this audit, identified the actions taken by EIA that should result in closure of the CARs. The actions taken include development of Headquarters Line Procedure (HLP)-SL1Q, Control of EIA Software, and the Lifecycle Plan for the Form RW-859 Nuclear Fuel Data Survey and the PC-INM. Both of these documents are currently undergoing QAP 6.2 document review. It is projected that upon acceptance by OCRWM and subsequent issuance of these two documents, the corrective actions for the above listed CARs can be verified and closed.

CAR HQ-93-01

This CAR related to the performance of procedure reviews prior to being trained to QAAP 5.1, Revision 3. During the course of this audit, no personnel were found to have performed procedure reviews without being trained to the applicable procedure. The corrective action for this CAR was determined to be satisfactory.

CAR HQ-93-03

This CAR related to Lead Auditor certification packages not including objective evidence of examination contents. During the audit, several Lead Auditor certification packages were reviewed. The packages contained a record which referenced the lesson plan used for Training and Examination of Lead Auditors. The corrective action for this CAR was determined to be satisfactory.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by OCRWM management.

1. Responsible organizations should provide action plans addressing issues identified in the 1993 Management Assessment to the Director, OCRWM, in a timely manner.
2. Clarify the wording in QAP 7.2, Supplier Evaluation, to exclude "affected organizations" from the Qualified Supplier List (QSL).
3. Additional emphasis should be placed upon the in process CAR files to ensure that they are current, complete, and accurately document the various steps of the corrective action process.
4. Transmit the old study plan QA record packages located in the QRC to the proper Yucca Mountain Project (YMP) custodian.
5. Additional amounts of time are currently being spent correcting errors (editorial only) in the data provided by the utilities. This is not a deficient condition, but does prolong the processing time required to accept the data. It is recommended that the portion of the RW-859 program used for data collection (performed by the utilities) be updated to include error checking on selected fields of input.

7.0 LIST OF ATTACHMENTS

- Attachment 1: Personnel Contacted During the Audit
- Attachment 2: Audit Details
- Attachment 3: List of Objective Evidence Reviewed During the Audit
- Attachment 4: Information Copy of CAR

ATTACHMENT 1

Personnel Contacted During The Audit

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
Andersen, K.	RW-1/Policy Specialist			X
Andress, A.	EIA/Z, Inc./Sr. Programmer		X	
Barrett, L.	RW-2/Deputy Director	X	X	X
Baumbach, R.	HQAD/QA Program Lead		X	X
Betts, C.	HQAD/QA Specialist		X	
Booth, W.	Weston/QA Mgr.			X
Brandt, H.	RW-15/Acting Director	X		X
Breese, J.	RW-10/Acting Director	X		X
Brient, R.	NRC/Observer	X		X
Bronushas, D.	EIA/Z, Inc./Programmer		X	
Brownstein, A.	RW-432/Chief		X	
Cannaday, V.	HQAD/Tech. Specialist	X		X
Carlson, J.	RW-37/Division Director	X	X	
Chou, H.	EIA/EI-523/ORA		X	
Clark, R.	RW-3.1/Division Director	X	X	X
Coutier, W.	HQAD/Auditor	X		X
Desell, L.	RW-45/Division Director			X
Diaz, M.	YMQAD/DOE Representative	X		X
Dreyfus, D.	RW-1/Director	X	X	X
Ellis-Brown, D.	M&O/Rec. Control Specialist		X	
Farmer, W.	M&O QA/Observer	X		X
Frank, N.	HQAD/Auditor	X		
George, J.	HQAD/Sr. QA Specialist		X	
Gibbard, K.	EIA/EI-523/ORA	X	X	
Harris, M.	Weston/QA Assistant			X
Hendrix, D.	HQAD/QA Specialist		X	
Hinojosa, R.	YMQAD/Auditor	X		X
Hollaren, T.	EIA/Z, Inc./Programmer		X	
Holliday, R.	HQAD/Auditor	X		X
Horseman, M.	HQAD/Verification Lead	X	X	
Horton, D.	RW-3/Director	X	X	X
Jackson, D.	EIA/EI-532/ORA		X	
Johnson, J.	RW-31/QA Coordinator	X		
Keener, G.	M&O QA/Observer	X		
Leahy, J.	RW-14/Contract Analyst	X	X	
Lentz, H.	HQAD/Sr. QA Specialist		X	
Liggett, W.	EIA/EI-532/Team Leader		X	
Little, C.	EIA/Z, Inc./Energy Specialist	X	X	
Long, S.	RW-36/Admin. Asst.	X		

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
Lukasik, C.	RW-131/Acting Director	X	X	X
Maudlin, R.	YMQAD/Auditor	X		X
Mayes, F.	EIA/Branch Chief	X	X	
McCarty, W.	EIA/Z, Inc./Sr. Energy Specialist		X	
Milner, R.	RW-30/Acting Director	X		X
Minning, R.	RW-1/Special Assistant	X		X
Murthy, R.	RW-3.1/QA Specialist			X
Nelson, D.	RW-30/Executive Director	X		
Palabrica, R.	ASTA Engineering/Program Mgr.		X	
Ransom, K.	HQAD/CAR Coordinator		X	
Richerson, P.	HQAD/Clerk		X	
Rouso, S.	RW-40/Director			X
Ruffin, G.	M&O/QRC Manager		X	
Senderling, M.	RW-30/Gen. Engineer	X	X	X
Shelor, D.	RW-40/Deputy Director			X
Skuchko, S.	RW-45/Mgmt. Specialist	X	X	
Smith, P.	RW-44/General Engineer		X	
Spraul, J.	NRC/Observer	X		X
Summerson, J.	RW-22/Physical Scientist		X	
Svinicki, K.	RW-44/General Engineer		X	
Swift, T.	HQAD/Sr. QA Specialist		X	
Threatt, D.	HQAD/Sr. QA Specialist		X	
Thorpe, J.	EIA/Z, Inc./Sr. Energy Specialist		X	
Van, T.	RW-37/Team Leader		X	X
Vlahakis, J.	RW-3.1/Team Leader			X
Wagner, L.	HQAD/Division Manager	X	X	X
Weber, C.	RW-3.1/QA Specialist		X	
Wowak, W.	Weston/Program Mgr.			X
Wood, T.	RW-14/Division Director	X	X	

LEGEND:

ORA = Operations Research Analyst

ATTACHMENT 2

Audit Details

The following is a summary of the OCRWM QA Program activities covered during the audit. The list of objective evidence reviewed and specific procedures audited is provided in Attachment 3.

1.0 ORGANIZATION

The evaluation of QA Program Element 1.0 was based upon review of the procedural requirements, evaluation of applicable documentation produced as a result of procedural implementation, personnel interviews, and examination of objective evidence to determine the degree of compliance with selected requirements from OCRWM implementing procedure QAP 1.1. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

QAP 1.1, Organization

- Verify that the current organization (chart) is consistent with this procedure.
- Verify that delegation of authority is accomplished by approving procedures or issuing memorandums of delegation.
- Verify that the current organization (chart) is consistent with this procedure.
- Verify that delegation of authority is accomplished by approving procedures or issuing memorandums of delegation.
- Verify that approving procedures and memorandums of authority are being captured as QA Records.
- Determine if any quality disputes required resolution with the Director OCRWM.
- Verify that the Director, Office of Quality Assurance (OQA) has knowledge and experience in management and QA.
- Verify that the Director, OQA is independent from cost and schedule when items and activities are subject to QARD controls.

Results:

Based upon interviews with RW-1, -2, -3, EIA, and Z, Inc. personnel, the recent OCRWM reorganization, effective July 10, 1994, EIA Organization Chart, and a review of the QA Controls Document, the implementation of the above requirements was determined to be satisfactory. The effectiveness of QA Program Element 1.0 was determined to be satisfactory.

2.0 QUALITY ASSURANCE PROGRAM

The evaluation of QA Program Element 2.0 was based upon review of the procedural requirements, evaluation of applicable documentation produced as a result of procedural implementation, personnel interviews, and examination of objective evidence to determine the degree of compliance with selected requirements from OCRWM implementing procedures QAPs 2.4, 2.5, 2.6, 2.7, 2.8, 2.10, and QAAPs 2.1, 2.2, and 2.3. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

QAAP 2.1, Indoctrination and Training

- Verify that the supervisor prepares an initial or revises an existing Indoctrination and Training (I&T) matrix whenever new personnel are assigned or previously assigned personnel receive a new position or changes to duties within a position.
- Verify that the I&T matrix code is identified on the I&T matrix.
- Verify the assigned instructor prepares a lesson plan and forwards to QA Training Officer and verify that lesson plans are approved by the QA Training Officer.
- Verify that the employee signs an attendance record for classroom training and that the training instructor forwards the attendance record to the QA Training Officer for entry into the training database.
- Verify that the employee documents the completion of self-study requirements on the I&T matrix.
- Verify the employee documents the completion of classroom training by signing an attendance record.

- Verify that after all self-study and classroom training has been completed, the employee signs all pages of the I&T matrix and obtains the supervisors signature.
- Verify the Training Officer reviews the I&T matrix for completion and enters the data into the training database. Verify that subsequent documentation of completed self-study and classroom training is entered into the training database by the QA Training Officer.
- Verify that the employee forwards, at the end of each quarter, a quarterly update of the latest status to the supervisor who signs the I&T matrix and forwards it to the QA Training Officer.
- Verify that the QA Training Officer periodically issues reports for information or action, and for review of essential data for accuracy and completeness.

Results:

The evaluation was based on personal interviews and evaluation of selected documentation such as initial I&T Matrices, quarterly I&T updates, Lesson Plans, Training Data Sheets, and supporting documentation. The results revealed satisfactory implementation with the exception of one isolated condition. During the course of the audit, it was noted that documented evidence did not exist for four individuals to demonstrate that they were current on procedures that were applicable to activities that they had performed. This condition was corrected during the audit and is identified in Section 5.5.2.1 of this report. In addition, a follow-up to previously identified CAR HQ-93-01 was performed and the results are discussed in Section 5.5.3 of this report.

Based on the above, implementation of QAAP 2.1 was determined to be satisfactory.

Requirements:

QAAP 2.2, Verification of Personnel Qualifications

- Supervisors shall develop position descriptions for those employees who perform, under their direct supervision, activities subject to QA program controls.
- If a change in duties and responsibilities for a given position requires a change to the established minimum qualifications, the supervisor shall revise the position description and reevaluate the existing personnel within that position.

- The supervisor shall review a prospective employee's SF-171, resume or application for employment and shall verify, to the extent possible, accuracy of the information provided against the minimum education and experience required for the position.
- The supervisor shall complete the Position Qualification Statement (PQS) and attach objective evidence of verification, such as statements from colleges and signed and dated telephone conversation records, that support the stated education and experience.
- When relevant education and experience cannot be verified, the supervisor shall provide a written statement with justification for the personnel assignment attached to the PQS. Justification should include why verification was not possible and address specific factors such as past performance, training, and other available information.
- The supervisor shall transmit a copy of the completed PQS with supporting documentation to the appropriate administrative support personnel within OCRWM or the direct support contractor organization to complete the personnel hiring process.
- Upon completion of the hiring process, the supervisor shall transmit the complete PQS with supporting documentation directly to the QRC in accordance with QAAP-17.1.
- The supervisor shall also retain a copy as the office working file. The working file shall be maintained in a locked cabinet.
- The supervisor shall establish the employee's I&T requirements on the I&T matrix in accordance with QAAP 2.1 only after the PQS has been completed in accordance with Subsection 6.2.
- Prior to completion of all I&T on the I&T matrix; the supervisor may assign the employee to any specific activity covered by the employee's position description provided that:
 - a. The employee has completed the relevant I&T required for that activity; and
 - b. The employee has satisfied any special requirements contained in any QAAP covering the activity.

Results:

Selected personnel record packages containing position descriptions, position

qualification statements, verification of education and experience, and supporting documentation were reviewed. During this review, deficiencies were found in three packages. This condition was documented on CAR YM-94-060 as described in Section 5.5.1 of this report. With the exception of the adverse condition identified in CAR YM-94-060, implementation of QAAP 2.2 was determined to be satisfactory.

QAAP 2.3, Establishing Quality Assurance Program Controls

Requirements:

- **Verify that OCRWM program activities and associated QA program controls are identified in a QA controls document.**
- **Verify that the QA Controls Document:**
 - a. **provides a description of each office's applicable function or work definition, and**
 - b. **identifies the applicable QA program controls to be implemented.**
- **Verify the QA Controls Document has been formatted as outlined in Attachment I, Format for QA Controls Document.**
- **Verify the Director, OCRWM; the Director, OQA; and the Associate and Office Directors have developed descriptions of their assigned responsibilities at function and if necessary, work levels.**
- **Verify that for each description that has applicable QA program requirements specified, a determination of the applicability of the QARD has been made and determination documented on Attachment II, QA Program Controls Matrix and Attachment III, QA Program Controls Basis Sheet.**
- **Verify that when the QARD is applicable, the Quality Assurance Program Document has been implemented and documented on the QA Program Controls Matrix sheet.**
- **Verify that each Associate or Office Director has submitted:**
 - a. **Function or work definitions**
 - b. **Associated QA Program Controls Matrices**
 - c. **QA Programs Controls Basis Sheets to the Director, OQA for incorporation into the QA Controls Document.**

- Verify that the Associate Director for Program and Resource Management has reviewed and concurred with the function work definitions for conformance to approved mission and function statements.
- Verify the Director, OQA has reviewed the QA Controls Document, and concurred by signing the QA Program Controls Basis Sheets.
- Verify the Director, OCRWM reviews and approves the QA Controls Document prior to issuance.
- Verify the QA Controls Document is maintained as a controlled document by OQA.
- Verify the QA Controls Document is maintained as a QA Record.

Results:

Based upon an evaluation of the approved and issued QA Controls Document, Revision 1, the implementation of QAP 2.3 was determined to be satisfactory.

QAP 2.4, Maintenance of the QARD

No implementation (responsibility transferred to YMQAD).

QAP 2.5, Peer Reviews

No implementation.

QAP 2.6, Readiness Reviews

No implementation.

QAP 2.7, Management Assessment

Requirements:

Director OCRWM:

- a. Directs an annual management assessment of QA program.
- b. Appoints team leader.
- c. Ensures review of objective evidence of leader's training in QARD and QAP 2.7.

- d. Issues notification letter to OCRWM Associate and Office Directors.

Management Assessment Team Leader:

- a. Develops Schedule
- b. Selects Team
- c. Assures Team qualifications via review of objective evidence
- d. Instructs team members in performance
- e. Specifies methods of performance in plan
- f. Develops, signs, and forwards plan to Director, OCRWM

Director OCRWM approves plan

Team Members:

- a. Perform assigned portions of plan
- b. Provide results, potential problems, draft recommendations, and list of personnel contacted
- c. Notify leader of potential adverse conditions

Team Leader:

- a. Conducts meetings with team
- b. Briefs Management
- c. Ensures corrective action is initiated per QAP 16.1

Team Leader:

- a. Documents results in report
- b. Obtains team member input and concurrence with report content
- c. Signs report and forwards to Director, OCRWM

Director OCRWM approves and issues report to all Associate and Office Directors.

Associate and Office Directors:

- a. Review report for their areas
- b. Provide responses
- c. Respond to CARs
- d. Issue memorandum to Director OCRWM when all actions are complete

Director, OCRWM:

- a. Evaluates responses
- b. Directs tracking of recommendations to closure
- c. Directs processing of QA records

Results:

Based upon an evaluation of the 1992 and 1993 Management Assessments and associated documentation, implementation of QAP 2.7 was determined to be satisfactory. One recommendation was offered for OCRWM management consideration as described in Section 6.1.

QAP 2.8, Surveillance

Requirements:

- Verify that the Surveillance Team Leader determines the scope of the surveillance and documents it on a Quality Assurance Surveillance Record (QASR).
- Verify that the Surveillance Team Leader signs and dates the QASR and forwards to the Quality Assurance Division Director (QADD) for concurrence. Verify that the QADD documents concurrence on the QASR.
- Verify that the surveillance team documents the specific requirements to be used as the bases for evaluation on the QASR. Verify that CARs, as applicable, are generated in accordance with QAP 16.1.
- Verify that the Surveillance Team Leader signs and dates the completed QASR and that the QADD signs and dates the QASR indicating approval and distributes the QASR to management of the organization subject to surveillance and others as appropriate.

Results:

The evaluation was based on personal interviews and evaluation of selected documentation such as QASRs, supporting documentation, and CARs, as applicable.

Based on the above, implementation of QAP 2.8 was determined to be satisfactory.

QAP 2.10, Hold Points (HPs)

Requirements:

- Procurement documents shall provide notice to affected organizations.
- HP status shall be tracked by a centralized system maintained by the Office of Systems and Compliance, Configuration Management Branch.
- An impact evaluation is required.
- HPs shall be identified on appropriate documents.
- HPs shall not be substituted for stop work or to track or control adverse conditions.
- The Responsible Director (RD) shall initiate HPs using Attachment . I.
- RD shall notify affected organizations by memorandum, directly or by the Contracting Officer's Representative (COR), requesting input regarding impact.
- Disputes shall be resolved through normal management chain.
- Affected organizations shall incorporate HPs into appropriate documents.
- Affected organization notifies RD when work has reached HP.
- HP shall remain in place until verified, released, or cancelled.
- RD shall provide written justification.
- Changes shall be noted on a new Attachment I.
- All changes shall be forwarded to the tracking coordinator and system updated.
- RD shall notify affected organizations.
- Tracking coordinator is responsible for maintaining an updating tracking system.
- Tracking coordinator shall prepare a monthly summary report.
- Summary report shall be distributed to affected and responsible organizations, and all OCRWM offices.

- Hold Control Sheet - Attachment I is designated on lifetime QA record.

Results:

Based upon an evaluation of selected hold point status logs and associated documentation, implementation of QAP 2.10 was determined to be satisfactory.

Overall Effectiveness Statement

Based upon satisfactory implementation of the various implementing procedures discussed above, the effectiveness of QA Program Element 2.0 was determined to be satisfactory.

4.0 PROCUREMENT DOCUMENT CONTROL
7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

The evaluation of QA Program Elements 4.0 and 7.0 was based upon review of the procedural requirements, evaluation of applicable documentation produced as a result of procedural implementation, personnel interviews, and examination of objective evidence to determine the degree of compliance with selected requirements from OCRWM implementing procedures QAP 7.2 and HLP 7.1Q. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

QAP 7.2, Supplier Evaluation

No implementation.

HLP 7.1Q,

- Verify that the RD, upon determining the need to procure services:
 - a. Documents work scope and determines applicability of OCRWM QARD.
 - b. Documents services determined not subject to QARD.
 - c. Determines whether OCRWM or supplier's implementing document apply for performance.
 - d. Documents QA requirements for direct support.
 - e. Continues implementation for OCRWM managed organizations.

- **The Responsible Director:**
 - a. **Determines procurement type.**
 - b. **Initiates a QAP 6.2 review of procurement document.**

Procurement from field contractors

- **RD requests HQAD evaluate QA program.**
- **HQAD Director ensures agency is qualified and provides memorandum to RD.**
- **RD coordinates with COR changes are documented in procurement documents.**
- **Director, Configuration Management Division assembles procurement QA record package and enters into OCRWM system.**
- **RD ensures deliverables and records in coordination with COR.**
- **Verify procurement documents contain:**
 - a. **Scope of work.**
 - b. **Technical requirements.**
 - c. **QA program requirements.**
 - d. **Right of access.**
 - e. **Provisions for readiness reviews or HPs.**
 - f. **Provisions that supplier ensures compliance with OCRWM prior to offering to OCRWM.**
 - g. **Documentation submittals, schedule, and maintenance.**
- **Methods for Acceptance of Services shall include:**
 - a. **source verification**
 - b. **technical verification**
 - c. **surveillance or audit**
 - d. **review of objective evidence**
- **Procurement documents are classified as lifetime QA records.**

Results:

Based upon an evaluation of selected Work Authorization Directives (WADs), task directives, and program guidance letters, the effectiveness of QA Program Elements 4.0 and 7.0 was determined to be satisfactory. One recommendation was offered for OCRWM management consideration as described in Section 6.2.

5.0 IMPLEMENTING DOCUMENTS

The evaluation of QA Program Element 5.0 was based upon review of the procedural requirements, evaluation of applicable documentation produced as a result of procedural implementation, personnel interviews, and examination of objective evidence to determine the degree of compliance with selected requirements from OCRWM implementing procedure QAP 5.1. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

QAP 5.1, Quality Assurance Program Procedures

- The Requesting Organization, upon determining the need for procedure development, change, or cancellation:
 - a. Completes Section I of the Document Action Request (DAR).
 - b. Obtains a DAR number from the OQA, HQ Division for requests involving H-prefixed procedures or from the Project Control Branch (PCB) for requests involving QAPs, Administrative Procedures, or Y-prefixed procedures.
- The Responsible Director:
 - a. completes Section II of the DAR using the instructions provided;
 - b. approves or rejects the DAR and returns copies of the signed DAR to the Requesting Organization and to the OQA or PCB as appropriate; and
 - c. obtains a unique procedure number.
- The preparer:

- a. develops draft replacement pages for an interim change or a draft of the entire procedure for a revision, incorporating the changes approved on the DAR;
 - b. returns the draft documents to the RD.
- The RD initiates and coordinates review in accordance with QAP-6.2, including:
 - a. assigning the review to the organizations or disciplines listed in the procedure being reviewed as having responsibility for implementing the procedure, except reviews of changes which are assigned only to those organizations or disciplines that are affected by the change. If assigning review of a local procedure that supplements a QAP, the RD for that QAP is included among the reviewers.
 - b. specifies the use of the appropriate review criteria from the standard review criteria provided in QAP-6.2
 - c. insures that the final procedure is printed on procedure pages and identifies each change with a vertical line in the margin adjacent to the change unless the change history indicates that the entire procedure has been revised;
 - d. specifies the effective date in the change history of the procedure;
 - e. signs and dates the approval block on the procedure title page.
 - The Director, OQA indicates concurrence with by signing and dating the block provided on the procedure title page.
 - The RD ensures that the QARD Requirements Traceability Network (RTN) Matrix is updated in accordance with the requirements of QAP-2.4.

Results:

Based upon evaluation of selected DARs and QARD Implementation Matrices, the effectiveness of QA Program Element 5.0 was determined to be satisfactory.

6.0 DOCUMENT CONTROL

The evaluation of QA Program Element 6.0 was based upon review of the procedural requirements, evaluation of applicable documentation produced as a result of procedural implementation, personnel interviews, and examination of objective

evidence to determine the degree of compliance with selected requirements from OCRWM implementing procedures QAAP 6.1 and QAP 6.2. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

QAAP 6.1, Document Control

- The responsible manager shall, prior to issuing documents, designate documents for controlled issue in accordance with the criteria identified in Subsection 5.2.
- The responsible Associate or Office Director shall approve controlled distribution of documents within their primary area of responsibility.
- The following shall be submitted to the Director, OQA for documents covered by this procedure:
 - a. One approved (signed) document original.
 - b. The required distribution list for initial issue of the document or requested changes, if any, to the existing distribution list for the document or manual.
 - c. Special instructions for distribution, if any, required or recommended.
- The Director, OQA ensures that:
 - a. Each controlled document has a unique title or number and effective date identified on the document.
 - b. Each controlled copy is identified.
 - c. Each controlled copy is assigned a unique copy number.
 - d. Records indicate the assigned copy holder of each controlled copy by copy number.
- The Director, OQA shall establish and maintain a controlled document index.
- The index (controlled document) shall consist of one or both of the following:

- a. **A table of contents (TOC) for each controlled manual that identifies each document in the manual by number, title, revision, or Interim Change Notice (ICN) number, and effective date. A new table of contents shall be issued each time a document is added or revised.**
 - b. **For documents not controlled as part of a controlled manual, a list identifying each such individually controlled document. The list shall identify each document by number and title, revision or ICN number, and effective date. This list, if required, shall be updated annually or as major changes occur and distributed to the document recipients.**
- **The Director, OQA shall prepare a Document Transmittal for each distribution of a controlled document and distribute a copy of the Document Transmittal with the controlled copy to all personnel on the approved distribution list. The Document Transmittal shall contain any necessary instructions, to include action to be taken with superseded documents and for acknowledging receipt.**
 - **The Director, OQA shall make a record of the return of the Document Transmittal including the document number, revision number, date the recipient signed the acknowledgement, controlled copy number, and that recipient acknowledges receipt.**
 - **If the Document Transmittal has not been returned, signed, to the OQA by the acknowledgement required date specified, the OQA formally requests that the controlled document be updated or the OQA will take appropriate action.**
 - **Revisions and ICNs to controlled documents shall be controlled in the same manner as the original controlled document. The effective date and revision shall be plainly visible on the document coversheet.**
 - **The Document Transmittal shall instruct the recipient to destroy or return superseded material or clearly label it "SUPERSEDED" and shall inform the recipient that signing the acknowledgement so attests that the action was taken.**
 - **The Director, OQA, shall maintain a controlled distribution list for each document or manual covered by this procedure. The distribution list includes each controlled copy holder or location and the copy number.**
 - **Requests for changes to the controlled distribution list shall be made by memorandum and directed to the Director, OQA.**

- When a document holder is removed from a distribution list, the Director, OQA shall notify the person via a Document Transmittal, to destroy the document, mark it "SUPERSEDED," or return it to OQA. The document holder or other responsible person shall sign and return the Document Transmittal to verify that the document has been removed from use.
- At least annually copies of the distribution list for each controlled document or group of controlled document shall be transmitted by the Director, OQA to the Director, OCRWM and the Associate or Office Directors for review and updating (if appropriate).
- Completed Document Transmittals and a copy of the distribution list for controlled distributions are submitted to the QRC in accordance with QAAP 17.1.

Results:

Based upon an evaluation of selected distribution lists, document transmittals, and associated correspondence, implementation of QAAP 6.1 was determined to be satisfactory.

QAP 6.2, Document Review

Requirements:

Verify that the Review Coordinator:

- Initiates the Document Review Record (DRR) and Comment Sheet.
- Documents the review criteria.
- Identifies the applicable review criteria for each reviewer on the DRR.
- Signs and dates the DRR and Comment Sheet.

Verify that the Document Reviewer:

- Records comments or indicates that there are no comments on the Comment Sheet.
- Identifies mandatory comments with an asterisk (*) and identifies non-mandatory comments with a code letter.

- Signs the REVIEW COMPLETED BY block on the DRR.

Verify that the Review Coordinator:

- Develops responses to comments.
- Ensures that the document is modified as indicated in the responses to the comments.

Verify that the Document Reviewers:

- Indicate agreement with the responses to their own mandatory comments by initialing and dating the ACCEPT block on the Comment Sheet adjacent to the appropriate response.
- Sign and date the CONCURRENCE block on the DRR.

Verify that the Review Coordinator:

- Reviews the returned DRRs and Comment Sheets to ensure that all concurrence signatures have been obtained.

Verify that the Review Coordinator:

- Processes a final draft, marked "Change Control Board Review Draft," to the board for review and comment.
- Completes the processing of the document, including processing of QA records, in accordance with the governing document if board approval is obtained.

Results:

Based upon an evaluation of selected DRRs and their associated comment sheets, implementation of QAP 6.2 was determined to be satisfactory.

Overall Effectiveness Statement

Based upon satisfactory implementation of QAAP 6.1 and QAP 6.2 as discussed above, the effectiveness of QA Program Element 6.0 was determined to be satisfactory.

16.0 CORRECTIVE ACTION

The evaluation of QA Program Element 16.0 was based upon review of the procedural requirements, evaluation of applicable documentation produced as a result of procedural implementation, personnel interviews, and examination of objective evidence to determine the degree of compliance with selected requirements from OCRWM implementing procedures QAPs 16.1, 16.2, and 16.3. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

QAP 16.1, Corrective Action

- Verify that OCRWM personnel, upon discovering a potential condition adverse to quality, complete the initiators actions on the CAR.
- Verify that the Quality Assurance Representative (QAR) evaluates the adverse condition for significance, determines if a stop work condition exists, and determines the type of actions required for resolution.
- Verify that the QAR directs preparation of CAR issuance correspondence that identifies the CAR coordinator, and requests the responsible individual through the correspondence to respond to the CAR by the due date.
- Verify that the CAR Coordinator assigns a CAR number and enters the information in a log. Verify that the QADD assigns a response due date and approves the CAR for issuance by signing and dating the CAR.
- Verify the CAR Coordinator maintains the original CAR, issuance correspondence, CAR responses, transmittal correspondence, requests for extensions, and notification correspondence as applicable.
- Verify that the CAR Coordinator updates the CAR Log as changes in status occur. Verify that requests for response extension include justification for the delay.
- Verify that the QAR evaluates extension requests and accepts or denies it via notification correspondence and indicates the new due date. Verify that the QADD concurs with the QAR's evaluation of the extension request by signing the notification response.

- Verify the QAR reviews the response and proposed actions to determine if they will resolve the adverse condition and if so, recommends acceptance of the response. Verify the QADD concurs with the QAR's recommendation for acceptance and signs and dates the CAR. Verify that the QADD signs the notification correspondence and issues to responsible individual.
- Verify that the responsible individual transmits a written request for extension of corrective action completion dates if it becomes evident that the actions will not be completed as scheduled.
- Verify that the QAR upon completion of the actions identified in the approved response, performs and documents verification to determine that corrective actions have been satisfactorily implemented and indicates acceptance by signing and dating the CAR. If the QAR determines corrective actions to be unacceptable, the QADD upon concurrence signs and dates the request for additional action and issues to responsible individual.
- Verify the QADD approves closure of the CAR by signing and dating the appropriate block. Verify the QADD issues the correspondence notifying the responsible individual that the CAR is closed and forwards the CAR and notification letter the CAR Coordinator.
- Verify the CAR Coordinator updates the CAR Log to indicate CAR closure. Verify that the CAR Coordinator process the QA records as appropriate.

Results:

The evaluation was based on personal interviews and evaluation of selected documentation such as the CAR log, CAR packages and supporting documentation. The results indicated satisfactory implementation of the above requirements with the exception of one isolated condition. During the course of the audit, it was noted that documented evidence did not exist to indicate that an extension request to the corrective action due dates for CARs HQ-92-022, -023, and -029 had been processed. The due date for completion of the corrective action was December 31, 1993. This condition was corrected during the audit and is identified in Section 5.5.2.2 of this report. One recommendation was offered for OCRWM management consideration as described in Section 6.3.

Based on the above, implementation of QAP 16.1 was determined to be satisfactory.

QAP 16.2, Stop Work

No implementation.

QAP 16.3, QA Program Trend Evaluation

Requirements:

Trend Evaluation:

- Verify that the Director, YMQAD, on a quarterly schedule prepares a draft "Quality Assurance Program Quarterly Trend Report" and forwards the report, including any CARs, to the Director, HQAD, for review and concurrence.
- Verify that the Director, HQAD indicates concurrence with the report by signing and dating the cover page of the report; and forwards the report to the Director, OQA.
- Verify that the Director, OQA signs the "Quality Assurance Program Quarterly Trend Report" and issues any CARs resulting from the trend evaluation to the Responsible Managers of affected organizations in accordance with QAP 16.1.
- Verify that the Director, OQA distributes the "Quality Assurance Program Quarterly Trend Report" to OCRWM Associate and Office Directors and other organizations, as appropriate; and directs the transmittal of QA records in accordance with Section 7.0.

Results:

Based upon an evaluation of selected Quality Trend Reports, HQAD input to selected Quality Trend Reports, and CAR YM-93-070 resulting from a Quality Trend Report, the implementation of QAP 16.3 was determined to be satisfactory.

Overall Effectiveness Statement

Based upon the above, the effectiveness of QA Program Element 16.0 was determined to be satisfactory.

17.0 QUALITY ASSURANCE RECORDS

The evaluation of QA Program Element 17.0 was based upon review of the procedural requirements, evaluation of applicable documentation produced as a result of procedural implementation, personnel interviews, and examination of objective evidence to determine the degree of compliance with selected requirements from OCRWM implementing procedures QAAP 17.1 and Implementing Line Procedure (ILP) 12.17.01. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

QAAP 17.1, QA Records Management

- Verify that the RD develops, maintains and submits to the QRC at least annually a list of QA records and QA Records Packages (QRPs) expected to be generated as a result of activities under their responsibility.
- Verify that the RDs generate, and forward to the QRC, a list of personnel within their organization who are authorized to assemble, review, and validate QRPs. This list shall include the printed name, written signature, and initials of each authorized validator.
- Verify that each Office, Division, or Branch maintains a log of the specific QA records packages they have established and the associated QRP identification numbers assigned.
- Verify that prior to transmittal of an individual QA record to the QRC, the record originator identifies a specific QA records package to which that record shall be assigned.
- Verify that the record originator sends a QA record to the QRC as soon as it is completed and approved or accepted.
- Verify that the record originator marks the letters "QA" in the upper right-hand corner of the first page of the QA record.
- Verify that the record originator ensures that:
 - a. The QA record is properly authenticated.
 - b. The QA record is complete, including all attachments and enclosures.
 - c. Written and typed QA records are legible, reproducible, and microfilmable.
 - d. QA records that are drafts are marked "Draft."
- Verify that subsequent to a satisfactory review and any necessary corrections, the record originator prepares a QA Record Transmittal and submits the QA record to the QRC.

- Verify that the QRC maintains record traceability for special-process and one-of-a-kind records received and transferred to the Central Records Facility (CRF) for processing and storage.
- Verify that preliminary drafts of documents are not identified or maintained as records.
- Verify that, draft versions of QA records-in-process issued for formal review and comment or concurrence prior to approval of the final document, and associated documents, shall be identified and processed as QA records as follows:
 - a. Draft documents shall be marked "Draft" on the front page
 - b. Comments on drafts and the resolution of those comments shall be recorded as a separate document, and not as handwritten notes on the draft document.
 - c. Copies of draft documents, associated comments, and comment resolutions shall be filed and retained in the QA records package of the final approved document.
- Verify that the QRC maintains QA training and qualification records packages in locked cabinets with controlled access.
- Verify that the record originator notifies the QRC when the activity or activities for a given QRP are complete and requests a list of the QA records that have been received and retained under that QRP identification number.
- Verify that the QRP validator reviews the package and individual records to:
 - a. Arrange the documents in a logical sequence
 - b. Purge any exact duplicates, incomplete records, or other records that do not belong in the QRP, and identify any missing records needed to complete the package.
- Verify that the QRP validator ensures that any needed corrections made during the above review are properly performed.
- Verify that the QRP validator, with QRC assistance, obtains, reviews, verifies, and inserts any missing records.

- Verify that the QRP validator with assistance of the QRC, shall complete a QA Records Package TOC.
- Verify that the QRP validator performs a final inventory of the package to verify that the TOC accurately reflects the QA records contained in the package and signs and dates the "Validated By:" block on the TOC.
- Verify that the QRC processes the completed QRP in accordance with QRC and CRF procedures.
- Verify that corrections to QA records shall be made by the record originator or individual authorized by the originating organization.
- Verify that corrections to documents made prior to QRP validation are limited to the following:
 - a. Drawing a single line through incorrect information, inserting corrected or additional information where appropriate, and initialing and dating the entries.
 - b. Superseding the incorrect document and replacing it with a corrected version that has undergone appropriate review and approval.
 - c. The corrected document shall be transmitted to the QRC in accordance with this procedure as a new and separate QA record.
- Verify if corrections are made to a QA record after the associated QA records package has been validated, the revised document is processed as a revision to the previously submitted QA records package.
- Verify that the record originator observes the following precautions while handling and processing materials that will become QA records:
 - a. Ensures that documents and other materials that will become QA records are protected from deterioration, loss, or damage,
 - b. Protects against damage from spillage of liquids,
 - c. Keeps smoking materials and other heat sources a reasonable distance from records,
 - d. Keeps magnetic media records a reasonable distance from sources of magnetic fields (including telephones), and

- e. When not in use or attended, keep documents or materials designated to become QA records locked in a secured area.
- Verify that the record originator replaces, restores or develops a substitute QA record following determination that a record has been lost or damaged to a degree that it is no longer complete or legible. Replacement QA records shall be processed and controlled in accordance with this procedure.
- Verify that the QRC maintains a microfilm copy of QA records packages to be used as the OCRWM Working File.

ILP 12.17.01, Quality Records Center Implementing Line Procedure

Requirements:

- Verify that the QRC Manager maintains the following information from originating organization (OCRWM HQ Branch, Division, or Office).
 - a. A list of the types of QA records and QRPs generated by the originating organization.
 - b. A list of personnel within the originating organization who are authorized to assemble, review and validate QRPs.
- Verify that the QRC Manager assigns a unique QRP identification number upon notification of the creation of a QRP.
- Verify that the QRC Manager maintains a log of QRPs established for each originating organization and the associate QRP identification numbers.
- Verify that the QRC Manager maintains a list of individual QA records in each package, and retains this list at the front of each records package file.
- Verify that the QRC staff reviews each transmittal to ensure that all QA records listed are the actual records received, and that the transmittal has provided all required information.
- Verify that the QRC staff signs and dates the transmittal, retains a photocopy for QRC files, and returns the original to the originator.
- Verify that upon receipt the QRC staff inspects each QA record and that written/typed records are legible, reproducible, and microfilmable.

- Verify that the QRC receives two (2) copies of "Special-Process" and "One-of-a-kind" QA Records.
- Verify that the QRC Manager determines special handling requirements and provides instructions to responsible QRC staff.
- Verify that QA training and qualification records, including auditor certification records, are privileged records that are maintained as a special system of records under the Privacy Act (DOE System 80).
- Verify that QA training and qualification records are processed separately from non-privileged records and are strictly controlled by the QRC Manager.
- Verify training and qualification records are maintained in the QRC as QA records until the QRPs have been completed.
- Verify that corrections to QA records are not made by the QRC staff.
- Verify that when the QRC staff identifies discrepancies with the QA record or QA record transmittal that cannot be resolved with the record originator, that a Rejection Record is initiated and assigned a tracking number.
- Verify that the QRC staff maintains a Rejected Record Log.
- Verify that the QRC Manager provides the record originator with a list of all QA records that have been received and retained under the corresponding QRP identification number, when requested.
- Verify that corrections to QA records are made by the record originator or other authorized individual in accordance with QAAP 17.1.
- Verify that correction to QA records are processed as a revision to the previously submitted records package.
- Verify that the QRC staff:
 - a. Prepares QRC Records Package Transmittals identifying the QRP being transmitted to the CRF.
 - b. Provides special instructions on the QRC Records Package Transmittal for QA training and qualification records packages.
 - c. Retains photocopies of QRC Records Package Transmittals.

- d. Sends the QRP, along with the QRC Records Package Transmittal to the CRF.
- e. Receives the signed transmittal back from the CRF, and retains the transmittal for reference.
- Verify that for revisions to QRPs the QRC staff:
 - a. Assigns the revised QRP a sequential revision number.
 - b. Transmits the TOC with the revised records package to the CRF for processing.
- Verify that access to records by individuals other than OCRWM Program staff and participants has been authorized by the QRC through responsible Program staff and/or the Freedom of Information Action Officer.
- Verify that when authorized personnel request duplicates of records from the QRC that:
 - a. Requests are recorded on a QRC Record Retrieval Request.
 - b. Hardcopy is made from the microfilm of the record.
- Verify that the following QRC documents are handled as QA Records:
 - a. QA Records Package Log
 - b. Rejected Record Log
 - c. QRC Records Package Transmittals

Results:

Implementation of the above requirements was determined to be satisfactory based upon the review of selected open and closed QA records and QA records packages associated with OCRWM quality affecting activities and the various procurements evaluated under QA Program Elements 4.0 and 7.0. One recommendation was offered for OCRWM management consideration as described in Section 6.4.

The effectiveness of QA Program Element 17.0 was determined to be satisfactory.

18.0 AUDITS

The evaluation of QA Program Element 18.0 was based upon review of the procedural requirements, evaluation of applicable documentation produced as a result of procedural implementation, personnel interviews, and examination of objective evidence to determine the degree of compliance with selected requirements from OCRWM implementing procedures QAPs 18.1 and 18.2. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

QAP 18.1, Auditor Qualification

- Verify that the supervisor signs, dates and forwards the Auditor Qualification Record to the Director, OQA when training is complete.
- Verify that the Director, OQA reviews the Auditor Qualification Record and approves qualification of the prospective auditor by signing and dating the approval block.
- Verify that the supervisor verifies the achievement of a minimum of 10 points, using the scoring system described on the back of the Auditor/Lead Auditor Qualification Form and attests to the Lead Auditors ability to communicate effectively by signing and dating the Audit Communication Skills Section of the Lead Auditor Qualification Record.
- Verify that the supervisor verifies the prospective Lead Auditors participation in the minimum number of QA audits or equivalent verifications and that prospective Lead Auditors are administered an examination that meets the criteria in Subsection 6.5 and ensures the examination administrator completes the examination portion of the Lead Auditor Qualification/Certification Record.
- Verify that the supervisor checks the Initial Certification block on the Lead Auditor Qualification/Certification Record, signs that the required training is complete, and forwards it to the Director, OQA for processing.
- Verify that the supervisor attests to the prospective Lead Auditors ability to communicate effectively and checks the prior certification block on the Lead Auditor Qualification/Certification Record and forwards to the Director OQA for processing for Lead Auditors having acceptable prior certification.

- Verify that the Lead Auditor annually documents maintenance of proficiency by completing the Lead Auditor Maintenance of Proficiency Record and that the Director, OQA annually evaluates the proficiency of each Lead Auditor and determines whether to extend the qualification or require retraining before extending the qualification and documents the results on the Lead Auditor Maintenance of Proficiency Record.

Results:

Based upon evaluation of selected Auditor/Lead Auditor Qualification Packages, implementation of QAP 18.1 was determined to be satisfactory. In addition, follow-up to previously identified CAR HQ-93-03 was performed and the results are discussed in Section 5.5.3 of this report.

Requirements:

QAP 18.2, Audit Program

- Verify the Director, OQA directs the development of an annual audit schedule of internal and external audits and updates the schedule as necessary by reviewing and approving the annual audit schedule and updates and distributes the schedule to affected organizations.
- Verify that the ATL develops an Audit Plan, signs and dates the plan, prepares an audit notification letter, and forwards the plan and notification letter to the Director, OQA for review, approval and issuance.
- Verify that the audit team members prepare checklists to guide them in the audit process and completes the checklist recording objective evidence examined and maintaining the list of personnel contacted.
- Verify the ATL conducts a preaudit meeting with the audit team and appropriate management and staff of the organization to be audited and documents this on an attendance record.
- Verify that audit team members draft CARs in accordance with QAP 16.1, as applicable.
- Verify the ATL conducts a postaudit meeting to present the results of the audit and documents attendance on a meeting attendance record.
- Verify that the ATL prepares and signs the audit report and forwards it along with a transmittal letter to the Director, OQA for review, approval, and issuance to the audited organization and any other organizations, as appropriate.

- Verify that the ATL completes assembly of the QA records package in accordance with Section 7.0.

Results:

The evaluation was based on personal interviews and evaluation of selected audit plans, notification letters, one audit report, and supporting documentation from audits in process. As of the date of this audit, the required documentation was complete for one audit. The documentation (i.e., Audit Reports, completed checklists, etc.) was in-process for two additional audits, but had not yet been completed. The audit package that was complete had been performed prior to the effective date of QAP 18.2, Revision 6. The results indicated satisfactory implementation of the above requirements with the exception of one isolated condition. During the course of the audit, it was noted that documented evidence did not exist to demonstrate that two technical specialists used in the performance of audit HQ-94-01 had read and understood the Audit Guide for Technical Specialists. This condition was resolved during the audit and is documented in Section 5.5.2.3 of this report.

Based upon the above, implementation of QAP 18.2 was determined to be adequate.

Overall Effectiveness Statement

Based upon the above, the effectiveness of QA Program Element 18.0 was determined to be satisfactory.

APPENDIX A - HIGH LEVEL RADIOACTIVE WASTE FORM PRODUCTION

The evaluation of QARD Appendix A was based upon selected requirements from the QARD and a review of the approved Waste Acceptance Technical Baseline Documents. Compliance with the waste acceptance documents was based upon personnel interviews and review of the approved baseline documents. Due to the current reorganization and the infancy of this program, only a limited number of program documents are currently undergoing the review process. The remaining documents will be developed in the future.

Requirements:

QARD, Appendix A, High Level Radioactive Waste Form Production

- Verify that Line Management is planning, scheduling, and conducting readiness reviews at significant transitional events both leading up to and during waste form production.

- Verify that Line Organizations are controlling and documenting waste form development in a manner that ensures that resulting waste form qualification data is suitable for use and can be independently reconstructed and evaluated.
- Verify that implementing documents identify responsibilities for performing waste form development work and contain requirements for:
 - a. Selection and qualification of personnel.
 - b. Evaluation of results obtained from waste form development work.
 - c. Documentation of waste form development work including final results.
- Verify that Line Management establishes measures for controlling item and technical modifications to the waste form production process.
- Verify that items and technical documents subject to modification control include:
 - a. Waste form and canistered waste form.
 - b. Processing and process control plans and implementing documents.
 - c. Waste Form Compliance Plans (WCPs), Waste Form Qualification Reports (WQRs), and Production Records.

Results:

The results of the review revealed that the OCRWM has adequately addressed the requirements of the QARD for those selected requirements listed above. Based on interviews with Waste Acceptance personnel and on the flow-down from the Civilian Radioactive Waste Management System Requirements Document to the Waste Acceptance-Systems Requirements Document to the Waste Acceptance Product Specifications (WAPS) through the WCP, it was determined that each producer site provides for the planning, scheduling, conduct of readiness reviews, special reviews, tests, and analysis throughout waste form production. The WCP outlines a plan for compliance with the WAPS by providing data from waste form testing and analysis documented on WQRs. The list of producers include: Savannah River, West Valley, and Hanford.

The Environmental Restoration (EM) and Waste Management (RW) Memorandum of Agreement provides for membership on corresponding Change Control Boards and Technical Review Groups. Both EM and RW participate in Interface Control Working Group and Waste Acceptance meetings.

The effectiveness of QARD Appendix A was determined to be satisfactory.

APPENDIX B - TRANSPORTATION

The evaluation of QARD Appendix B was based upon selected requirements from the QARD and a review of the available documentation and information provided by interview of Office of Waste Acceptance, Storage and Transportation personnel and review of the Request For Proposal (RFP) for Multipurpose Canister (MPC) systems. There has been a relatively small amount of activity due to the current reorganization and the infancy of this program. Documents are currently being developed to implement this program.

Requirements:

QARD, Appendix B, Transportation

- Verify measures are established to assure that affected organizations that perform/conduct transport of spent fuel and high-level radioactive waste have in place a QA program that meets the requirements of 10CFR Part 71, Subpart H and has been accepted by the NRC and OCRWM.

Results:

The results of the review revealed that the OCRWM has adequately addressed the requirements of the QARD for those selected requirements listed above. As a result of interviews with OCRWM personnel, it was identified that the M&O has issued a RFP, "RFP - A20000000-01717-6600-00001, Revision 2," for the MPC. The M&O, through the RFP, Statement of Work, Paragraph 4.2, directs the "Seller" shall employ a QA Program that "furnishes all those planned actions and systematic actions necessary to assure that the MPC systems will perform satisfactorily in service." "The Sellers QA Program(s) shall (1) comply with 10CFR Part 71, Subpart H, and be approved by the NRC, and (2) comply with 10CFR Part 72, Subpart G, and be approved by the NRC as well as comply with the OCRWM QARD and be approved by the Buyer...." The RFP is presently "on the street" but a contract had not been placed at the time of the audit.

The effectiveness of QARD Appendix B was determined to be satisfactory.

SUPPLEMENT I - SOFTWARE

The evaluation of Supplement I was based on selected requirements from the QARD and a review of the proposed EIA implementing procedures. Compliance with QARD requirements was based upon review of the procedural requirements, evaluation of

applicable documentation produced as a result of procedural implementation, interviews with EIA and Z, Inc. personnel, and examination of objective evidence to determine the degree of compliance with selected requirements from the OCRWM QARD and EIA proposed procedures HLP-SI.1Q, Control of EIA Software, and the Lifecycle Plan for the Form RW-859, Nuclear Fuel Data Survey and the PC-INM.

The specific requirements selected for evaluation are listed below.

Requirements:

QARD, Supplement I, Software

- Verify documentation for the development of the computer software at specific lifecycle stages.
- Verify software verification and software validation process for developed or modified software.
- Verify software documentation should consist of:
 - Requirements Information
 - User Information
 - Validation Information
 - Information on Reviews
 - Functional Requirements
 - Design Requirements Information
 - Verification Information
- Verify software Configuration Control system being used to enforce the orderly creation, distribution and subsequent changes to software baselines.
- Verify software verification and software validation activities are being accomplished or reviewed by an independent individual or organization, one who did not work on the original software development or modification.
- Verify software verification is performed and documented to ensure that the products of a life cycle phase meet the requirements established for that phase.
- Verify software validation of modifications to released software items includes regression testing.
- Verify each version or revision of a software item is uniquely identified and labeled.

- **Verify changes to baseline elements, including retirement and withdrawal, are being formally controlled and documented.**
- **Verify documentation for changes to baseline elements contain a description of the change, the rationale for the change, and the identification of affected baseline elements.**
- **Verify changes are being formally evaluated and approved by the organization responsible for approving the baseline element.**
- **Verify changes are being made to software baselines and information concerning approved changes are being transmitted to all organizations affected by the changes.**
- **Verify configuration status accounting includes the following:**
 - **A listing of the approved baseline elements and unique identifiers.**
 - **The status of proposed and approved changes to the baseline elements.**
 - **A brief chronology of the software items, including descriptions of the changes made between versions of software items.**
- **Verify defect reporting and resolution system is being integrated with the software configuration management system to ensure formal processing of defect resolutions.**
- **Verify software defect reporting and resolution systems include the following controls:**
 - **Documentation and resolution of defects.**
 - **Review and approval of resolutions before changes are made to baseline elements.**
 - **Notification of affected organizations.**
- **Verify defects identified in software that adversely impacts previous applications and will result in a condition adverse to quality are documented and controlled in accordance with Section 16.0 of the QARD.**
- **Verify media containing a copy of the completed/released software items are being controlled to prevent inadvertent damage or degradation.**

- Verify affected organizations have established procedures for controlling and documenting the use of released software items and that the procedures are sufficient to allow an independent repetition of the use of software.
- Verify software uses are being approved and independently reviewed to ensure that the software selected is applicable to the problem being solved and that inputs and assumptions are valid and traceable.
- Verify if the use of a software item falls outside the range of validation, further validation is being performed prior to use.

Results:

The results of the review revealed that EIA has not adequately addressed the requirements of the QARD for those selected requirements listed above. EIA does however meet the requirements imposed upon them by the Office of Statistical Standards (OSS). The OSS standards are detailed in their requests for documentation. However, they do not meet the QARD Supplement I requirements listed above. These conditions were previously identified and documented on CARs HQ-92-022, -023, and -029.

The effectiveness of QARD Supplement I was determined to be unsatisfactory.

TECHNICAL EVALUATION:

The EIA is performing two tasks subject to the QARD for OCRWM. One task is to develop and maintain the RW-859 Nuclear Fuel Data Survey. This system is a source of detailed technical data relative to potential repository wastes. The data describes factors such as physical descriptions and chemical composition of spent nuclear fuel. The second task requires the development and maintenance of the PC-INM. This computer model provides nuclear fuel cycle forecasts for uranium and enrichment services requirements, spent fuel discharges, and annual nuclear electric generation forecasts.

The evaluation of the Form RW-859 Nuclear Fuel Data Survey and the PC-INM was based on interviews with EIA and Z, Inc. personnel and examination of objective evidence. The areas evaluated to verify the technical adequacy of implementation are listed below:

- The programmer's knowledge of the impact of the software that they are required to develop and modify.
- The programmer's understanding of the different computer programming languages and software programs that they are using to generate the software system.

- The impact of the PC-INM projections data on quality-affecting work within OCRWM.
- The induced round-off error in the PC-INM projections resulting from transferring the system to a personal computer (compared to using the mainframe computer).
- Methods used in the test plan to verify and validate the product of the test.
- Amount of error checking and corrections to data received from the utilities.
- Access control for the software and the system that houses the software.
- Format of the data in the database.
- Extent of the changes being made to the software system.
- Corrective actions, if any, are taken when it is determined that an error or defect in encountered in the software.
- The extent of the problems with the data when it arrives from the utilities.
- The type of controls used to handle the software and data within the office.
- Actions taken if the data in the transmitted copy needs to be updated prior to incorporation into the database.
- Accessible copies of out of date software systems.
- The programmers interest in making the data entry system more user friendly for the utilities.
- List where the copies of the data tapes are being sent during the review and approval process.

Results:

The results of the evaluation revealed that EIA and Z, Inc. technical personnel hold a solid understanding of the programs and programming languages required to perform their assigned tasks. All of the programs being used meet the technical performance requirements being placed upon them. Changes to the programs primarily are restricted to cosmetic and user-friendliness rather than errors or deficiencies in the coding.

Early in the audit, questions concerning the need for OCRWM QA controls for the

PC-INM projections information were asked by EIA and Z, Inc. personnel. A concentrated effort was initiated to determine the uses of the results from these programs. Users at Battelle Pacific Northwest Laboratories, Oak Ridge National Laboratories, Roy F. Weston, Inc., the OCRWM M&O contractor, EIA, and OCRWM were contacted during this search. It was determined that the RW-859 data and the first 10 years of the "no new orders" projection data from the PC-INM have been used in preparation of the Design Procurement Specification for the MPC. In addition, the data will be used as input to the Characteristics Data Base.

This usage causes both the RW-859 and the PC-INM to be subject to QARD requirements as defined by QAAP 2.3, Establishing Quality Assurance Program Controls, Paragraph 5.2.1.

The audit team concluded that the processes used were technically adequate in accordance with EIA standards; however, those processes were not documented and approved in accordance with OCRWM QARD Supplement I requirements. Therefore, the results of the technical review of the RW-859 and PC-INM are considered to be indeterminate. These conditions were previously identified and documented on CARs HQ-92-022, -023, and -029. One recommendation was offered for OCRWM management consideration as described in Section 6.5.

ATTACHMENT 3

List of Objective Evidence Reviewed During the Audit

QA PROGRAM ELEMENT 1.0, "ORGANIZATION"

Procedures:

QAP 1.1, Revision 0, "Organization"

Objective Evidence:

Memorandum of Reorganization from RW-1, dated 7/8/94
Quality Assurance Controls Document, Revision 1, dated October 1990
Energy Information Administration Organization Chart, dated October, 1993

QA PROGRAM ELEMENT 2.0, "QUALITY ASSURANCE PROGRAM"

Procedures:

QAAP 2.1, Revision 2, "Indoctrination and Training"
QAAP 2.2, Revision 1, "Verification of Personnel Qualifications"
QAAP 2.3, Revision 1, "Establishing Quality Assurance Program Controls"
QAP 2.7, Revision 2, "Management Assessment"
QAP 2.8, Revision 1, "Surveillance"
QAP 2.10, Revision 0, "Hold Points"

Objective Evidence:

QAAP 2.1

Initial I&T training matrices and all quarterly updates were reviewed for the following individuals:

Charles Betts; Vance Cannady; Conrad Coloumbe; Walter Coutier; Kathy Gibbard; and Craig Little*

* NOTE: These records were reviewed by R. L. Maudlin

Lesson Plans:

LP TR05, Problem Identification Control, Revision A
LP TR02B, Technical Document Preparation and Review, Revision A
LP TR02A, Preparation and Control of QA Documents, Revision B

Student Training History Report (Training Data Sheets) were reviewed for the following individuals:

Charles Betts, 7/21/94
Conrad Coloumbe, 7/21/94

Vance Cannady, 7/21/94
Walt Coutier, 7/21/94

QAAP 2.2

QRC personnel record packages examined:

SY80-92-0312.00	Beesabathuni (Ram) Murthy
SY80-92-0624.00	Carl Weber
SY80-93-0868.00	Dennis C. Threatt
SY80-93-0940.00	Dennis C. Threatt
SY80-93-0406.00	Marlin Horseman
SY80-92-0475.00	Marlin Horseman
SY80-92-0318.00	Dwight Shelor
SY80-92-0324.00	Ronald Milner
SY80-93-0941.00	Walter R. Coutier
SY80-93-0851.00	Walter R. Coutier
SY80-92-0138.00	Thomas Preisser
SY80-93-0850.00	Robert C. Baumbach
SY80-93-0953.00	Robert C. Baumbach

QATSS office working files examined:

Dennis C. Threatt
Walter R. Coutier
Marlin Horseman

Robert C. Baumbach
Thomas Preisser

Personnel folders for the following EIA and Z, Inc. personnel:

Craig Little
Kathy Gibbard
David Andress

QAAP 2.3

QA Controls Document, Revision 1, control copy #00393

QAP 2.7

RW-131 Action Plan Response, dated 6/22/94, to 1993 Management Assessment Report

QA Record Package QRP-93-0766.00 for 1992 Management Assessment

QA Record Package QRP-93-0767.00 for 1993 Management Assessment

Training record files:

92-0004.00	92-0456.00	92-0009.00	92-0457.00
92-0321.00	92-0585.00	92-0461.00	93-0946.00
92-0458.00	93-0862.00		

QAP 2.8

QA Surveillance Records:

HQ-SR-94-02, conducted 01/10-14/94
HQ-SR-94-03, conducted 03/14-16/94
HQ-SR-94-04, conducted 03/08-10/94
HQ-SR-94-08, conducted 04/04-14/94

QAP 2.10

Hold Point Status Log, dated 3/11/94
Hold Point Status Log, dated 4/30/94
Hold Point Status Log, dated 7/15/94

QA PROGRAM ELEMENT 4.0, 'PROCUREMENT DOCUMENT CONTROL' AND QA PROGRAM ELEMENT 7.0, 'CONTROL OF PURCHASED ITEMS AND SERVICES'

Procedures:

HLP 7.1Q, Revision 0, "Procurement of Services"

Objective Evidence:

Work Authorization Directives WADs 94-01-02, 94-03-01, 94-03-03, 94-09-10, 94-09-20, 94-09-32/33, 94-09-35, and 94-09-36

Task Directives TDs 94-03, 94-03a, and 94-14

Program Guidance Letters to RW-32, dated 4/4/94, and to RW-40, dated 5/23/94

QA PROGRAM ELEMENT 5.0, "IMPLEMENTING DOCUMENTS"

Procedures:

QAP 5.1, Revision 6, "Quality Assurance Program Procedures"

Objective Evidence:

Document Action Requests examined:

DAR-012 for procedure HLP-6.1Q, Revision 0
DAR-014 for procedure HLP-7.1Q, Revision 0
DAR-027 for procedure HLP-2.1Q, Revision 0
DAR-033 for procedure HLP-SI.1Q, Revision 0

QARD Implementation Matrices (QARD Matrix) examined:

QARD Matrix Section 6 for procedure HLP-6.1Q
QARD Matrix Section 2, Section 4, and Section 7 for procedure HLP-7.1Q
QARD Matrix Section 2 for procedure QAP-2.5

QA PROGRAM ELEMENT 6.0, "DOCUMENT CONTROL"

Procedures:

QAAP 6.1, Revision 2, "Document Control "
QAP 6.2, Revision 2, "Document Review "

Objective Evidence:

QAAP 6.1

QA Controlled QAAP Distribution List, Revision 49
QA Controlled QAAP Distribution List, Revision 52
QA Controlled QAAP Distribution List, Revision 50
QA Controlled ILP Distribution List, Revision 6

Distribution list for ILP 12.17.01, dated 1/15/92

Document Transmittal, dated 4/18/94, to holders of controlled document numbers 00167, 00174, 000257, and 00404 for removal of documents from controlled distribution lists

Document Transmittal, dated 4/26/94, for issuance of procedure HLP-7.1Q, Revision 0 and associated TOC to holder of QAAP manual, copy numbers 56 and 382

QATSS Interoffice Memorandum, dated 3/24/94, from Mike Donovan to R. W. Clark regarding controlled copies of OCRWM QARD and procedures

Science Applications International Corporation Letter 1060-0072, dated 9/24/93, from L. Wagner to D. G. Horton

QRP-94-0849.00, transmittal to QRC for QAAP Manual Distribution List, Revision 52, dated 7/12/94

Procedures HLP 6.1Q, Revision 0 and HLP 7.1Q, Revision 0 cover sheets for effectivity date and revision number

Notification to holder of controlled copy no. 100 regarding TOC of QAAP Manual

QAAP Manual TOC, Revision 49 to holders of controlled copies 00012, 00042, 00211 and 00231

QAP 6.2

DRRs and associated comment sheets for the following procedures and documents:

- DRR for procedure HLP 2.1Q, Revision 0, Draft A
- DRR for procedure HLP 6.1Q, Revision 0, Draft A
- DRR for M&O RTN Matrix
- DRR for EM-343 QARD Implementation Matrix
- DRR for HLP-SI.1Q, Revision 0, Draft A

QA PROGRAM ELEMENT 16.0, "CORRECTIVE ACTION"

Procedures:

- QAP 16.1, Revision 6, "Corrective Action"
- QAP 16.3, Revision 0, "QA Program Trend Evaluation"

Objective Evidence:

QAP 16.1

The following CAR Packages were reviewed:

<u>CAR Number:</u>	<u>Status:</u>	<u>Date:</u>
HQ-92-022	Open	10/21/92
HQ-92-023	Open	10/21/92

HQ-92-029	Open	10/21/92
HQ-93-013	Open	3/18/93
HQ-93-024	Closed	5/21/93
HQ-93-029	Closed	8/04/93
HQ-94-006	Open	3/29/94
HQ-94-008	Open	3/29/94
HQ-94-013	Open	4/28/94

QAP 16.3

Quality Trend Report (1/93-12/93)
Quality Trend Report (4/93-3/94)
HQA input to trend report, dated 1/11/94
HQA input to trend report, dated 10/7/93
CAR YM-93-070, dated 7/14/93

QA PROGRAM ELEMENT 17.0, "QUALITY ASSURANCE RECORDS"

Procedures:

QAAP 17.1, Revision 2, "QA Records Management"
ILP 12.17.01, Revision 2, "Quality Records Center Implementing Line Procedure"

Objective Evidence:

QA Records Package Identification Numbers Log, dated 7/16/94

QA Records Package Identification Number Status Report, dated 7/16/94

OCRWM List of Employees Performing Assignments Against the QARD

OCRWM QA Records Center Individual Records Report for QRP-91-0432.00

OCRWM QRC Systems 80 Package List

OCRWM QRC Records Notice Sheet for QRP-93-0748.00 for one-of-a-kind records, RW-40 (Z, Inc.), dated 7/31/91

OCRWM QA Records Package Log (page), Special Record for Microfilm Received from CRF 7-27-93, close-out source numbers RW-431-92-0007, RW-3-93-5070 through RW-3-93-5080, Reel No. 20024-1017-1054, RW-131

Z, Inc. memorandum, dated 3/25/94, from C. Little to QRC listing records expected for both RW-859 and PC-ICM work.

Records Package Transmittals:

RW-131

QRP-93-0742.00 QRP-92-0595.00 QRP-90-0370.00

RW-22

QRP-90-0057.00 QRP-90-0152.00 QRP-90-0153.00
QRP-90-0154.00

RW-321

QRP-90-0095.00 QRP-90-0097.00 QRP-90-0101.00
QRP-90-0104.00 QRP-91-0566.00 QRP-92-0629.00

RW-323

QRP-92-0671.00

RW-52

QRP-93-0707.00

RW-53

QRP-93-0707.00

Other Records Packages, Transmittals, and TOC:

QRP-91-0568.00 MRS Systems Requirements Document, Revision 0, dated 6/17/94.

Systems 80 Records Package, SY80-92-0156.00 for Auditor/Lead Auditor/Tech. Spec., dated 4/20/93, marked "Privileged Records - Special Processing Required"

Systems 80 Records Package, SY80-92-0157.00 for Auditor/Lead Auditor/Tech. Spec., dated 4/20/93, marked "Privileged Records - Special Processing Required"

Systems 80 Records Package, QA Records Transmittal, dated 7/13/94, for RW-131, Annual Quality Records Package Closing of Records, containing 39 individual SYS80 Records

QA Records Transmittal, dated 5/12/94, INM tape and model package

QA Records Transmittal, dated 6/4/93, RW-859 form information

QA Records Package TOC for W. Bolden QA Qualification and Training, dated 2/10/94

QA PROGRAM ELEMENT 18.0, "AUDITS"

Procedures:

QAP 18.1, Revision 3, "Auditor Qualification"
QAP 18.1, Revision 4, "Auditor Qualification"
QAP 18.2, Revision 6, "Audit Program"

Objective Evidence:

QAP 18.1

The following Auditor and Lead Auditor (L/A) Qualification Packages were reviewed:

<u>Name</u>	<u>Status</u>	<u>Initial</u>	<u>Recert</u>
W. Coutier	L/A	03/03/94	N/A
T. Swift	L/A	10/08/92	10/19/93
F. Bearham	L/A	10/03/91	10/09/92 & 11/02/93
C. Coloumbe	Auditor	10/18/93	N/A
C. Betts	Auditor	05/18/94	N/A
M. Horseman	L/A	03/29/93	2/24/94
D. Threatt	Auditor	09/07/93	N/A

QAP 18.2

OCRWM FY 94 Audit Schedule, Revision 3

Audit Plans for audits HQ-94-01, HQ-94-02, and HQ-94-03

Audit Report Package for audit HQ-94-01

In process documentation for audits HQ-94-02 and HQ-94-03 (i.e., Attendance Records, Checklists, etc.)

Training records for Technical Specialists who participated in audit HQ-94-01 (i.e., Attachment IV)

APPENDIX A - HIGH LEVEL RADIOACTIVE WASTE FORM PRODUCTION

Procedure:

QARD RW/DOE-0333P, Revision 0, Appendix A, High Level Radioactive Waste Form Production

Objective Evidence:

DOE-RW/EM Memorandum of Agreement for Coordination of Waste Acceptance Process Activities between The Office of Civilian Radioactive Waste Management (RW) and The Office of Environmental Restoration and Waste Management, dated 10/4/91

OCRWM High-Level Radioactive Waste Requirements and Interactions, a presentation by Steve Gomberg, dated 6/15/94

OCRWM Waste Acceptance Systems Requirements Document, Revision 1, dated March 1994 (SRD)

DOE-EM Waste Acceptance Product Specification, Revision 0, for Vitrified High-Level Waste Forms

DOE-DWPD Waste Form Acceptance Plan, WSRC-IM-91-116-0, Part 6, Item 100, Quality Assurance Specification, Revision 2, dated 6/93 (WCP)

Memorandum of Reorganization from RW-1, dated 7/8/94

APPENDIX B - TRANSPORTATION

Procedure:

QARD RW/DOE-0333P, Revision 0, Appendix B, Transportation

Objective Evidence:

M&O RFP, A20000000-01717-6600-00001, Rev. 2, dated 5/20/94, Page 24, Section 4.2, "MPC Statement of Work"

DOE-OCRWM Letter from D. Shelor to C. J. Haughey, NRC, dated 6/21/94

SUPPLEMENT I - SOFTWARE

Procedure:

QARD RW/DOE-0333P, Revision 0, Supplement I, Software

Objective Evidence:

EIA Standard 88-03-02, Data Systems Development - October 1985

EIA Standard 88-03-03, Data Systems Documentation - October 1985

EIA Standard 91-01-01, Model Acceptance Standard - February 1991

EIA Standard 91-01-02, Active Model Inventory Requirements - October 1991

EIA Standard 91-01-03, Model Documentation - October 1991

EIA Standard 91-01-04, Model Archival - October 1991

EIA Standard 91-01-05, Proprietary Models - June 1992

HLP-SI.1Q, Control of EIA Software - undergoing development

**Lifecycle Plan for the Form RW-859 Nuclear Fuel Data Survey and the PC-INM
- undergoing development**

For the current copy of the RW-859 Program:

Data Requirements Document - August 1992

Functional Requirements Document - October 1992

System/subsystem Specification - November 1992

Program Specification - December 1992

Data Base Specification - January 1993

Test Plan - February 1993

Test Analysis Report - March 1993

Data User's Manual - January 1993

Operations Manual - February 1993

Program Maintenance Manual - March 1993

**Nuclear Fuel Cycle Requirements System (PC-INM) Benchmarking Procedures Report
- January 1992 and January 1993**

DOE/EIA-M051(92) PC-INM Model Documentation

QA Transmittal of RW-859 Documentation - June 1993

QA Transmittal of PC-INM Documentation - May 1994

EIA Proposed Work Program in Support of the Office of Civilian Radioactive Waste Management for Fiscal Year 1994, dated December 1993

ATTACHMENT 4

Information Copy

of

Corrective Action Request

ORIGINAL
 THIS IS A RED STAMP

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO.: <u>YM-94-060</u> PAGE: <u>1</u> OF <u>2</u> QA
CORRECTIVE ACTION REQUEST		
1 Controlling Document QAAP-2.2, Revision 1, Verification of Personnel Qualifications		2 Related Report No. OCRHM QA Audit YMP-94-07
3 Responsible Organization RW-3.1	4 Discussed With R. Clark/L. Wagner	
5 Requirement: QAMP-2.2, Revision 1 states: (1) Paragraph 6.1.1 - "Supervisors shall develop position descriptions for those employees who perform under their direct supervision, activities subject to QA Program control." (Continued on next page)		
6 Adverse Condition: Contrary to the above requirements, a review of records for three QATSS personnel revealed the following: (1) No objective evidence of documented position descriptions, (2) No objective evidence of statements of qualifications for positions being held, (3) No objective evidence that a copy of the completed PQS with supporting documentation has been transmitted to the appropriate administrative support personnel as evidenced by the signed transmittal sheet at the HQ QATSS office, (4) Records at the QAC are incomplete, and (5) The working files at the HQ QATSS office are incomplete.		
9 Does a Significant Condition Adverse to Quality exist? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	3 Response Due Date: 20 Working Days from Issuance
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination		
12 Recommended Actions: 1) Perform an investigation to determine extent of deficiencies. 2) Correct all deficiencies cited and any other deficiencies found during the investigation to determine the extent of the deficiency. (Continued on next page)		
7 Initiator Raul A. Bincjosa <i>JE Rogers for</i> ^{7/29/94}	14 Issuance Approved by: QADD <i>[Signature]</i> for Date 7-29-94	
15 Response Accepted QAR _____ Date _____	16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR _____ Date _____	18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____	20 Closure Approved by: QADD _____ Date _____	

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

6 CAR NO.: YM-94-060
PAGE: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

5 Requirements (continued)

- (2) Paragraph 6.2.2 - "The supervisor shall complete the Position Qualification Statement (Attachment 2) (PQS) and attach objective evidence of verification, such as statements from colleges, and signed and dated telephone conversation records that support the stated education and experience."
- (3) Paragraph 6.3.1 - "The supervisor shall transmit a copy of the completed PQS with supporting documentation to the appropriate administrative support personnel...to complete the hiring process."
- (4) Paragraph 6.3.2 - "Upon completion of the hiring process, the supervisor shall transmit the completed PQS with supporting documentation directly to the Quality Records Center (QRC) in accordance with QAMP-17.1, QA RECORDS MANAGEMENT."
- (5) Paragraph 6.3.3 - "The supervisor shall also retain a copy as the office working file...."

13 Recommended Action(s) (continued)

- 3) Determine the root cause and install or reinforce existing controls to prevent recurrence.