Rec'd with letter 3/26/93

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

AUDIT REPORT

OF THE

CRWMS M&O ACTIVITIES

VIENNA, VA

AUDIT HQ-93-03

FEBRUARY 1 - 5, 1993

Prepared by: R Dennis Brown Date: 3/4/93
R. Dennis Brown
Audit Team Leader
Headquarters Quality Assurance Division

Approved by: [signature] Date: 3/26/93
Donald G. Horton
Director
Office of Quality Assurance

102.7

1.0 EXECUTIVE SUMMARY

OCRWM's Office of Quality Assurance performed a QA audit of the CRWMS M&O activities in Vienna, Virginia February 1 - 5, 1993. This was the first OCRWM audit of M&O activities. The audit team concluded that M&O QA Program implementation was marginally effective. Of the eleven criteria audited, two were determined to be ineffective. Three criteria were marginally effective, three were effective, and three were determined to be indeterminate.

Eight deficiencies requiring only remedial action, were identified and corrected during the course of the audit. Nine Corrective Action Requests (CARs) were written to document those deficiencies that could not be corrected during the audit or that required more than remedial action to correct. The CARs pertained to procedural preparation and adequacy, computer software products identifiers, audits, auditor qualification, verification of education, and indoctrination and training. Additionally, nine recommendations were offered for M&O management's consideration.

2.0 SCOPE

The audit evaluated the CRWMS M&O's QA Program adequacy, compliance, and effectiveness as implemented at its offices in Vienna, Virginia.

2.1 QA Program Elements/Requirements

The following QA program elements were evaluated during the audit:

1 - Organization
2 - Quality Assurance Program
3 - Design Control
4 - Procurement Document Control
5 - Instructions, Procedures, Plans, and Drawings
6 - Document Control
7 - Control of Purchased Items and Services
16 - Corrective Action
17 - Quality Assurance Records
18 - Audits
19 - Computer Software

Requirements were drawn from the DOE/RW-0214, *Quality Assurance Requirements Document* (QARD); M&O *Quality Assurance Program Description* (QAPD), Revisions 2 and 3; and the applicable M&O *Quality Administrative Procedures* (QAPs).

2.2 Technical Areas

No Technical Specialists were utilized on the audit since the M&O had just began to implement QA Program Element 3 under its own QA Program. Prior design control activities performed by M&O personnel had been accomplished in accordance with the OCRWM QA Program.

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members (see Attachment 1 for initial assigned areas of responsibility) and observers.

Title	Name	Organization
Audit Team Leader	R. Dennis Brown	CER/HQAD
Auditors	Fred Bearham	CER/HQAD
	Pete Chomentowski	Weston/HQAD
	Leonard Gordon	Weston/HQAD
	Hank Greene	CER/HQAD
	Marlin L. Horseman	CER/HQAD
	Robert L. Howard	Weston/HQAD
	F. Hugh Lentz	CER/HQAD
	Lester W. Wagner	CER/HQAD
Observers	John T. Buckley	USNRC, DC
	Jack G. Spraul	USNRC, DC
	Robert Brient	SWRI/USNRC
	Sam Horton	SAIC/YMQAD

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at the CRWMS M&O offices in Vienna, Virginia on February 1, 1993. Daily debriefings were held with the General Manager and his senior staff. The postaudit meeting was held at the M&O offices in Virginia on February 5, 1993.

Personnel contacted during the audit are listed in Attachment 2. The list also indicates personnel who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that implementation of the M&O QA Program was marginally effective.

Three QA Program Elements were effectively implemented: 1 - Organization, 2 - QA Program, and 19 - Computer Software.

Implementation of three QA Program Elements were marginally effective: 5 - Instructions, Procedures, and Drawings; 6 - Document Control; and 17 - Quality Assurance Records.

Two QA Program Elements were ineffectively implemented: 16 - Corrective Action and 18 - Audits.

Due to the lack of implementation, QA Program Elements 3 - Design Control, 4 - Procurement Document Control, and 7 - Control of Purchased Items and Services were considered to be indeterminate.

5.2 QA Program Audit Activities

Details of the QA program audit activities, including objective evidence reviewed, are included in Attachment 3.

5.3 Technical Activities

No technical audit activities were performed. See Paragraph 2.2.

5.4 Summary of Deficiencies

The audit team identified 17 deficiencies during the audit. Eight deficiencies were corrected prior to the postaudit meeting.

A synopsis of the deficiencies documented as Corrective Action Requests (CARs) and those corrected during the audit are detailed below. Copies of the CARs are included as Attachment 4.

5.4.1 Corrective Action Requests (CARs)

As a result of the audit, the following CARs were issued:

CAR HQ-93-13

M&O Quality Administrative Procedures (QAPs) did not adequately address qualitative and quantitative acceptance criteria for performing activities affecting quality. Numerous examples of various M&O QAP deficiencies are identified in this CAR.

CAR HQ-93-14

Computer software product identifiers did not agree with QAP-19-2 requirements.

CAR HQ-93-15

Deficiencies identified on audits and surveillances were not being documented on CARs as required by QAP-16-1.

CAR HQ-93-16

Lead Auditor, Auditor, and Technical Expert qualification documentation and records were not complete as required by QAP-18-1.

CAR HQ-93-17

QA Program Element effectiveness data was not being prepared as required by QAP-18-2.

CAR HQ-93-18

QAPs were not being prepared in accordance with the requirements of QAP-5-1.

CAR HQ-93-19

The M&O was not adequately verifying the educational background of personnel as required by QAP-2-2.

CAR HQ-93-20

Personnel were performing quality affecting work prior to receiving appropriate indoctrination.

CAR HQ-93-21

Audit reports did not contain all required information.

5.4.2 Deficiencies Corrected During the Audit

Deficiencies which were considered isolated in nature and only required remedial action were corrected during the audit. The following deficiencies were identified and corrected during the audit:

A. The QAP-2-9 records package did not contain the final issued procedure. The original was located and placed in the package during the audit.

B. QAP-3-6 requires that "the software CM/design organizations shall complete the request/approval for CI identifier and submit the original to the M&O CM organization manager for review and approval."

   The software CM organization had not submitted software configuration item identifiers to the CM organization. Once the omission was identified the software CM organization submitted all assigned CI numbers to the CM organization. No further corrective action was deemed necessary.

C. Paragraph 3.7 of the M&O QAPD states "Internal and external design interfaces are identified by an interface control document and controlled in accordance with the M&O Configuration Management Plan and approved procedures."

   The M&O does not use the Configuration Management Plan to control design interface. The Manager, Systems Engineering indicated that Interface Control Documents would be developed after the CRWMS interface specification is complete; this is consistent with the OCRWM Systems Engineering Management Plan, Revision 2.

   The QA Manager directed his staff (memo dated Feb. 3, 1993) to delete the reference to the Configuration Management Plan in the forthcoming Revision 4 to the M&O QAPD. The QAPD will be withdrawn as soon as the M&O begins to implement the recently issued revision to the OCRWM QARD (DOE/RW-0333P).

D. Paragraph 3.3, Design Inputs, in the M&O QAPD references "10CFR70". The correct reference should be "10CFR72".

The M&O QA Manager will changes the reference to "10CFR72" in the forthcoming Revision 4 to the QAPD (memo dated Feb. 3, 1993).

E. QAP-5-1 requires that "all drafts that proceed beyond the preliminary draft stage but were never finalized with pertinent correspondence including Procedure Review Records and reason(s) for not being finalized" be treated as QA records. Revision 2 of QAP-2-3 was never issued; no written justification existed for it not being issued.

A memo dated February 2, 1993 was written to the QAP-2-3 records package explaining why Revision 2 was never issued. This was an isolated case and requires no further corrective action.

F. During the audit it was discovered that the CAR Status Log had several discrepancies. CAR records were reviewed and the Log was corrected prior to the postaudit meeting.

G. The M&O just recently had enough data to trend CARs. The Quarterly Quality Assurance Program Status and Trend Report had not been issued yet. During the audit the QA Manager formally issued the initial report (February 3, 1993).

H. QAP-17-6 requires that microfilm rolls be labelled with specific information. A review of the labelling indicated that not all information had been provided. The identification was reviewed and labelling was revised during the audit.

6.0 RECOMMENDATIONS

6.1 During interviews it was indicated that the Training Department could be more proactive in aiding QA Program implementation if they knew about M&O quality problems in a more timely manner. The Training Department should be included in the distribution of M&O audit reports, CARs, surveillance reports, and similar verification activity information. The Training Department could then factor more quality issues into the various training courses.

6.2 There are several requirements for "plans" identified throughout the M&O QA Program (eg., in QAP-6-1 and the M&O QAPD). The audit team recommends that the QA Program requirements for "plans" be re-evaluated with respect to the level of controls required for various Plans. For example, Technical Document Preparation Plans are being used to control certain M&O activities and do not require QAP-6-1 controls.

6.3 QAP-3-8, Paragraph 5.2 requires verification of procurement specifications. Step 5.2.4 requires that the verifier sign a Certification of Procurement Specification after all interdiscipline and external reviews are complete. This step appears in the procedure before the steps requiring interdiscipline and external reviews (Paragraphs 5.3 and 5.4).

QAP-3-8 should be rearranged to match the intended sequence of events.

6.4 The QAP-4-1 definition of procurement document should include "Memorandum Purchase Order" and "Task Order". The audit team identified that these were the documents which would most likely transmit QA program requirements to M&O contractors.

6.5 QAP review criteria/instructions included with draft procedures require that all reviewers evaluate the QAP against the QARD, the QAPD, and all input documents referenced in Paragraph 3.0 of the draft QAP. This requirement certainly does not provide for an efficient use of capability and time. In addition, the practice may weaken the review. Most reviewers are not familiar with all referenced documents. They might assume that someone with more expertise will review the draft procedure against certain referenced standards.

The M&O should provide more specific duties or responsibilities when assigning QAP review criteria.

6.6 The M&O may consider placing an identifier (such as a 'Q') on documents which are subject to the requirements of the OCRWM QARD.

6.7 The audit team noted that QAP-17-1 definitions of "Authentication", "Validation," and "Completed" were not universally understood by M&O personnel. The audit team strongly recommends that these terms be clarified and the process be reviewed for improvement.The process should ensure adequate record protection and retrievability throughout the record's lifetime.

6.8 The audit team noted a lack of planning for the logical preparation of QA records packages. Multiple audit reports (93-NSA-01 and 92-NSA-02) were located in the same records package. Also, one records package contained mixed audit reports and audit logs. In some cases records sources felt that the table of contents (transmittal) was only used to identify the records they were sending to the LRC and the LRC would know how to package them. The M&O should clarify the records package submittal and validation processes identified in QAP-17-1.

6.9 The M&O should clearly document when Software Configuration Control Board (SCCB) meetings are considered "emergency meetings". Limited attendance requirements are acceptable pursuant to QAP-19-2 for these types of SCCB meetings.

7.0 LIST OF ATTACHMENTS

Attachment 1: Audit Team Assignments
Attachment 2: Personnel Contacted
Attachment 3: Audit Details (including a listing of objective evidence)
Attachment 4: Copies of the CARs

ATTACHMENT 1

Audit Team Assignments

Audit Team Leader: Dennis Brown

TEAM	PERSONNEL	CRITERIA	IMPLEMENTING PROCEDURES
"A"	Les Wagner Hugh Lentz Dennis Brown	16, 18, 19	QAPs 2-4, 2-5, 16-1, 16-2, 18-1, 18-2, 19-1, 19-2
"B"	Rob Howard Len Gordon Pete Chomentowski	3, 4, 7	QAPs 3-1, 3-2, 3-5, 3-6, 3-7, 3-8, 3-9, 3-13, 3-14, 4-1, 7-1
"C"	Fred Bearham	1, 2	QAPs 1-1, 2-1, 2-2, 2-3, 2-6, 2-9
"D"	Marlin Horseman Hank Greene	5, 6, 17	QAPs 5-1, 6-1, 17-1, 17-2, 17-4, 17-5, 17-6

ATTACHMENT 2

Personnel Contacted During The Audit

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
W. Bailey	M&O/TRW	Manager, Systems Analysis		X	
K. Baxter	M&O/TRW	Records Analyst I		X	
F. Bearham	CER	Auditor	X		X
B. Bernhardt	M&O/TRW	Subcontracts and Purchasing Manager		X	
W. Black	M&O/TRW	Charlotte, QA staff		X	
R. Boyt	M&O/TRW	Systems Engineer		X	X
J. Brackett	M&O/Duke	M&O QA Manager	X	X	X
W. Bradley	M&O/Duke	QA Manager, MRS			
R. Brient	USNRC	Observer	X		
D. Brown	CER	Audit Team Leader	X		X
J. Buckley	USNRC	Observer	X		
G. Carruth	M&O/TRW	Manager, Systems Integration	X	X	X
P. Chomentowski	Weston	Auditor	X		X
G. Chulick	M&O/B&W	Manager, Training	X	X	X
M. Collins	M&O/TRW	QA Engineer	X		X
J. Cowles	M&O/TRW	Chief Engineer	X		X
S. Cummings	M&O/TRW	Mgmt. Systems Analyst			X
H. Dameron	M&O/TRW	Sr. Technical Specialist	X	X	X
T. Eaves	M&O/Duke	QA Verification Specialist II		X	
J. Elliott	M&O/Duke	Manager, Requirements/ Licensing	X		
W. Farmer	M&O/Duke	Sr. Technical Specialist		X	X
M. Feruque	M&O/TRW	Engineer/Scientist		X	

ATTACHMENT 2

Personnel Contacted During The Audit

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
S. Gibson	M&O/TRW	Records Analyst I		X	
R. Godman	M&O/TRW	Assistant General Manager, Operations	X	X	X
L. Gordon	Weston	Auditor	X		X
A. Greenburg	M&O/RDA	Senior Staff	X		
H. Greene	CER	Auditor	X		X
V. Harris	M&O/TRW	Sr. Executive Secretary	X		X
S. Hoffman	M&O/TRW	TQM Development Specialist		X	X
M. Horseman	CER	Auditor	X		X
P. Horsmon	M&O/Duke	QA Technical Specialist	X	X	X
D. Horton	OQA/RW-3	Director, OQA	X		
S. Horton	SAIC	Observer (YMQAD)	X		
R. Howard	Weston	Auditor	X		X
J. Jackson	M&O/TRW	QA Manager, Nevada Site		X	
B. Jennings	M&O/TRW	Records Supervisor		X	
C. Kelly	M&O/TRW	Training Administrator		X	
M. King	M&O/TRW	Sr. Staff Engineer	X		
A. Kubo	M&O/TRW	Assistant General Manager, Systems	X	X	
L. Lee	M&O/TRW	Records Group Leader		X	
H. Lentz	CER	Auditor	X		X
E. Leonard	M&O/TRW	Engineer/Scientist	X		
P. Lovett	M&O/TRW	Systems Engineer	X	X	
A. Mace	M&O/TRW	V&V Analyst		X	X

ATTACHMENT 2

Personnel Contacted During The Audit

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
E. McDonnell	M&O/TRW	Manager, Contracts /Subcontracts	X		X
J. Miller	M&O/TRW	Manager, Systems Engineering	X	X	X
R. Morgan	M&O/Duke	QA Manager, Vienna	X	X	X
R. Murthy	HQAD/RW-3.1	Observer (HQAD)			X
F. Nash	M&O/Duke	Sr. QA Staff	X	X	X
D. Nolan	M&O/JAI	Engineer/Supv., Casks	X	X	X
J. Penahaker	M&O/TRW	Asst. Project Manager		X	
R. Portman	M&O/TRW	Manager, Records and Information			X
M. Penovich	M&O/B&W	Training Manager, Las Vegas	X		
D. Robertson	M&O/Fluor	Engineer/Scientist		X	
R. Robertson	M&O/TRW	M&O/General MGR	X	X	X
S. Robinson	M&O/TRW	Engineer/Scientist		X	
S. Sareen	M&O/TRW	Sr. Staff Engineer	X		X
V. Sauers	M&O/TRW	Manager, Software Configuration Management		X	X
P. Schlereth	M&O/B&W	Sr. QA Engineer	X	X	X
W. Schneider	M&O/TRW	Manager, Subcontracts		X	
A. Segrest	M&O/Duke	Manager, MRS Design		X	
M. Shepard	M&O/TRW	Records Supervisor		X	
V. Skrinak	M&O/TRW	Manager, Secretariat	X	X	X
J. Spraul	USNRC	Observer	X		X

ATTACHMENT 2

Personnel Contacted During The Audit

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
W. Standley	M&O/TRW	Manager, Modeling and Databases	X	X	X
L. Stern	M&O/TRW	Manager, Management Systems	X		X
R. Tagg	M&O/TRW	Contract Specialist		X	
C. Tankersly	M&O/TRW	Engineer/Scientist			X
A. Tayfun	M&O/TRW	Records Manager	X	X	X
W. Teer	M&O/JAI	Manager, Transportation	X	X	X
J. Tierney	M&O/TRW	Manager, Quality Engineering	X	X	X
M. Vance	M&O/TRW	QA Engineer	X	X	
G. Vaslos	M&O/Fluor	Manager, Internal Audits	X	X	X
G. Vawter	M&O/TRW	Manager, Storage and Transportation	X	X	X
P. Viggiano	M&O/TRW	QA Technical Specialist	X		X
L. Wagner	CER	Auditor	X		X
T. Walter	M&O/TRW	Software Conf. Mgmt. V&V Analyst		X	X
J. Watson	M&O/B&W	Lead Instructor/Supervisor	X	X	X
R. White	M&O/TRW	Manager, Human Resources and Training	X		X

ATTACHMENT 3

Audit Details

The following is a description of QA program audit activities covered during the audit. Section A contains a narrative of the audit details. Objective evidence reviewed during the audit is contained in Section B.

A. QA PROGRAM AUDIT ACTIVITIES

1.0 ORGANIZATION

1.1 General

The evaluation of this QA program element was based on personnel interviews and a review of the current CRWMS M&O organizational structure.

The CRWMS M&O General Manager was interviewed regarding the M&O organization, oversight responsibilities, control of subcontractors, Program Assessments/Management Reviews, personnel evaluations, content of progress meetings and work subject to the requirements of the QARD performed at Vienna,VA; Charlotte, NC; and Las Vegas, NV. An M&O counterpart has been assigned for all appropriate RW positions and contract representatives are assigned to interface with team members. The General Manager conducts frequent meetings with various levels of OCRWM and M&O senior management and is active in program assessment and personnel evaluations.

The current organization chart was reviewed with the General Manager; all key positions were adequately staffed. The M&O QA Manager has the organizational freedom to independently address QA Program issues.

The audit team interviewed the Assistant General Managers for Operations and Systems. Each Assistant General Manager was familiar with the M&O QA Program and the specific areas of quality affecting work within their respective organizations.

Twenty (20) personnel at the M&O Maryland Ave., DC office are performing licensing support and MRS siting work; at this time neither of these functions has been designated as quality affecting.

ATTACHMENT 3

Audit Details

1.2 Quality Disputes (QAP-1-1)

The audit team interviewed the M&O Quality Assurance Manager and discussed the procedure used by M&O personnel to escalate disputes and differences of opinion to appropriate levels of management.

There is no evidence that a quality dispute has ever been documented, but M&O CAR-92-SR-C-018 was written in response to a difference of opinion. The QA Manager stated that disputes and differences of opinion are usually resolved by informal discussion and escalation is unnecessary.

1.3 Management Assessment (QAP-2-7)

Interviews with QA personnel established that a preliminary draft procedure, QAP-2-7, had been sent out for review; the first management assessment is tentatively scheduled for the middle of calendar year 93.

1.4 Conclusion

This QA Program Element was considered to be effectively implemented.

2.0 QA PROGRAM

2.1 Indoctrination And Training (QAP-2-1)

The audit team reviewed QAP-2-1, Revision 2 and Revision 3 since Revision 3 has only been in effect for a few months. Implementation of QAP-2-1 was discussed with the Training Manager and the Training Administrator. The training staff were very cognizant of the procedural requirements. The audit team reviewed 28 records packages to verify that training records for individuals performing quality affecting activities had been completed in accordance with the requirements of QAP-2-1. CAR HQ-93-20 identifies deficiencies in this area.

The auditors verified that the General Manager and Department Managers are assigning their personnel to complete indoctrination and training requirements.

ATTACHMENT 3

Audit Details

Previous revisions of QAP 2-1, *Indoctrination and Training*, required the maintenance of an Indoctrination and Training Matrix, but later revisions deleted this requirement. The current practice is for supervisors to assign training by means of a memorandum. Classroom training is documented by signing the attendance record and self/study is documented by the employee completing the Reading/Self-Study Record which is also signed by the supervisor.

The auditors verified that the "core" QA Program documents were included as part of training requirements for M&O personnel performing quality affecting activities.

The monthly training schedule was reviewed and found satisfactory. Training packages were found to contain the required lesson plans, attendance sheets, and applicable training matrices.

2.2 Verification of Personnel Qualifications (QAP-2-2)

The implementation of this procedure was discussed with the Training Manager. He was knowledgeable of the procedural requirements and explained his efforts to assure compliance. The audit team reviewed 28 records packages to verify that the personnel qualification records for individuals performing quality affecting activities had been completed in accordance with the requirements of QAP-2-2. There was inadequate objective evidence that the M&O Human Resources Manager had verified and documented the highest level of education for six individuals. In addition, four personnel were identified during the YMP-93-07 audit. This condition is identified in CAR HQ-93-19.

2.3 Development and Conduct of Training (QAP-2-9)

The auditor reviewed the process for training instructors, preparing lesson plans and processing associated records. The training for instructors consists of the following modules and is a 5 day course: Introduction, Psychology of Learning, Instructional Challenges, Systematic Approach to Training, Training Aids, Presenting the Instruction and Evaluation and Testing. Instructor training files for Nash, Denton, Ashe and Whitley were reviewed and were found satisfactory. The originator of a quality affecting document is usually the preparer of the lesson plan and the instructor for the applicable course. See Recommendation 6.1 regarding a suggested improvement in this area.

ATTACHMENT 3

Audit Details

The audit team also discussed quality affecting activities with senior management (Godman, Kubo, Teer and Carruth) and verified that managers understand their responsibilities to determine appropriate training. Training designated by Mr. Teer for four Transportation personnel and Mr. Carruth for four Systems personnel was reviewed and found to be adequate.

2.4 Classification of Items and Determination of Quality Affecting Activities (QAP-2-3)

No Q-list for items will be generated until post conceptual design activities are initiated. Seven different technologies are at present proposed for the MRS and a Q-list will be developed when a final strategy is selected.

The classification of quality affecting activities is a senior management responsibility. In discussion with Assistant General Managers Godman and Kubo and Supervisors Teer (Transportation) and Carruth (Systems) it was determined that criteria for the classification of activities affecting quality were bring established by M&O senior management. The Quality Assurance Classification Methodology Document for the MRS is in draft.

2.5 Readiness Reviews (QAP-2-6)

Readiness review activities were discussed with M&O QA personnel. The auditor reviewed records of two Readiness Reviews. One Readiness Review was performed to determine the M&O readiness to perform quality affecting work and the other was performed to assess readiness to start work on the Engineered Safeguards Facility (ESF). Each records package contained documentation supporting the planning, personnel assigned, attribute checklists, open item lists and reports. Correspondence directing the performance of the reviews and issued CARs were also reviewed. It was noted that personnel interviewed (including senior management) were very knowledgeable regarding the Readiness Review process and the documentation requirements.

2.5 Conclusion

Despite problems identified in CARs HQ-93-19 and -20, the audit team determined that QA Program Element 2 was being effectively implemented.

ATTACHMENT 3

Audit Details

3.0 DESIGN CONTROL

3.1 Technical Document Review (QAP-3-1)

The audit team determined that the Phase 1 Cask Procurement Specification was the only technical document that had undergone the QAP-3-1 review process. The audit team reviewed the draft Phase 1 Cask Procurement Specification and related documentation to verify it had been reviewed in accordance with QAP-3-1 as required by QAP-3-8. The Manager, Transportation and the Document Preparer had selected a review team and had initiated the QAP-3-1 review as required. The review team included the QA Manager and other individuals knowledgeable in the technical areas addressed in the document. The review team was provided specific review criteria and documented their comments on Document Review Records. Since the comment resolution phase of the review was not complete, comment resolution could not be verified.

3.2 System Conformance Reviews (QAP-3-2)

The audit team interviewed the Manager, Systems Engineering, the Manager, Storage and Transportation, and the Manager, MRS Design and determined that the requirements of QAP-3-2 had not yet been implemented for system conformance reviews. The Manager, MRS Design indicated that an earlier version of QAP-3-2, entitled *Design Reviews*, had been used to conduct a design review (not a system conformance review) of the Monitored Retrievable Storage (MRS) Conceptual Design Report. The OCRWM Headquarters Quality Assurance Division had already evaluated this QAP-3-2 review of the MRS Conceptual Design Report as part of Surveillance HQ-SR-92-04.

3.3 Development of Technical Documents (QAP-3-5)

The audit team sampled two Technical Document Preparation Plans (TDPPs) to verify implementation and compliance with QAP-3-5:

- the TDPP for the Transportation System Requirements Document, Revision 1 dated January 26, 1993

ATTACHMENT 3

Audit Details

- the TDPP for the CRWMS Interface Specification, Revision 0 dated January 15, 1993.

Note: Two other TDPPs were considered as part of the audit sample (the TDPP for the MRS Conceptual Design Report and the Cask Acquisition Management and Procurement Plan) but were not selected for review. The Cask Acquisition Management and Procurement Plan was developed in accordance with QAP-3-8 for administrative and management convenience, and the TDPP for the MRS Conceptual Design Report was reviewed as part of the OCRWM OQA Surveillance HQ-SR-92-04.

The audit team verified that the TDPPs included the format required by Attachment I of QAP-3-5. The TDPPs were approved by the cognizant Office Manager as required by QAP-3-5.

The audit team interviewed the Manager, Systems Integration and determined that drafts of the Transportation Systems Requirements Document and the CRWMS Interface Specification were not complete; therefore the remaining requirements of QAP-3-5 could not be verified.

See Recommendation 6.2 for suggested improvements in this area.

3.4 Configuration Item Identifiers (QAP-3-6)

The audit team interviewed the Manager, Configuration Management to determine the extent of the implementation of QAP-3-6. The Manager, Configuration Management indicated that a block of Configuration Item (CI) identifiers had been assigned to the Software Configuration Management (CM) Organization but that no other CI identifiers had been assigned. The M&O Configuration Management Organization is waiting for the OCRWM configuration identification portion of the configuration management program to become active before it assigns configuration item identifiers to system elements.

The audit team reviewed the Request/Approval for CI Identifiers that documented the assignment of the Software Configuration Item Identifiers.

ATTACHMENT 3

Audit Details

See CAR HQ-93-14 and Paragraph 5.4.2 of this report for details regarding deficiencies identified in this area.

3.5 Interface Control (QAP-3-7)

The audit team interviewed the Manager, Systems Engineering; the Manager, Storage and Transportation; and the Manager, MRS Design to determine if Interface Control Documents (ICDs) have been developed in accordance with QAP-3-7, Revision 1. QAP-3-7 has not been implemented. The Manager, Systems Engineering indicated that ICDs would be developed after the CRWMS interface specification is complete; this is consistent with the OCRWM Systems Engineering Management Plan, Revision 2.

The audit team also reviewed QAP-3-7 for correct translation of requirements from the M&O QAPD. See Paragraph 5.4.2 for details regarding deficiencies identified in this area.

3.6 Procurement Specifications (QAP-3-8)

The audit team interviewed the Manager, Transportation; the Supervisor, Cask System Development; and the Senior Engineer, Cask System Development to assess the status of the procurement specification being prepared for the Cask Acquisition RFP. The Manager, Transportation indicated that the specification is still in the draft stage and that the final RFP is not expected to be out until August or September 1993. The audit team reviewed the draft cask acquisition procurement specification and determined that the draft procurement specification was not prepared in accordance with the Procurement Specification Format or the Main Text Outline specified in QAP-3-8. However, the draft specification did meet the format prescribed by OCRWM in a letter from R. A. Milner to R. G. Vawter dated August 19, 1992 which directed the M&O to use the format documented in a letter from R. G. Vawter to R. A. Milner dated August 8, 1992.

The draft procurement specification contained applicable design inputs, such as regulatory requirements, codes, standards, design bases, and quality assurance requirements as required by QAP-3-8.

ATTACHMENT 3

Audit Details

The audit team interviewed a Systems Engineer to get clarification on when the procurement specification verification step required by QAP-3-8 takes place; the procedure steps covering this requirement are unclear. He indicated that the verification takes place after all other required reviews are complete. See Recommendation 6.3.

An Interoffice Correspondence (IOC) assigned two verifiers for the Cask Procurement Specification. The IOC directed the individuals to perform a preliminary verification on the draft procurement specification. The IOC also indicated that the specification would be sent back for final verification after the QAP-3-1 technical review was complete. Since the QAP-3-1 technical review of the procurement specification is not complete, the final verification has not been performed and the Certification of Procurement Specification is not complete. QAP-3-8 has not been fully implemented for the Cask Acquisition Procurement Specification.

No other quality affecting procurement specifications have been prepared to date.

3.7 Engineering Calculations and Analysis (QAP-3-9)

The audit team interviewed the Manager, Systems Engineering; the Manager, Storage and Transportation; and the Manager, MRS Design to determine if any engineering calculations or analyses had been performed in accordance with QAP-3-9. QAP-3-9 has not been implemented. However, the auditor also reviewed QAP-3-9 for correct translation of QAPD requirements and determined the procedure was deficient in the one area. This deficiency is addressed in CAR HQ-93-13.

3.8 Assignment of Document Identifiers (QAP-3-13)

QAP-3-13 was cancelled on February 1, 1993. The audit team interviewed M&O personnel and determined that QAP-3-13 had not been completely implemented because it was a companion procedure to QAP-3-6, Configuration Item Identifiers. The M&O Configuration Management Organization is waiting for the OCRWM configuration identification portion of the configuration management program to become active before it fully implements QAP-3-6.

ATTACHMENT 3

Audit Details

3.9 Project Milestone Reviews (QAP-3-14)

The audit team interviewed the Manager, Systems Engineering; the Manager, Storage and Transportation; and the Manager, MRS Design to determine if any Project Milestone Reviews had been conducted in accordance with QAP-3-14, Revision 1. QAP-3-14 has not been implemented.

3.10 Conclusion

Due to the status of the design documents and activities reviewed, the audit team concluded that the effectiveness of QA Program Element 3 is indeterminate.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Procurement Document Control (QAP-4-1)

The auditors reviewed the Preliminary Draft RFP for the Phase I Cask Acquisition and the Preliminary Draft of the Statement Of Work (SOW) for compliance with QAP-4-1 requirements for the preparation, review, and approval of procurement documents. The audit team verified the correct preparation and initiation of review of the RFP and the SOW. The completion of the review and approval of the documents is contingent on the continuation of the Phase I Cask Procurement activities.

The audit team reviewed eight procurements for work which was being performed by M&O organizations performing quality affecting work. At the time of the audit, it was determined thorough interviews and reviews of procurement documents that none of these procurements was quality affecting.

See Recommendation 6.4 for a suggested improvement in this area.

4.2 Conclusion

Due to the status of these documents and corresponding activities, the audit team concluded that the effectiveness of QA Program Element 4 was indeterminate.

ATTACHMENT 3

Audit Details

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 Preparation of M&O Quality Administrative Procedures and Implementing Line Procedures (QAP-5-1)

The audit team reviewed QAP-2-3 Revisions 2 and 3, and QAP-17-1 documents and records packages as objective evidence that the requirements of QAP-5-1 were being properly implemented.

The audit team reviewed the procedures to assure that they were arranged in the seven section format as required; that each QAP stated who was responsible for developing and maintaining the QAP and; that the procedures had been reviewed by those M&O Managers who have responsibilities in the procedure.

The audit team also reviewed procedure records to assure that the standard procedure transmittal memos identified "review instructions/ criteria" as required by Paragraph 5.3.2 of QAP-5-1 (QAP-5-1 identifies a "cookbook approach" for preparing review criteria [Attachment III]). There was evidence that indicated that mandatory comments had been received on Procedure Review Records as required by the definition of mandatory comments in Paragraph 3.2.10. Additionally, records packages were reviewed to assure they contained all required documentation, including the final issued document. One isolated case was corrected during the audit. See Paragraph 5.4.2 for details.

Procedures were reviewed to assure that changes were identified using change bars, as required by QAP-5-1. A review of cancelled QAP-3-13 indicated the QAP cancellation process was performed with QAP-5-1 and was effective.

The PCN approval process was reviewed in accordance with QAP-5-1 requirements. PCN approvals included only the responsible manager and the QA Manager. Original procedures required approval of the M&O General Manager. This reduced approval level of management was documented on M&O CAR 93-QC-C-001 (1/20/93).

PCN records packages were reviewed at the LRC; all associated records were included.

ATTACHMENT 3

Audit Details

With one exception identified in CAR HQ-93-18, the Expedited Procedure Change Notice System implementation complied with QAP-5-1 requirements.

The QAPD and QAPs are required to be reviewed when changes in upper-tier documents occur. The audit team found no objective evidence that this had been accomplished for the recent changes to these documents. See CAR HQ-93-18.

The two year procedure review process had not been implemented since no procedure was more than two years old. See CAR HQ-93-18 for related deficiencies in this area.

QAP-5-1 addresses the preparation and maintenance of QAPs and ILPs. The audit team could not find procedural requirements for the preparation and maintenance of the M&O QAPD; however, it is recognized that the new OCRWM QARD does not require the M&O to maintain a QAPD.

See recommendation 6.5 for a suggested improvement in this area. See CARs HQ-93-13 and HQ-93-18 for further details concerning the deficiencies.

5.2 Conclusion

Based on the objective evidence reviewed, the audit team concluded that QA Program Element 5 is not being effectively implemented.

6.0 DOCUMENT CONTROL

6.1 Document Control (QAP-6-1)

The M&O system for controlling QAPs was reviewed. This was accomplished through interviews with personnel and a review of objective evidence of procedure implementation. All activities performed by the Document Control Center were found to be in satisfactory and effectively implemented. The team did not verify that controlled document holders actually had applicable revisions to QAPs since the M&O had previously initiated CAR 93-QC-C-003 for problems in this area.

ATTACHMENT 3

Audit Details

The audit team has determined that activities performed by the Document Control Center are effective. Until the M&O CAR is closed, the document user portion of the document control process is considered to be indeterminate.

See Recommendation 6.6 for a suggested improvement in this area.

6.2 Conclusion

Based on the objective evidence reviewed and the significance of the recent M&O CAR, the audit team concluded that implementation of QA Program Element 6 is marginally effective.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Control of Purchased Items and Services (QAP-7-1)

The audit team reviewed the Cask Acquisition Management and Procurement Plan, the Preliminary Draft RFP for the Phase I Cask Acquisition and the Preliminary Draft Statement of Work (SOW) for compliance with requirements to control procurement of items and services. No quality affecting activities covered by QAP-7-1 have been initiated with regard to Phase I Cask Acquisition.

The audit team reviewed eight procurements issued to M&O subcontractors to support various program activities.

The audit team reviewed the RFP issued to E. J. Bentz and Associates, Transnuclear and Sierra Nuclear. These documents were for professional services and were determined to involve activities not affecting quality.

The audit team reviewed Memorandum of Purchase Orders (MPOs) issued to Martin Marietta Energy Systems, Pacific Northwest Labs and Lawrence Livermore National Labs. These documents were for professional services and were determined to be non-quality affecting.

The audit team reviewed the Purchase Requisition issued to National Underground Storage Inc. (NUS) for lease of a storage vault and archival services. As this is a quality affecting activity, the audit team verified that the

ATTACHMENT 3

Audit Details

process for issuing the Purchase Requisition complied with the applicable requirements of QAP-7-1.

7.2 Conclusion

Due to the status of the procurement documents and associated activities reviewed, the audit team concluded that the effectiveness of QA Program Element 7 was indeterminate.

8.0 CORRECTIVE ACTION

8.1 Corrective Action (QAP-16-1)

M&O personnel were interviewed concerning the information included in the CAR Status Report (log). From the list of CARs (total 27 closed, 15 open), a sample of seven closed and seven open CARs was selected for audit.

The log contained several incorrect or incomplete entries. See Paragraph 5.4.2 for more detail in this area.

A review of the sampled CARs indicated that they were initiated, approved, concurred with, issued, verified, and closed properly.

The M&O had previously recognized several discrepancies with the CAR process and had documented them on one of the open CARs reviewed by the audit team.

Quarterly CAR Status Reports have not been issued; however, upper management attends the OCRWM monthly Program Management Reviews. The status of CARs was being reviewed with all management during these meetings.

See CAR HQ-93-13 for details regarding QAP-16-1 procedural deficiencies.

ATTACHMENT 3

Audit Details

8.2 Stop Work (QAP-16-2)

The auditors interviewed M&O personnel concerning the initiation of Stop Work Notification Reports (SWNRs). The M&O informed the team that they had not issued any SWNRs. This was verified by reviewing the Stop Work block on various CAR forms.

8.3 Quality Assurance Program Status and Trend Reporting (QAP-2-4)

The audit team interviewed M&O personnel concerning the information included in the QMIS Data Base. At present, the only information in the QMIS is CAR data. They have plans to add Readiness Review open items, procedure information, and verification report information.

The QMIS Administrator & the Quality Engineering Manager review the QMIS for input to the Quarterly QA Program Status and Trend Report. See Paragraph 5.4.2 for more detail regarding this area.

See CAR HQ-93-13 for more detail regarding procedural deficiencies.

Upon review of the trend report, the audit team considered the analysis and presentation of the required information to be complete and effective.

8.4 Conclusion

The audit team concluded, based on CAR HQ-93-13, a review of the M&O CAR and similar observations, that QA Program Element 16 was not being effectively implemented.

9.0 QUALITY ASSURANCE RECORDS

9.1 Program Records Management: Record Source Responsibilities (QAP-17-1)

The auditors reviewed compliance to QAP-17-1 by conducting interviews and reviewing available objective evidence.

ATTACHMENT 3

Audit Details

QAPs were required to identify those records which were considered to be QA records. All QAPs (39) were reviewed in accordance with QAP-5-1, Attachment II Records requirements. See CAR HQ-93-18.

Records were required to be sent to the Local Records Center (LRC) within 10 days after authentication. Eight of 12 records reviewed were not to the LRC within 10 days of authentication. See Recommendation 6.7 for more detail concerning this area.

All packages reviewed had properly prepared record transmittals.

In-process records in the possession of record sources were being adequately protected from loss and damage. QAP-2-3, Rev. 3 "in process" records and "in process" training records were found to be adequately protected from loss and damage.

Upon receipt, LRC personnel review records for accountability, identification, etc. If required, the LRC has been contacting the record source for corrections. Only one formal request had been made and all requirements of QAP-17-1 were met.

Records packages were being properly validated. Several packages were reviewed for completeness and logical compilation. See Recommendation 6.8 regarding suggested improvements in this area.

One-of-a-kind and special process records were reviewed to assure they were being properly processed. Microfiche from Oak Ridge National Laboratory was properly identified and processed.

The audit team reviewed the storage of privileged records in the LRC, Central Records Facility (CRF), and the Training Department. All areas provided controlled access to the records. All records were stored in 1 hour fire rated cabinets. Data from privileged records in the Training Department were being entered into a database; upon completion the records will be transmitted to the LRC.

The audit team requested retrieval of several specific records; they were quickly and effectively retrieved from the microfilm or hard copies.

ATTACHMENT 3

Audit Details

See CAR HQ-93-13 for details of procedural deficiencies.

9.2 Program Records Management: Receipt and Handling of Program Records (QAP-17-2)

The audit team identified that records were being properly stored in 1 hour fire rated cabinets; electronic records were properly processed; LRC requested corrections (external) were accompanied by a Records Discrepancy Notice; records had received accession numbers and were arranged in accession number sequence in records packages; and records provided to the CRF for microfilming were being processed in accordance with QAP requirements.

9.3 Program Records Management: Microfilming Program Records (QAP-17-4)

PCN QAP-17-4 R0, P01, recently issued, stated that all microfilming will be accomplished at the Las Vegas offices of the M&O. This PCN eliminated most of the Vienna activities associated with microfilming.

9.4 Program Records Management: Indexing Program Records (QAP-17-5)

Records being processed through the CRF were found to be properly protected and System 80 records were secured in the records vault. (Note: M&O CAR 92-QA-C-030 identified the need for additional environmental controls in the records vault.)

The auditors reviewed objective evidence that demonstrated that records were indexed in accordance with QAP-17-5 and the "OCRWM Indexing Manual;" that the quality control review of indexing activities was being performed and was effective; and that batch sheets were being used to track records as they were being processed.

9.5 Program Records Management: Storage, Retrieval and Disposition of Program Records (QAP-17-6)

Currently all records are being identified as Lifetime records; however, RIDS are being prepared that will properly classify the records. The audit team verified that records stored in the LRC, the CRF, the records vault, and

ATTACHMENT 3

Audit Details

temporary storage areas was accomplished in accordance with QAP-17-6. Record storage areas had a posted access listing.

Silver master microfilm was being stored in the Records Vault in accordance with procedural requirements. See Paragraph 5.4.2 for a deficiency that was corrected during the audit.

Letters identifying personnel authorized access to the permanent storage facilities (National Underground Storage [NUS]) were reviewed and found to be adequate. In addition, the previous audit report of NUS (performed by the previous subcontract - KOH) and the 1993 NUS audit notification letter were reviewed and found satisfactory. This audit is scheduled for March 8 through 12, 1993.

There is a requirement that the M&O provide OCRWM with a semiannual list of hard copies of records in storage greater than six months. Due to microfilming problems no microfilmed hard copies are greater than six months old and therefore this report has not yet been issued.

9.6 Conclusion

The audit team concluded that activities being performed by the LRC and CRF were being performed in accordance with QAP requirements. Instances of confusion on the part of record sources and procedural inadequacies were identified. The audit team concluded that implementation of QA Program Element 17 was marginally effective.

10.0 AUDITS

10.1 Qualification of Audit Personnel (QAAP 18.1)

The qualification records of Lead Auditors, Auditors and Technical Experts were examined in detail. A list of Lead Auditors, Auditors, and Technical Experts were selected from recently performed audits.

The auditor reviewed qualification records for evidence of required education, experience, training, leadership and communication skills, technical experience (Technical Experts), examinations, and audits performed. Previous certification

ATTACHMENT 3

Audit Details

records were examined for the cases where the individual was certified by the M&O based upon that previous certification.

Numerous qualification record deficiencies were identified by the auditor. See CAR HQ-93-16.

10.2 Audits (QAP-18-2)

The auditors interviewed M&O personnel concerning audit schedules and audits conducted during FY92 and FY93. The team was able to verify that all QARD elements had been audited. There were no supplier QA Programs audited; the only quality affecting supplier is scheduled to be audited in March.

From the twenty internal audits conducted, a sample of eight was selected for review. The planning, notification, and audit meeting activities were being performed in accordance with applicable QAP-18-2 requirements.

From the review of the audit reports, the audit team concluded that the M&O auditors were not consistently reporting all required information. See CAR HQ-93-21.

The M&O is also required to periodically summarize effectiveness data to provide a program-wide assessment of the effectiveness of the QA Program. See CAR HQ-93-17.

Observations, concerns, and recommendations were reviewed for seven sampled audit reports; deficient conditions were identified that are normally written as CARs and tracked accordingly. See CAR HQ-93-15.

In addition, the procedure was considered inadequate because it did not sufficiently address several requirements. See CAR HQ-93-13.

10.3 QA Surveillance (QAP-2-5)

M&O personnel were interviewed concerning the surveillance program. A tentative surveillance schedule and a memo regarding their plans for future

ATTACHMENT 3

Audit Details

surveillances were reviewed. There is no requirement to document the schedule.

A sample of three completed and one ongoing surveillance was selected from a total of seven listed by the M&O. Checklists were being used, the affected organizations were properly notified, and reports were issued as required. The surveillance reports contained required information and were approved, issued, and distributed as required by QAP-2-5. See Recommendation 6.9 concerning the issuance of a November surveillance report.

The audit team concluded that QAP-2-5 is very narrow in scope and the requirements for schedules and timeliness of issuing reports are not addressed. Surveillance Report 93-SRS-02 (performed in November 1992) had not been issued. Also, the procedure does not specifically require distribution of the report to the surveilled organization. See CAR HQ-93-13.

Two problems were identified in two of the surveillance reports reviewed. The first concerned the lack of summarizing activities surveilled (i.e listing objective evidence reviewed during the surveillance). Since this was only identified on two of the reports reviewed and that the information was available on the Surveillance Checklist, no further action is required on this item.

The second problem was that the M&O identified deficiencies and did not document them as CARs. See CAR HQ-93-015.

10.4 Conclusion

The audit team concluded that verification activities were not consistently being performed in accordance with QAP requirements. Inadequate personnel qualification records, procedural inadequacies, and incomplete audit/surveillance reports were identified. The audit team concluded that the implementation of QA Program Element 18 (audits and surveillances) was ineffective.

ATTACHMENT 3

Audit Details

11.0 COMPUTER SOFTWARE

11.1 Computer Software Verification and Validation (QAP-19-1)

The audit team interviewed the M&O Verification and Validation (V&V) Analyst concerning the computer software programs that had been verified or validated and approved by the M&O for "Quality Affecting Work" (QAW). At present there has been no "developed" computer software at Vienna, Charlotte or Las Vegas offices that has been verified or validated for QAW. The only six quality affecting software packages were found to be part of the Characteristics Database and were recently acquired from Oak Ridge National Labs (ORNL). These six packages have been defined by the M&O as "acquired Scientific and Engineered Software (SES) previously approved for use in QAW by OCRWM." Given this information three of the six programs were reviewed for compliance with requirements.

The M&O V&V Analyst provided the V&V record packages for the selected software packages. Based upon a discussion with the V&V Analyst and a review of the selected software record packages it was identified that the requirements of both QAP-19-1 and the Computer Software Quality Assurance Plan (CSQAP) were being met.

One procedural disparity was identified during the audit process. See CAR HQ-93-13 for the details.

11.2 Software Configuration Management (QAP-19-2)

The audit team interviewed the M&O Software Configuration Manager (SCM) concerning computer software programs that have been approved and released by the M&O for "Quality Affecting Work" (QAW). To date there has been no computer software at either Charlotte or Las Vegas offices that has approved and released for QAW and only the six software packages identified in Paragraph 11.1 have been approved and released for QAW by the M&O. Due to the limited number of QAW software programs in use at the M&O, the positions of M&O SCM and the Vienna SCM are currently being filled by one individual. Charlotte and Las Vegas offices are currently working on establishing configuration management organizations but until they are

ATTACHMENT 3

Audit Details

established all software control activities will be accomplished through the Vienna office.

Three of the six programs were reviewed for compliance with the requirements of QAP-19-2. Based upon discussion with the M&O SCM and a review of the Software Configuration Control Board (SCCB) software record packages selected it was concluded that the requirements of both QAP-19-2 and the Computer Software Quality Assurance Plan (CSQAP) were being met except as identified in CAR HQ-93-14. See Recommendation 6.9 concerning "emergency" meetings of the SCCB.

Also see CAR HQ-93-13 for examples of procedural problems with QAP-19-2.

11.3 Conclusion

With the exception of the adverse condition identified in CAR HQ-93-14, the audit team concluded that computer software activities were being performed in accordance with QAP requirements. The audit team concluded that QA Program Element 19 was effectively implemented.

ATTACHMENT 3

Audit Details

B. OBJECTIVE EVIDENCE REVIEWED DURING THE AUDIT

Quality Administrative Procedures -

QAP-2-1, Rev. 3	Indoctrination and Training
QAP-2-3, Rev. 2, 3	Classification of Items and Determination of Quality-Affecting Activities (PCN QAP-2-3, R3, P01)
QAP-2-4, Rev. 1	Quality Assurance Program Status and Trending Report
QAP-2-5, Rev. 1	QA Surveillance
QAP-2-9, Rev. 0	Development and Conduct of Training
QAP-3-1, Rev. 2	Technical Document Review
QAP-3-2, Rev. 2	System Conformance Reviews
QAP-3-5, Rev. 2	Development of Technical Documents
QAP-3-7, Rev. 1	Interface Control
QAP-3-8, Rev. 1	Procurement Specifications
QAP-3-9, Rev. 1	Engineering Calculations and Analyses
QAP-3-13, Rev. 1	Assignment of Document Identifiers (PCN QAP-3-13, R1, P02)
QAP-3-14, Rev. 0	Project Milestone Reviews
QAP-4-1, Rev. 0	Procurement Document Control

ATTACHMENT 3

Audit Details

QAP-5-1, Rev. 1	Preparation of M&O Quality Administrative and Implementing Line Procedures
QAP-6-1, Rev. 1	Document Control
QAP-7-1, Rev. 0	Control of Purchased Items and Services
QAP-16-1, Rev. 0	Corrective Action Report (PCN QAP-16-1, R0, P01)
QAP-16-2, Rev. 0	Stop Work
QAP-17-1, Rev. 2	Program Records Management: Record Source Responsibilities
QAP-17-2, Rev. 0	Program Records Management: Receipt and Handling of Program Records and Record Packages (PCNs QAP-17-2, R0, P01, and P02)
QAP-17-4, Rev. 0	Program Records Management: Microfilming Program Records
QAP-17-5, Rev. 0	Program Records Management: Indexing Program Records
QAP-17-6, Rev. 0	Program Records Management: Storage, Retrieval, and Disposition of Program Records.
QAP-18-2, Rev. 1	Audits
QAP-19-1, Rev. 1	Computer Software Verification and Verification
QAP-19-2, Rev. 1	PCN P01, Software Configuration Management

ATTACHMENT 3

Audit Details

Procedure Review Records (PRRs) -

QAP-2-1
QAP-2-3
QAP-2-9
QAP-5-1
QAP-16-1
QAP-17-1

Procedure Change Notices (PCNs) -

QAP-3-13
QAP-17-4
QAP-17-5
QAP-17-6

Records Packages - (Tracking Number)

92-10-0213
QAP-2-1, Rev. 3
QAP-2-3, Rev. 2
QAP-2-9, Rev. 0
QAP-6-1, Rev. 1
QAP-16-1, Rev. 0
QAP-17-1, Rev. 2
CAR-92-MR-C-001

Procedure Review Instructions/Criteria Memos -

QAP-2-3, Rev. 2
QAP-2-3, Rev. 3
QAP-17-1, Rev. 2

QAP/ILP Review Sheets

QAP-2-3, Rev. 3
QAP-17-1, Rev. 2

ATTACHMENT 3

Audit Details

Training Coordination Sheets

QAP-2-3

Records Areas Access and Validation Lists

Access to LRC
Access to CRF
Access to Privileged Records
Validation List

Audits Reports and Records

Audit AK-92-01 (KOH) of Nuclear Underground Storage (3/9-12/92)

Audit 93-NSA-01
Audit 92-MD/SLA-01
Audit 92-SY/OPA-01
Audit 92-SEA-01
Audit 92-TRA-01
Audit 92-MRA-02
Audit 92-SRA-02
Audit 92-MRA-04
Audit 92-SY/OPA-01

Audit Log dated 11/3/92
Audit Log dated 12-21-92
Audit Schedule (Rev. 6)

CRWMS Quarterly QA Program Status and Trend Report, dated 01-29-93, approved 01-30-93, issued 02-03-93

QMIS Data Base (CAR Portion) printout, dated 02-01-93

Memo to M&O QA Managers from Frank Nash, Surveillances Within the M&O, dated 01-19-93

ATTACHMENT 3

Audit Details

Surveillances: (including checklists)

93-SRS-01, conducted 11-11-92, report 11-17-92
93-STS-01, conducted 10-12 to 16-92, report 12-04-92
92-MRS-03, conducted 9-28 to 10-2-92, report 10-6-92
93-SES-01, ongoing

CRWMS M&O Vienna Surveillance Schedule, dated 1-29-93, not officially issued

Corrective Action Reports:

92-MD-C-004, opened 02/26/92, closed 04/27/92
92-QA-C-006, opened 04/08/92, closed 10/13/92
92-HR-C-013, opened 05/21/92, closed 10/13/92
92-SR-C-018, opened 06/10/92, closed 08/25/92
92-NS-C-021, opened 06/11/92, closed 11/13/92
92-SO-C-023, opened 07/01/92, closed 10/27/92
92-QA-C-031, opened 10/01/92, closed 11/16/92
92-HR-C-011, opened 05/21/92,
92-QA-C-015, opened 05/28/92,
92-QA-C-030, opened 10/01/92,
92-QA-C-032, opened 10/09/92,
93-QL-C-001, opened 01/20/93,
93-QL-C-003, opened 01/27/93,
93-QL-C-004, opened 01/28/93,

CAR Status Report (log), received 01-08-93, revised 02-04-93

Quality Assurance Status, Program Management Review, dated 01-27-93
Quality Assurance Status, Program Management Reviews, dated 04-29-92, 05-15-92, 06-25-92, 07-22-92, 08-26-92, 09-23-92, 10-28-92, 12-03-92, 12-21-92

M&O Internal Audit Schedule, Revision 7, dated 01-26-93
M&O Internal Audit Schedule, Revision 6, dated 10-30-92
M&O Internal Audit Schedule, Revision 5, dated 08-04-92
M&O Internal Audit Schedule, Revision 4, dated 05-11-92
M&O Internal Audit Schedule, Revision 3, dated 02-24-92
M&O Internal Audit Schedule, Revision 2, dated 01-19-92

ATTACHMENT 3

Audit Details

Matrix for CRWMS M&O Internal Audit Summary, dated 12/31/92

CRWMS M&O QAPD, Revision 2, dated 06-14-91
CRWMS M&O QAPD, Revision 3, dated 11-30-92

Computer Software Quality Assurance Plan, Rev. 1, TSO.920803.0485

Configuration management records packages:

CDB_H, high-level waste database system

CDB_R, radiological database system

CDB_S, serial number database system

verification and validation records packages:

CDB_H, high-level waste database system

CDB_R, radiological database system

CDB_S, serial number database system

Software Problem Report Log (Vienna)

CSCI Log (Vienna)

CSCI Log (M&O)

Document Problem Report Log (Vienna)

Document Log (Vienna)

minutes of M&O SCCB meeting on 11/30/92
minutes of M&O SCCB meeting on 1/25/93
minutes of Vienna SCCB meeting on 11/9/92
minutes of Vienna SCCB meeting on 11/17/92
minutes of Vienna SCCB meeting on 11/24/92

ATTACHMENT 3

Audit Details

minutes of Vienna SCCB meeting on 12/15/92
minutes of Vienna SCCB meeting on 1/22/93

M&O Organization chart

Interface documents and training matrix for Godman

Lists of quality affecting work for each department

Training packages for 28 personnel

V. Sours	C. Cherkofohy	J. Tierney
V. McCormick	J. Willis	A. Hodson
O. Gilstrap	S. Robinson	A. Segrest
T. Brackett	Ann Mace	W. Teer
C. Carruth	Lee Bice	B. Cole
J. Domeron	N. Collins	L. Smith
L. Berkowitz	J. Leffmon	
D. Domeron	W. Hunt	
R. Tagg	C. Jennings	
R. Lovett	F. Nash	

Lesson plans for Instructor courses QAPs 3.1 & 3.10

Readiness Review records for Readiness Review performed to allow the M&O contractor to commence Quality Affecting Work (4/6-22/92) and Readiness Review performed to allow start of ESF work 9/16-30/92.

Draft QAP-2-7, Management Assessment

Draft of QA Classification Methodology Document for MRS

Interoffice Correspondence from W. Teer to G. R. Boyt, dated May 15, 1992 assigning personnel to perform QAW and assigning training requirements.

letter from R. A. Milner to R. G. Vawter dated August 19, 1992
letter from R. G. Vawter to R. A. Milner dated August 8, 1992

ATTACHMENT 3

Audit Details

Technical Document Preparation Plan for CRWMS Interface Specification, Revision 0, dated January 15, 1993

Technical Document Preparation Plan for the Transportation System Requirements Document, Revision 1, dated January 26, 1993

Request/Approval form for Configuration Item Identifiers approved by J. J. Penahaker on October 6, 1992 documenting assignment of software configuration item identifiers

M&O Configuration Management Plan

Procurement Contracts / Documents Reviewed:

1. E. J. Bentz and Associates
   - RFP No. J852-RDT-92-132
   - SOW Doc. No. J852-RDT-92-131, Dated 07/01/92.

2. Martin Marietta Energy Systems
   - MPO No. VA-CS-RDT-11/92-326
   - SOW Doc No. VA-CS-RDT-11/92-325, Dated 11/12/92.

3. Pacific Northwest Labs
   - MPO Doc. No. VA-CS-RDT-11/92-334.

4. Lawrence Livermore National Labs
   - MPO Doc. No. VA-CS-RDT-11/92-342.

5. TransNuclear
   - RFP No. J852-RDT-91-283.

6. Sierra Nuclear
   - RFP No. J852-RDT-91-282

7. National Underground Storage Inc. (NUS)
   - Purchase Requisition No. AT5504.

ATTACHMENT 3

Audit Details

8. Micro D International
   - Purchase Order No. DX1082LJ3.

9. Preliminary Draft RFP for Phase I Cask Acquisition, dated 8/28/92.

10. Preliminary Draft Statement of Work, dated 8/28/92.

11. Cask Acquisition Management and Procurement Plan, Doc.No.20-06-DA.AO-MD-70001-00, dated 9/14/92.

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

[8] CAR NO. HQ-93-13
DATE: 2/17/93
PAGE: 1 OF 6
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document
M&O Quality Assurance Program Description, Rev. 3

[2] Related Report No.
Audit HQ-93-03/YMP-93-07

[3] Responsible Organization
M&O (Vienna and Nevada)

[4] Discussed With
R. Robertson, J. Brackett/L. Faust (NV)

[5] Requirement:

Section 5.0 states in part, "M&O quality affecting activities are prescribed by plans, procedures, and drawings. Procedures include or reference the appropriate quantitative and qualitative acceptance criteria for determining the acceptance of prescribed activities..." and Section 5.1 states in part: "...The M&O Quality Administrative Procedures (QAPs) and Implementing Line Procedures (ILPs) incorporate the committed requirements from the applicable sections of the QARD. QA ensures that all applicable quality assurance requirements are addressed prior to approval..."

[6] Adverse Condition:

The CRWMS M&O Quality Administrative Procedures (QAPs) do not meet all of the requirements of the CRWMS M&O QAPD and in some instances do not reflect current practice.

QAP-1-1	QAP-3-9	QAP-18-1
QAP-2-1	QAP-5-1	QAP-18-2
QAP-2-2	QAP-6-1	QAP-19-1
QAP-2-4	QAP-16-1	QAP-19-2
QAP 2-5	QAP-17-1	

(Continued on Page 2)

[9] Does a significant condition adverse to quality exist? Yes X No__
If Yes, Circle One: (A) B C

[10] Does a stop work condition exist?
Yes__ No X ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date:
March 31, 1993

[12] Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

[13] Recommended Actions:

[7] Initiator Denny Brown Date 3/12/93	[14] Issuance Approved by: QADD Carl E Hebron for Date 3/18/93
[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.

CAR NO. HQ-93-13
DATE: 2/17/93
PAGE: 2 OF 6
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

Adverse Condition (cont'd)

There was objective evidence that the M&O was implementing the requirements of their QAPD and the OCRWM QARD for most of the QA Program Elements. Examples of QAPs that are inadequate or do not reflect current practice that were identified as a result of Audit HQ-93-03 include:

1. QAP-5-1, *Preparation of M&O Quality Administrative and Implementing Line Procedures:*

   A. The QAP does not include the M&O QAPD requirement that "...preparation, review, approval, issuance, and ..." of plans, procedures, and drawings be "accomplished prior to the start of quality affecting work."

   B. The procedure does not address distribution requirements for PCNs to individual procedure holders. The current procedure requires that the Table of Contents be provided with controlled copies of PCNs. Note: The audit team dos not necessarily recommend that this requirement be included in QAP-5-1.

   C. The procedure states that "comments returned after the established due date are considered non-mandatory." This practice may allow significant procedural comments to go unresolved.

   D. Attachment II gives instructions on QAP format. The instructions for Section 6 - Records are not clear concerning identification of QA Records versus Program records.

   E. Attachment III does not adequately describe review criterion. It needs to specify that each procedure might have specific review criteria which are not already listed in Attachment III. Also, M&O QAPD, Section 6.0, lists review criteria not included in Attachment III.

   F. The Records section of the procedure indicates that non-mandatory comments are part of Procedure Review Records. This is not consistent with Paragraph 5.3.4A.

   G. The procedure does not clearly state that the author is responsible for preparing the records package and transmitting it to the LRC.

2. QAP-6-1, *Document Control:*

   A. As required by QAP-5-1, this procedure does not specifically identify the individual or organization responsible for development and maintenance of QAP-6-1.

   B. The Document Control Center (DCC) is required to review controlled document packages for correctness. The procedure should clarify that technical correctness is not verified by the DCC.

   C. The criteria for determining if a document should be controlled or not needs clarification. Note: During the audit it appeared that Technical Document Preparation Plans (TDPPs) should be controlled since they meet the criteria. However, it was concluded that TDPPs do not have to be to QAP-6-1.

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

CAR NO. HQ-93-13
DATE: 2/17/93
PAGE: 3 OF 6
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

Adverse Condition (cont'd)

2. QAP-6-1, *Document Control*: (cont'd)

   D. Paragraphs 5.1.6 describes the controls necessary to issue "unverified portions" of controlled documents. Paragraph 5.3.2B describes the controls necessary to issue "unverified, not complete" controlled documents. The requirements do not agree.

   E. The procedure does not clearly state that the author is responsible for preparing the records package and transmitting it to the LRC.

3. QAP-17-1, *Program Records Management*: Record Source Responsibilities:

   A. The procedure is not clear on the meaning of "authentication," "validation," "completion," or "record/records package." M&O personnel had different opinions on what these terms meant.

   B. There are many "responsibilities" identified in Section 4.0 which are not identified in the Procedure Section (5.0).

   C. Paragraphs 5.6.4 and 5.6.5 are redundant.

   D. QA Records are not specified in Section 6.0 of the procedure.

   E. Attachment III discusses requirements for electronic files which are different than the requirements for electronic files identified in Attachment VI of QAP-17-2.

   F. The procedure fails to address the maximum time period that records can be held in temporary storage. This is an NQA-1 requirement.

   G. The term "SCP" is referenced but not defined.

   H. Paragraph 5.3.2 (Records Packages) does not discuss the logical arrangement of documents.

   I. The procedure requires that records flow from the Record Source to the LRC and back again many times. This repeated activity increases the changes of losing or damaging records.

   J. The procedure fails to identify that lost or corrected records need to be re-generated and re-approved by the original preparers and reviewers (including senior management).

4. QAP-2-4, *Quality Assurance Program Status and Trend Reporting*:

   A. The procedure does not incorporate all the elements of the M&O QAPD, Rev. 2, Para. 16.7.

   B. The procedure does not reflect current organizational titles.

5. QAP-19-1, *Computer Software Verification and Validation*:

   A. The procedure needs to include the SQAP requirement to perform and document User Manual verification. Note: This activity was being performed.

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

CAR NO. HQ-93-13
DATE: 2/17/93
PAGE: 4 OF 6
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

Adverse Condition (cont'd)

6. QAP-19-2, *Software Configuration Management*:

   A. Current methods of identifying software/documents needs to be reflected.

   B. The relationships of the SCMPs to the procedure needs clarity.

   C. The procedure does not include adequate requirements for the control and issuance of the Computer Software Configuration Item identifiers. The M&O Configuration Manager's responsibilities need to be addressed.

   Note: The format and organization of QAP-19-2 do not allow personnel to utilize the procedure in a manner which will provide a consistent satisfactory output.

7. QAP-16-1, *Corrective Action*:

   During review of CAR processing, it was apparent (see recently issued M&O CAR) that the sequence of events required by the CAR form are contrary to the sequence of events required by the procedure. This discrepancy has contributed to significant delays in performing certain required steps in the CAR process.

8. QAP-3-9, Engineering Calculations and Analysis:

   M&O QAPD Revision 3 section 3.4.3 states that "...technical reviews shall ensure that the document being reviewed is applicable, correct, complete, and meets established requirements." The results of the technical reviews are required to be documented. This procedure does not specify technical review criteria for engineering analyses or require the results of the review to be documented.

9. QAP-2-5, *QA Surveillance*:

   A. The M&O QAPD requires that the results of a surveillance be reported in a timely manner. The procedure does not address this requirement.

   B. The procedure does not designate the distribution for surveillance reports.

10. QAP-18-2, *Audits*:

    The procedure does not designate the distribution for audit reports.

Examples of QAPs that are inadequate or do not reflect current practice that were identified as a result of Audit YMP-93-07 include:

11. QAP-1-1, *Escalation of Quality Disputes*

    Paragraph 6.1 requires that completed Quality Concerns Exit Interview Forms be maintained in accordance with QAP-17-1. The CRWMS M&O did not keep procedure QAP-1-1 revised to reflect current practice. Nine of the nine Quality Concerns Exit Interview Forms reviewed during the audit had not been processed to the LRC. The decision was made not to process these documents as QA records.

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

CAR NO. HQ-93-13
DATE: 2/17/93
PAGE: 5 OF 6
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

Adverse Condition (cont'd)

Note: The CRWMS M&O had a draft revision to QAP-1-1 dated 12/18/92 that deleted this requirement as part of the proposed change. The draft procedure was "on hold" awaiting a revision to QAP-5-1. During the audit the CRWMS M&O generated an expedited change, PCN No. P01 to QAP-1-1, Revision to delete the requirement.

12. QAP-6-1, *Document Control*:

a. CRWMS M&O QAPD, Revision 3, Section 6.1.1 requires that: "...Minor changes, such as *inconsequential editorial corrections, do not require the same review and approval.* Persons authorized to implement a minor change are clearly delineated." QAP-6-1 does not clearly delineate who is authorized to make minor changes.

b. QAP-6-1, Paragraph 5.4.5H states, "The Document Control Center shall take appropriate action based on the nature of the request...Providing a copy of an uncontrolled document that can be used for information purposes only. The copy shall be stamped UNCONTROLLED or other wording that clearly communicates that the copy is not a controlled copy." Document Control Center does not stamp UNCONTROLLED the copies of uncontrolled documents used for information purposes. The procedure did not reflect current practice. The stamp UNCONTROLLED is no longer needed since all controlled documents are marked with a red ink stamp. An expedited PCN (initiated 2/25/93 and approved by the Location QA Manager on 3/1/93) deleted this requirement; however, this PCN was not distributed to the QAP Manual Holders as of 3/3/93.

13. QAP-2-1, *Indoctrination and Training*:

CRWMS M&O QAPD, Revision 3, Section 2.5.2 requires: "...Indoctrination and Training on the QAPD is required of all personnel performing quality affecting activities...Proficiency of personnel performing quality affecting activities shall be maintained through additional training as required by supervision."

QAP 2-1, Paragraph 5.4.1 allows a Waiver of Required Training to exempt CRWMS M&O personnel from all or part of the program indoctrination requirements, and paragraph 5.2 states that additional training may be performed.

14. QAP-2-2, *Verification of Personnel Qualifications*:

CRWMS M&O QAPD, Revision 3, Section 2.5.1 requires: "...Qualifications of personnel employed by the M&O are detailed in applications or resumes. These qualifications are matched against position descriptions that establish the minimum education level and experience requirements for the position ... The required education and experience are verified."

QAP-2-2, Revision 1, Paragraph 5.2.3 allows the M&O manager or supervisor to provide justification for personnel assignment when minimum education and experience cannot be verified. The CRWMS M&O QARD does not provide for this exception.

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

CAR NO. HQ-93-13
DATE: 2/17/93
PAGE: 6 OF 6
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

Adverse Condition (cont'd)

15. QAP-5-1, *Preparation of M&O Quality Administrative and Implementing Line Procedures*:

a. CRWMS M&O QAPD, Revision 3, Section 6.1.2 requires: "Document issuance and distribution is controlled to ensure that correct, applicable, and current documents are available to M&O personnel performing quality affecting activities..." The procedure does not provide for the control of ILP number assignment. The procedure is not clear on who is responsible for the assignment and maintenance of the ILP numbers so that duplication will not occur.

b. Paragraphs 5.4.1 and 5.4.2 state in part, "Once the QAP/ILP is approved, it shall be submitted by the procedure author to the M&O Headquarters (HQ) Document Control Center for copying and distribution in accordance with QAP-6-1 ... PRRs and supporting documentation shall be submitted by the procedure author to the M&O Local Records Center..." ILPs are distributed by the Nevada Document Control Center and supporting documentation are submitted to the Nevada Local Records Center. The procedure needs to be revised to reflect current practice.

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

[8] CAR NO. HQ-93-014
DATE: 2/17/93
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document
M&O QAP-19-2, Rev. 1, PO1 and QAP-3-6, Rev. 1

[2] Related Report No.
Audit HQ-93-03

[3] Responsible Organization
M&O (Vienna)

[4] Discussed With
V. Sauers

[5] Requirement:

a) QAP-19-2, Paragraph 5.3.2.2 , CSCI Naming Format, states "The format ... has been established to identify and track CRWMS M&O software products".
b) SCMP-11, Paragraph 4.1.1, Document Identifier, states "The format ... has been established to identify and track CSCI documentation".
c) QAP-19-2, Paragraph 5.1.5, Baseline Displays, states " All interactive software ... shall display to the computer screen the following SCM status message for a minimum of three seconds upon software execution".
d) QAP-3-6, Paragraph 5.3.2, states "Prior to approving a CI and input into the CM data base the M&O CM organization will verify the CI identifiers and nomenclature assigned to avoid duplication errors."

[6] Adverse Condition:

a) Computer Software Configuration Item (CSCI) identifiers were found to be in accordance with QAP-3-6 and not QAP-19-2 as required (eg. used A00020002.AAX01.0 instead of 30.93.1011-DAh1.1).
b) CSCI document identifiers were found to be in accordance with QAP-3-13 (which has been cancelled) and not QAP-19-2/SCMP-11 as required (eg. used A00020002/AA-27-00002-00, Rev.0 instead of 30.93.1011-DAh1.1SdA).
c) The computer screen display for the six Characteristics Database programs did not identify these programs as being approved for Quality Affecting Work as required by QAP-19-2.
d) The CSCI identifiers, once assigned by the Software Configuration Manager, were not being given to the M&O Configuration Manager as required by QAP-3-6.

[9] Does a significant condition adverse to quality exist? Yes__ No X
If Yes, Circle One: A B C

[10] Does a stop work condition exist? Yes__ No__ ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date: March 31, 1993

[12] Required Actions: ☒ Remedial ☐ Extent of Deficiency ☒ Preclude Recurrence ☐ Root Cause Determination

[13] Recommended Actions:

Remedial action for adverse condition d) was completed prior to the conclusion of the audit and only the action taken to prevent recurrence is necessary. Remedial action was accomplished by the Software Configuration Manager, who provided a list of issued CSCI identifiers to the M&O Configuration Manager.

[7] Initiator Les Wagner Date 2/5/93	[14] Issuance Approved by: QADD Carl E Kelm for Date 3/18/93
[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

REV. 08/91

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

[8] CAR NO. HQ-93-015
DATE: 2/17/93
PAGE: 1 OF 2
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document
M&O QAP-16-1, Rev. 0

[2] Related Report No.
Audit HQ-93-03

[3] Responsible Organization
M&O (Vienna)

[4] Discussed With
G. Vaslos

[5] Requirement:

a) Paragraph 5.1.1. states: "Upon discovering an apparent deficiency, M&O personnel shall promptly initiate a Corrective Action Report ....."

b) Paragraph 5.6.1 states: "The CAR Coordinator shall track the progress and status of CARs...."

[6] Adverse Condition:

Based on review of obs- ations, concerns, and recommendations (Total of 39) identified during seven surveillances and audits conducted afte[illegible] 1992, five of these conditions should have been a) documented as CARs and b) tracked accordingly. Details are as follows:

1. Audit Report 92-MRA-04, Observation #7: "DRRs were prepared, resolved with the design organizations, and replies accepted by the design review leader, rather than the individual team member as specified in QAP-3-2, Rev. 0, which was in effect at the time.

2. Audit Report 92-MRA-04, Observation #13: "Quarterly CAR Status Report should be prepared and distributed to M&O Management to keep management abreast of Corrective Action Status as required by QAP-16-1."

(See continuation page)

[9] Does a significant condition adverse to quality exist? Yes X No__
If Yes, Circle One: A (B) C

[10] Does a stop work condition exist?
Yes__ No X ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date:
March 31, 1993

[12] Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

[13] Recommended Actions:
Reevaluate observations, concerns, and recommendations for deficiencies on previous M&O verification activities. For those deficiencies identified, determine current status and issue CARs for those not corrected.

[7] Initiator F. H. Lentz Date 2/5/93	[14] Issuance Approved by: QADD Date 3/18/93
[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. HQ-93-015
DATE: 2/17/93
PAGE: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

[6] Adverse Condition: (continued)

3. Audit Report 92-MRA-04, Observation #16: "Procedures QAPs-17-1, and -17-2 do not specify maximum allowable time limits for temporary storage of QA records as required by NQA-1, Section 4.4.2."

4. Audit Report 92-SRA-02, Concern #3: "QAP-17-6, Rev. 0 requires that twice yearly, the CRF Managers review hardcopy records inventory and provide OCRWM a status report of records in storage for 6 months or longer. There is no evidence that status reports have been provided to OCRWM."

5. Surveillance Report MRS-92-03, Observation #3: "The LRC staff did not have authentication/validation lists from all applicable responsible managers as required by QAP-17-2, Rev. 0, Section 5.13.1."

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

[8] CAR NO. HQ-93-16
DATE: 2/17/93
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document: M&O QAP-18-1, Rev. 0, P01

[2] Related Report No. Audit HQ-93-03

[3] Responsible Organization: M&O (Vienna)

[4] Discussed With: G. Vaslos, J. Brackett

[5] Requirement:

A. Paragraph 5.1.2 states that the Quality Assurance Manager can accept current Lead Auditor certifications to NQA-1 if supporting evidence is provided. For new Lead Auditors, Paragraph 5.2.1 states that the candidate shall complete a *Lead Auditor Qualification Form*.

B. Paragraph 5.5.1 states that Auditor candidates shall pass a written examination that evaluates comprehension of auditing and QA program requirements.

C. Paragraph 5.6.1 requires that Technical Experts participate in the M&O Technical Expert Training program.

[6] Adverse Condition:

A. Three of six Lead Auditor Qualification Forms were evaluated (Hodgson, Nash, and Petrie). The experience and management section of the Form was not completed correctly for Hodgson and Petrie. Maintenance of proficiency was not properly documented for Petrie. No objective evidence of the Lead Auditor examination or its contents were located for Petrie and Nash. There was no objective evidence of four of the five required audits for Petrie.

B. Contrary to the above, there was no evidence on Auditor Qualification Forms (Tierney, Jackson, Hoffman, and Hunt) that individuals had passed a written examination. The M&O currently has 11 "qualified" Auditors.

C. There was no evidence that Technical Experts Jennings and Denton had participated in the M&O Technical Expert Training Program. The M&O currently has three "qualified" Technical Experts.

[9] Does a significant condition adverse to quality exist? Yes__ No X
If Yes, Circle One: A B C

[10] Does a stop work condition exist? Yes__ No__ ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date: March 31, 1993

[12] Required Actions: ☒ Remedial ☒ Extent of Deficiency ☐ Preclude Recurrence ☐ Root Cause Determination

[13] Recommended Actions:

1. Re-review all Lead Auditor/Technical Expert qualification records, and, as appropriate, amend records to include additional required information. For adverse conditions A and C above.
2. Review QAP-18-1 to reconsider requirement in Paragraph 5.5.1.

[7] Initiator: R. Dennis Brown — Date 2/5/93	[14] Issuance Approved by: QADD — Date 3/18/93
[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

REV. 08/91

ATTACHMENT 4

Information Copies of Corrective Action Requests

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

[8] CAR NO. HQ-93-017
DATE: 2/17/93
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document: M&O QAP-18-2, Rev. 1

[2] Related Report No.: Audit HQ-93-03

[3] Responsible Organization: M&O (Vienna)

[4] Discussed With: G. Vaslos, B. Morgan

[5] Requirement:

Paragraph 5.1.3 states: "Checklists containing attributes reflecting the qualitative effectiveness of quality program elements audited are used to document effectiveness data during audits. These data are summarized to provide effectiveness evaluations for elements of the quality program..... Periodic summary and integration of these data is accomplished to program-wide assessment of the effectiveness of the quality program."

[6] Adverse Condition:

The periodic summary and integration of effectiveness data to accomplish a program-wide assessment is not being performed.

[9] Does a significant condition adverse to quality exist? Yes__ No X
If Yes, Circle One: A B C

[10] Does a stop work condition exist? Yes__ No__ ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date: March 31, 1993

[12] Required Actions: ☒ Remedial ☐ Extent of Deficiency ☐ Preclude Recurrence ☐ Root Cause Determination

[13] Recommended Actions:

[7] Initiator: FH Lentz F. H. Lentz Date 2/5/93	[14] Issuance Approved by: QADD Carl E. Walter Date 3/18/93
[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

REV. 08/91

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

[5] CAR NO. HQ-93-18
DATE: 2/17/93
PAGE: 1 OF 2
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document: M&O QAP-5-1, Rev. 1

[2] Related Report No.
Audit HQ-93-03

[3] Responsible Organization
M&O (Vienna)

[4] Discussed With
J. Brackett

[5] Requirement:

1. Paragraph 5.8.5 requires that "QAPs and ILPs are reviewed for changes as upper-tier documents (e.g. the QARD and the M&O QAPD) are changed. These reviews shall be performed by the responsible manager and documented by memo or PRR... memos documenting the QAP/ILP review due to changes in upper-tier documents shall be submitted to the LRC in accordance with QAP-17-1".

2. Paragraph 5.2.1 requires that "Each QAP and ILP shall be developed using the format in Attachment II, QAP/ILP Format and Development Instructions. Details on what is to be included in each section are contained in Attachment II." .... Also in Attachment II Paragraph 4 requires that the QAP "state the specific responsibilities for those M&O personnel who have actions required by the QAP/ILP."... and ...."Each QAP/ILP shall state who is responsible for developing and maintaining the QAP/ILP." (Continued on page 2)

[6] Adverse Condition:

1. No objective evidence was found indicating that the QAPs were reviewed against the requirements of the recent ICNs to the QARD and changes made in Revision 3 of the M&O QAPD.

2. Numerous procedures (QAPs) have specific responsibilities identified in the Responsibilities Sections. Many of these responsibilities are not included in procedural requirements. Some procedures (e.g. QAPs 6-1 and 17-1) do not specify who is responsible for developing and maintaining the QAP.

(Continued on page 2)

[8] Does a significant condition adverse to quality exist? Yes X No__
If Yes, Circle One: A (B) C

[10] Does a stop work condition exist?
Yes__ No X ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date:
March 31, 1993

[12] Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

[13] Recommended Action

1. QAP-5-1 be completely reviewed and revise to ensure adequacy.

2. Review and revise other QAPs to ensure conformance to the revised QAP-5-1.

[7] Initiator	[14] Issuance Approved by:
M. L. Horseman Martin Horseman Date	QADD Carl E Nelson for Date 3/18/93
[15] Response Accepted	[16] Response Accepted
QAR Date	QADD Date
[17] Amended Response Accepted	[18] Amended Response Accepted
QAR Date	QADD Date
[19] Corrective Actions Verified	[20] Closure Approved by:
QAR Date	QADD Date

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

[6] CAR NO. HQ-93-18
DATE: 2/17/93
PAGE: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

[5] Requirement: (continued)

3. Paragraph 5.3.2 states in part "... the PRR (Procedure Review Record) shall be completed with review instructions/criteria for performing the review..."

4. Paragraph 5.5.2A requires that ".... Changes in the QAP/ILP revision shall be designated by change bars in the retyped QAP/ILP."

5. Paragraph 5.6.5 states in part "The expedited PCN shall be effective for only 60 calendar days from the date established ...During that 60 days period, a formal PCN (or QAP/ILP revision) shall be processed for approval..."

6. Paragraph 5.8.4 requires that "Every time a QAP or ILP is revised, the two year clock (for the two year adequacy review) is restarted beginning on the effective date of the latest revision as long as the review of the revision is thorough, confirms the procedure's adequacy and in compliance with applicable requirements, and is so made clear in the PRR review criteria."

7. Attachment II, Section 6. Records states that QA Records are to be identified in Section 6.0 of the QAPs.

8. Paragraph 5.3.4A states all "All comments from the reviewing organization shall be consolidated as one set of comments..."

[6] Adverse Condition: (continued)

3. *There is no objective evidence that adequate review instructions or review criteria are being established for the* review of QAPs (e.g. QAPs 2-3 and 17-1). Note: This is a similar condition to the one noted in M&O CAR 92-OP-C-016 dated 5-29-92. *This indicates that previous corrective action was inadequate.*

4. QAP procedural changes were not consistently delineated by change bars (e.g. QAP-2-3).

5. Expedited PCN-QAP-3-31, Rev. 1, PO2 was written to replace a previously expired expedited PCN (PCN-QAP-3-13, Rev. 1, PO1). The procedure requires a formal PCN or procedural change after the expiration period.

6. There is no objective evidence (memo or PRR) indicating whether or not the revision review satisfies the two year review requirement.

7. The Records section (6.0) of this procedures does not identify which records are QA Records. Note: Cancellation memos and QAP/ILP Training Coordination Sheets should be considered.

8. Comments received from the Las Vegas M&O were not being consolidated.

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

[8] CAR NO. HQ-93-19
DATE: 2/17/93
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document:
M&O QAP-2-2, *Verification of Personnel Qualifications*, Rev. 1

[2] Related Report No.
HQ-93-03/YMP-93-07

[3] Responsible Organization
M&O (Vienna and Nevada)

[4] Discussed With
E. Chulick/R. White/L. Faust (NV)

[5] Requirement:

Paragraph 5.2.1 requires the verification and documentation of education and experience of individuals performing quality affecting work.

[6] Adverse Condition:

Six of 28 personnel records reviewed did not contain adequate verification of education. (Cole, Hunt, Bice, Carruth, McCormick, and L. Smith)

During Audit YMP-93-07, 4 of 26 CRWMS M&O-Nevada personnel training records reviewed did not contain adequate verification of education. All four instances involved lack of verification of high school education.

[9] Does a significant condition adverse to quality exist? Yes X No_
If Yes, Circle One: A (B) C

[10] Does a stop work condition exist?
Yes_ No X ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date:
March 31, 1993

[12] Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

[13] Recommended Actions:

Establish methodology for verification of education for personnel performing quality affecting work.

[7] Initiator P. Chomentowski Date 2/5/93	[14] Issuance Approved by: QADD Carl F Ulrich Date 3/18/93
[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

REV. 08/91

Information Copies of Corrective Action Requests

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

[6] CAR NO. HQ-93-20
DATE: 2/17/93
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document: M&O QAP-2-1, Rev. 3 *Indoctrination and Training*

[2] Related Report No. Audit HQ-93-03

[3] Responsible Organization: M&O (Vienna)

[4] Discussed With: E. Chulick/R. Robertson

[5] Requirement:

Paragraph 5.1.1 requires that managers/supervisors ensure that personnel receive appropriate ..rination prior to performing quality affecting activities.

[6] Adverse Condition:

Seven out of 28 personnel records reviewed for personnel performing quality affecting activities did n.. ..ain evidence of indoctrination to QAP-3-6, *Configuration Item Identifiers*, and QAP-3-8, *Procurement Specification.* (Sauers, Robinson, Penahaker, Willis, Dameron, Berkowitz, and Tagg)

[9] Does a significant condition adverse to quality exist? Yes__ No X
If Yes, Circle One: A B C

[10] Does a stop work condition exist? Yes__ No X ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date: March 31, 1993

[12] Required Actions: ☒ Remedial ☒ Extent of Deficiency ☐ Preclude Recurrence ☐ Root Cause Determination

[13] Recommended Actions:

[7] Initiator: P. Chomentowski Date 2/5/93	[14] Issuance Approved by: QADD Carl E Halvorson Date 3/18/93
[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

REV. 08/91

Information Copies of Corrective Action Requests

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

[8] CAR NO. HQ-93-021
DATE: 2/17/93
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

[1] Controlling Document: M&O QAPD, Rev. 2 and QAP-18-2, Rev. 1

[2] Related Report No.: Audit HQ-93-03

[3] Responsible Organization: M&O (Vienna)

[4] Discussed With: G. Vaslos, B. Morgan

[5] Requirement:

QAPD, Paragraph 18.6, Audit Reporting states: "Audit Reports .....will include the following information:

Summary of audit results, including a statement regarding the effectiveness of the quality assurance program elements audited."

QAP-18-2, Attachment II, Paragraph VII, Summary of Evidential Document states: "Provide a summary of evidential documents reviewed, persons interviewed, and the results of reviews and interviews, that is, a summary of checklist contents."

[6] Adverse Condition:

Twenty audit reports were evaluated and the following eight contained neither effectiveness statements nor summaries of checklist contents:

Audit Reports

- 92-SEA-01
- 92-TRA-01
- 92-MRA-02
- 92-MD/RLA-01
- 92-SRA-02
- 92-MRA-04
- 93-MRA-01
- 92-SY/OPA-01

[9] Does a significant condition adverse to quality exist? Yes X No__
If Yes, Circle One: A (B) C

[10] Does a stop work condition exist? Yes__ No X ; If Yes - Attach copy of SWO
If Yes, Circle One: A B C D

[11] Response Due Date: March 31, 1993

[12] Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ Root Cause Determination

[13] Recommended Actions:

[7] Initiator: FH Lentz F. H. Lentz Date 2/5/93	[14] Issuance Approved by: QADD Carl F. Kaestner Date 3/18/93
[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