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HQ-93-01  
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**U.S. DEPARTMENT OF ENERGY  
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
OFFICE OF QUALITY ASSURANCE**

**AUDIT REPORT**

**OF THE**

**OCRWM HQ ACTIVITIES INCLUDING  
YMP QUALITY ASSURANCE DIVISION ACTIVITIES  
WASHINGTON, DC  
LAS VEGAS, NV**

**AUDIT NUMBER HQ-93-01**

**NOVEMBER 30 - DECEMBER 10, 1992**

Prepared by: R Dennis Brown

Date: Jan. 23, 1993

**R. Dennis Brown  
Audit Team Leader  
Headquarters Quality Assurance Division**

Approved by: Donald G. Horton

Date: 2/22/93

**Donald G. Horton  
Director  
Office of Quality Assurance**

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## 1.0 EXECUTIVE SUMMARY

The audit team concluded that the OCRWM QA Program continues to be effectively implemented. At the Yucca Mountain Quality Assurance Division, three of the four criteria audited were found to be effective, while one criterion was found to be marginally effective. At OCRWM Headquarters, all seven criteria were being effectively implemented. Overall, all seven audited criteria were being effectively implemented.

Seven deficiencies requiring only remedial action, were identified and corrected during the course of the audit. Eight 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. Additionally, thirteen recommendations were offered for OCRWM management's future consideration.

## 2.0 SCOPE

The audit evaluated compliance to and effectiveness of the OCRWM QA Program as implemented at OCRWM Headquarters and the Yucca Mountain Quality Assurance Division.

### 2.1 QA Program Elements/Requirements

The following QA program elements were evaluated during the audit:

- 1 - Organization
- 2 - Quality Assurance Program
- 5 - Instructions, Procedures, Plans, and Drawings
- 6 - Document Control
- 16 - Corrective Action
- 17 - Quality Assurance Records
- 18 - Audits

The audited requirements were drawn from the DOE/RW-0214, *Quality Assurance Requirements Document (QARD)*; DOE/RW-0215, *Quality Assurance Program Description (QAPD)*; and the applicable *Quality Assurance Administrative Procedures (QAAPs)*, *Implementing Line Procedures (ILPs)*, *YMP Quality Management Procedures (QMPs)*, and *YMP Administrative Procedures (APs)*.

## **2.2    Technical Areas**

No Technical Specialists were utilized on the audit since Criterion 3 was not in the audit scope.

## **3.0    AUDIT TEAM AND OBSERVERS**

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

Audit Team Leader	R. Dennis Brown	CER/HQAD
Auditors	* Stephen Dana	SAIC/YMQAD
	Michael J. Donovan	CER/HQAD
	Hank Greene	CER/HQAD
	Marlin L. Horseman	CER/HQAD
	Sam Horton	SAIC/YMQAD
	Robert L. Howard	Weston/HQAD
	F. Hugh Lentz	CER/HQAD
	Lester W. Wagner	CER/HQAD

\* Note:        S. Dana co-served as Audit Team Leader by reviewing all areas which R. D. Brown had any procedural implementation responsibility relative to QA Program Elements 16 and 18.

Observers	Englebrecht von Tiesenhausen	Clark County, NV
	John Gilray	USNRC, NV
	John T. Buckley	USNRC, DC
	Jack G. Spraul	USNRC, DC
	Kenneth R. Hooks	USNRC, DC
	Y. T. Hong	KAERI, Korea

## **4.0    AUDIT MEETINGS AND PERSONNEL CONTACTED**

The YMQAD preaudit meeting was held at the DOE YMQAD office in Las Vegas on November 30, 1992. A daily debriefing was held with the Director, YMQAD. Daily audit team meetings were held to discuss potential deficiencies and other concerns. A YMQAD postaudit meeting was held at DOE's Las Vegas offices on December 3, 1992.

The Headquarters preaudit meeting was held in the Forrestal Building in Washington, DC on December 7, 1992. A daily debriefing was held with RW Office Directors and Associate Directors. Daily audit team meetings were held to discuss potential deficiencies and other concerns. The overall postaudit meeting was held in the Forrestal Building on December 10, 1992.

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 the OCRWM QA Program continues to be effectively implemented.

At OCRWM Headquarters, all seven of the audited criteria were being effectively implemented.

At YMQAD, three of the audited criteria were being effectively implemented. One criterion was marginally effective.

### **5.2 QA Program Audit Activities**

Details of the QA program audit activities for OCRWM Headquarters and YMQAD, including objective evidence reviewed, are included in Attachments 3 and 4 respectively.

### **5.3 Technical Activities**

Technical activities were not evaluated during this audit. Audit HQ-93-07, scheduled later this year will include technical activities. Several surveillances of technical areas have recently been performed.

### **5.4 Summary of Deficiencies**

The audit team identified 15 deficiencies during the audit. Seven (7) deficiencies were corrected prior to the post audit meeting.

A synopsis of deficiencies documented on Corrected Action Requests (CARs) and those corrected during the audit are detailed below. Copies of the CARs are included as Attachment 5.

#### **5.4.1 Corrective Action Requests (CARs)**

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

##### **CAR HQ-93-01**

A Headquarters individual performing procedure reviews was not trained to QAAP 5.1, Revision 3.

##### **CAR HQ-93-02**

One Headquarter individual's QAAP Manual and QARD/QAPD Manual was not current.

##### **CAR HQ-93-03**

Lead Auditor certification record packages did not include "objective evidence of examination contents".

##### **CAR HQ-93-04**

Audit schedules were not sent to the TPOs and QA Managers. The FY-92 Surveillance Schedule did not receive 1st and 2nd quarter reviews by the Director, OQA.

##### **CAR HQ-93-05**

The RW-30 Occurrence Reporting and Processing System was not identified in the Quality Assurance Controls Document.

##### **CAR HQ-93-06**

Root cause determinations were not being performed on YMP significant CARs. Evaluations of CAR responses at YMP were not adequate. Verifications of corrective action at YMP was inadequate.

##### **CAR HQ-93-07**

Headquarters personnel were not included on the required listing of individuals performing quality affecting work.

##### **CAR HQ-93-08**

Several quarterly Indoctrination and Training Matrices Updates were not documented.

#### **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. Quality Assurance Manuals 0224, 0226, 0235, and 0244 were not properly updated to incorporate ICN 4.2 to the QAR and ICN 3.2 to the QAPD. These deficiencies were corrected during the course of the audit.
- B. CAR YM-92-056 was determined to be a "significant condition adverse to quality", however, it was not included in the trend data base; as required by QAAP 2.9. This CAR was added to the trend data base during the audit.
- C. Procedure QAAP 16.1, Para. 6.1.13, requires that the responsible OCRWM Associate Director or Office Director (AD or OD) having line responsibility for the work performed by the TPO's organization, receive a copy of the CAR. The OD, Office of Geologic Disposal (C. Gertz) was removed from the CAR distribution list. Mr. Gertz was added back to the CAR distribution list during the audit.
- D. Paragraph 6.2.2 of QAAP 16.1, Revision 4 required that if the requested due date of a Corrective Action Request (CAR) was not met, the responsible manager had to submit a written request for extension to the applicable QADD prior to the due date on the CAR. Contrary to this requirement, corrective action responses for the following CARs were not submitted by the due date nor were there written requests for extension in the CAR files prior to the due date.
  - CAR HQ-92-017, due 11/20/92
  - CARs HQ-92-013 through 92-015, due 12/07/92 (the week of the audit)

The responses to the four CARs were received prior to the completion of the audit. The response to CAR HQ-92-017 was clearly overdue, but appears to be an isolated case.

- E. There was no evidence of YMQAD audit report distribution of Audit YMP-92-09. The distribution list was located and placed in the applicable quality records package during the audit.
- F. There was no evidence of YMQAD surveillance report package (YMP-92-029) being authenticated. No table of contents form or other transmittal form was with the package. The package was authenticated during the audit.
- G. QAAP 18.2, Revision 5, Paragraph 6.3.2 requires that the Audit Team Leader sign and date the Audit Plan. Contrary to the requirement, the Audit Plan for Headquarters Audit 92-02 was signed by an individual other than the Audit Team Leader, without objective evidence of authority or delegation. The Audit Team Leader, did, in fact, prepare the Audit Plan. A memo documenting this fact and documenting the telephone authority to sign on his behalf were provided during the audit.

## **6.0 RECOMMENDATIONS**

### **6.1 The audit team determined that:**

- a) the implementation of the FY91 Management Assessment recommendations is not being tracked and verified;
- b) the tracking of this implementation is not a violation of QARD or QAAP 2.7 requirements; and
- c) the FY93 Management Assessment team investigated the implementation status of the FY91 Management Assessment recommendations.

To better reflect the overall intent of performing management assessments, the audit team recommends that QAAP 2.7 be revised to incorporate requirements to track and/or verify the implementation of assessment recommendations.

The audit team further recommends that RW-30 determine the status of and begin formally tracking the actions required by the FY91 Management Assessment recommendations.

- 6.2 The requirements in Paragraphs 6.5.4 and 6.2.1 of QAAP 6.1 are being implemented by the annual review of the controlled document distribution list initiated by the Director, OQA. The audit team recommends that one of these duplicative requirements be eliminated during the next revision of QAAP 6.1.
- 6.3 Paragraph 5.4 of QAAP 16.2 requires that "CARs that identify significant conditions adverse to quality", be evaluated to determine whether a Stop Work condition exists in accordance with the criteria in QAAP 16.1. CAR YM-92-033 provides a recommendation to "stop the submittal of records". The Stop Work block on CAR is checked "no" and based on the auditors review of the CAR to the SWO criteria, this CAR does not meet the SWO criteria. Training on QAAP 16.1 and 16.2 should include the precaution that language in the "recommended action" block of CARs not imply stopping work is necessary if delineated conditions of QAAP 16.2 for stop work are not present.
- 6.4 The audit team recommends the following requirements in QAAP 2.1 receive management attention:
- a) The procedure is difficult to follow and does not flow from one logical step to the next. The procedure might be flow charted to assure that readers understand the process and are able to implement the process in a logical sequence.
  - b) The procedure contains redundant statements, for example:
    - Paragraphs 6.5.4 and 6.5.7, 1st sentence, state the same requirement.
    - Paragraphs 6.3.1 and 6.3.2 state the same requirement.
  - c) The need for quarterly updates for status reporting should be reviewed. During the review of training records, quarterly updates could not be located in all cases (reference CAR HQ-93-08). The process should be streamlined so that maintenance of training requires the minimum number of steps possible.
- 6.5 QAP 6.2 requires that document reviewers identify mandatory comments with a code letter (a, b, or c) corresponding to the applicable criterion provided in Section 3.2 of the procedure. All sampled mandatory comments were resolved. The audit team recommends that the process used to identify mandatory and non-mandatory comments be re-evaluated when revising the QAP to incorporate the requirements of the new QARD (DOE/RW-0333).



- 6.6 It was noticed while examining the Corrective Action Request (CAR) Log, CAR HQ-91-031 was never used to document a deficient condition; however, CAR HQ-91-031 continues to be shown in the CAR Log. Based on this, two recommendations are provided. (1) CAR HQ-91-031 should be documented as an invalid CAR number. A written explanation of the disposition of this CAR number should be provided and forwarded to the Quality Records Center with the CAR HQ-91-031 records package. (2) if HQAD plans to continue pre-assigning blocks of CAR numbers, then QAAP 16.1, should be reviewed on how to process CAR numbers that are not used.
- 6.7 It is recommended that the OCRWM Surveillance Schedule include the surveillances being conducted by YMQAD. The FY92 OCRWM Surveillance Schedule did not include any YMQAD surveillances.
- Note: Many of the YMQAD surveillances have been "unscheduled".
- 6.8 YMQAD surveillance reports do not always clearly discuss the effectiveness of a process or adequacy of an end product. It was noted that verifying effectiveness was not part of the scope of several surveillances conducted during FY 92. The audit team recommends that this requirement be reviewed for intent.
- 6.9 The C1, C2, and C3 element designator shown on the audit schedule were consistently modified for each audit conducted in FY 92. Valid reasons for modification were identified for each case. The team recommends discontinuing using these designators as they are more suited to performing compliance based audits. The audit plans clearly identify the audit scopes.
- 6.10 It is recommended that during QA records training at YMP for Records Sources, additional emphasis be placed on completing the Table of Contents form. While auditing YMP record packages, there were several cases (audit report packages, CAR packages, surveillance report packages) of blocks requiring "Tracking Number" and "Description" being left blank. The Tracking Number was only used for additions to original packages. No additions to Records Packages were audited.
- 6.11 Record Sources are ensuring that QRP numbers and WBS numbers are being placed on Quality Records Packages. The same number (1.2.9.3) appeared on all QA Records reviewed during the audit. The LRC Supervisor indicated that personnel do not ask for sorts on either the QRP or WBS number. Records are being retrieved using other numbers. We recommend evaluating the value of using these two numbers on Quality Records Packages.

- 6.12** There appears to be conflicting procedural requirements concerning training records. The QAPD requires that training records be authenticated and AP-1.8Q requires that authenticated records be submitted to the LRC within 10 days of authentication. However, AP-1.18Q then contradicts the QAPD by stating that a document package is not a QA record until it is authenticated. The audit team recommends that training records be maintained in the LRC versus in the training office files and that apparent conflicts between documents be evaluated and resolved.
- 6.13** The audit team felt that CARs written for significant conditions adverse to quality are essentially treated like any other CAR (with only additional corrective action steps required). The audit team felt that "significant" CARs should receive greater emphasis from YMP personnel, including management. The audit team suggests that the criteria identified in QAAP 16.1 to determine significant conditions adverse to quality require further clarification in the QAAP; additional training may be necessary. In addition the importance of identifying and processing "significant conditions adverse to quality" should be emphasized from all levels of management.

## **7.0 LIST OF ATTACHMENTS**

- Attachment 1: Audit Team Assignments
- Attachment 2: Personnel Contacted During the Audit at Headquarters
- Attachment 3: Audit Details - OCRWM Headquarters
- Attachment 4: Audit Details - Yucca Mountain Project Office QA Division (YMQAD)
- Attachment 5: Copies of the CARs

## ATTACHMENT 1

### Audit Team Assignments

Audit Team Leader: Dennis Brown

<u>TEAM</u>	<u>PERSONNEL</u>	<u>CRITERIA</u>	<u>IMPLEMENTING PROCEDURES</u>
"A" (HQ)	Dennis Brown Hugh Lentz Marlin Horseman	1, 2, 17	<u>QAAPs</u> 2.6, 2.7, 2.10, 17.1 <u>ILPs</u> 12.17.01
"B" (HQ)	Rob Howard Steve Dana	2, 5, 6	<u>QAAPs</u> 2.1, 2.2, 2.4, 6.1 <u>QAPs</u> 5.1, 6.2
"C" (HQ)	Mike Donovan Sam Horton Hank Greene	2, 16, 18	<u>QAAPs</u> 2.3, 2.9, 16.1, 16.2, 18.1, 18.2, 18.3
"D" (YMP)	Marlin Horseman Hank Greene Rob Howard Dennis Brown	2, 16, 18	<u>QAAPs</u> 2.9, 16.1, 16.2, 18.1 18.2, 18.3 <u>QMPs</u> 16-03
"E" (YMP)	Les Wagner Dennis Brown Rob Howard	2, 5, 6, 17	<u>QAPs</u> 5.1, 6.2 <u>QMPs</u> 02-01 <u>APs</u> 1.18Q

## ATTACHMENT 2

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**Personnel Contacted During The Audit  
Of Headquarters**

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
J. Arpia	RW-131	Training Coordinator		X	
K. Bar	Asta Engr.	Mgmt. Assess. Team Leader		X	
J. Bartlett	RW-1	Director, OCRWM	X	X	
D. Borchardt	Weston	Engineer		X	
H. Brandt	RW-13	Division Director			X
S. Brocoun	RW-22	Division Director	X	X	
D. Brown	TRW	QRC Attendant		X	
R. D. Brown	CER	Audit Team Leader	X		X
A. Brownstein	RW-432	Branch Chief	X		
J. Buckley	USNRC	Observer	X		X
J. Carlson	RW-43	Division Director	X	X	X
B. Cerny	RW-12	Division Director	X		
P. Chomentowski	Weston	Sr. Quality Specialist	X		X
R. Clark	RW-3.1	Division Director	X	X	X
S. Dana	SAIC	Auditor	X		
N. DelGobbo	RW-422	Branch Chief	X		
L. Desell	RW-331	Branch Chief	X		
M. Donovan	CER	Auditor	X		X
S. Gomberg	RW-322	Branch Chief	X		
C. Good	CER	CAR Coordinator		X	
L. Gordon	Weston	Sr. Quality Specialist			X
R. Hahn	Weston	Sr. Tran. Analyst		X	
D. Hendrix	CER	QA Specialist, Training		X	
K. Hooks	USNRC	Observer			X
M. Horseman	CER	Auditor	X		X
S. Horton	SAIC	Auditor	X		X
D. Horton	RW-3	Director, OQA	X	X	
R. Howard	Weston	Auditor	X		X

# ATTACHMENT 2

## Personnel Contacted During The Audit Of Headquarters

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NAME	ORGAN.	TITLE	PRE	CONTACT	POST
J. Imam	RW-22	Physical Scientist		X	
T. Johnson	RW-3	Audit Coordinator	X		
J. Jones	RW-422	Physical Scientist	X	X	
D. Kane	RW-421	General Engineer	X		
D. Kim	RW-332	Mgmt. Assess. Coordinator		X	
P. Kumar	RW-421	General Engineer	X		
W. Lake	RW-431	General Engineer		X	
J. Leahy	RW-53	Contracting Officer's Repr.		X	
W. Lemeshefsky	RW-32	Acting Division Director		X	X
H. Lentz	CER	Auditor	X		X
C. Lukasik	RW-131	Branch Chief		X	
P. Manzoni	Ast Engr.	QA Specialist		X	
J. Marchand	Weston	Senior QA Specialist		X	
M. Meyer	CER	Project Manager	X		X
R. Milner	RW-40	Associate Director	X	X	
T. Nguyen	RW-322	General Engineer		X	
G. Parker	RW-332	Branch Chief	X		
M. Payton	RW-432	Analyst	X		
F. Peters	RW-2	Deputy Director, OCRWM	X	X	
F. Prior	Weston	Sr. Quality Engineer	X		X
C. Quan	RW-323	Physical Scientist	X		
J. Roberts	RW-30	Acting Assoc. Director	X	X	X
S. Rousso	RW-10, 50	Associate Director	X	X	
G. Ruffin	TRW	Manager, QRC		X	
M. Senderling	RW-321	General Engineer	X	X	
J. Spraul	USNRC	Observer	X		X
D. Stucker	RW-22	General Engineer	X	X	
J. Summerson	RW-22	Physical Scientist	X		

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## Personnel Contacted During The Audit Of Headquarters

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
J. Thompson	Weston	Tran. Engineer		X	
V. Trebules	RW-42	Division Director	X		
T. Troung	RW-321	General Engineer		X	
T. Van	RW-323	Branch Chief	X	X	
J. Vlahatis	RW-332	Contracting Officer's Report		X	
C. Weber	RW-3.1	QA Specialist		X	
J. Williams	RW-421	Branch Chief	X		X
T. Wood	RW-52	Contracting Officer's Repr.		X	
W. Wowak	Weston	Deputy Program Manager		X	

## Personnel Contacted During The Audit Of Yucca Mountain Quality Assurance Division

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
A. Arceo	SAIC	QA Representative		X	
S. Bates	SAIC	QA Representative		X	
N. Brogan	SAIC	CAR Coordinator	X	X	X
D. Brown	CER	Audit Team Leader	X		X
T. Casilli	TRW	Records Ctr. Supervisor		X	
N. Cox	SAIC	QA Representative		X	
S. Dana	SAIC	QA Engineer	X		
M. Diaz	DOE	QA Audit Lead	X	X	X
J. Gilray	USNRC	Observer	X		X
H. Greene	CER	Auditor	X		X
C. Hampton	DOE	QA Programs Lead	X	X	X
J. Heaney	SAIC	QA Representative		X	
Y. T. Hong	KAERI	Senior Engineer	X		
M. Horseman	CER	Auditor	X		X

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Personnel Contacted During  
The Audit Of Yucca Mountain  
Quality Assurance Division

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
R. Howard	Weston	Auditor			X
K. Jerome	TRW	Records Ctr. Attendant		X	
R. Klemens	SAIC	QA Engineer		X	
F. Kratzinger	SAIC	QA Engineer		X	
J. Martin	SAIC	QA Representative		X	
H. Masuda	DOE	QA Secretary		X	
R. Maudlin	Mactec	QA Representative		X	
P. Osborne	SAIC	Office Coordinator		X	
R. Powe	SAIC	QA Audit Lead	X	X	X
R. Spence	DOE	Director, YMQAD	X	X	X
J. Therien	SAIC	QA Programs Lead		X	
E.v. Tiesenhausen	Clark County	Observer	X		X
L. Wagner	CER	Auditor	X		X
C. Warren	Mactec	Surveillance Lead	X	X	X

Audit Details - OCRWM Headquarters

The following is a summary of QA program audit activities covered during the Headquarters portion of 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**

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

The current organization chart was reviewed with the Director, OCRWM. All positions were adequately staffed. There was adequate objective evidence to indicate that OCRWM was interfacing with Federal regulatory agencies, the nuclear industry, affected states, and local governments concerning quality assurance matters.

The Director, Office of Quality Assurance (OQA) was still sufficiently independent from the OCRWM line organizations. He has also continued to review the QA Program descriptions and revisions thereto of the HQ-managed program Participants. The Office of Quality Assurance is still maintaining an effective quality assurance information system.

The audit team interviewed RW-20, RW-30, and RW-40 management. Each Associate Director was cognizant with the OCRWM QA Program and the areas of quality affecting work within their respective organizations.

The audit team reviewed organization charts which show adequate delegation of authority for the HQ Quality Assurance and the YMP Quality Assurance Divisions.

This QA Program Element was considered to be effectively implemented.

**2.0 QA PROGRAM**

**2.1 Indoctrination And Training (QAAP 2.1)**

The audit team interviewed the QA Training Officer (QATO) and the QA Training Coordinator and determined that both individuals exhibited an in-depth knowledge of the procedural requirements and an understanding of how the process is implemented.



**Audit Details - OCRWM Headquarters**

Supervisors had prepared initial or revised an existing Indoctrination and Training (I&Ts) matrices when new personnel were assigned or changes were made to job duties within a position. I&T matrices were reviewed to verify acceptance of data input and to determine if training to QAP 3.5 and/or QAP 6.2 had been accomplished. Thirty four (34) preparers and/or reviewers for OCRWM Technical Requirement Documents were selected for review of their I&T matrices.

The QATO had properly entered data from the I&T matrices into the training database.

The QATO was reviewing the I&T matrix for proper preparation and completion. The QATO utilizes a "I&T Matrix Checklist" and a "Notification of Incorrect Indoctrination & Training Matrix." Neither of the documents are in the procedure; however, they provide evidence the review was performed. See Recommendation 6.4 for suggested improvement to the procedure.

Lesson plans were being used for classroom training and were approved by the QATO. The audit team reviewed lesson plans for QA courses TR07A, TR10, and QAAP 2.1. All courses contained learning objectives identifying training content and standards of performance. Lesson plan for QAAP 2.1 had been revised to accommodate changes in the procedure.

Completed I&T matrices, attendance records, and lesson plans were being maintained in the Quality Records Center (QRC). However, 14 of the 34 I&T matrices reviewed were located at the TRW office in Vienna. Prior to the post-audit meeting the I&T matrices were transmitted by TRW to RW-30 for review by the audit team and subsequent transmittal to the QATO.

The auditor reviewed six I&T matrices to determine if the individuals had been trained to QAAP 5.1, Revision 3, prior to performing quality affecting activities.

See CARs HQ-93-01, HQ-93-07, HQ-93-08 for details regarding identified deficiencies.

**2.2 Establishing QA Program Controls (QAAP 2.3)**

QAAP 2.3 was evaluated based upon interviews with personnel in organizations required to implement the procedure. Presentations by each line organization during the preaudit meeting that identified ongoing work were also utilized to determine whether the need for QA Controls had been adequately evaluated.

Audit Details - OCRWM Headquarters

Activities listed in the *Quality Assurance Controls Document* (QACD), Table 6-1-1 for RW-22 were compared to those identified by RW-22 personnel during the audit entrance meeting. Personnel from RW-22 were also interviewed. They indicated that the activities listed in the QACD adequately cover all ongoing activities. They did also indicate, however, that the QACD is not entirely correct as it implies that RW-22 is responsible for initiating certain activities, when in fact, they only provide reviews and advisory services on tasks initiated by other organizations.

Personnel were also interviewed at RW-3, RW-10, RW-40, and RW-50. No work activities were identified that are not covered in the current QACD. Documentation approving the October 1990 reorganization of OCRWM were reviewed at RW-10. The work descriptions in the current QACD are consistent with the responsibilities identified in that reorganization.

See CAR HQ-93-05 for details regarding identified deficiencies.

**2.3 Preparation And Maintenance Of the QARD and QAPD (QAAP 2.4)**

The audit team interviewed the Director, HQAD to determine what actions are being taken to revise QAAP 2.4 to accommodate the new Quality Assurance Requirements and Descriptions (QARD) document. The Director, HQAD stated the procedure is being revised at this time to accommodate the new QARD.

The format, content, the method of modifying the QARD and QAPD were acceptable. Documentation and review of ICNs was acceptable. ICN 4.2 (QARD) and ICN 3.2 (QAPD) were reviewed utilizing QAP 6.2. QAAP 2.4 states that QAAP 2.5 must be used for document review; however, QAAP 2.5 has been superseded by QAP 6.2. This procedural inconsistency will be changed upon revision of QAAP 2.4.

Records generated per QAAP 2.4 were being adequately maintained in the QRC.

**2.4 Readiness Review (QAAP 2.6)**

The auditors discussed the requirement and need for readiness reviews with Offices RW-22, RW-30, and RW-40. Up to this date, OCRWM HQ has not had a need to conduct a readiness review. One readiness review for the activities concerning the MRS Safety Analysis Report had been considered but not scheduled.

Audit Details - OCRWM Headquarters

**2.5 Management Assessment (QAAP 2.7)**

The audit team interviewed RW-1 to determine:

- Responsibility for Management Assessment (MA)
- Team Leader/team selection
- MA team direction
- MA plan approval
- MA team independence
- Status/tracking of responses to the FY91 Management Assessment recommendations

The audit team found the above items to be satisfactory except that FY91 MA recommendations are not being tracked and not all have been implemented. No CAR was written since the tracking of recommendations is not a QAAP 2.7 requirement. See Recommendation 6.1 for suggested improvements to the procedure.

The audit team interviewed the DOE/RW Contracting Officer's Representative and the current Management Assessment Team Leader with regards to the status of implementing the FY92 MA plan. A preliminary FY92 MA report was to be issued by 1/8/93.

The audit team obtained training information for the FY92 MA team from the RW training coordinator and the QRC and verified that the team had been trained to the requirements of the QARD, QAPD, and QAAP 2.7. All team members listed in the plan, except two, had properly completed I&T Matrices. The Team Leader indicated that the two exceptions were not being used for the assessment; this fact will be documented in the FY92 MA report.

**2.6 QA Program Trend Evaluation and Reporting (QAAP 2.9)**

The implementation of QAAP 2.9 was verified through interview with the Director, HQAD and through review of documents generated during implementation of the procedure. Each of the four quarterly trend reports for FY92 were reviewed. No adverse trends were identified by OCRWM HQ or YMPO. The closure of one trend identified in 1991 at YMPO was described in one of the quarterly reports.

Each quarterly trend report contained the overall OCRWM trend report and the reports prepared by each QADD. The content of each report was verified to be in accordance with QAAP 2.9, as was the distribution of resulting reports to

**Audit Details - OCRWM Headquarters**

appropriate management. Procedural requirements for implementing appropriate measures to correct adverse trends could not be evaluated since no trends have been detected during the past year.

**2.7 Hold Points (QAAP 2.10)**

The audit team interviewed the Hold Point Tracking Coordinator and each of the specific hold point coordinators. A Summary Report of Hold Points and Hold Control Sheets (HCSs) was reviewed. Three hold points have been initiated and all three were properly documented. In addition, the Responsible Directors (Milner and Roberts) had notified the affected organizations by memo requesting input regarding impacts. In one case (Hold Point 003), the affected organization (RW-20) made some changes that were accepted by the originating organization (RW-30).

The HCSs were issued to authorize hold point emplacement and hold point numbers were issued. In one case, the HCS was not signed (name typed) by the Tracking Coordinator. This was corrected during the audit.

The "Forecast Completion Date" for all three hold points had passed. This date was changed on the Summary Report during the audit to "TBD" for Hold Points 001 and 002, and 3/1/93 for Hold Point 003. None of the three had reached the designated hold point; and therefore, the audit team could not verify that the proper notification was given. Changes to the hold points are anticipated. A discussion with all coordinators indicated they were aware of the change process identified in QAAP 2.10.

The Summary Report of Hold Points did not indicate the "Affected Organization" as required by procedure. This was corrected during the audit.

There was some confusion about who maintains the Hold Point Record Packages. During interviews with the coordinators, the requirement that the originators process the records package was emphasized.

Hold Point 002 was communicated to the M&O directly by RW-40. The procedure requires that the Contracting Officer's Representative (COR) (T. Wood) make this communication and coordinate hold point implementation. The COR had been involved and was on distribution for the letter from RW-40 to the M&O. Future hold points to non-OCRWM organizations will be processed directly through the COR.

**Audit Details - OCRWM Headquarters****2.8 Overall Effectiveness**

The problems identified in CARs HQ-93-01, -05, -07, and -08, reflect narrow, isolated cases. The audit team concluded that QA Program Element 2 was being effectively implemented at Headquarters.

**3.0 INSTRUCTIONS AND PROCEDURES****3.1 Preparation, Review, and Approval of Quality Assurance Administrative Procedures (QAAP 5.1, Rev. 3)**

The audit team sampled four of seven records packages for Quality Assurance Administrative Procedures prepared or revised in 1992 to verify that they were prepared and reviewed in accordance with QAAP 5.1, Rev. 3. The audit team also reviewed records packages for QAP 3.5, Revision 2; QAP 5.1 Revision 4; and QAP 6.2 Revision 0 to verify that they were prepared and reviewed in accordance with QAAP 5.1, Revision 3.

The team reviewed Document Review Records (DRRs) and verified that the DRRs were completed for the review relative to the identified acceptance criteria. Mandatory comments on completed DRRs were resolved between reviewers and preparers; the draft procedure was updated to reflect the comments. Resolution of both mandatory and non-mandatory comments were addressed on DRRs.

The team reviewed the revision records or procedures and verified that the preparer had completed and signed the revision record and the Director, OQA had made the determination as to whether the changes were major or minor and had completed the training block.

The team also verified that the QAPs met the format and content requirements of QAAP 5.1, Revision 3. The QAPs under review did not meet the content requirements of QAAP 5.1, Revision 3; however, special format and content requirements for the QAPs were specified in the review criteria for those procedures and the audit team verified that those requirements were met in the approved QAPs.

**3.2 Quality Assurance Program Procedures (QAP 5.1, Rev. 4)**

The audit team determined that QAP 5.1, Revision 4 has been implemented only once since it became effective. It was used to process an Interim Change Notice to a procedure. The team verified that QAAP 18.1, Revision 5, ICN 1 was processed in accordance with QAP 5.1, Revision 4.

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**3.3 Preparation and Revision of Implementing Line Procedures (QAAP 5.2)**

No development or revision activity has taken place since the last QA audit of OCRWM Headquarters (HQ-92-01).

**3.4 Overall Effectiveness**

The audit team concluded that QA Program Element 5 was being effectively implemented.

**4.0 DOCUMENT CONTROL**

**4.1 Document Control (QAAP 6.1)**

The audit team verified that documents were controlled by QAAP 6.1, Quality Assurance Procedures and Quality Assurance Manuals are being handled in accordance with the procedure. This included reviewing Quality Records Packages QRP-92-0610.00 and QRP-92-0627.00 and verifying that:

Distribution Lists for revisions to controlled documents were approved by the Director, OQA.

Controlled documents had unique title and identification numbers, were identified with a red stamp, were sent to controlled copy holders, and the Table of Contents was revised each time a change was made to a document.

Instructions to controlled document recipients clearly described what to do with revisions and superseded documents.

Requests to add personnel to controlled distribution lists were accomplished via formal memorandum. See Recommendation 6.2 regarding suggested improvements to this procedural requirement.

The audit team sampled 14 of 65 QAP Manuals and Quality Assurance Manuals issued to OCRWM Headquarters personnel to verify that up-to-date procedures were available and being used. The sample was drawn from those personnel identified as recently performing quality affecting work.

See CAR HQ-93-02 for details regarding identified deficiencies.

Audit Details - OCRWM Headquarters

**4.2 Document Review (QAP 6.2)**

The audit team reviewed QRP-91-0566.00 while it was in the process of being prepared to verify that the Waste Acceptance Systems Requirements Document, Rev. 0, had been reviewed in accordance with QAP 6.2, Revision 0.

The audit team verified that the review coordinator had prepared the appropriate portions of the Document Review Records (DRR) and had specified appropriate review criteria in a manner consistent with QAP 6.2. The review package appeared to include appropriate background information. The team also verified that the coordinator had appropriately assigned organizations to review the Waste Acceptance Systems Requirements Document and had specified a reasonable due date for completing the review.

The audit team sampled eight out of fifteen Document Review Records to verify that reviewers had performed the review using the specified review criteria and that comments were appropriately documented on the DRRs. The auditors also interviewed two reviewers to verify that they had used and understood the specified review criteria. The review coordinator had responded to all comments, regardless of whether the comment was designated as mandatory or not. The review coordinator also ensured that the responses for those comments designated as mandatory were accepted by the reviewers. See Recommendation 6.5 for suggested improvements to the procedure.

The audit team sampled five of fifteen reviewers and verified that they had received training on QAP 6.2, Revision 0 and that they had the education and experience sufficient to perform the review. (See audit details for QA Program Element 2.)

Since the records package for the QAP 6.2 review of the Waste Acceptance Systems Requirements Document was in the process of being prepared during the time of the audit the audit team was unable to verify the complete turnover of the records to the records facility.

**4.3 Overall Effectiveness**

The audit team concluded that Headquarters was effectively implementing QA Program Element 6.

**5.0 CORRECTIVE ACTION**

**5.1 Corrective Action (QAAP 16.1)**

The audit team reviewed the Corrective Action Request (CAR) Log, a large sample of open and closed CARs and associated correspondence, and several CAR Status Reports. See Recommendation 6.6 for suggested improvements in this area.

**5.2 Stop Work (QAAP 16.2)**

Upon investigation of implementation of QAAP 16.2, it was determined that no stop work orders have been issued since the last audit. Several significant Corrective Action Requests were reviewed; none met the requirements for stop work.

**5.3 Overall Effectiveness**

The audit team concluded that Headquarters was effectively implementing QA Program Element 16.

**6.0 QUALITY ASSURANCE RECORDS**

**6.1 QA Records Management (QAAP 17.1)**

The audit did not include portions of QAAP 17.1 that were recently covered during Surveillance HQ-SR-92-05, in August 1992. CAR HQ-92-017 was written based on findings from that surveillance.

The audit team selected 14 closed QA Records Packages from a total of 324 closed packages. Only four RW offices had closed packages (OQA had closed 304). These packages were reviewed for:

- "QA" designator in upper right hand corner
- Originator requirements
- Transmittal requirements
- Draft copy requirements
- Validator requirements
- Correction requirements



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The audit team found the packages to be satisfactory; however, see Recommendation 6.11 for suggested improvements in this area.

The audit team had a concern about the logical order of one RW-50 records package. The RW-50 QA records package validator, J. Leahy supplied a satisfactory explanation for the existing order of the package.

The audit team interviewed RW Offices 22, 30 and 40 concerning their responses to CAR HQ-92-017. Each office was submitting a response and was initiating the related corrective action. The acceptance of the responses by OQA had not been performed.

#### **6.2 Quality Records Center Implementing Line Procedure (ILP 12.17.01)**

The audit team interviewed the QRC Manager with regard to the following ILP items:

- Lists of QA record/authorized personnel from RW Offices (sampled for each RW Office)
- Transmittals to QRC (sampled six transmittals)
- Inspection of records by QRC (sample of two)
- Handling of privileged records
- Resolving record problems (verbal)
- Record review and correction (examples only)
- Transmitting of records to CRF (two examples)
- QRC Records (their logs/transmittals-sampled three, reviewed Table of Contents for each package)

From the lists of QA records/authorized personnel, the audit team found that RW-40 had not reviewed their lists during the past year. RW-40 submitted revised listings during the audit.

The audit team reviewed the storage area with the QRC Manager; the facilities were satisfactory. The QRC was a locked room with limited access (authorized access was posted). Privileged records were kept in a locked file and the privileged portion of personnel records were color coded.

The audit team discovered that the CRF had not produced microfilm copies for the past year. The QRC, however, has been maintaining a hardcopy of QA records to meet the availability requirements. The audit team issued a memo to the M&O audit team leader to investigate this problem during the audit scheduled in February of 1993. Two other concerns were included in the memo: the interface between the QRC ILP and the M&O Quality Assurance Procedures (QAPs); and the referencing of Federal Standards in the QAPs.

Audit Details - OCRWM Headquarters

**6.3 Overall Effectiveness**

Based on a detailed review of the OCRWM Headquarters QA Records system and facilities, the audit team concluded that QA Program Element 17 was being effectively implemented.

**7.0 AUDITS**

**7.1 Qualification of Audit Personnel (QAAP 18.1)**

The qualification records of Auditors and Lead Auditors were examined in detail. A random list of Auditors and Lead Auditors were selected and their documentation was reviewed to determine procedural compliance. During the review of Lead Auditor examination records, it was discovered that several records packages did not contain objective evidence of the contents of examinations.

See CAR HQ-93-03 for details regarding identified deficiencies.

**7.2 Audit Program (QAAP 18.2)**

Implementation of the audit process was examined based on a detailed review of two Headquarters audit reports (HQ-92-001 and HQ-92-002). All required audit correspondence was reviewed and found to be satisfactory. In addition, audit schedules (FY 92 and 93) and supporting documentation associated with the audit scheduling process were reviewed.

**7.3 Surveillance Program (QAAP 18.3)**

The audit team reviewed surveillance schedules, reports, and associated documentation. Three surveillance reports were sampled. The surveillances had been properly conducted in accordance with the requirements of QAAP 18.3.

See CAR HQ-93-04 for details on identified deficiencies.

**7.4 Overall Effectiveness**

The audit team concluded that OCRWM Headquarters was effectively implementing QA Program Element 18 (audits and surveillances).

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#### **B. OBJECTIVE EVIDENCE REVIEWED AT HEADQUARTERS**

Handout of presentation made by Stephen Brocoum, Office of Geologic Disposal Analysis and Verification Division Functions and Responsibilities, dated 12/07/92.

Handout of presentation made by John Roberts RW-30 Organizations Structure, dated 12/09/92.

Organization chart for RW-30, Office of Systems and Compliance, dated 4/29/91.

#### **PROCEDURES**

QAAP 2.1, Revision 2, *Indoctrination and Training*

QAAP 2.4, Revision 0, *Preparation and Maintenance of the QARD and QAPD*

#### **I&T MATRICES REVIEWED**

C. Weber	RW-3	B. Teer	TRW
D. Stucker	RW-22	R. Eble	TRW
M. Popa	RW-321	W. Hollaway	TRW
J. Imam	RW-22	J. Stringer	TRW
P. Bunton	RW-331	V. McCormick	TRW
T. Nguyen	RW-321	J. McConaghy	TRW
P. Kumar	RW-421	R. Justice	TRW
D. Kane	RW-421	J. McCleary	TRW
M. Senderling	RW-30	K. Bhattacharyya	TRW
D. Borchardt	WESTON	H. Benton	TRW
J. Thompson	WESTON	N. Seagle	TRW
R. Hahn	WESTON	J. Miller	TRW
L. Wade	WESTON	S. Gomborg	TRW
M. Donovan	CER	P. Lovett	TRW
L. Clem	TRW	L. Warren	TRW
W. Bailey	TRW	L. Lindsey	TRW
B. Cole	TRW	A. Jenkins	TRW
		W. Law	TRW

#### **TRAINING COURSES**

QAAP 2.1, *Indoctrination and Training*

TR07A, *QA Program Effectiveness*

TR10, *OCRWM Auditor/Lead Auditor*

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"List of Employees Performing Assignment Against the QARD" (printout provided by the Training Coordinator, no revision or date)

"Training Information Management System" (printout from CER database, dated 12/8/92)

"Notification of Incorrect Indoctrination and Training Matrix" (non-proceduralized, no revision or date, provided by Training Coordinator)

"I&T Matrix" (non-proceduralized, no revision or date, provided by the Training Coordinator)

*Quality Assurance Controls Document (QACD), Revision 1, October, 1990.*

Document Review Record (DRR) for QACD Revision 1, 10/10/90

Memo from AD-122 approving OCRWM Reorganization, 10/19/90

Quality Assurance Trends Report, FY-92 4th Quarter, 10/26/92

Quality Assurance Trends Report, FY-92 3rd Quarter, 07/24/92

Quality Assurance Trends Report, FY-92 2nd Quarter, 05/01/92

Quality Assurance Trends Report, FY-92 1st Quarter, 03/16/92

QRP-91-0461.00, QA Records Package for FY91 Management Assessment (closed)

Memo to Kanai Bar from John Bartlett, Management Assessment, dated 8/31/92.

DE-AC01-92RW00254, Office of Civilian Radioactive Waste Management QA Management Assessment and Support to Self-Assessment Unit Statement of Work, dated 08/19/92.

Memo to OCRWM Associate and Office Directors from John Bartlett, 10/23/92, Kick-Off Meeting for the OCRWM Quality Assurance Management Assessment, dated 10/22/92.

Quality Assurance Management Assessment Final Plan, prepared by Asta Engineering, Inc., dated 10/9/92.

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List of Management Assessment Interviews from K. Bar, dated 11/3/92.

Indoctrination and Training Matrices for FY92 management assessment team:

K. Bar	F. Jan
R. Cerzosimo	M. Kruger
J. Chickneas	P. Manson
E. Graber	W. Vocke
K. Highfill	

### HOLD CONTROL SHEETS

HCS-001, Hold point prior to the submittal of Safety Analysis Reports (SARs) to the NRC for cask designs

HCS-002, Hold point prior to issuance of RFP for acquisition of Phase 1 casks

HCS-003, Hold point for the review of new baseline documents to ensure consistency and the inclusion of all requirements prior to the documents becoming effective.

Summary Report of Hold Points, dated 11/30/92.

### QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES

QAAP 18.1, Revision 3, *Qualification of Audit Personnel*  
QAAP 6.1, Revision 2, *Document Control*  
QAAP 5.1, Revision 3, *Preparation and Revision of Quality Assurance Administrative Procedures*  
QAAP 2.10, Revision 0, *Hold Points*  
QAAP 2.7, Revision 1, *Management Assessments*  
QAAP 16.1, Revision 4, *Corrective Action*  
QAP 3.5, Revision 2, *Technical Document Preparation*  
QAP 5.1, Revision 4, *Quality Assurance Program Procedures*  
QAP 6.2, Revision 10, *Document Review*

Quality Assurance Procedure Manuals and Quality Assurance Manuals Numbers 006, 012, 019, 021, 022, 024, 025, 051, 081, 096, 224, 226, 235, and 244

Waste Acceptance Systems Requirements Document Rev. Records Package #QRP-91-0566.00 (in process) including the following.

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M&O Interoffice memorandum from P. Lovett to Document Reviewers  
Document Review Records prepared by S. Gomberg (Review Coordinator)  
Completed DRRs from E. Benz, W. Teer, J. Replogue, A. Mozhi, J. Cassidy

RW-3 Memorandum requesting annual review of controlled distribution lists

### **QUALITY RECORDS PACKAGES**

QRP-91-0486.00 for QAP 51, Revision 4  
QRP-91-0487.00 for QAP 6.2 Revision 0  
QRP-92-0607.00 for QAP 3.5 Revision 2  
QRP-91-0454.00 for QAAP 2.2 Revision 1  
QRP-92-0628.00 for QAAP 2.10 Revision 0  
QRP-91-0486.00 for QAAP 16.1 Revision 4  
QRP-91-0483.00 for QAAP 2.7 Revision 1

Completed Document Action Request for QAAP 18.2, Revision 5, ICN 1

Quality Records Package QRP-92-0627.00 for QAP 3.5, Rev 0; QAP 5.1, Rev. 4; and  
QAP 6.2, Rev. 0

Quality Records Package QRP-92-0610.00 for QAAP 2.10, Rev. 0

CARs HQ-92-013 through 92-015; 91-001 through 91-031  
92-019 through 92-031; 91-039, 92-008  
92-007; 92-011; 92-010; 91-033 through 91-042

QA Records Package for CARs HQ-91-034, 92-011, 92-010 and 92-007.

Headquarters CAR Status Reports dated 12/4/92; 11/30/92; 11/13/92; 11/6/92.

Training Files for QAAP 16.1 (Rev. 5): C. Good, D. Brown, T. Swift, T. Rodgers, C.  
Morell.

### **QA RECORDS PACKAGES**

QRP-91-0461.00, FY91 Management Assessment  
QRP-92-0589.00, Implementing Line Procedure ILP 12.17.01, Revision 2  
Development  
QRP-90-0346.00, QACD, Revision 1  
QRP-90-0387.00, FY91 Audit Schedule  
QRP-91-0528.00, Corrective Action CAR HQ-91-030

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QRP-92-0608.00, Surveillance OCRWM  
QRP-90-0141.00, Draft MRS Site Requirements & Considerations QAAP 3.5  
QRP-90-0155.00, Draft MRS Site Requirements & Considerations QAAP 3.1  
QRP-91-0471.00, Peer Review of Initiative I Task Design Requirements  
QRP-91-0573.00, MRS Design Requirements  
QRP-92-0668.00, MRS Facility Conceptual Design Requirements  
QRP-90-0361.00, Oak Ridge Operations Office FY1991 Program Guidance Letter  
QRP-91-0667.00, FY1991 Program Guidance Letter - EIA  
QRP-90-0160.00, Implementation of OCRWM QA Program Under KOH Systems, Contract DE-AC01-87RW00131

CAR HQ-92-017, from Surveillance HQ-SR-92-05, conducted 8/92

Response to Corrective Action Request (CAR) HQ-92-017 from RW-30, dated 11/18/92

Response to Corrective Action Request (CAR) HQ-92-017 from RW-422, dated 11/30/92

Response to Corrective Action Request (CAR) HQ-92-017 from RW-22, dated 12/09/92

Listing of QA Records Package Identification Numbers prepared by QRC, dated 12/02/92

QA Records Package Table of Contents for QRP-90-0160.00 validated by Judy Leahy, dated 9/18/92

### **QA RECORDS PACKAGES**

QRP-90-0368.00, RW-1/2 List of Records/Personnel  
QRP-90-0369.00, RW-3 List of Records/Personnel  
QRP-92-0692.00, RW-321 List of Records/Personnel  
QRP-90-0092.00, RW-30 List of Records/Personnel  
QRP-90-0372.00, RW-40 List of Records/Personnel  
QRP-90-0373.00, RW-50 List of Records/Personnel  
QRP-90-0166.00, QAPD, Revision 1 Development  
QRP-90-0373.00, Individual Record Report (Log)  
QRP-90-0145.01, Revision for Records Package  
QRP-92-0631.00, Signed Transmittal from CRF  
QRP-92-0022.00, QRC Package of Transmittals

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QRP-90-0338.00, QA Records Package Logs  
QRP-92-0654.00, QA Records Package Logs  
QRP-92-0336.00, QRC Records Package Transmittals  
QRP-92-0337.00, QRC Records Package Transmittals  
QRP-92-0406.00, QRC Records Package Transmittals

**Transmittal to QRC for the following QA Records Packages -**

Source Code - 92-0092,	RW-50
- 92-0371,	RW-321
- 92-0036,	RW-10
- 92-0231,	RW-22
- 92-4582,	RW-3
- 92-4388,	RW-3
- 92-0337,	RW-321
- 92-4388,	RW-3
- 92-0965,	RW-3 Replacement Record

**Transmittal of QRP Validation Personnel List/QA Records List from RW-40, dated 12/09/92**

**ASTM E119-83, Fire Endurance & Fire Hose Stream Tests Non-Load Bearing Partition, Design WP 733, One Hour Gold Bond Building Products, dated 12/03/84**

### **INDIVIDUAL AUDIT/LEAD AUDITOR QUALIFICATIONS**

**T. Higgins, D. Hendrix, T. Swift, R. Brown, F. Bearham, R. Schaeffer, J. Martin, W. Booth, J. Marchand**

**Audit Schedules for FY-1992, 1993 and Revisions**

**Audit Reports - HQ-92-001, 92-02**

**QA Correspondence - Notification and Closure Letters**

**FY92 Surveillance Schedule and Revisions.**

**Surveillance Reports, HQ-SR-92-01, 92-04, 92-05 and 92-06**

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



Audit Details -- Yucca Mountain  
Project Office QA Division (YMQAD)

**A. QA PROGRAM AUDIT ACTIVITIES**

**1.0 QUALITY ASSURANCE PROGRAM**

Project Office Indoctrination and Qualification Training (QMP 02-01)

The audit team verified that YMQAD personnel training records contained, as appropriate, the following:

- Position Qualification forms
- Training Assignment forms (identified required training was completed prior to start of work).
- Indoctrination (scope and completion was documented)
- Self Study forms (identified required training was completed prior to start of work).
- Verification of education and experience documents
- Maintenance/additional training documents.

The training records were found to be complete and current for the areas and individuals reviewed.

Based on a detailed review of indoctrination and training records, it was determined that YMQAD is effectively implementing QA Program Element 2.

**2.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS**

Based upon interviews with YMQAD personnel, it was determined that currently QAP 5.1 and this QA Program Element's activities are controlled and implemented by OCRWM Headquarters personnel. This area was deemed not applicable for YMQAD.

**3.0 DOCUMENT CONTROL**

Based upon interviews with YMQAD personnel, it was determined that currently QAP 6.2 and other YMP document control procedures are not the responsibility of YMQAD. This area was deemed not applicable for YMQAD.

Audit Details -- Yucca Mountain  
Project Office QA Division (YMQAD)

**4.0 CORRECTIVE ACTION**

**4.1 Corrective Action (QAAP 16.1)**

The audit team selected a sample of eleven CARs for review. Eight of these described significant conditions adverse to quality (out of nine total significant CARs written at YMPO FY92). A review of YMPO issued CARs indicated a reduction in FY92 versus FY91 (76 versus 88). All eleven CARs in the sample were reviewed to ensure that the following requirements were met:

Proper completion of the CAR form, the signature of the CAR initiator, and an assigned unique CAR number. No deficiencies were identified.

Evidence that the QADD evaluated the CAR for validity, significance, and stop work (significant CARs only). This is indicated by the QADD signature on the CAR form. No deficiencies were identified; however, see Recommendation 6.13 for suggested improvements in this area.

Response due dates and proper completion of "required actions" section of CAR (Note: for significant conditions adverse to quality all four "required actions" are required.)

Any recommendations provided in Block 13 of the CAR form are consistent with the condition described.

The completeness of CAR working files.

The correctness of the CAR Log.

The CAR distribution and response required memo.

Adequacy of Corrective action responses QAR evaluation of corrective action response.

QAR verification of corrective action and CAR closure.

Extension requests and approval.

See CAR HQ-93-06 for details on identified deficiencies.

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### Audit Details -- Yucca Mountain Project Office QA Division (YMQAD)

#### **4.2 Stop Work (QAAP 16.2)**

No Stop Work Orders (SWOs) were issued since the last OCRWM HQ Audit. Eight CARs designated "Significant Condition Adverse to Quality" were reviewed and utilized as the sample for this portion of the audit. Based on this review and interviews with three Quality Assurance Representatives, the sample CARs were evaluated correctly in accordance with Paragraph 5.4 of QAAP 16.1. A review of the individual CAR forms indicated that Block 10 on the CAR forms were marked "NO", correctly indicating that the criteria of paragraph 5.4 was not met and that a Stop Work condition does not exist. See Recommendation 6.3 for suggested improvements in this area.

Interviews with YMQAD management and three Quality Assurance Representatives indicate knowledge and familiarity with the Stop Work criteria and this procedure.

Based on reviews of the sample "significant" CARs and interviews with the Quality Assurance Representatives, the procedure is adequate as written.

#### **4.3 QA Program Trend Evaluation and Reporting (QAAP 2.9)**

The audit team interviewed the Trend Report Coordinator to determine whether all CARs depicted as "Significant Conditions Adverse to Quality" were in the database. CAR YM 92-056 was a "Significant Condition Adverse to Quality"; however, it was not included in the Trend Data Base. The CAR was added to the Trend Data Base during the audit. Four YMQAD Trend Reports were reviewed and found to be satisfactory. The distribution of the RW-3 Quality Assurance Program Quarterly Trends Report included all RW management and participant TPOs as required.

The Trend Report format included all required sections. To date there has been no need to use statistical methods to analyze for trends; therefore, there was no audit of this area. Also, since no trends have been identified, there has been no need to issue a CAR for any adverse or generic trends.

#### **4.4 Standard Deficiency Reporting System (QMP 16-03)**

The audit team reviewed the records for the two open Standard Deficiency Reports (SDR) and two SDRs recently closed. The two open SDRs were properly documented with respect to extensions and requests for extension. The two closed SDRs contained complete documentation in the "working folder". No deficiencies were noted. QMP 16-03 is no longer used to document conditions adverse to quality. As of October 1990 these conditions have been documented in accordance with QAAP 16.1.

Audit Details -- Yucca Mountain  
Project Office QA Division (YMQAD)

**4.5 Overall Effectiveness**

Both the areas of "stop work" and trending appear to be effectively implemented at YMQAD. However, due to the conditions identified on CAR HQ-93-06, QA Program Element 16 is considered to be marginally effective for YMQAD.

**5.0 QUALITY ASSURANCE RECORDS**

**Records Management: Las Vegas Source Responsibilities (AP-1.18Q)**

The audit team verified that completed records/record packages were transmitted to Local Records Center (LRC) as required and that the records/record packages:

- were legible, with changes appropriately marked, complete or otherwise identified
- were identified as "privileged" when required
- had all blanks filled in or marked "NA"
- were properly identified as required
- contained a table of contents and an acknowledged transmittal form
- were authenticated by appropriate personnel
- were processed by appropriately trained/indoctrinated individuals

The audit team found the LRC to be receiving records/record packages in a timely fashion with the following comments:

- Blocks were not filled in, identified as "NA", or a statement provided that "blanks are intentional" on the record package table of contents. Because these blocks are only used for tracking the status of incomplete record packages and the packages reviewed were complete, it was determined this was not a deficiency. However, see Recommendation 6.10 for suggested improvements in this area.
- One surveillance report (YM-SR-92-029) was found in the LRC without the required transmittal form, or a table of contents, or evidence it had been authenticated. This isolated problem was corrected prior to completion of the audit.

Audit Details -- Yucca Mountain  
Project Office QA Division (YMQAD)

- During the audit, it was determined that the original training records for YMQAD personnel were not in the Local Records Center. All training records for currently employed DOE/contractor personnel were being kept in the SAIC Training Center. One terminated individual's training record (terminated in April of 1992) was reviewed and had not been transmitted to the LRC. See Recommendation 6.12 for suggested improvements in this area.

Based upon the review of the control of numerous QA records packages, the audit team concluded that QA Program Element 17 was being effectively implemented by YMQAD.

**6.0 AUDITS**

**6.1 Qualification of Audit Personnel (QAAP 18.1)**

The audit team verified that three YMP QA personnel were certified as auditors in accordance with QAAP 18.1, Revision 3. The sample was based on personnel who had performed audits during 1992.

**6.2 Audit Program (QAAP 18.2)**

The audit team verified that six YMP QA personnel were certified as Lead Auditors in accordance with QAAP 18.1, Revision 3. The verification included a review of certification forms and audit reports to verify that personnel had participated in the audits identified on their certification.

Audit schedules were reviewed and found satisfactory; however, see Recommendation 6.9 for a suggested improvement in this area.

Audit plans for YMPO Audits YM-92-09, -92-10, -92-12, -92-21, 92-22, and 92-24 were reviewed and found to contain the appropriate requirements. The Audit Team Leader had signed the plans.

The audit team verified that the Director, OQA approved the audit plans and issued the plan and notification letters to the audited organizations. Completed audit checklists were reviewed; it was verified that they were being used to guide audit activities. The audit team reviewed pre-audit and post-audit attendance records and verified that pre-audit and post-audit meetings were being conducted and documented.

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### Audit Details -- Yucca Mountain Project Office QA Division (YMQAD)

Based on reviewing audit reports it was verified that:

- Auditors were maintaining lists of objective evidence used to determine effective implementation of program requirements and lists of personnel contacted during the audit.
- Audit reports were being prepared using a format similar to the example shown in QAAP 18.2; adequacy and effectiveness statements were provided for the areas audited, the ATLs signed the audit reports, and the Director, OQA had approved the reports.

The team verified that audit reports were properly distributed to the audited organizations.

#### **6.3 Surveillance Program (QAAP 18.3)**

The auditors reviewed five surveillance reports issued in FY92. None of the surveillances were "scheduled" and therefore, were not included on the OCRWM Surveillance Schedule. YMQAD's position was that all their surveillances are conducted on a short notification schedule and therefore they have no time to input to the quarterly OCRWM Surveillance Schedule. See Recommendation 6.7 for suggested improvements in this area.

Most surveillances did not have a formal pre or post surveillance meeting and therefore, most did not have formal meeting attendance sheets. All surveillances were conducted, using either checklists or marked-up procedures along with an Assignment Traveler. In addition, of the five surveillance reports reviewed, only YM-SR-92-019 included an effectiveness statement. See Recommendation 6.8 for suggested improvements in this area.

Interviews with YMQAD management and the Surveillance Team Leaders indicated a good understanding of the surveillance process and QAAP 18.3 requirements.

#### **6.4 Overall Effectiveness**

Based on a thorough review of auditor qualification records, audit reports, and surveillance reports, the audit team concluded that YMQAD was effectively implementing QA Program Element 18.

Audit Details -- Yucca Mountain  
Project Office QA Division (YMQAD)

**B. OBJECTIVE EVIDENCE REVIEWED AT YMQAD**

Qualifications of the following "Record Sources" in accordance with AP-1.18Q were reviewed:

Amelia I. Arceo	Stephen R. Dana
Sandra D. Bates	Catherine E. Hampton
James Blaylock	Robert H. Klemens
Juanita J. Brogan	Frank J. Kratzinger
Robert B. Constable	Richard E. Spence

Qualifications of the following "Quality Assurance Representative (QAR)" in accordance with QAAP 16.1 were reviewed:

Amelia I. Arceo	Sam H. Horton
James Blaylock	John S. Martin
Neil D. Cox	Richard L. Maudlin
Mario R. Diaz	Richard E. Spence
Gerard Heaney	

Qualifications of the following personnel performing surveillances in accordance with QAAP 18.3 were reviewed:

Sandra D. Bates	Robert H. Klemens
Stephen R. Dana	Frank J. Kratzinger
Gerard Heaney	

Qualifications of the following personnel performing audits in accordance with QAAP 18.1 were reviewed:

Amelia I. Arceo	John R. Matras
Robert E. Harpster	Cynthia H. Prater
Richard A. Kettell	Thomas E. Vandel
John S. Martin	Richard L. Weeks

Qualifications of the following personnel performing reviews of Branch Technical Procedures in accordance with BTP-QAD-001 were reviewed:

Sandra D. Bates	Terry W. Nolan
Robert E. Harpster	James H. Rusk
Sam H. Horton	Thomas E. Vandel
Richard A. Kettell	Richard L. Weeks

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**Audit Details -- Yucca Mountain  
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**CARs and Supporting Documentation:**

YM-92-045	YM-92-056
YM-92-021	YM-92-033
YM-92-065	YM-92-023
YM-92-062	YM-92-018
YM-92-059	YM-92-007
YM-92-041	

**CAR Log dated 12/1/92**

The following Corrective Action Reports (CARs), designated as "Significant Condition Adverse to Quality", were utilized as the sample for the review of "Stop Work":

YM-92-018	YM-92-059
YM-92-023	YM-92-062
YM-92-033	YM-92-076
YM-92-056	YM-92-004

**SDRs:**

018 (still open)  
596 (still open)  
571 (closed)  
584 (closed)

**SDR Log, dated 12/2/92**

YMQAD inputs to the QA Program Trend Report for the first, second, third, and fourth quarters for FY-92

Record packages for the following CARs were reviewed at the Local Records Center (LRC) for compliance with AP-1.18Q:

YM-92-017	YM-92-023
YM-92-018	YM-92-045
YM-92-021	YM-92-056



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**Audit Details -- Yucca Mountain  
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**YMQAD Surveillance Log dated 11/19/92 (FY 92 Final) Surveillances:**

YM-SR-92-005	M&O/LV
YM-SR-92-019	SAIC, USGS, & RSN/NTS
YM-SR-92-023	YMPO/LV
YM-SR-92-026	YMPO/NTS
YM-SR-92-029	YMPO/NTS

**REQUESTED SURVEILLANCES FOR FY-92 (Print-out)**

**Lead Auditor Certifications for:**

Amy Arceo	Donald Harris
Cynthia Prator	Gerard Heaney
John Matras	Richard Weeks
John Martin	Tom Higgins

**Auditor Certifications for:**

Tom Vandell  
Richard Kettel  
Richard Harpster

**Audit Packages for audit numbers:**

YMP-92-10	YMP-92-22
YMP-92-24	YMP-91-01
YMP-92-01	YMP-91-05
YMP-92-04	

**Records packages for the following surveillances were reviewed at the Local Records Center (LRC) for compliance with AP-1.18Q:**

YM-SR-92-002	YM-SR-92-023
YM-SR-92-005	YM-SR-92-026
YM-SR-92-019	YM-SR-92-029

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<b>CORRECTIVE ACTION REQUEST</b>		
<sup>1</sup> Controlling Document QAAP 2.1, Rev. 2, Indoctrination and Training		<sup>2</sup> Related Report No. Audit HQ-93-01
<sup>3</sup> Responsible Organization RW-22	<sup>5</sup> Discussed With S. Broccom, D. Stucker	
<sup>6</sup> Requirement:  Paragraph 6.5.1 requires that training requirements for a job duty be completed prior to performing the duty.		
<sup>7</sup> Adverse Condition:  During Fiscal Year 1992, an individual performed a QAAP 5.1 procedure review of draft procedures QAP 3.5, QAP 5.1, and QAP 6.2; however, no evidence was found that the individual was trained to QAAP 5.1, Revision 3 (revision in effect at the time the review was performed).  Note: This was the only case identified of the numerous samples reviewed.		
<sup>8</sup> Does a significant condition adverse to quality exist? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> <u>X</u> If Yes, Circle One: A B C	<sup>10</sup> Does a stop work condition exist? Yes <input type="checkbox"/> No <input type="checkbox"/> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C	<sup>11</sup> Response Due Date: 2/22/93
<sup>12</sup> Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
<sup>13</sup> Recommended Actions:		
<sup>9</sup> Initiator Steve Dana <u>SD</u> Date <u>1/29/93</u>	<sup>14</sup> Issuance Approved by: QADD Date	
<sup>15</sup> Response Accepted QAR Date	<sup>16</sup> Response Accepted QADD Date	
<sup>17</sup> Amended Response Accepted QAR Date	<sup>18</sup> Amended Response Accepted QADD Date	
<sup>19</sup> Corrective Actions Verified QAR Date	<sup>20</sup> Closure Approved by: QADD Date	

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<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document QAAP 6.1, Rev. 2, Document Control		2 Related Report No. Audit HQ-93-01
3 Responsible Organization RW-22	4 Discussed With S. Brocoun, D. Stucker	
5 Requirement:  Paragraph 6.3.3. states that the recipient shall ensure that the controlled document is updated in compliance with the instructions provided and ....		
6 Adverse Condition:  QAP Manual #00022 did not contain the current revisions of the following procedures: QAAPs 18.1, 18.2 and 16.1. Also superseded versions of QAAP 16.1, 16.2, and 18.1 are still in the Manual. This Manual is used by several RW-20 personnel performing quality-affecting work.  Also, QAM Manual: #00022, is not updated to incorporate the changes to the QARD for ICN 4.2 and the changes to the QAPD for ICN 3.2.  Note: This was the only deficient set of manuals from the samples reviewed.		
7 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	8 Does a stop work condition exist? Yes ___ No ___; If Yes - Attach copy of SWO If Yes, Circle One: A B C	9 Response Due Date: 2/22/93
10 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
11 Recommended Actions:		
12 Initiator: <i>Robert Howard</i> Robert Howard	13 Issuance Approved by:	
Date <u>1-19-93</u>	QADD	Date
14 Response Accepted QAR	15 Response Accepted QADD	
Date	Date	
16 Amended Response Accepted QAR	17 Amended Response Accepted QADD	
Date	Date	
18 Corrective Actions Verified QAR	19 Closure Approved by: QADD	
Date	Date	

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<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document QAAP 18.1, Rev 3, Qualification of Audit Personnel		2 Related Report No. Audit HQ-93-01
3 Responsible Organization RW-3	4 Discussed With Bob Clark, Dick Spence	
5 Requirement:  Paragraph 7.1 states "Qualification/Certification Records, Qualification Maintenance Records, <u>objective evidence of examination contents</u> ...are considered QA records".		
6 Adverse Condition:  Contrary to the above four (2 YMQAD and 2 HQAD) Lead Auditor certification record packages did not include "objective evidence of examination contents". The Audit Team reviewed seven OCRWM Lead Auditor certification record packages.		
7 Does a significant condition adverse to quality exist? Yes <u>  </u> No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes <u>  </u> No <u>  </u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C	11 Response Due Date: 2/22/93
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions:		
7 Initiator <u>Hank Greene</u> <u>1/19/93</u> Date	14 Issuance Approved by: QADD Date	
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	

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		DATE: 01/18/93
		PAGE: 1 OF 1 QA
<b>CORRECTIVE ACTION REQUEST</b>		
<b><sup>1</sup> Controlling Document</b> QAAP 18.2 Rev. 5, Audit Program; QAAP 18.3 Rev. 3 Surveillance Program	<b><sup>2</sup> Related Report No.</b> Audit HQ-93-01	
<b><sup>3</sup> Responsible Organization</b> RW-3	<b><sup>4</sup> Discussed With</b> B. Clark	
<b><sup>5</sup> Requirement:</b>  <p>Paragraph 6.1.3 of QAAP 18.2 requires that audit schedules and updates be transmitted to the Associate and Office Directors, Participant Technical Project Officers (TPO) and QA Managers.</p> <p>Paragraph 6.1.3 of QAAP 18.3 requires in part that the Director, OQA review the surveillance schedule at least quarterly and revise as necessary to assure adequate coverage.</p>		
<b><sup>6</sup> Adverse Condition:</b>  <p>Contrary to the above requirement, no objective evidence was provided to indicate that Revisions 3 and 4 of the audit schedule for Fiscal Year (FY) 1992 were transmitted to the TPO and QA Managers. In addition, there was no objective evidence to show the FY-93 Audit Schedule was sent to the TPO.</p> <p>The initial surveillance schedule (Rev. 0) for fiscal year 1992 was issued on 6/4/92. As this is the final month of the third quarter of FY-92, there was no evidence that the schedule was reviewed and revised as necessary during the first two quarters.</p>		
<b><sup>9</sup> Does a significant condition adverse to quality exist?</b> Yes ___ No <u>X</u> <b>If Yes, Circle One: A B C</b>	<b><sup>10</sup> Does a stop work condition exist?</b> Yes ___ No ___ <b>If Yes - Attach copy of SWO If Yes, Circle One: A B C</b>	<b><sup>11</sup> Response Due Date:</b> 2/22/93
<b><sup>12</sup> Required Actions:</b> <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination		
<b><sup>13</sup> Recommended Actions:</b>		
<b><sup>7</sup> Initiator</b> <i>[Signature]</i> Sam Horton	<b><sup>14</sup> Issuance Approved by:</b> QADD _____ Date _____	
<b><sup>15</sup> Response Accepted</b> QAR _____ Date _____	<b><sup>16</sup> Response Accepted</b> QADD _____ Date _____	
<b><sup>17</sup> Amended Response Accepted</b> QAR _____ Date _____	<b><sup>18</sup> Amended Response Accepted</b> QADD _____ Date _____	
<b><sup>19</sup> Corrective Actions Verified</b> QAR _____ Date _____	<b><sup>20</sup> Closure Approved by:</b> QADD _____ Date _____	

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CORRECTIVE ACTION REQUEST		
<sup>1</sup> Controlling Document QAAP 2.3, Rev. 1, Establishing QA Program Controls		<sup>2</sup> Related Report No. Audit HQ-93-01
<sup>3</sup> Responsible Organization RW-30		<sup>4</sup> Discussed With J. Roberts
<sup>5</sup> Requirement:  Paragraph 6.1 requires that each Associate and Office Director "develop descriptions of their assigned responsibilities at a function and, if necessary, a work level...to...identify the applicable QA program controls.... Paragraph 6.3 then provides requirements for documentation to be included in the Quality Assurance Controls Document (QACD). Note: documentation is required whether or not QA program controls apply.		
<sup>6</sup> Adverse Condition:  Activities that are assigned to RW-30 regarding the Occurrence Reporting and Processing System (ORPS) are not identified in the QACD.		
<sup>7</sup> Does a significant condition adverse to quality exist? Yes <u>  </u> No <u>X</u> If Yes, Circle One: A B C	<sup>10</sup> Does a stop work condition exist? Yes <u>  </u> No <u>  </u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C	<sup>11</sup> Response Due Date: 2/22/93
<sup>12</sup> Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
<sup>13</sup> Recommended Actions:  Document the necessary evaluation. Since the QACD is being withdrawn, no revision to the QACD is required.		
<sup>14</sup> Initiator <u>Michael J. Donovan</u> 1/18/93 Mike Donovan Date	<sup>15</sup> Issuance Approved by: QADD Date	
<sup>16</sup> Response Accepted QAR Date	<sup>17</sup> Response Accepted QADD Date	
<sup>18</sup> Amended Response Accepted QAR Date	<sup>19</sup> Amended Response Accepted QADD Date	
<sup>20</sup> Corrective Actions Verified QAR Date	<sup>21</sup> Closure Approved by: QADD Date	

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CORRECTIVE ACTION REQUEST		
1 Controlling Document QAAP 16.1, Rev. 4, Corrective Action		2 Related Report No. Audit HQ-93-01
3 Responsible Organization RW-3.2	4 Discussed With R. Spence, C. Warren	
5 Requirement: <ol style="list-style-type: none"> <li>1. Paragraph 6.1.7 states in part "...for significant conditions adverse to quality, required actions shall include investigative action to determine extent, investigative action to determine root cause...."</li> <li>2. Paragraph 6.3.1 states in part: "...the QAR shall evaluate the response to ensure that it addresses the required elements and that the proposed actions will sufficiently resolve the adverse condition."</li> <li>3. Paragraph 6.4.1 states in part: "...the QAR shall verify that the accepted actions identified in the response have been satisfactorily implemented".</li> </ol> <p style="text-align: right;">(cont.)</p>		
6 Adverse Condition: <ol style="list-style-type: none"> <li>1. A review of six (6) CARs for significant conditions adverse to quality indicated that two (2) (YM-92-056 and YM-92-062) did not require root cause determination; YM-92-062 also did not require investigative actions to determine the extent.</li> <li>2. Based on interviews and reviews of CAR documentation, CAR responses are not always being adequately evaluated. Examples include CARs YM-92-005, YM-92-056 and YM-92-045: all were accepted, but either did not address the root cause or addressed it in inadequate fashion.</li> </ol> <p style="text-align: right;">(cont.)</p>		
9 Does a significant condition adverse to quality exist? Yes <u>X</u> No <u>  </u> If Yes, Circle One: A <u>(B)</u> C	10 Does a stop work condition exist? Yes <u>  </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 2/22/93
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination		
13 Recommended Actions:		
1 Initiator M. Horseman <i>Martin Horseman</i> Date <u>1/18/93</u>		14 Issuance Approved by: QADD _____ Date _____
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 _____

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**<sup>1</sup> Requirement: (Cont)**

4. Paragraph 5.3 states: "CARs shall be evaluated in accordance with the following criteria to determine if the identified condition is a significant condition adverse to quality: ..."

**<sup>1</sup> Adverse Condition: (Cont)**

3. The verification of several CARs (YM-92-056 for example) was inadequately performed since the actions identified in the accepted response were inadequate. The inadequate responses should have also been detected during the CAR verification process.
4. Based on interviews with several QARS, the criteria identified in Paragraph 5.3 of QAAP 16.1 to determine CAR significance is not being uniformly interpreted.



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<b>CORRECTIVE ACTION REQUEST</b>		
<sup>1</sup> Controlling Document QAAP 2.1, Rev. 2, Indoctrination and Training		<sup>2</sup> Related Report No. Audit HQ-93-01
<sup>3</sup> Responsible Organization RW-30	<sup>4</sup> Discussed With J. Roberts, M. Senderling	
<sup>5</sup> Requirement:  Paragraph 5.4.4 requires that supervisors inform the QA Training Officer (QATO), by memo, of any permanent and non-permanent personnel under their supervision who are performing duties subject to QA Program Controls.		
<sup>6</sup> Adverse Condition:  A review of the "List of Employees Performing Assignments Against the QARD", provided to the QATO, revealed that thirteen (13) individuals performing quality affecting activities were not on the list.  NOTE: Based upon discussion with OCRWM Management, it was identified that these individuals were M&O and not OCRWM or direct support personnel.		
<sup>9</sup> Does a significant condition adverse to quality exist? Yes <u>      </u> No <u>X</u> If Yes, Circle One: A B C	<sup>10</sup> Does a stop work condition exist? Yes <u>      </u> No <u>      </u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	<sup>11</sup> Response Due Date: 2/22/93
<sup>12</sup> Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
<sup>13</sup> Recommended Actions:  OCRWM Management stated that Procedure QAAP 2.1 was never intended to apply to individuals other than OCRWM and direct support personnel. Based upon this QAAP 2.1 needs to be revised to clarify and address: (Continued on page 2)		
<sup>14</sup> Initiator Steve Dana <u>SDana</u> Date <u>1/25/93</u>	<sup>15</sup> Issuance Approved by: QADD _____ Date _____	
<sup>16</sup> Response Accepted QAR _____ Date _____	<sup>17</sup> Response Accepted QADD _____ Date _____	
<sup>18</sup> Amended Response Accepted QAR _____ Date _____	<sup>19</sup> Amended Response Accepted QADD _____ Date _____	
<sup>20</sup> Corrective Actions Verified QAR _____ Date _____	<sup>21</sup> Closure Approved by: QADD _____ Date _____	

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#### CORRECTIVE ACTION REQUEST (Continuation Page)

<sup>5</sup> Requirement: (Cont)

- 1) That QAAP 2.1 applies only to OCRWM and direct support personnel:
- 2) How individuals who are not OCRWM or direct support personnel will be determined to be qualified and trained for work subject to the QARD and:
- 3) What records are necessary to document this qualification and training

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<b>OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.</b>		CAR NO. <u>HQ-93-08</u> DATE: <u>11/18/93</u> PAGE: <u>1</u> OF <u>2</u> QA
<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document QAAP 2.1, Rev. 2, Indoctrination and Training		2 Related Report No. Audit HQ-93-01
3 Responsible Organization RW-30	4 Discussed With M. Senderling	
5 Requirement:  Paragraph 6.5.12 requires that the employee forwards, at the end of each quarter, a Quarterly Update of the latest status to the supervisor, who signs and forwards it to the QA Training Officer. In those cases where personnel have had no I&T activity during the quarter, supervisors may elect to forward a memo to the QA Training Officer listing those personnel and stating no new I&T has occurred since last quarter.		
6 Adverse Condition:  During a review of thirty I&T records at the QRC, the following individuals did not have either a third Quarter Update, or a memo on file with the QATO stating that no I&T had occurred:  <ul style="list-style-type: none"> <li>• L. Lindsey</li> <li>• A. Jenkins</li> <li>• W. Law</li> <li>• P. Lovett</li> </ul> NOTE: Based upon discussion with OCRWM Management, it was identified that these individuals were M&O and not OCRWM or direct support personnel.		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> 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	11 Response Due Date: 2/22/93
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions:  OCRWM Management stated that Procedure QAAP 2.1 was never intended to apply to individuals other than OCRWM and direct support personnel. Based upon this QAAP 2.1 needs to be revised to clarify and address: (Continued on page 2)		
14 Initiator Steve Dana <u>[Signature]</u> Date <u>1/25/93</u>	15 Issuance Approved by: QADD _____ Date _____	
16 Response Accepted QAR _____ Date _____	17 Response Accepted QADD _____ Date _____	
18 Amended Response Accepted QAR _____ Date _____	19 Amended Response Accepted QADD _____ Date _____	
20 Corrective Actions Verified QAR _____ Date _____	21 Closure Approved by: QADD _____ Date _____	

**ATTACHMENT 5**  
**Corrective Action Requests**

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RADIOACTIVE WASTE MANAGEMENT  
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**CORRECTIVE ACTION REQUEST (Continuation Page)**

<sup>1</sup> Requirement: (Cont)

- 1) That QAAP 2.1 applies only to OCRWM and direct support personnel:
- 2) How individuals who are not OCRWM or direct support personnel will be determined to be qualified and trained for work subject to the QARD and:
- 3) What records are necessary to document this qualification and training