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

AUDIT REPORT

OF THE

U. S. DEPARTMENT OF ENERGY YUCCA MOUNTAIN SITE CHARACTERIZATION OFFICE

LAS VEGAS, NEVADA AUDIT NUMBER YMSCO-ARC-97-22 JULY 28 THROUGH AUGUST 1, 1997

Date: 8/29/97

Date: 9/12/97

Prepared by: Gary D/Wood

Audit Team Leader Office of Quality Assurance

Approved by:

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



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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit YMSCO-ARC-97-22, the audit team determined that the Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Site Characterization Office (YMSCO), with the exception of non-implemented program elements and areas where deficiencies existed, is satisfactorily implementing applicable portions of the QA Program described in the OCRWM Quality Assurance Requirements and Description (QARD) Document, DOE/RW-0333P, Revision 7, and the OCRWM and YMSCO implementing procedures. QA Program Elements 1.0, 2.0, 3.0, 6.0, 7.0, 15.0, 16.0, 17.0, 18.0 and Supplements II, III and V were found satisfactory by the audit team. QA Program Element 5.0 was determined to be marginal due to a deficiency related to procedures not being implemented as written. There was found to be no implementation by YMSCO of QA Program Elements 4.0 and Appendix C. In addition, QA Program Elements 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0; Supplements I and IV; and Appendices A and B were determined not to be applicable to YMSCO activities.

The audit team identified one deficiency during the course of the audit that resulted in the issuance of one Deficiency Report (DR) described in Section 5.5.2 of this report. There were six deficiencies identified by the audit team that were corrected prior to the post-audit meeting. These conditions are described in Section 5.5.4 of this report. Additionally, there were four recommendations resulting from the audit which are detailed in Section 6.0 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy, compliance, and effectiveness of YMSCO in implementing the QA Program as described in the QARD and the OCRWM and YMSCO procedures.

The following QA Program Elements/Requirements were evaluated during the audit, in accordance with the approved audit plan.

QA PROGRAM ELEMENTS/REQUIREMENTS

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Implementing Documents
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services

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15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
18.0	Audits
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement V	Control of the Electronic Management of Data
Appendix C	Mined Geologic Disposal System

The following QA Program Elements/Requirements were not reviewed during the audit because they are not applicable to the YMSCO scope of work.

8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
12.0	Control of Measuring and Test Equipment
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test and Operating Status
Supplement I	Software
Supplement IV	Field Surveying
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation

3.0 AUDIT TEAM AND OBSERVERS

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

Name/Title/Organization	<u>QA Program Elements/Requirements,</u> <u>Technical Areas, Processes, Activities</u> <u>or End-Products</u>
Gary Wood, Audit Team Leader, OQA	1.0, 2.0 and Appendix C.
James Graff, Auditor, OQA	1.0, 2.0, 3.0, 4.0 and 5.0.
William Glasser, Auditor, OQA	6.0 and 15.0.
Richard Kettel, Auditor, OQA	2.0, 5.0, and 17.0.

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Lawrence McGrath, Auditor, OQA

2.0, 5.0, and 6.0.

James Ziemba, Auditor, OQA

Kenneth McFall, Auditor, OQA

3.0, Supplements II, III, and V.

Charlie Warren, Auditor, OQA

2.0 and Supplement III.

2.0, 7.0, 16.0, and 18.0.

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at the YMSCO offices in Las Vegas, Nevada, on July 28, 1997. A daily debriefing and coordination meeting was held with the YMSCO management, and daily audit team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a post-audit meeting held at the YMSCO offices on August 1, 1997. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the pre-audit and post-audit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 <u>Program Effectiveness</u>

The audit team concluded that, overall, the QA Program is adequate and is being satisfactorily implemented by YMSCO for the scope of this audit. The results for each program element evaluated are contained in Attachment 2, Summary Table of Audit Results.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no stop work orders, immediate corrective actions or related additional items resulting from this audit.

5.3 **QA Program Audit Activities**

A summary table of audit results is provided in Attachment 2. The audit checklists contain the details of the audit evaluation along with identification of the objective evidence reviewed. The checklists are maintained as QA Records.

5.4 <u>Technical Audit Activities</u>

There were no technical activities evaluated during the audit.

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5.5 <u>Summary of Deficiencies</u>

The audit team identified one deficiency during the audit for which one DR has been issued. Six additional deficiencies were identified and corrected prior to the post-audit meeting.

Synopses of the deficiency documented as a DR and those corrected during the audit are detailed below. The DR has been transmitted under a separate letter.

5.5.1 Corrective Action Requests (CAR)

None

5.5.2 Deficiency Reports

<u>YM-97-D-078</u>

The audit revealed that several of the OCRWM and YMSCO procedures in their present state cannot be or are not being implemented as written. Personnel interviews conducted during the audit revealed that some of the procedures contain improper sequencing of work, assign work to incorrect functions/personnel/positions, and assign work to functions/positions that no longer exist due to changes in organizational responsibilities. Some of the procedures make reference to and direct implementation of superseded procedures. In addition, some procedures lack sufficient clarity to assure consistency in work products.

5.5.3 Performance Reports

None

5.5.4 Deficiencies Corrected During the Audit

The following Deficiencies were identified and corrected during the audit:

 YAP-6.2Q, Revision 1, "Distribution, Maintenance, and Use of Controlled and Managed Documents;" and the QARD, Section 6.2.5c, require the control of superseded documents to prevent their inadvertent use. The audit team identified several procedures that have been superseded which remain in effect to complete in process work

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initiated under the procedure. These procedures are not to be used for work initiated after the effective date of the superseding procedure. However, the procedures available for use (controlled hard copies or controlled electronic copies) did not provide this status information. As a result of this deficiency, all procedures were reviewed for similar condition, assessed for potential impact (none identified), and were appropriately "flagged" to prevent inadvertent use. In addition, an ICN for YAP-6.2Q was issued to address this concern.

- 2) YAP-15.1Q, Revision 3, ICN 1, "Control of Nonconformances," requires that the Office of Quality Assurance (OQA) provide concurrence and final review of nonconformance reports (NCR). The audit team identified one NCR for which the reviewing QA representative had not documented the review date, and four NCRs where the Potentially Reportable block had not been conpleted. These NCRs were corrected/completed and reviewed by the audit team prior to the post-audit conference.
- 3) YAP-15.1Q, Revision 3, ICN 1, Paragraph 6.1, requires that relevant NCR correspondence be maintained as lifetime QA records. The audit team noted that one NCR number had been issued and subsequently canceled. A memorandum had been issued to address the cancellation of the NCR. However, a copy of the memorandum was not distributed to the records center. To correct this deficiency, a copy of the memorandum was provided to the records center prior to the completion of the audit.
- 4) YAP-15.1Q, Revision 3, ICN 1, requires that all actions specified by NCR disposition be completed prior to closing the NCR. Contrary to this requirement, the audit team identified two instances of NCR closure prior to completion of all actions required by the NCR dispositions. An evaluation of the extent of this condition by responsible personnel revealed three additional instances of premature closure. These NCRs were added to an existing open NCR originally written against the CRWMS M&O for the same type of deficiency and a memorandum restating NCR closure requirements was issued to the responsible section personnel prior to audit completion.
- 5) The audit team identified nine DRs that cited a root cause was required but did not include the required AP 16.4 Attachment form. Review of these DRs revealed that the responding organization provided "root

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cause" was in reality "apparent cause." The initiating Quality Assurance Representative (QAR) had not required a root cause analysis, nor was a root cause analysis appropriate for the identified deficiency. The DRs were changed to reflect that a root cause was not required.

6) YAP-2.7Q, Revision 0, ICN 1, "Item Classification and Maintenance of the Q-List." The audit team identified one instance where insufficient evidence to support completion of appropriate acceptance review could not be readily produced for review by the auditor. The objective evidence was subsequently produced and reviewed by the auditor prior to audit completion.

5.5.5 Follow-up of Previously Identified CARs and DRs

Follow-up of the DRs issued as a result of the 1996 OQA audit of the YMSCO provided the following status:

YM-96-D-095: Open. Response has been accepted.

YM-96-D-096: Open. Closure is in process.

YM-96-D-097: Closed

YM-96-D-098: Closed.

YM-96-D-099: Closed.

YM-96-D-100: Open. Corrective action to be completed 9/30/97

YM-96-D-102: Open. Corrective action to be completed 9/4/97.

6.0 **RECOMMENDATIONS**

The following recommendations resulted from the audit and are presented for consideration by the YMSCO management:

 YAP-6.2Q, Revision 1, Paragraph 6.2, requires normal processing for a controlled document within five working days. It is recommended that the five day time period for "normal processing" of controlled documents be evaluated for possible revision. It may be prudent to state that the five days is a guideline rather than a requirement.

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- The following two DOE/YMSCO procedures are implemented by the CRWMS M&O with little or no implementation by YMSCO personnel, and it is recommended that these procedures be evaluated during the next compliance audit of the CRWMS M&O:
 - a. YAP-SIII.3Q, Revision 1, "Processing of Technical Data on the Yucca Mountain Site Characterization Project."
 - b. YAP-5.8, Revision 0, "Technical Document Preparation."
- 3) It is recommended that initial audit dates and triennial audit dates be documented on the Qualified Supplier List (QSL) without waiting for the Supplier Evaluation Report to be issued by the organization qualifying the supplier. This should ensure that the QSL is accurate and up to date, prevent possible missed triennial due dates, and aid in the identification of upcoming audit dates.
- 4) There is an inconsistency in the level of detail included in the audit checklists. It is recommended that YMSCO management provide additional guidance relative to the level of detail to be included in the checklists. This would readily allow an independent verification of the of the auditors conclusions without recourse to the auditor.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit Attachment 2: Summary Table of Audit Result

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ATTACHMENT 1 Personnel Contacted During the Audit <u>Las Vegas, Nevada</u>

NAME	ORGANIZATION	CONTACT	MEETINGS PRE POST
Catherine Hampton	DOE/OQA	Х	X X
Albert Williams	DOE/OQA		Х
Mario Diaz	DOE/OQA	Х	X X
Wesley Barnes	DOE/YMSCO		X
Christine Mayo	DOE/YMSCO		Х
Richard Craun	DOE/YMSCO		X
Richard Spence	DOE/YMSCO	X	Х
Eric Lungaard	DOE/YMSCO		Х
Terry Mueller	M&O/Records	Х	X X
Jan Verden	M&O/Records	. X	Х
Emily Cooper	DOE/YMSCO		Х
Vincent Iorii	DOE/YMSCO	Х	Х
Lester Wagner	OQA/QATSS		X X ·
Henry Greene	OQA/QATSS	X	X X
Harvey Dove	MTS/Golder	Х	
Raymond Mele	MTS/BAH		X X
Sandra Moore	M&O/TPM	X	X X
Ruth Belanger	M&O/TPM	Х	X X
Jerri Adams	DOE/YMSCO		X X
John Therien	OQA/QATSS		XX.
Lauretta Rost	DOE/YMSCO		Х
Sandra Rouse	DOE/YMSCO	X	X X
Robert Barton	DOE/YMSCO	. X	X X
James Blaylock	DOE/OQA	Х	X X
Drew Coleman	DOE/YMSCO		X X
Kenneth McFall	OQA/QATSS		X X
Lawrence McGrath	OQA/QATSS		X X
James Ziemba	OQA/QATSS		X X
William Glasser	OQA/QATSS		
James Graff	OQA/QATSS		X X
Charles Warren	OQA/QATSS	•	X X
Richard Kettel	OQA/QATSS		ХХ
Gary Wood	OQA/QATSS		X X
Michael Goyda	OQA/QATSS	•	X X

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ATTACHMENT 1 Personnel Contacted During the Audit <u>Las Vegas, Nevada</u>

	NAME	ORGANIZATION	CONTACT		TINGS POST
	Robert Hasson	OQA/QATSS			Х
	Woody Hudson	OQA/QATSS			Х
	Julie Hang	M&O/TPM			Х
	James Compton	DOE/YMSCO		\mathbf{X}^{+}	Х
	Charles Fox	DOE/YMSCO			Х
	Betty Cruz	M&O/SE&I		Х	Х
	Sandra Bolden	M&O/Records			Х
	Thomas Fortner	DOE/YMSCO	Х	•	
	Dean Stucker	DOE/YMSCO	X		
•	Christopher Lewis	M&O/SMF	Х		
	Robert Yasek	DOE/YMSCO	Х		
	Loren Thompson	M&O/Geophysics	Х		
	Heather Gibson	M&O/Records	Х		
	Kathleen Jerome	M&O/Records	Х		
	Diane Ridolfi	DOE/YMSCO	Х		
	Kathleen Clemensen	DOE/YMSCO	X		
	Wayne Kozai	DOE/YMSCO	X		
	Dennis Threatt	OQA/QATSS	4	Х	
	Daniel Tunney	OQA/QATSS		Х	
	Scott Bowlinger	M&O/Records	Х		
	Terri Badedine	M&O/Records	Х		
	Bimal Mukhopadhyay	MTS/BAH	Х		
	Claudia Newbury	DOE/YMSCO	X		
	Debra Sult	OQA/QATSS		Х	
	Richard Maudlin	OQA/QATSS		Х	
	Daniel Klimas	OQA/QATSS		Х	
	C. Humphries-Alder	OQA/QATSS	Х		
	Donald Harris	OQA/QATSS		Х	
	James Clark	OQA/QATSS		Х	
	Michael Malone	OQA/QATSS		Х	
	Robert Habbe	OQA/QATSS		Х	
	James Replogle	DOE/YMSCO	Х		
	Jon White	DOE/YMSCO	\mathbf{X}		
	Ronald Oliver	DOE/YMSCO	X		

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ATTACHMENT 1 Personnel Contacted During the Audit <u>Las Vegas, Nevada</u>

NAME	ORGANIZATION	CONTACT	MEETINGS PRE POST
Linda Manter	M&O/TPM	Х	
Vicky Obrad	M&O/TMP	Х	
David Osborne	OQA/QATSS	X	
John Martin	OQA/QATSS	X	

LEGEND:

M&O:	Civilian Radioactive Waste Management System Management and Operating
	Contractor
MTS:	Management and Technical Support Services
BAH:	Booze Allen and Hamilton
TPM:	Technical Publications Management
SMF:	Sample Management Facility
SE&I:	Systems Engineering and Integration

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ATTACHMENT 2 AUDIT YMSCO-ARC-97-22 DETAIL SUMMARY AUDIT RESULTS

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEWED	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1.0	QAP 1.1, R4/0	pgs. 1-3			SAT	SAT	
	YLP 1.1-Q- YMSCO, R2/0	pgs. 4-5			SAT	SAT	SAT
2.0	QAP 2.4, R1/0	pgs. 6-10	DR YM-97-D-078		UNSAT	UNSAT	
	QAP 2.5, R1/1	pgs. 11-13			SAT	SAT	
	QAP 2.6, R3/0	pgs. 14-15			SAT	LOA	
	QAP 2.8, R1 & 2/0	pgs. 16-19			SAT	SAT	SAT
	YAP-2.1Q, R1/0	pgs. 20-23	DR YM-97-D-078		SAT	UNSAT	
	YAP-2.4Q, R0/0	pgs. 24-31			SAT	LOA	
	YAP-2.6Q, R1/3	pgs. 32-3 6			SAT	SAT	
	YAP-2.7Q, R0/1	pgs. 37-39	DR YM-97-D-078 CDA #6		UNSAT	SAT	
	YAP-5.4Q, R0/0	pgs. 89-90			SAT	LOA	
	YAP-5.6Q, R0/5	pgs. 94-97			SAT	SAT	
	YLP-2.1Q- YMSCO, R1/2	pgs 40-51			SAT	SAT	

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ATTACHMENT 2 AUDIT YMSCO-ARC-97-22 DETAIL SUMMARY AUDIT RESULTS

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEWED	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
3.0	YAP-6.1Q, R1/0	pgs. 64-65			SAT	SAT	
	YAP-3.3Q, R0/1	pg. 63			SAT	LOA	
	YAP-3.5Q, R3/1	pgs. 52-56			SAT	SAT	SAT
	YAP-3.6Q, R0/1	pgs. 57-59			SAT	LOA	
	YAP-3.7Q, R0/0	pgs. 60-62			SAT	LOA	
4.0	YLP-4.1Q- YMSCO, R0/2	pgs. 66-74			SAT	LOA	LOA
5.0	QAP 5.1, R7/1	pgs. 75-84			SAT	SAT	
	YAP-5.1Q, R3/0	pgs. 99-103	DR YM-97-D-078		UNSAT	SAT	
	YLP-5.1Q, YMSCO, R1/0	pgs. 104-105			SAT	SAT	MARGINAL
	YAP-5.8Q, R0/0	pg. 98		#2	SAT	LOA	
6.0	QAP 6.2, R3/1	pgs 111-115			SAT	SAT	SAT
	YAP-6.2Q, R1/1	pgs. 106-110	CDA #1	#1	SAT	SAT	
7.0	QAP 7.2, R2/0	pgs. 116-119		#3	SAT	SAT	
	AP-7.4Q, R2/0	pgs 120-121			SAT	SAT	SAT
	YAP-12.1Q, R0/0	pgs 122-124			SAT	LOA	

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ATTACHMENT 2 AUDIT YMSCO-ARC-97-22 DETAIL SUMMARY AUDIT RESULTS

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEWED	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
15.0	YAP-15.1Q, R3/1	pgs. 125-129	CDAs #2, 3 & 4		SAT	SAT	SAT
16.0	AP-16.1Q, R2/0	pgs. 130-133			SAT	SAT	
	AP-16.2Q, R2/0	pgs. 134-136		· · · · · · · · · · · · · · · · · · ·	SAT	SAT	
	AP-16.3Q, R1/0	pgs. 137-140		· · · · · · · · · · · · · · · · · · ·	SAT	SAT	SAT
	AP-16.4Q, R0/0	pg. 141	CDA #5		SAT	SAT	
17.0	AP-17.1Q, R0/0	pgs. 142-145			SAT	SAT	
	YAP-17.2Q, R0/0	pgs. 146-150			SAT	LOA	SAT
18.0	QAP 18.1, R5/0	pgs 151-154	DR YM-97-D-078		SAT	SAT	
	QAP 18.2, R7/0	pgs. 155-157	DR YM-97-D-078	#4	SAT	SAT	SAT
	QAP 18.3, R1/0	pgs. 158-159			SAT	SAT	
SUPP II	YAP-2.8Q, R1/0	pg. 160	CDA #6		SAT	SAT	
	YAP-SII.1Q, R1/1	pg. 164			SAT	SAT	
	YAP-SII.2Q, R3/0	pg. 162			SAT	LOA	SAT
	YAP-SII.4Q, R0/0	pg. 163			SAT	LOA	

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ATTACHMENT 2 AUDIT YMSCO-ARC-97-22 DETAIL SUMMARY AUDIT RESULTS

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEWED	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
SUPP III	YAP-SIII.1Q, R1/0	pgs. 165-166			SAT	LOA	
	YAP-SIII.3Q, R1/0	pg. 167		#2	SAT	LOA	
	YAP-SIII.4Q, R0/1	pgs. 168-169			SAT	SAT	SAT
	YAP -2 .11Q, R0/0	pg. 161			SAT	SAT	
	YAP-5.5Q, R0/0	pgs. 91-93			SAT	LOA	
	YAP-SIII.5Q, R0/0	pg. 170			SAT	SAT	
SUPP V	YLP-5.2Q- AMA, R0/1	pgs. 85-88			SAT	SAT	SAT
APPENDIX C	QARD, R7	pg. İ			N/A	LOA	LOA
TOTAL		Pages 170	7	4		SAT	······

"DOCUMENTS REVIEWED" INCLUDE THE REFERENCED PROCEDURE OR PROCESS STEP AND THE ASSOCIATED RECORDS/OBJECTIVE EVIDENCE

LEGEND:

CDA CORRECTED DURING AUDIT DR DEFICIENCY REPORT LOA LACK OF ACTIVITY SAT SATISFACTORY UNSAT. UNSATISFACTORY