QA: QA

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

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT YMSCO-ARC-01-14

OF THE

YUCCA MOUNTAIN SITE CHARACTERIZATION OFFICE

AT

LAS VEGAS, NEVADA

AUGUST 6-14, 2001

Prepared by:_____ Date:_____
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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Compliance-Based Audit YMSCO-ARC-01-14, the audit team determined that the Yucca Mountain Site Characterization Office (YMSCO) organization is not satisfactorily and effectively implementing the examined portions of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM) DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description* (QARD), and implementing procedures.

QARD Program Sections 1.0, 16.0, 17.0, Supplements II and III were determined to be effectively implemented based on the activities evaluated. QARD Program Sections that were evaluated and determined to be unsatisfactory were 2.0, 3.0, 4.0, 5.0, 6.0, and 7.0. QARD Program Sections Supplements I and Appendix C were not evaluated due to the lack of activity in those areas. QARD Program Sections 8.0, 9.0, 10.0, 11.0, 12, 13.0, 14.0, 15.0, 18.0, Supplement IV and V, Appendix A and B were determined to be not applicable to YMSCO.

The audit team identified six conditions adverse to quality (CAQ) during the audit that resulted in the issuance of four deficiency reports (DR) described in paragraph 5.5.2, one Deficiency Identification and Referral (DIR) described in paragraph 5.5.3, and one CAQ that was corrected prior to the post-audit meeting as described in paragraph 5.5.4.

DR YMSCO-01-D-138 addresses training requirements on the Individual Development Plan (IDP) in which there is no objective evidence of satisfactory completion.

DR YMSCO-01-D-141 addresses procurement requirement packages in which there was no objective evidence of documentation of comments and comment resolution. Additionally one procurement package contained the Office of Quality Assurance (OQA) comments, in which the comment resolution was not documented.

DR YMSCO-01-D-140 addresses AP-6.1Q, Revision 6, ECN 1, *Controlled Distribution*, the document owner was identified in the OCRWM program documents database as R. N. Wells, Office of Information Management. The individual entered on the Document Control Action Request (DCAR) as the document owner was D. Keller, Records Management. For AP-17.1Q, Rev. 2, ICN 0, record source responsibilities for inclusionary records, the document owner is identified in the OCRWM Program Documents Database (OPDD) as R. N. Wells. The individual entered on the DCAR as document owner is D. Keller and signed for by D. Gibson, Review Coordinator.

DR YMSCO-01-D-139 addresses AP-7.5Q, Revision 0, ICN 2, BSCN 1, *Submittal, Review, and Acceptance of Deliverables*, where there was no objective evidence of reviews and/or comment resolution for several Q deliverables.

DIR-01-08 to YMSCO-01-D-118 addresses AP-5.1Q, Revision 2, *Plan and Procedure Preparation, Review, and Approval*, where the requirements matrix did not contain the required information.

In addition, the effectiveness of corrective actions related to two previously closed DRs was evaluated with satisfactory results. The details are described in paragraph 5.5.6.

There are three recommendations, which are detailed in Section 6.0 of this report.

2.0 SCOPE

Auditors representing OQA conducted the compliance-based audit to assess, through interviews with cognizant personnel, reviews of documentation, and evaluation of procedures, the adequacy and effectiveness of the YMSCO implementation of the OCRWM QA Program, as described in the QARD and implementing procedures.

The audit team also reviewed closed deficiency documents assigned to YMSCO, which are related to the audit scope and that were generated during the previous QA audits or surveillances to evaluate the effectiveness of the completed corrective actions.

In accordance with the approved audit plan, the following QA Program Sections were evaluated:

1.0	Organization
2.0	Quality Assurance Program
3.0	Design Control
4.0	Procurement
5.0	Implementing Documents
6.0	Document Control
7.0	Control Of Purchased Items and Services
16.0	Corrective Action
17.0	Quality Assurance Records
Supp II	Sample Control
Supp III	Scientific Investigation

QARD Program Sections not evaluated due to no activity in those areas were:

Supp I	Software
App C	Monitored Geologic Repository

QARD Program Sections determined not applicable to YMSCO were:

8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
12.0	Control of Measuring and Test Equipment
13.0	Handling, Storage, and Shipping
14.0	Inspection Test and Operating Status

15.0	Nonconformances
18.0	Audits
Supp IV	Field Surveying
Supp V	Control of the Electronic Management of Data
App A	High-Level Waste Form Production
App B	Storage and Transportation

3.0 AUDIT TEAM MEMBERS AND OBSERVERS

Donald J. Harris, Audit Team Leader, Navarro Quality Services (NQS), Las Vegas, NV
George T. Harper, Auditor, NQS, Las Vegas, NV
Dennis C. Threatt, Auditor, NQS, Las Vegas, NV
William Belke, Observer, Nuclear Regulatory Commission (NRC), On-Site Representative, Las Vegas, NV

4.0 AUDIT MEETING AND PERSONNEL CONTACTED

The Pre-Audit Meeting was held on August 6, 2001, at YMSCO office in Las Vegas, NV. Daily team observer debriefing meetings were held by audit team members to report the progress of the audit and discuss any problem areas, including potential CAQ. Daily management meetings were held to advise YMSCO management and staff on the pertinent audit information as it was developed. The audit was concluded with a Post-Audit Meeting held on August 14, 2001 at YMSCO offices in Las Vegas, NV.

Personnel contacted during the audit, including those who attended the Pre- and Post-Audit Meetings are listed in Attachment 1, “Personnel Contacted During the Audit.”

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that overall YMSCO is not implementing the QA program in a satisfactory manner. The deficiencies identified during the audit, while not significant, are indicative of a failure to follow the implementing procedure and/or properly document the details required to be completed by the procedure. The audit results for each program section evaluated is contained in Attachment 2, “Summary Table of Audit Results.”

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions as a result of the audit.

5.3 Audit Activities

Attachment 2, "Summary Table of Audit Results" provides the results for each QA Program Section audited. Details of audit activities, including objective evidence reviewed, are documented in the audit checklists. The checklists are administered as QA records in accordance with the directions of QAP 18.2, Revision 8, *Internal Audit Program*.

5.4 Technical Audit Activities

The audit did not perform any technical evaluations.

5.5 Summary of Deficiencies

The audit team identified a total of six CAQ during the audit from which four DRs and one DIR have been issued. One CAQ was identified and corrected during the audit (CDA) prior to the post-audit meeting. Details of the CAQ are addressed in paragraph 5.5.2 for DRs; in paragraph 5.5.3 for the DIR; and in paragraph 5.5.4 for the CDA.

5.5.1 Corrective Action Reports (CAR)

None.

5.5.2 Deficiency Reports (DR)

YMSCO-01-D 138. AP-2.1Q, Revision 1, BSCN 1, *Indoctrination and Training of Personnel*, requires completion of training for work subject to the QARD to be documented on the IDP. Contrary to the requirements, three YMSCO staff members documented completion of training on the IDP, with no objective evidence of completion on Training Records Report, Status Report by Jobs or Training Attendance Record.

YMSCO-01-D-141. LP-4.1Q-OCRWM, Revision 1, *Procurement Action.* Procurement packages require that the Assistant Managers/ Directors and OQA to review and document all technical and QA comments and forward to requestor for resolution. Contrary to the requirements, three record packages fail to contain comments from required reviewers, and in one case the statement of work has documented QA comments with no documentation of comment resolutions.

YMSCO-01-D-140. AP-6.1Q, requires the DCAR document owner to print and sign name, enter date signed and enter the document owners organization, department, location and/or mail stop and telephone number. Contrary to the requirements, on AP-6.1Q, the document owner in the

OCRWM program documents database is identified as R. N. Wells, Office of Information Management. The individual entered on the DCAR as the document owner is D. Keller, Records Management. Another example is for AP-17.1Q, the document owner is identified in the OPDD as R. N. Wells. The individual entered on the DCAR as document owner is D. Keller and signed for by D. Gibson, Review Coordinator.

YMSCO-01-D-139. AP-7.5Q requires Technical Monitor or Contracting Officer Representative if no Technical Monitor, to review QA deliverables and record comments on a comment sheet and include in the records package. Additionally, Attachment 3 requires that the Rev/ICN/Draft date be indicated in block 14a for deliverables that are accepted or rejected. Contrary to the above requirements, there were no comments for reviews of Q deliverables for TDR-MGR-PA-000001 or TDR-MGR-SE-000004. The Review Record forms were included in the records package TDR-MGR-SE-000004 for the designated reviewers, several of which identified mandatory comments; however, no comment or comment resolution documentation was included in the record package. Additionally, the Rev/ICN/Draft date was not completed on the Yucca Mountain Site Characterization Project Deliverable Acceptance Review forms for TDR-MGR-SE-000004, TDR-MGR-PA-000001, or TDR-WIS-MD-000002.

5.5.3 Deficiency Identification and Referral (DIR)

DIR-01-08. AP-5.1Q, paragraph 5.2.3c, requires the preparer, "If the procedure implements QARD requirements and/or Integrated Safety Management (ISM) (QARD, Appendix I) requirements to prepare or update a requirements matrix in accordance with Attachment 9, "Requirements Matrix Input," which requires a "Q" requirements matrix for an existing procedure: 1) Run a 012 report from Requirements Traceability Network (RTN) Web for a listing of QARD requirements implemented by the procedure; 2) identify the affected organizations to which the procedure applies; 3) identify the proposed revision/change numbers; 4) markup the requirements matrix as necessary, for a procedure cancellation.

Contrary to the requirements, Requirements Matrix for procedure AP-6.1Q, Revision 6, ICN 0, *Controlled Distribution*, and AP-17.1Q, Revision 2, ICN 1, did not contain the required information. For AP-6.1Q as 014 RTN Report was run, which did not identify the affected organization, and AP-17.1Q, Revision 2, ICN 1, a 012 RTN Report was run, which did not identify the affected organizations or the revision/change numbers. This CAQ has been identified in a DIR to DR YMSCO-01-D-128.

5.5.4 Deficiencies Corrected During the Audit (CDA)

AP-17.1Q, Revision 2, ICN 1, paragraph 5.1, states in part: a) the Signature and Initial List must contain the signature and initial for every individual working on the OCRWM program within the organization. b) Update the organization's Signature and Initial List when a new individual began performing OCRWM-related work for the organization by submitting a new Signature and Initials List, listing the new individual, to the Record Processing Center (RPC). Contrary to the requirements, the YMSCO Organization Signature and Initial Lists were dated 1999. The Signature and Initials Lists are not reflective of the current YMSCO organization. This CAQ was considered isolated in nature requiring only remedial action. The Signature and Initials Lists were updated prior to the post-audit meeting, the lists were evaluated against the current organization chart and verified as cross-referenced to the previous list records MOL numbers.

5.5.5 Nonconformances

None.

5.5.6 Follow-up of Previously Identified Conditions Adverse to Quality

YMSCO-00-D-112. QARD, Section 6.2.5c, disposition of obsolete or superseded documents shall be controlled to preclude use for work. Section 6.2.5c, a method shall be established to identify current status of each controlled document.

This DR was determined not to be a CAQ and was voided by the initiator. AP-6.1Q, Revision 5, ICN 0, identified three methods a document user can determine the correct version of the controlled document. The voiding of this DR occurred on 10/16/00, and was concurred with by the audit team.

YMSCO-00-D-113. AP-2.3Q, Revision 0, ICN 0, *Documenting and Verifying Traceability*, the RTN assist the YMSCO in accomplishing the following goals as stated in AP-2.3Q: Ensuring that YMSCO-approved upper-tier requirements are fully satisfied by lower-tier implementing documents. The hardcopy of the Yucca Mountain Project-Requirements Document is considered the controlled source of information for the Monitored Geologic Repository Requirements Document requirements and are not traced using the RTN. AP-2.3Q was canceled on 3/16/01 to eliminate the confusion. The corrective action was determined to be effective.

6.0 RECOMMENDATIONS

1. The position descriptions should specify the minimum education and experience requirements for each position, and the verification of the education and experience should be documented in accordance with AP-2.2Q, Revision 1, *Establishment and Verification of Required Education and Experience of Personnel.*

   The position descriptions for federal employees are written and processed in accordance with the procedures established by the United States Office of Personnel Management, which provides the basic and alternates for satisfying the requirements for a position. The position description's cover sheet only references the occupation series code and grade, but fails to specifically address the education and experience required and the DOE letter on education and employment verification only makes a statement it was verified. Based on the current position description and education and experience verification letter, it is difficult to determine if the candidate satisfied the basic or alternate requirements, or what specific degree held or work experience qualified the person for the position.

   A lesson learned from the National Spent Nuclear Fuel Program (NSNFP), which resulted in NSNFP revising the position descriptions of key personnel, was a NRC request for additional information, prior to the transfer of the Fort Saint Vrain spent fuel storage installation. The request for additional information includes the following related to personnel qualifications:

   a) Provide specific minimum qualification requirements for each of the DOE positions described in the Safety Analysis Report. A statement of a baccalaureate degree and five years experience does not provide sufficient basis to determine the qualification to manage.

   b) Strengthen the qualification requirements for contractor staffing to include a minimum level of technical experience for each supervisor and managerial position.

2. The DOE, Position Description form DOE 35.11 (8-86) is inconsistent in the way it is being completed, especially when compared against other position description's completed cover sheets. An instruction for completing the form should be considered for consistency.

3. Revise AP-3.9Q, Revision 0, *Interface Management Process.* There are seven DARs applicable to this procedure (six accepted and one pending) ranging in age from 3 months to 23 months). In addition, it is not clear what this procedure is intended to develop as a product to address the AP-3.9Q procedure purpose. The procedure does not provide an adequate description of a comprehensive management system.

7.0 ATTACHMENTS

Attachment 1, Personnel Contacted During the Audit
Attachment 2, Summary Table of Audit Results
Attachment 3, Acronyms / Abbreviations

ATTACHMENT 1

YMSCO-ARC-01-14
PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Dick Morrissette	BSC/Integrated Safety Analysis		X	
Ed Ziegler	BSC/Integrated Safety Analysis		X	
Kathleen Thompson	BSC/Records		X	
Lana Colehour	BSC/Records Supervisor		X	
Chris Lewis	BSC/Sample Management		X	
David S. Rhodes	BSC/Special Projects		X	X
Elaine Spangler	BSC/Training		X	
Donald Horton	Deputy Project Manager (Technical)		X	X
Richard Taft	MTS/Manager	X		X
Robert Fish	MTS/Office of Project Execution	X		X
Mattie Cavalier-Roberts	MTS/Technical Resources		X	X
Deborah Kirby	MTS/Technical Resources	X	X	X
Kathryn Knapp	MTS/Technical Resources	X	X	X
Frank Kratzinger	MTS/Technical Resources			X
Barbara McKinnon	MTS/Technical Resources			X
Raymond Mele	MTS/Technical Resources	X	X	X
Bimal Mukhopadhyay	MTS/Technical Resources	X		
John Savino	MTS/Technical Resources		X	
Gary Sequeira	MTS/Technical Resources		X	
Janice Verden	MTS/Technical Resources		X	
Nancy Smith	MTS/Technical Resources		X	
Jim Harper	MTS/Technical Resources		X	
Dave Sassani	MTS/Technical Resources		X	
Lester Wagner	Navarro Qualitiy Services			X
Robert Hasson	Navarro Quality Services	X		X
Robert Latta	NRC/Las Vegas			X
Dee Jensen	Office of Information Management	X		

Name	Organization	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
David Warriner	Office of Information Management	X	X	X
Stephan Brocoum	Office of Licensing & Regulatory Compliance	X		X
Emily Cooper	Office of Licensing & Regulatory Compliance		X	X
Victor Trebules	Office of Project Control	X		X
James Compton	Office of Project Control	X	X	X
Suzanne Mellington	Office of Project Execution	X		X
Catherine Hampton	Office of Project Execution	X	X	X
Drew Coleman	Office of Project Execution		X	
Paul Harrington	Office of Project Execution		X	
Joe Price	Office of Project Execution		X	
Birdie Hamilton-Ray	Office of Project Support	X	X	X
Dorothy Callier	Office of Project Support	X	X	X
J. C. De La Garza	Office of Project Support	X		
Linda Quering	Office of Project Support	X	X	
Lenora Gilbert	Office of Project Support		X	
Frank Young	Office of Project Support		X	
James Blaylock	Office of Quality Assurance			X
Russell Dyer	Project Manager	X		X

ATTACHMENT 2

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SUMMARY TABLE OF AUDIT RESULTS

QARD Elements	Implementing Documents	Title	Details Checklist	Deficiency Reports	CDAs	Recom-mendations	Program Adequacy	Procedure Compliance	Elements Overall
1.0	LP-1.1Q-0CRWM	Organization	pgs 1-2	-	-	-	SAT	SAT	SAT
2.0	AP-2.1Q	Indoctrination & Training	pgs 3-4	YMSCO-01-D-138	-	#2	SAT	UNSAT	SAT
	AP-2.2Q	Verification of Education/Experience	pgs 5-6	-	-	#1	SAT	SAT	
	AP-2.20Q	Self Assessments	pgs 7-11	-	-		SAT	SAT	
	YAP-2.7Q	Item Classification & Maintenance of Q-List	pg 12	-	-	-	SAT	SAT	
3.0	AP-3.9Q	Interface Management Process	pg 13a	-	-	#3	UNSAT	N/I	N/I
4.0	LP-4.1Q-OCRWM	Procurement Actions	pgs 13-16	YMSCO-01-D-141	-	-	SAT	UNSAT	SAT
5.0	AP-5.1Q	Plans & Procedure Preparation, Review & Approval	pgs 17-23	DIR-01-8, YMSCO-01-D-128	-	-	SAT	UNSAT	SAT
6.0	AP-6.1Q	Controlled Documents	pgs 24-27	YMSCO-01-D-140	-	-	SAT	UNSAT	SAT
	AP-6.28Q	Document Review	pgs 28-31	-	-	-	SAT	SAT	
7.0	AP-7.5Q	Submittal, Review & Acceptance of Deliverables	pgs 32-36	YMSCO-01-D-139	-	-	SAT	UNSAT	SAT
16.0	AP-16.1Q	Management of Conditions Adverse to Quality	pgs 37-39	-	-	-	SAT	SAT	SAT
17.0	AP-17.1Q	Records Source Responsibilities for Inclusionary Records	pgs 40-44	-	#1	-	SAT	SAT	SAT
SII	YAP-SII.1Q	Submittal, Review & Approval of Request for YMSCO Geologic Specimens	pgs 45-46	-	-	-	SAT	SAT	SAT
SIII	AP-SIII.2Q	Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data	pgs 47-48	-	-	-	SAT	SAT	SAT
	AP-SIII.5Q	YMSCO Field Verification of Geophysical Operations	pg 49	-	-	-	SAT	SAT	
	AP-SIII.6Q	Geophysical Logging Programs for Subsurface-Based Testing Program Boreholes	pg 50	refer to YMSCO-01-D-101	-	-	SAT	SAT	

ATTACHMENT 3
YMSCO-ARC-01-14

ACRONYMS / ABBREVIATIONS

CAQ.	Condition Adverse to Quality
CDA	Corrected During the Audit
DCAR	Document Control Action Request
DIR	Deficiency Identification and Referral
DOE	U.S. Department of Energy
DR	Deficiency Report
IDP	Individual Development Plan
ISM	Integrated Safety Management
NQS	Navarro Quality Systems
NRC	Nuclear Regulatory Commission
OCRWM	Office of Civilian Radioactive Waste Management
OPDD	OCRWM Program Document Database
OQA	Office of Quality Assurance
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
RPC	Records Processing Center
RTN	Requirement Traceability Network
YMSCO	Yucca Mountain Site Characterization Office