

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

**AUDIT REPORT
OF THE
YUCCA MOUNTAIN SITE CHARACTERIZATION OFFICE
(YMSCO)**

AUDIT NUMBER HQ-94-04

LAS VEGAS, NV JULY 25-29, 1994

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Approved By: Donald G. Horton Date: 9/8/94
Donald G. Horton
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit HQ-94-04, the audit team determined that the implementation of the Yucca Mountain Site Characterization Office (YMSCO) QA program in accordance with the Quality Assurance Requirements Document and associated implementing procedures is effective.

This audit was designed to evaluate the YMSCO QA Program implementation as described in the Quality Assurance Requirements Document and the related implementing procedures used to perform YMSCO, Yucca Mountain Quality Assurance Division (YMQAD), and the Sample Management Facility (SMF) activities.

In summary, of the seventeen QA Program Elements audited for implementation of procedures identified in the Requirements Traceability Network (RTN) Matrix, twelve were determined to be satisfactory, one was determined to be marginal due to a Corrective Action Request (CAR) previously written by YMQAD, and four had insufficient activity to evaluate.

Thirteen (13) deficiencies, requiring only remedial action, were corrected during the audit. Nine (9) recommendations were identified for YMSCO, YMQAD, and SMF management consideration. The deficiencies and recommendations are described in Section 5 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy and implementation of the OCRWMS YMSCO QA Program as described in the Quality Assurance Requirements Document and the related implementing procedures used to perform YMSCO, YMQAD, and SMF activities.

The QA Program Elements and requirements evaluated during the audit, in accordance with the published Audit Plan, are as follows:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 11.0 Test Control
- 15.0 Control of Nonconforming Items

- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits
- SI Computer Software
- SII Sample Control
- SIII Scientific Investigation
- SIV Field Surveying
- App. C MGDS

The following QA Program Elements and Appendices were not reviewed during the audit because neither YMSCO, YMQAD, nor SMF currently have any assigned responsibilities in these areas.

- 8.0 Identification and Control of Items
- 9.0 Control of Special Processes
- 10.0 Inspection
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 14.0 Inspection, Test and Operating Status
- AppA High Level Radioactive Waste Form Production
- AppB Transportation

Requirements were drawn from the Quality Assurance Requirements Document and the YMSCO implementing Quality Administrative Procedures (QAPs), Administrative Procedures (APs & YAPs), and related YMSCO location-specific line procedures.

3.0 AUDIT TEAM AND OBSERVERS

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

<u>NAME</u>	<u>ORGANIZATION</u>	<u>QA PROGRAM ELEMENT/REQUIREMENT</u>
AUDITORS		
Marlin Horseman	QATSS	Audit Team Leader
Dennis Threatt	QATSS	Elements 5, 15, 16, SIV, App. C
Amelia Arceo	QATSS	Elements 3, 6, 17
Fred Bearham	QATSS	Elements 2, 3, 11, SII, SIII
Charles Betts	QATSS	Elements 2, 3
Robert Harpster	QATSS	Elements SII, SHI
Hugh Lentz	QATSS	Elements 1, 2, 4, 18
Emily Reiter	QATSS	Elements 2, 4, 5, 6, 7
Tom Swift	QATSS	Elements 2, 3, SI

OBSERVERS

Bill Belke NRC
Susan Zimmerman State of Nevada

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

Preaudit meetings were held at the YMSCO offices in Las Vegas, NV on July 25, 1994. A daily debriefing and status meeting was held with YMSCO management and staff to discuss issues and potential deficiencies. The audit was concluded with postaudit meetings held at YMSCO offices in Las Vegas, NV on July 29, 1994. Personnel contacted during the audit are listed in Attachment 1. The list also identifies those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, in general, the YMSCO Quality Assurance Program implementation for the scope of this audit is effective. Individually, QA Program Elements 1.0, 2.0, 3.0, 5.0, 6.0, 11.0, 15.0, 16.0, 17.0, 18.0, SII and SIII are being satisfactorily implemented. Implementation of QA Program Element 4 was determined to be marginal. Implementation of QA Program Elements 7, SI, SIV, and Appendix C could not be evaluated due to a lack of activity.

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

The details of the audit evaluation along with objective evidence reviewed are contained within the audit checklists. The checklists are submitted as QA Records.

A summary table of audit results is provided in Attachment 2.

5.4 Technical Activities

Because the audit was conducted to evaluate adequacy and implementation of the OCRWMS YMSCO QA Program, the audit team did not evaluate any technical activities.

5.5 Summary of Deficiencies

The audit team identified thirteen deficiencies, all were corrected prior to the postaudit meeting.

Deficiencies corrected during the audit are detailed below.

5.5.1 Corrective Action Requests (CARs)

No CARs were issued as a result of the audit.

5.5.2 Deficiencies Corrected During The Audit (CDA)

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

- 1 YLP-1.1Q QAP 1.1 identifies letters of Delegation of Signature Authority as QA records. YLP-1.1Q did not require them to be processed as a QA record. An ICN to YLP-1.1Q was issued during the audit to provide consistency with QAP 1.1 requirements.
- 2 QAP 5.1 DAR 948 was issued with the wrong page count and did not identify an attachment to be associated with the DAR. The DAR was corrected and reissued during the audit.
- 3 YAP-2.2Q Study Plan Comment Resolution Forms and Study Plan Review Checklists were not completed as required. During the audit, a memo was issued (Justification for Uncompleted Forms, dated 7/28/94) adequately justifying the incomplete forms. In addition, an ICN was issued to YAP-2.2Q to revise the forms for clarity to preclude recurrence.

- 4 QAP 18.2 Audit YMP-94-02 checklists did not always identify "Remarks" and "Results". During the audit, the checklists were properly completed.
- 5 QMP-03-09 Change Evaluation forms, containing the "Just-in-time training" statement were incorrectly documented as N/A in one case and in two other cases incorrectly referenced ICN 3 when ICN 4 was applicable. All forms were corrected during the audit.
- 6 QAP 18.2 Audit YMP-94-02 was conducted 12/93. The audit records package had not been sent to the LRC. During the audit, the Audit Plan, the Audit Report, and the checklists were properly transmitted to the LRC.
- 7 QAP 16.1 A CAR was signed for the QADD by an individual without delegated signature authority. During the audit, the QADD reviewed and signed the CAR. This was the only case noted.
- 8 QAP 16.1 A CAR was voided prior to being issued (the CAR number had been assigned). Notification correspondence was not sent to the Responsible Individual as required by the procedure. During the audit the CAR was issued, immediately closed, and the appropriate correspondence provided.
- 9 QAP 16.1 Significant CARs issued to USGS were not provided to the OCRWM Director responsible for the work. During the audit, all significant CARs were reviewed and copies were forwarded to the appropriate OCRWM Directors.
- 10 YAP-17.1Q Computer tapes being maintained in the LRC were not being provided with adequate protection from excessive heat (exceeding 90° F). The tapes were removed from the LRC area and are being stored at Security Archives, Las Vegas.
- 11 YLP-2.1Q The verification of education and experience for a direct support contractor was incomplete. The verification was satisfactorily completed.

- 12 AP-1.5Q The procedure requires the Controlled Document Issuance Authorization (CDIA) to identify the Document Originator's full name and telephone number and additionally, the signature of the approval authority. CDIA's did not contain this information. During the audit, an ICN was issued to delete the requirement for the unnecessary information.
- 13 YAP-17.1Q Non-QARD required provisions of the procedure were not implemented. YMQAD was in the process of issuing a CAR relating to YAP-17.1Q. YMQAD agreed to add this deficiency to the CAR.

6.0 RECOMMENDATIONS

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

1. Establish a methodology for qualification of existing data. YAP-SIII.1Q contains responsibilities and requirements but does not identify a methodology.
2. The following steps are recommended based on QARD paragraph III.2.4.D.2 and should be considered in planning and documenting the qualification of existing data in accordance with YAP-SIII.1Q:
 - a) Identify data that may require qualification
 - b) Establish priorities for qualification
 - c) Determine data that can be qualified by procedure comparison and data that may require peer review.
 - d) Consider utilizing a database to capture the data.
3. Evaluate the procedural description (QMP-02-09) of the process for submitting requests for proficiency training and provide a Training Coordinator to facilitate development and scheduling of requested training. (reference paras. 5.6, 5.7, and 5.8).
4. The Audit Team recommends that WI-RED-015, Calibration of Balance Scales, be revised to require a set number of low value readings be taken to address the working range of the instrument.
5. Consider the possible cancellation of AP-5.48Q and AP-5.39Q - these procedures have not been implemented for two years.

6. Although implementation of YAP-17.1Q was evaluated during this audit, the Audit Team recommends that the planned surveillance of YAP-17.1Q implementation be performed as scheduled to provide a more in-depth evaluation of the activities associated with records processing.
7. The Audit Team recommends that QAP 2.6, Readiness Review, be revised to better identify specific prerequisites, programmatic requirements, and program objectives that a Readiness Review is to evaluate.
8. The Audit Team recommends that YMQAD perform a surveillance to further evaluate the process used to verify DOE personnel education and experience.
9. The Audit Team recommends that specific items identified in the evaluation review of QMP-04-02 and QMP-04-03 be evaluated during the verification of closure of CAR YM-93-086.

7.0 LIST OF ATTACHMENTS

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

ATTACHMENT 1

PERSONNEL CONTACTED DURING THE AUDIT

NAME	TITLE	CONTACT	MEETINGS	
			PRE	POST
F. Afsher	Senior Staff		X	X
A. Arceo	Auditor	X	X	X
P. Banta	Programmer/Analyst	X		
R. Barton	Deputy Manager, AMSL	X	X	X
R. Baumeister	AMESH/DOE			X
F. Bearham	Auditor	X	X	X
J. Becket	Tech. Data Base Administrator	X		
B. Belke	NRC/Sr. QA Engineer			X
C. Betts	Auditor	X	X	X
M. Bishop	AMA		X	
M. Blanchard	Sr. Technical Administrator	X	X	X
S. Bodner	TDM M&O Manager	X		
R. Boehm	Informal Observer		X	
B. Bowser	Senior Site Representative			X
J. Calovini	Technical Lead	X		
J. Coombs	Technical Illistrator	X		
D. Crawley	Physical Scientist	X		
R. Crowley	Study Coordinator for DOE	X		
B. Cruz	Manager, YMSCO CM/CCB	X	X	
M. Diaz	General Engineer	X	X	
W. Dixon	AMESH		X	
D. Donavan	M&O/WCFS	X		X
J. Dyer	Deputy Project Manager		X	X
H. Ebner	Records Management	X	X	
J. Estella	Staff Advisor	X	X	X
J. Gandi	IRM			X
J. Gardiner	Project Engineer	X		
P. Gibson	Records Clerk	X		
J. Gilray	NRC On-Site Representative		X	
W. Girdley	Field Coordinator	X		
C. Glenn	NRC DWM		X	
A. Goetz	Information Management		X	
T. Grant	Job Pkg. Records Coordinator	X		
H. Greene	QA Division Manager	X		X
B. Hamilton-Ray	Contract Specialist	X	X	X
C. Hampton	QA Specialist	X		X
J. Harper	Manager		X	X
R. Harpster	Auditor	X	X	X
D. Harris	Sr. QA Specialist	X		
S. Harris	QA Engineer	X		
S. Harris-Womach	DCC/Lead	X		
D. Harrison	Engineer		X	

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NAME	TITLE	CONTACT	MEETINGS	
			PRE	POST
J. Hartley	Division Manager	X		
R. Helms	Sr. Staff TPO	X	X	
J. Herbert	Records Clerk	X		
C. Hermes	Senior Geologist	X		
M. Horseman	Lead Auditor	X	X	X
D. Horton	Director, OQA			X
B. Hutchinson	General Engineer	X		
K. Jerome	Records Clerk	X		
R. Jiu	CCB Support		X	X
S. Johnson	Human Resources Manager	X		
K. Johnson	Manager			X
M. Jones	Computer Specialist	X		
S. Jones	Asst. Mgr., Scientific Programs	X	X	X
N. Jones	RIB Administrator	X		
J. Justice	M&O Training Specialist	X		
R. Keele	Program Manager		X	
D. Klimas	M&O Liaison			X
F. Lentz	Auditor	X	X	X
C. Lewis	Curator	X		
L. Linden	Field Geologist	X		
C. Lively	Personnel Administrator	X		
C. Lugo	Department Manager	X		
M. Malone	Sr. QA Specialist			X
S. Maslou	Sr. QA Specialist	X		
J. Matras	QA Engineer	X		
R. Maudlin	Sr. QA Specialist	X	X	
K. McFall	QA Specialist			X
A. Mendenhall	Senior Geologist	X		
D. Merritt	SMF Geologist	X		
D. Mikkelson	Technical Staff			X
S. Mishra	Acting Mgr., Performance Assess.	X		
S. Moore	Production Coordinator	X		
R. Noyers	Study Plan Coordinator	X		
M. Powell	Institutional Specialist	X		
R. Quittmeyer	Manager, Site Tech. Integration	X		
C. Redkop	Training Officer	X		
E. Reiter	Auditor	X	X	X
J. Replogle	Engineer			X
J. Richard	Technical Staff CCB Support	X		
R. Riding	Training Division Manager	X	X	X
P. Roberts	Record Coordinator	X		
T. Rogers	Audit Lead			X
D. Roper	Administrative Assistant	X		
S. Rouse	Management Analyst	X		
J. Schmit	Sr. QA Specialist	X		
J. Schrecongost	Contracting Officer	X		

NAME	TITLE	CONTACT	MEETINGS	
			PRE	POST
R. Schreinr	Project Engineer	X		
C. Shannon	Records Clerk	X		
W. Simecka	Asst. Mgr., Eng. & Field Ops.	X		
A. Simmons	Physical Scientist	X		
S. Smith	Department Manager	X		
W. Smith	DCC Supervisor	X		
P. Smith	Sr. QA Specialist	X		
B. Smith	DCC Supervisor	X		
E. Spangler	Technical Review Coordinator	X		
R. Spence	Director, YMQAD	X	X	X
R. Spooner	Consultant	X	X	X
D. Sult	Technical Administrator	X		
D. Sult	Technical Administrator	X		
T. Swift	Auditor	X	X	X
A. Tacelli	Records Manager	X		
L. Tate	Records Supervisor	X		
C. Taylor	Technical Reviewer	X		
J. Therien	QA Programs Lead	X	X	X
C. Thompson	Informal Observer		X	
M. Thompson	Configuration Management	X		
D. Threatt	Auditor	X	X	X
R. Vawter	M&I Manager		X	X
J. Verden	Records Manager	X		
D. Warriner	Records Manager		X	
K. Worcester	Records Management Lead	X		
S. Wright	CCB Specialist	X		
J. Zimmerman	Manager, Plans & Programs	X	X	X

ATTACHMENT 2

SUMMARY TABLE OF AUDIT RESULTS

DISCUSSION

For the seventeen QA Program elements and requirements evaluated during the audit, the implementation of twelve was determined to be satisfactory. Those elements were: 1.0, 2.0, 3.0, 5.0, 6.0, 11.0, 15.0, 16.0, 17.0, 18.0, Supplement II, and Supplement III. Among these twelve elements, there were thirteen deficiencies corrected during the audit.

Based on the multiple deficiencies documented on a previously written YMQAD.CAR, the implementation in the area of Procurement Document Control, Element 4.0, was determined to be marginal.

Of the seventeen QA Program elements, four were unable to be evaluated for implementation due to insufficient activity. QA Program elements not evaluated for implementation were: 7.0, Supplement I, Supplement IV, and Appendix C.

ATTACHMENT 2
SUMMARY TABLE OF AUDIT RESULTS

AUDIT HQ-94-04 DETAIL SUMMARY

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	CARs	CDA	RECOMMEND	ADEQUACY	COMPLIANCE	OVERALL
1	QAP 1.1, R0	pgs. 1-4					SAT	SAT
	YLP 1.1Q, R0	pgs. 1-4		1			SAT	
	ILP 1.4/YMPO-Q R0 I1	pg. 1					CANCELLED	
2	QAP 2.4 R1	pgs. 1-6					SAT	SAT
	QAP 2.5 R0	pgs. 1-5					lack of activity	
	QAP 2.6 R3	pgs. 1-11			7		lack of activity	
	QAP 2.7 R2	pgs. 1-7					lack of activity	
	QAP 2.8 R1	pgs. 1-6					SAT	
	AP-5.21Q R4	pgs. 1-10					SAT	
	AP-5.39Q R0	pgs. 1-6			5		lack of activity	
	AP-5.48Q R0	pgs. 1-3			5		lack of activity	
	AP-6.17Q R1 I2	pgs. 1-9					MARGINAL	
	YLP-2.1Q R0	pgs. 1-13		11	8		SAT	
	YLP-2.2Q-QAD R0	pgs. 1-4					SAT	
	QMP-02-09 R1 I3	pgs. 1-8			3		SAT	
3	QAP 3.5 R2	pgs. 1-9					lack of activity	SAT
	AP-3.3Q R5 I1	pgs. 1-4					SAT	
	AP-5.3 R2	pgs. 1					lack of activity	

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SUMMARY TABLE OF AUDIT RESULTS

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	CARs	CDA	RECOMMEND	ADEQUACY	COMPLIANCE	OVERALL
3 (con't)	AP-5.16Q R0 I1	pgs. 1-4					lack of activity	SAT
	AP-5.19Q R2 I2	pgs. 1-6					SAT	
	AP-5.20 R1 I1	pgs. 1					lack of activity	
	AP-5.24Q R1 I2	pg. 1					SAT	
	YAP-2.1Q R1	pgs. 1-5					SAT	
	YAP-2.2Q R0	pgs. 1-8		3			SAT	
	YAP-3.2Q R0	pgs. 1-13					SAT	
	YAP-3.4Q R1	pgs. 1-9					SAT	
	QMP-03-09 R3 I4	pgs. 1-7		5			SAT	
4	AP-4.1Q R0 I3	pgs. 1-3					MARGINAL	MARGINAL
	QMP-04-02 R0	pgs. 1-9			9		MARGINAL	
	QMP-04-03 R0 I3	pgs. 1-9			9		MARGINAL	
5	QAP 5.1 R6	pgs. 1-8		2			SAT	SAT
	YAP-5.1Q R1	pgs. 1-7					SAT	
	YAP 5.2Q R0	pgs. 1-3					SAT	
6	QAP 6.2 R2	pgs. 1-5					SAT	SAT
	AP-1.5Q R8	pgs. 1-7		12			SAT	
	YLP-3.2Q-AMEFO R0	pg. 1					SAT	

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SUMMARY TABLE OF AUDIT RESULTS

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	CARs	CDA	RECOMMEND	ADEQUACY	COMPLIANCE	OVERALL
7	QAP 7.2 R0	pgs. 1-10					lack of activity	lack of activity
	QMP-07-04 R2	pgs. 1-14					lack of activity	
11	YAP-5.5Q R0	pgs. 1-11					SAT	SAT
15	YAP-15.1Q R0 I1	pgs. 1-8					SAT	SAT
16	QAP 16.1 R6	pgs. 1-8		7, 8, 9			SAT	SAT
	QAP 16.2 R3	pgs. 1-5					SAT	
	QAP 16.3 R0	pgs. 1-2					SAT	
17	YAP-17.1Q R0	pgs. 1-9		10, 13	6		SAT	SAT
	AP-6.22Q R0 I1	pgs. 1-5					SAT	
18	QAP 18.1 R4	pgs. 1-8					SAT	SAT
	QAP 18.2 R6	pgs. 1-7		4, 6			SAT	
SUPP I	YLP-SI.1Q-QAD R0	pgs. 1-2					lack of activity	lack of activity
SUPP II	YAP-SII.1Q R1	pgs. 1-6			4		SAT	SAT
	YAP-SII.2Q R1	pgs. 1-4					SAT	
	YAP-SII.4Q R0	pgs. 1-8					SAT	
	YLP-SII.1Q-SMF R1	pgs. 1-10					SAT	
	YLP-SII.2Q-SMF R3	pgs. 1-5					SAT	
	YLP-SII.4Q-SMF R0	pgs. 1-3					SAT	

ATTACHMENT 2
SUMMARY TABLE OF AUDIT RESULTS

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	CARs	CDA	RECOMMEND	ADEQUACY	COMPLIANCE	OVERALL
SUPP II (con't)	YLP-SII.5Q-SMF R0	pg. 1					SAT	
	YLP-SII.6Q-SMF R0	pgs. 1-8					SAT	SAT
	YLP-SII.7Q-SMF R0	pgs. 1-5					lack of activity	
SUPP III	YAP-SIII.1Q R0	pgs. 1-2			1, 2		SAT	SAT
	YAP-SIII.2Q R0	pgs. 1-5					SAT	
	YAP-SIII.3Q R0	pgs. 1-4					SAT	
	YLP-SIII.1Q-EGG R0	pgs. 1-7					SAT	
SUPP IV	N/A	pg. 1					lack of activity	lack of activity
APP. C	N/A	pg. 1					lack of activity	lack of activity
TOTAL		376 pages	0	13	9			Effective

"DOCUMENTS REVIEWED" includes the referenced procedure or process step and the associated records/objective evidence

CARs Corrective Action Requests
CDA Corrected During Audit
RECOMMEND Recommendations
ADEQUACY .. Requirements in Procedures
COMPLIANCE Procedures Implemented
OVERALL ... Summary of Element