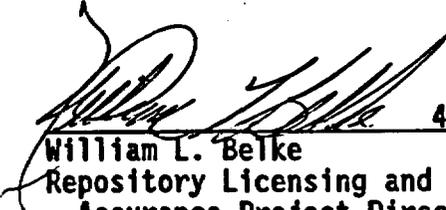


U.S. NUCLEAR REGULATORY COMMISSION
REPORT OF OBSERVATION AUDIT 93-08
OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION
AUDIT YMP-93-09
OF THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE


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1.0 INTRODUCTION

During April 5-9, 1993, members of the quality assurance (QA) staff of the NRC Division of High-Level Waste Management (HLWM) observed a U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD) audit of the Yucca Mountain Site Characterization Project Office (YMPO). The audit, YMP-93-09, was conducted at the YMPO offices in Las Vegas, Nevada and at the Sample Management Facility (SMF) on the Nevada Test Site Mercury, Nevada. The audit evaluated the adequacy and effectiveness of the YMPO QA program. Eight programmatic areas were audited. No technical activities and no YMQAD activities were audited during this audit; YMQAD activities will be audited later by the OCRWM OQA.

This report addresses the effectiveness of the YMQAD audit, and the adequacy of implementation of the QA controls in the audited areas of the YMPO QA program.

2.0 OBJECTIVES

The objectives of the audit by YMQAD were to determine whether the YMPO QA program and its implementation meet the applicable requirements and commitments of the OCRWM Quality Assurance Requirements Document (QARD), the OCRWM Quality Assurance Program Description (QAPD), and associated implementing procedures.

The NRC staff's objective was to gain confidence that YMQAD and YMPO are properly implementing the requirements of their QA program in accordance with the QARD, the QAPD, and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the YMPO implementation of the OCRWM QA program on direct observations of the auditors; discussions with audit team, YMPO, and YMPO contractor personnel; and reviews of the audit plan, the audit checklists, and other pertinent documents. The NRC staff has determined that YMQAD QA Audit YMP-93-09 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. Audit team members were independent of the activities that they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team finding that YMPO implementation of the OCRWM QA program is generally adequate. Four preliminary Corrective Action Requests (CARs) were discussed by the YMQAD audit team at the post-audit meeting: three against YMPO and one against the Management and Operations contractor (M&O). Also, several other potential CARs were acceptably resolved by the YMPO organization during the audit. None of the preliminary CARs identified by the YMQAD audit team is significant in terms of the overall OCRWM QA program as implemented by YMPO and the M&O.

OCRWM should continue to closely monitor YMPO and M&O implementation of their QA programs to ensure that the deficiencies identified during this audit are corrected in a timely manner and that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess YMPO and M&O implementation of their QA programs.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John G. Spraul	Observer	Center for Nuclear Waste Regulatory Analyses
William L. Belke	Observer	
Bruce Mabrito	Observer	

4.2 DOE

Kenneth T. McFall	Audit Team Leader (ATL)	YMQAD - Science Applications International Corp. (SAIC)
A. Edward Cocoros		YMQAD - MAC Technical Services Company (MACTEC)
Robert E. Harpster	Auditor	YMQAD - SAIC
John S. Martin	Auditor	YMQAD - SAIC
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Donald G. Horton	Observer	OCRWM - OQA

4.3 Other

Engelbrecht von Tiesenhausen	Observer	Clark County, Nevada
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5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This YMQAD audit of YMPO was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 5 plus Interim Change Notice (ICN) 1) and QAAP 16.1, "Corrective Action" (Revision 4). The NRC observation audit of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Scope of Audit

The audit scope included eight of the applicable QA programmatic elements listed below:

- 1.0 Organization
- 2.0 QA Program
- 5.0 Plans, Procedures, Instructions, and Drawings
- 6.0 Document Control
- 8.0 Identification and Control of Materials, Parts, Components, and Samples
- 12.0 Control of Measuring and Test Equipment

13.0 Handling, Storage, and Shipping
17.0 Quality Assurance Records

The audit team developed and utilized checklists based on the requirements in the QA implementing procedures for these programmatic elements. Individual auditors were assigned to audit compliance with specific QAAPs, Administrative Procedures (APs), Quality Administrative Procedures (QAPs), Quality Management Procedures (QMPs), and Branch Technical Procedures (BTPs). Auditing of QA Programmatic Element 8 "Identification and Control of Materials, Parts, Components, and Samples," was conducted simultaneously with auditing of QA Programmatic Element 13, "Handling, Storage, and Shipping."

Before the audit, QA Programmatic Element 9, "Control of Processes," was determined by YMQAD to be not applicable at YMPO because YMPO has no current activities to which this element applies. During the audit, it was found that insufficient activity had occurred under QA Programmatic Element 12, "Control of Measuring and Test Equipment," to allow an assessment of its effectiveness.

5.2 Timing of the Audit

The NRC staff believes the timing of this audit was appropriate for YMQAD to audit the pertinent QA activities of YMPO and for the staff to evaluate the YMQAD audit process and YMPO's implementation of the NRC OCRWM QA program. Quality affecting activities are in progress. This audit was scheduled in conformance with YMQAD's practice of auditing YMPO approximately semi-annually with each applicable QA programmatic element audited at least annually.

5.3 Examination of QA Programmatic Elements

Before the audit, the audit team prepared checklists to use during the audit. The checklists were based on the requirements of the procedures listed in Table 1 at the end of this report. During the audit, the checklists were used by the auditors to guide their interviews with YMPO and YMPO contractor personnel. During the course of the audit, the ATL reassigned auditors as required to complete the audit on schedule.

The NRC staff observed the YMQAD audit team's evaluation of QA programmatic elements 1, 2, 8/13, and 17. The NRC staff observed all or a portion of the YMQAD audit covering the procedures listed in Table 1 that have an asterisk.

The NRC staff observed that each of the auditors reviewed related documentation and interviewed at least a representative sample of YMPO/YMPO contractor personnel to determine their understanding and degree of implementation of the procedures. The auditors observed were well prepared and knowledgeable of the QA program requirements. They used their checklists effectively and pursued issues beyond the checklists when appropriate. They solicited comments and questions from the NRC observers in an acceptable manner. The NRC staff observations regarding the audit and the implementation of each appropriate QA programmatic element are discussed below.

5.3.1 Organization (Programmatic Element 1)

The auditing of this programmatic element involved the functional responsibilities of the Office of Geologic Disposal and numerous interrelated activities. The auditor scheduled a conference with ten YMPO senior staff members and questioned each of them from the audit checklist derived primarily from QMP-01-01. A variety of subjects were covered including the organizational structure and interfaces; requirements and functional responsibilities related to accepted work; notification to the Training Manager when personnel are reassigned; the identification, reporting, and resolution of quality-related issues; processing of change requests; incorporation of regulatory requirements into project plans and activities; and systems used to meet cost and schedule mandates.

The audit process allowed for thorough responses to the questions, even though the questions were general in nature. No significant deficiencies were identified within this programmatic element. The auditor's familiarity with ongoing YMPO activities was particularly beneficial in having the appropriate managers available for questioning. The audit of this programmatic element of the YMPO QA program was effective, and the NRC staff agrees with the audit team finding that the program implementation is adequate.

5.3.2 QA Program (Programmatic Element 2)

For this portion of the audit, the technical assessment report, "Qualification of Technical Data, Extreme Erosion for Yucca Mountain," was reviewed for QA programmatic aspects. This report was the only technical assessment completed and available since QMP-02-08 was revised. QMP-02-08 defines the method and responsibilities to be used for performing technical assessment reviews for the Yucca Mountain Project. The auditor verified the required documentation designating the Technical Assessment (TA) Chairperson, qualifications of the respective TA team members, comments, and comment resolution.

In addition, the Readiness Review (RR) report for the Construction and Construction Support Activities for Exploratory Studies Facility Package 1A was reviewed for compliance to QAAP 2.6. The RR was conducted by the M&O to assess whether the involved participants were ready to start construction activities associated with the construction and construction support activities for exploratory studies facility package 1A. The involved participants included the M&O, Raytheon Services Nevada, Reynolds Electrical and Engineering Company, and the Technical & Management Support Services Contractor. The selection process and qualifications of the RR team members were verified. Also, the auditor verified that the RR Plan had been appropriately reviewed and approved and that the prerequisites to be verified during the RR were developed and implemented. Open items resulting from RR findings were reviewed for content and to assure they were being effectively tracked for closure.

The auditor found that there was no objective evidence indicating that the RR Team Leader had been trained as required by QAAP 2.6 and documented this finding on a CAR. The auditor also documented on the same CAR that, as required by QAAP 2.6, there was no objective evidence for (1) appointment of

the RR Chairman (2) forwarding the RR Plan to the responsible director for approval, (3) clarifying the status of an open item for test control, (4) approval of the RR Report by the responsible Director prior to distribution, and (5) closure of open items of which some work has proceeded beyond the designated hold point.

The NRC staff initiated an Observer Inquiry requesting clarification on the independence of involved personnel in the RR process. It appeared questionable how total independence could be achieved when personnel from the same organization (M&O) are performing the RR when the M&O is also involved as a RR participant. The response was that although the personnel were from the same organization (M&O), they were considered independent of the work being performed since they do not physically report to the M&O office in Las Vegas. The RR team members were selected primarily based on their knowledge and expertise commensurate with the RR criteria. Based on this rationale and the contents and nature of the findings in the RR report, the NRC finds no evidence that would compromise the independence of the RR process.

The process for criteria and selection of items considered for placement of items on the Q-List was reviewed to verify compliance with the recently revised AP-6.17Q. The auditor found that many of the activities required to be implemented in accordance with AP-6.17Q had not been performed and, therefore, this portion of Programmatic Element 2 was considered to be indeterminate.

The audit of this programmatic element was effective. The NRC staff agrees with the auditor's preliminary assessment that with the exception of the items noted above, implementation of Programmatic Element 2 was adequate.

5.3.3 Identification and Control of Materials, Parts, Components, and Samples (Programmatic Element 8)

This element was combined with Element 13 for the purpose of this audit. The NRC observation results are discussed in Section 5.3.4 below.

5.3.4 Handling, Storage, and Shipping (Programmatic Element 13)

The auditor combined Programmatic Elements 8 and 13 in the audit checklist and spent three days at the SMF working through the 44 checklist items. The auditor met initially with the SMF Manager, the SMF Curator, and the Drilling Support Shift Supervisor and outlined his audit approach. He then went to a storage area and checked eight random soil sample containers per AP-6.26Q. He requested, received, and reviewed the Sample Collection Report for each sample. No deficiencies were noted.

To verify that samples/specimens were stored in accordance with Sample Overview Committee instructions, the auditor reviewed videotape of borehole core USW North Ramp Geologic 6, run numbers 79 through 85. The auditor recommended that the phrase "high resolution" be changed in the BTP-SMF-008 requirements for a camera since no clear definition of the term was readily

available. The YMPO Drilling Support staff indicated they would address the issue. No problems were encountered in the review and no discrepancies were cited.

To verify that ream cuttings were collected according to instructions provided by the Principal Investigator or the Sample Overview Committee, random cutting samples stored at the SMF were checked. The labelling and supporting documentation met all requirements. During the audit, it was determined that some "non-Q samples" had been misidentified, and the SMF staff corrected the error. The auditor increased his sample size to ensure that other samples were labelled correctly and the Sample Overview Committee instructions had been followed. No additional deficiency was identified in the labelling or in the supporting documentation.

BTP-SMF-002 requires that, prior to shipping borehole sample containers to the SMF, drilling support personnel prepare a Field Container Summary and Transmittal document that specifies borehole identification, number of containers in the shipment, and date of the shipment. Additionally, containers shipped must be identified by number, the sample type must be specified, the sequential container numbers must be present, and the depth interval must be listed. These requirements were verified by the auditor as he checked the Field Container and Transmittal forms from borehole I.D. 248 UE25 NRG-3, randomly sampling half of the documentation presented. No discrepancies were noted.

The process of removing specimens from samples for shipment and remnant return per BTP-SMF-006 was viewed by the auditor. Six random Specimen Removal Log items were checked to ensure the requestor's name and organization were present along with the borehole identification for each specimen, requested depth interval of each specimen, the interval reserved after Sample Overview Committee approval, actual depth interval of specimen, type of specimen removed, specimen identification, and other required information. All log entries were verified as being present and correct. In the Specimen Processing Room of the SMF, the auditor observed rock core cutting in accordance with the Principal Investigator's request and BTP-SMF-006. This included additional labelling of specimens, replacing orientation marks on cut pieces, generating labels for storage boxes, rebagging, marking, photographing, and returning the remaining sections back into the SMF Research Sample Container. The auditor did not identify any discrepancies in this portion of the audit.

The auditor identified several instances where the implementing procedures did not comply with AP-1.17Q which requires that forms be controlled relative to their use, development, and change. In contrast to the requirement, electronically generated forms were utilized at the SMF which were not controlled exactly as specified in AP-1.17Q in the implementation of BTP-SMF-002 and BTP-SMF-005. A preliminary CAR was issued to address the deficiency.

The audit of these programmatic elements was effective. The NRC staff agrees with the audit team that YMPO implementation of this programmatic element is adequate.

5.3.5 Quality Assurance Records (Programmatic Element 17)

Implementation of AP-1.18Q was primarily evaluated by interviewing the staff operating or otherwise involved with the Local Records Center (LRC) and examining a pre-selected sample of records. Based on these interviews with the YMPO and YMPO contractor staff, it is evident that the personnel understood and were operating in accordance with the procedure. The LRC maintains microfilm copies of the YMPO QA records, while "hard copies" and "one-of-a-kind" records are sent to a separate record storage facility. While auditing to AP-1.18Q, the auditor found that the M&O, responsible for the separate record storage facility, could not provide objective evidence that the storage facility had been evaluated by the M&O from a QA perspective. A preliminary CAR was written to correct this situation.

It had been reported that several job packages had been completed and forwarded to the LRC from the site. Investigation by the auditor into the implementation of AP-6.22Q showed that this was not the case. The Job Package Coordinators prepare a job package prior to starting the job at the site. When this job package is reviewed and approved, it is sent to the site with an authorization for the work to proceed. A copy is sent to the LRC. Several such job packages were requested by, delivered to, reviewed by, and found acceptable by the auditor. However, no work had been completed at the site such that the final job package could be completed and forwarded to the LRC.

Overall, the audit of Programmatic Element 17 was thorough and effective. The NRC staff agrees with the audit team's preliminary finding that implementation of Programmatic Element 17 was adequate.

5.3.6 Conclusions

The audit of the YMPO QA program evaluated the adequacy of implementing procedures and the effectiveness of implementation of the QA program. The auditors used appropriate checklists, interviewed YMPO and YMPO contractor personnel, and reviewed YMPO documentation. The audit was effective, and the NRC staff agrees with the audit team that the YMPO is adequately implementing its QA program in the areas audited.

5.4 Conduct Of Audit

The audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the YMPO QA program. In general the audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between YMPO management and the ATL (with an NRC observer present) to discuss the preliminary findings.

5.5 Qualification Of Auditors

The qualifications of the YMQAD ATL and auditors were reviewed by the NRC observers during the course of the audit and found to be acceptable. That is,

each auditor and the ATL meet the requirements of YMPO QMP-02-02, "Qualification of Quality Assurance Program Audit Personnel."

5.6 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and were knowledgeable of the applicable procedures. The audit plan for this audit included the audit scope, the audit schedule, a list of audit team personnel, a list of the activities to be audited, and audit checklist references.

5.7 Audit Team Independence

The audit team members did not have prior responsibility for performing the activities they audited. Members of the team had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence.

5.8 Summary of NRC Staff Findings

5.8.1 Observations

The NRC staff did not identify any observations relating to deficiencies in either the audit process or the OCRWM QA program as implemented by YMPO.

5.8.2 Good Practice

YMPO senior management demonstrated its interest in YMPO's implementation of its QA program by the YMPO Associate Director's presentation at the entrance meeting and by the attendance of the YMPO and other involved management at the daily audit status meetings. This was reflected in YMPO's acceptance of CARs and follow-up recommendations where improvements can be made to the YMPO quality system.

5.9 Summary of YMQAD Audit Findings

Within the scope of this audit, the audit team concluded that the YMPO QA procedures are adequate and that YMPO's QA program implementation in the areas audited is adequate except where corrective action is required as discussed in Section 5.3. The audit team provided four recommendations to improve the YMPO QA program, and four preliminary CARs resulted from the audit: three were against YMPO's implementation of its QA program and one was against the M&O. Several other preliminary CARs were acceptably resolved by the YMPO organization during the audit.

The four preliminary CARs which were not closed during the audit are discussed where indicated below:

<u>RESPONSIBLE ORGANIZATION</u>	<u>APPLICABLE PROCEDURE</u>	<u>PROGRAMMATIC ELEMENT</u>	<u>DISCUSSED IN SECTION</u>
YMPO	QAAP 1.6	2	5.3.2
YMPO	QAP-5.1	5	*
YMPO	AP-1.17Q	8/13	5.3.4
M&O	QAP-7.1	7	5.3.5

* This CAR is not discussed in the text. It involves an "at risk" ICN that remained in effect longer than allowed by the procedure.

Table 1 - Procedures used for Audit YMP-93-09

TITLE	NUMBER	REVISION
Readiness Review*	QAAP 2.6	2
Issuance and Maintenance of Controlled Documents	AP-1.5Q	0 w/ICN 1
Forms Control*	AP-1.17Q	1 w/ICN 1
Records Management: Las Vegas Record Source Responsibilities*	AP-1.18Q	1 w/ICN 1
Project Office Document Development, Review, Approval, and Revision	AP-6.1Q	4
Procedure for Requesting Samples for Examination at Yucca Mountain Site Characterization Project Sample Management Facility*	AP-6.3Q	1
Procedure for the Submittal, Review, and Approval of Requests for YMP Geologic Specimens*	AP-6.4Q	2 w/ICN 1
Classification of Items Important to Safety and Waste Isolation*	AP-6.17Q	1
Job Package Completion and Records*	AP-6.22Q	0
Submission and Documentation of Non-Borehole Samples to the Sample Management Facility	AP-6.26Q	1 w/ICN 1
Transport, Receipt, Admittance, and Processing of Borehole Samples for the Sample Management Facility*	BTP-SMF-002	3 w/ICN 1
Examination of Samples by Participants at the Sample Management Facility*	BTP-SMF-005	2
Removal of Specimens from Samples by the SMF for Shipment and Remnant Return*	BTP-SMF-006	3
Field Logging, Handling, and Documenting Borehole Samples*	BTP-SMF-008	3 w/ICNs 1-3
Staging, Packaging, and Documenting Neutron-Access Borehole Samples*	BTP-SMF-013	1
Quality Assurance Program Procedures	QAP 5-1	4
Document Review	QAP 6-2	0
Organization	QMP-01-01	0 w/ICNs 1-3
Organization	QMP-01-01	3
Project Office Indoctrination and Training	QMP-02-01	6
Technical Assessment*	QMP-02-08	1
Development and Conduct of Training	QMP-02-09	1
Project Office Document Development, Review, and Revision Process	QMP-06-04	5

* Procedures observed/partially observed by NRC during audit.