

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 93-07
FOR THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION
AUDIT NO. YMP-93-07 OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
SYSTEM MANAGEMENT AND OPERATING CONTRACTOR LAS VEGAS, NEVADA


03/31/93
William L. BeTke
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management


03/31/93
John T. Buckley
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management


03/31/93
Robert D. Brient (per telephone)
Center for Nuclear Waste
Regulatory Analyses

Reviewed and Approved by: 
03/31/93
Kenneth R. Hooks
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management

1.0 INTRODUCTION

From March 1-8, 1993, quality assurance (QA) staff of the U.S. Nuclear Regulatory Commission Division of High-Level Waste Management participated as observers on the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain QA Division (YMQAD) QA Audit No. YMP-93-07 of the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O) in Las Vegas, Nevada, and at the Nevada Test Site (NTS). The audit evaluated the adequacy and effectiveness of the M&O Las Vegas, Nevada QA program. The audit scope evaluated seven QA programmatic elements to determine whether the M&O QA program meets the requirements and commitments imposed by the OCRWM. No technical areas were evaluated by the audit team.

This report addresses the effectiveness of the YMQAD audit and the adequacy and effectiveness of implementation of QA controls of the M&O QA program.

2.0 OBJECTIVES

The objective of this YMQAD audit was to evaluate the implementation and effectiveness of the M&O QA program in meeting the applicable requirements of the OCRWM document, DOE/RW-0214, "Quality Assurance Requirements Document" (QARD), Revision 4. The NRC staff's objective was to gain confidence that YMQAD and the M&O are properly implementing the requirements of their QA programs in accordance with Title 10 Code of Federal Regulations (10 CFR) Part 60, Subpart G (which references 10 CFR Part 50, Appendix B) and the QARD.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the M&O QA program on direct observations of the auditors; discussions with the audit team and M&O personnel; and reviews of pertinent audit information (e.g., audit plan, audit checklists, and M&O documents). The audit was well organized and conducted in a professional manner. 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 has determined that audit YMP-93-07 was useful and effective. The NRC staff agrees with the YMQAD audit team's preliminary findings that the M&O QA program generally has adequate procedural controls in place and that the overall implementation of the M&O QA program is marginally effective. The M&O QA Program was adequate in four of the seven areas audited; two areas were unsatisfactory; and the remaining area marginally effective.

Three preliminary Corrective Action Requests (CARs) were issued by the YMQAD audit team; one in the area of procedure preparation, one in the area of inadequate procedures, and one in the area of nonconformance control. Two other conditions adverse to quality, pertaining to personnel qualifications and inadequate procedures, were noted. Due to their similarity in nature to

findings previously identified during the M&O Headquarters audit conducted February 1-5, 1993, in Vienna, Virginia, these deficiencies were added to the CARs developed during that audit. Another deficiency pertaining to the generation, processing, and distribution of Field Change Requests to drawings and specifications was noted during this audit. However, since the finding was within the Yucca Mountain Site Characterization Project Office's (YMPO) area of responsibility, the CAR was issued to YMPO.

The deficiencies identified in the CARs are not significant in terms of the overall M&O QA program and should not affect the quality of any M&O quality affecting activities if corrected in a timely manner.

4.0 AUDIT PARTICIPANTS

4.1 NRC

William L. Belke	Observation Team Leader	
John T. Buckley	Observer	
Robert D. Brient	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE

Richard E. Powe	Audit Team Leader (ATL)	Science Applications International Corp. (SAIC)
Amy Arceo	Auditor	SAIC
James Blaylock	Auditor	DOE/YMQAD
Gerald Heaney	Auditor	SAIC
Sam H. Horton	Auditor	SAIC
Fred Bearham	Observer	CER Corp. (OCRWM Headquarters)
Donald G. Horton	Observer	OCRWM Headquarters

4.3 State of Nevada

Susan Zimmerman	Observer
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4.4 Clark County, Nevada

Englebrecht von Tiesenhausen	Observer
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5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The M&O audit was conducted in accordance with OCRWM QA Administrative Procedure (QAAP) 18.2, "Audit Program," Revision 5, and OCRWM QAAP 16.1, "Corrective Action," Revision 4.

The NRC staff observation audit of the M&O audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Purpose/Scope of Audit

The purpose of the audit was to evaluate and determine whether the M&O QA program meets the requirements and commitments imposed by the OCRWM QARD, by verifying compliance with requirements and the extent and effectiveness of the implementation of the program relative to the programmatic elements listed below. The auditors used checklists based on the requirements in the M&O QA Program Description (QAPD), Sections 1, 2, 5, 6, 15, 16, and 17 (10 CFR Part 50 Appendix B Criteria I, II, V, VI, XV, XVI, and XVII) and other applicable documents pertaining to the following QA controls:

- 1 - Organization
- 2 - QA Program
- 5 - Plans, Procedures, and Drawings
- 6 - Document Control
- 15 - Control of Nonconforming Items
- 16 - Corrective Action
- 17 - Quality Assurance Records

The NRC staff observed the YMQAD audit team's evaluation of selected programmatic elements of the M&O QAPD. Only portions of some elements were observed. Therefore, some deficiencies identified by the audit team were not observed by the NRC staff. Such deficiencies will not be discussed in detail in this report.

5.2 Timing of the Audit

The NRC staff believes the timing of the M&O QA audit was appropriate since OCRWM conditionally approved the M&O QA program in July 1992 and fully approved it in September 1992. There was limited quality-affecting work being performed by the M&O but there were sufficient programmatic activities to support a programmatic/compliance type audit.

5.3 Examination of Programmatic Elements

The audit checklists were developed and based on the QA program requirements of the M&O Quality Administrative Procedures (QAPs) and Implementing Line Procedures (ILPs) listed below. During the audit, the auditors verified the adequacy of these implementing procedures and evaluated whether they accurately reflected the flowdown requirements from the M&O QAPD.

- QAP-1-1 Escalation of Quality Disputes
- ILP-QLP-2-1 Certification of Quality Control Inspectors
- QAP-2-1 Indoctrination and Training
- QAP-2-2 Verification of Personnel Qualifications
- QAP-2-3 Classification of Items and Determination of Quality Affecting Activities
- QAP-2-4 Quality Assurance Program Status and Trend Reporting
- QAP-2-5 QA Surveillance
- QAP-2-6 Readiness Review
- QAP-2-9 Development and Conduct of Training
- QAP-3-10 Engineering Drawings
- QAP-3-11 Design Specifications

QAP-5-1 Preparation of M&O Quality Administrative and Implementing Line Procedures
 QAP-6-1 Document Control
 ILP-NSP-6-1 Yucca Mountain Site Office Document and Records Center: Document Control Operations
 ILP-NSP-6-2 Nevada Document Review Tracking
 QAP-16-1 Corrective Action Report
 QAP-16-2 Stop Work
 ILP-NSP-17-1 Yucca Mountain Site Office: Document and Records Center: Record Services Operations
 QAP-17-1 Program Records Management: Record Source Responsibilities
 QAP-17-2 Program Records Management: Receipt and Handling of Program Records Packages
 QAP-17-4 Program Records Management: Microfilming Program Records
 QAP-17-5 Program Records Management: Indexing Program Records
 QAP-17-6 Program Records Management: Storage Retrieval and Disposition
 QAP-18-1 Certification of Audit Personnel
 QAP-18-2 Audits

5.3.1 Quality Assurance Program (Programmatic Element 2)

The auditor interviewed a representative sample of the M&O managers and supervisors and related documentation to verify whether personnel had received the required training, and whether any of the required training had been waived as permitted in QAP-2-1. Several of the M&O managers indicated they were not aware that this option existed but had no reason to invoke it. There were no instances where any of the required training had been waived. The auditor indicated that although training waivers were not a requirement of the QARD, a recommendation would be made to the M&O, to delete this option from QAP-2-1 in order to prevent any misuse or misunderstandings in the future.

M&O Training Department personnel were interviewed to determine how minimum education and experience requirements are established for Position Descriptions, including the quality-affecting responsibilities. Interviews with other M&O personnel were conducted to determine how training and retraining needs are established, conducted, and documented. Training documentation and certification records were reviewed to verify individuals had received the necessary training to perform the quality-affecting responsibilities delineated in the Position Descriptions. Resumes and related documentation were reviewed to determine how education and experience are verified.

ILP-NSP-6-2 requires the establishment of a Training Coordination Sheet (TCS) which lists the QAP or ILP the individual is required to be trained in, the effective date of the procedure, whether formal classroom training is required, and whether the TCS has been sent to the Training Manager for tracking. The auditor could not find any evidence of the TCS. Due to the similarity of this audit finding with other findings on this audit, the findings were combined into a single CAR stating that the M&O had not accomplished quality-affecting activities in accordance with its established procedural requirements.

The NRC staff noted during this audit, that there had been several examples where procedures are knowingly not being followed without documenting the authority or justification to do so. During the interview process with the Training Manager, it was stated that during the indoctrination and training of new employees, the Lesson Plan emphasizes that when a procedure cannot be followed, the individual should immediately notify their management for further guidance on how to proceed. The NRC staff expressed similar concerns in NRC Observation Audit Report No. 92-01 for OCRWM Headquarters QA Internal Audit No. HQ-92-001 in Washington, D.C., and Las Vegas, Nevada, and NRC Observation Audit Report No. 91-13 for OCRWM Audit No. 91-003 of the DOE Office of Environmental Restoration and Waste Management Waste Vitrification Branch in Germantown, Maryland. The NRC staff finds this to be a recurring condition and recommends DOE initiate corrective action to emphasize the importance of following procedures, and taking the necessary steps when a procedure cannot be followed. This concern is identified as an "Weakness" in Section 5.9.2 of this report and a written response is requested.

A presentation was given by the M&O to the auditors and observers on the quality classification process which clarified a number of questions in this area. QAP-2-3 covers classification but cannot be used (by direction of OCRWM) except for Monitored Retrievable Storage activities. For Yucca Mountain Site Characterization Project mined geologic disposal system activities, the M&O only uses QAP-2-3 for guidance. OCRWM Administrative Procedure, AP 6.17Q however, has been applied to performing "Determinations of Importance to Quality." The results of these determinations are provided to the OCRWM Assessment Team, which will make the actual classification of items for inclusion on the list of quality-affecting items. M&O staff indicated that design activities may be initiated on a not-yet classified item, but the work is at risk if the Assessment Team classification differs from that expected by the design group. The controls for classification and implementation at the M&O appeared effective.

Readiness Reviews were covered in the audit checklist, however, records of these activities were maintained in the M&O Vienna, Virginia, offices and not available to audit. The audit team and observers were uncertain of the effectiveness of the Readiness Reviews considering the extent of the audit team's findings of inadequate procedures. Although not discussed during this audit, it should be noted that as a result of the April 8-10, 1992, Internal Readiness Review of the M&O, a recommendation was made by the M&O Readiness Review Board on April 22, 1992, that the 30 M&O ILPs procedures should be re-reviewed for adequacy, consistency, and completeness due to the number of Readiness Review Team findings associated with the procedures. However, the scope of the Readiness Reviews seemed to be limited to determining the existence of the procedures and not their adequacy.

The audit of this programmatic element was effective. The NRC staff agrees with the auditors preliminary assessment that M&O implementation of Programmatic Element 2 is marginally effective.

5.3.2 Plans, Procedures, and Drawings (Programmatic Element 5.0)

The audit of this programmatic element entailed an examination of QAP-5-1. Record packages for QAP's 2-3, 16-1, and 17-1 were evaluated to determine

whether they were prepared in accordance with QAP-5-1. Based on the information reviewed, and discussions with the M&O staff, deficiencies were identified with both the adequacy and implementation of QAP-5-1.

QAP-5-1 was found to be inadequate in terms of providing qualitative and quantitative acceptance criteria for determining the acceptance of prescribed activities as required by Section 5.0 of the M&O QAPD. The auditors also identified seven adverse conditions with regard to the implementation of QAP 5-1. The following adverse conditions were identified on one CAR: (1) No objective evidence that QAP's are revised when upper tier documents are revised; (2) Inadequate review instruction and criteria; (3) Change bars are missing; (4) An expedited Procedure Change Notice (PCN) was written to replace an expired expedited PCN; (5) Nothing to indicate if a revision review constitutes the complete procedure review required every two years; (6) Responsibilities identified in the "Responsibilities" section are not addressed in the "Procedure" sections of various QAP's; and, (7) No procedure to control the preparation and maintenance of the M&O QAPD.

In consideration of the number of procedural findings by the audit team, there may not be as close an interface between the implementing procedure authors and the procedure users as desirable to assure total continuity. This may be attributed to the M&O Headquarters office in Vienna, Virginia writing and issuing the procedures to the M&O Las Vegas, Nevada, office without first verifying the adequacy of the procedures.

The audit of this programmatic element was thorough and effective. The auditors were well prepared and knowledgeable in the requirements of the M&O program in this area. The NRC agrees with the audit team's preliminary assessment that implementation of Programmatic Element 5 is unsatisfactory.

5.3.3 Document Control (Programmatic Element 6)

Document control activities conducted at the Document and Records Center (DRC) located on the NTS were observed. The DRC controls distribution of YMPO procedures and drawings at the NTS, using M&O NSP-6-1 and NSP-6-2. The audit of this programmatic element was effective and the implementation appeared adequate.

5.3.4 Control of Nonconforming Items (Programmatic Element 15)

The M&O QAPD indicates that nonconformance control was not an activity in which the M&O would be involved. However, the auditor had identified one nonconformance report initiated against the M&O, and two more in progress. Therefore, the checklist was expanded to cover this programmatic element. The M&O QA Manager indicated that the applicable OCRWM QA procedure would be used, but the OCRWM procedure does not address disposition on nonconformances. A CAR was issued to address the lack of an M&O nonconformance procedure, and, as a result, this programmatic element was considered to be unsatisfactory.

The auditor's familiarity in ongoing Yucca Mountain Site Characterization Project activities was particularly beneficial in recognizing this program deficiency. The audit of this programmatic element was effective and the implementation was unsatisfactory.

5.3.5 Corrective Action (Programmatic Element 16)

QAP-16-1 and the applicable portions of the M&O QAPD were used as a basis for the checklist and the audit of this programmatic element, as well as for determining the adequacy of QAP-16-1. Seven CARs initiated in Las Vegas in 1993, were reviewed. The Corrective Action program has had limited action since 1992, when the M&O was authorized to commence quality-affecting activities. The audit of this programmatic element was effective and the implementation appeared adequate.

5.3.6 Quality Assurance Records (Programmatic Element 17)

The audit of this element was conducted by evaluating QAP's 17-1, 17-2, 17-4, 17-5, and 17-6. Implementation of QAP 17-1 was evaluated by interviewing the staff of the Central Records Facility (CRF) and examining a sample of closed record packages. Based on interviews with the CRF staff, it is evident that there was some confusion within the M&O technical staff with regard to the difference between "records" and "records packages." This confusion has led to improperly prepared record transmittals and untimely submittal of documents to the CRF. For instance, the auditors discovered that one completed record package contained three different audit reports. The intent of the procedure is that each record package should contain documents on only one activity. In another instance, Surveillance Report 93-SRS-01 was located in two different packages.

In addition to the aforementioned procedural implementation problems, the auditors determined that NSP-17-1 did not adequately address acceptance criteria for determining what constitutes prevention of loss or damage to records from moisture, temperature, pressure, excessive light, and electromagnetic fields.

The requirements of QAP-17-2 were evaluated by examining the records storage facilities, and QA record packages submitted to the CRF. The auditors did not identify any major deficiencies with this portion of the audit.

A portion of the audit of records controls at the DRC and at the Local Records Center (LRC) in Las Vegas was observed. The DRC accumulates documents that may become records and provides a (two-hour fire-rated) temporary storage facility for this purpose. Generally, records receive a brief check at the DRC, and are immediately forwarded to the LRC in Las Vegas for complete checking and processing. ILP-NSP-17-1 was effectively used for this activity, although a number of its requirements had not yet been applied.

The LRC on the fifth floor in the Las Vegas, Nevada, Bank of America Building has been classified by the M&O as a one-hour fire-rated facility for temporary records storage. However, the room houses much electronic equipment and some appliances that remain on power day and night. When the room is locked and the lights are turned off at night, no other controls to limit potential fire sources were apparent. The intent of ANSI/ASME NQA-1, Supplement 17-1, paragraph 4.4.3, does not seem to be met by the LRC as operated during this

audit. The audit team made a recommendation for the M&O to assess the potential for a fire starting within the room and to decide what controls if any, are needed for limiting the potential for a fire. The audit report will request a response to this recommendation. The NRC staff also intends to follow-up on the M&O response to the audit team's recommendation.

Overall, the audit of Programmatic Element 17 was thorough and effective. The NRC observers agree with the auditor's preliminary conclusion that implementation of Programmatic Element 17 was marginally effective for the areas observed.

5.4 Conduct of Audit

The audit was conducted in a thorough and professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA aspects of the M&O QA program, being objective and perceptive in its conduct of the audit. Daily caucuses were held between the auditors and observers, and daily audit status meetings were held between M&O management and the ATL to discuss the potential findings and comments. All potential findings were immediately presented to affected personnel, giving them the opportunity to provide additional information or explanation when necessary. The audit checklists included the important controls addressed in the M&O QAPD and implementing procedures. The audit team used the checklists effectively during the interviews with personnel and review of documents. The observers were kept especially well informed during the audit.

There appears to be a certain degree of inconsistency and lack of clear guidance in the criteria used to determine when an individual deficiency is documented as a CAR condition, as opposed to being combined with several deficiencies which appear similar in nature. For example, during this audit, several deficiencies were combined into a single CAR written against Programmatic Element 5 (Plans, Procedures, and Drawings). In another instance, several deficiencies of a similar nature discovered during this audit were added to a CAR documented during the audit of the M&O Headquarters office in Vienna, Virginia. While the NRC staff agrees with combining similar deficiencies, it was noted that many of the deficiencies discovered will probably require separate corrective actions, root cause analyses, remedial actions, and corrective actions to prevent recurrence. This may cause unavoidable delays in closing the CARs in addition to accurately tracking and verifying the required information for closeout. This concern is identified as a weakness in Section 5.9.2 of this report and a response is requested.

5.5 Qualification of Auditors

The qualifications of the YMQAD audit team members are acceptable based on their certification in accordance with OCRWM QAAP 18.1, Revision 3, "Qualification of Audit Personnel."

5.6 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and knowledgeable in the M&O QAPD and implementing procedures. The Audit Plan/Book for YMP-93-07 included the audit team assignments and responsibilities, Audit Notification Letter, QA programmatic checklists, Audit Observer Inquiry forms, M&O organization charts, and the Yucca Mountain Project Directory of the M&O employees, phone number, organization and reporting relationship.

5.7 Audit Team Independence

With the exception of one audit team member, the audit team members did not have prior responsibility for performing the activities they investigated, and had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence from M&O personnel. One audit team member serves as the YMQAD QA Liaison between DOE and the M&O but this function did not detract in any manner from independently accomplishing the audit in an effective manner.

5.8 Review of Previous Audit Findings

5.8.1 Since this was the first audit of the M&O by the YMQAD, there were no open CARs from previous audit findings relating to this audit.

5.8.2 The NRC staff did not have any observations from previous audits relating to this audit that required resolution.

5.9 Summary of NRC Staff Findings

5.9.1 Observations

The NRC staff did not identify any observations relating to deficiencies in either the YMQAD audit process or the M&O Las Vegas, Nevada office QA program implementation.

5.9.2 Weaknesses

- The NRC staff is concerned about personnel knowingly not following implementing procedures without documenting the authority or justification to do so. This is a recurring problem as noted by the NRC staff in other NRC staff Audit Observation Reports. The NRC staff recommends DOE management initiate provisions which emphasize the importance of following procedures and the need to document corrective action measures when procedures cannot be followed. The NRC staff will carry this as an open item on the NRC/DOE Open Items List until satisfactory resolution is achieved. (see Section 5.3.1 for details)
- The NRC staff has a concern regarding the number of deficiencies combined into a single CAR, and how the corrective actions would be accurately tracked. The NRC staff will carry this as an open item on the NRC/DOE Open Items List until satisfactory resolution is achieved. (see Section 5.4 for details)

- The effectiveness of the Readiness Review process is questionable in view of the number of audit team findings. (see Section 5.3.1 for details)

5.9.3 Good Practices

- The DOE OCRWM Headquarters QA Manager was in attendance to observe this audit. When the auditor revealed potential problems associated with the Field Change Control process of design specifications, the QA Manager recognized the importance of this process, and indicated that a surveillance would be conducted shortly to identify any other potential problem areas.

- Also attending this audit was a representative from the OCRWM Headquarters Project Office for the purposes of observing how YMQAD conducts its audits. The NRC staff believes this is a worthwhile effort and that on future audits, DOE continues to encourage involved audit participants to attend both the OCRWM and YMPO audits to enhance consistency in the auditing process.

5.10 Summary YMQAD Audit Team Findings

The audit team identified three preliminary CARs written against the M&O QA program:

- Several examples of where M&O procedures were not being prepared in accordance with the requirements of the implementing quality assurance procedure (see Sections 5.3.1).
- Several examples where procedures did not address the methodology to fully accomplish the quality affecting activity (see Section 5.3.1).
- No procedure for dispositioning Nonconformance Reports (see Section 5.3.4)

Two preliminary CARs were identified and added to the preliminary CARs developed during the M&O Headquarters audit in Vienna, Virginia:

- Implementing procedures did not reflect all of the M&O QAPD requirements.
- Training records did not contain adequate verification of education.

One preliminary CAR was identified during this audit but was considered to be within the YMPO responsibility:

- Field Change Requests are not being processed in accordance with Administrative Procedure AP-3.5Q, "Field Change Control Process."