

Department of Energy

Office of Civilian Radioactive Waste Management Yucca Mountain Site Characterization Office P.O. Box 98608 Las Vegas, NV 89193-8608

WBS 9.1.2 OA

JUN 0 2 1994

L. Dale Foust Technical Project Officer for Yucca Mountain Site Characterization Project TRW Environmental Safety Systems, Inc. Bank of America Center, Suite P-110 101 Convention Center Drive Las Vegas, NV 89109

ISSUANCE OF SURVEILLANCE RECORD YMP-SR-94-045 RESULTING FROM YUCCA MOUNTAIN OUALITY ASSURANCE DIVISION (YMOAD) SURVEILLANCE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR (CRWMS M&O) AUDIT 94-MRA-01 (SCP:

Enclosed is the record of Surveillance YMP-SR-94-045 conducted by the YMQAD at the CRWMS M&O facilities in Charlotte, North Carolina, April 25-29, 1994.

The purpose of the surveillance was to verify that CRWMS M&O performed Audit 94-MRA-01 in accordance with CRWMS M&O Quality Assurance Procedure 18.2, Revision 2, "Audits," and to verify that the adequacy and implementation of the audit process meets the requirements of the Quality Assurance Requirements and Description Document, DOE/RW-0333P, Revision 0.

The Office of Civilian Radioactive Waste Management Office of Quality Assurance was very pleased with the planning, performance, and outcome of the audit. This audit demonstrated vast improvement in the CRWMS M&O audit process.

No Corrective Action Requests were issued as a result of this surveillance.

This surveillance is considered completed and closed as of the date of this letter. A response to this surveillance record and any documented recommendations is not required.

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If you have any questions, please contact either Robert B. Constable at 794-7945 or Daniel A. Klimas at 794-7696.

Richard E. Spence, Director Yucca Mountain Quality Assurance Division

YMQAD:RBC-3722

Enclosure:

Surveillance Record YMP-SR-94-045

cc w/encl:

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Surveillance No.	YMP-SR	-94-045

OFFICE OF RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

QUALITY ASSURANCE SURVEILLANCE RECORD					
SURVEILLANCE DATA					
¹ ORGANIZATION/LOCATION: TRW/Management and Operating (M&O) Contractor, Charlotte, NC	² SUBJECT: M&O Audit Process		³ DATE: 4/25-29/94		
⁴ SURVEILLANCE OBJECTIVE: Verify M&O performance of internal audit in accordance with applicable requirements.					
⁵ SURVEILLANCE SCOPE: To assess the adequacy and impl	ementation of the Ma	&O Audit Process.	SURVEILLANCE TO Team Leader: Dan Klimas Additional Team Mer Dennis Threatt		
PREPARED BY: Surveillance Team Leader	<u>4/13/94</u> Date	CONCURRENCE: A Division D		4/13/94 ate	
	SURVEILI	LANCE RESULTS			
⁹ BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS:					
See pages 2, 3 and 4.					
10SURVEILLANCE CONCLUSION	IS:				
See page 5.					
Surveillance Team Leader	1) 5/27/94 Date	12APPROVED BY: Only District D	o r	6.1.9 <u>4</u> ate	

Exhibit QAP-2.8.1

REV. 11/24/93

(Block 9 Continued) BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS:

The purpose of this surveillance was to observe the Civilian Radioactive Waste Management System (CRWMS) Management and Operating (M&O) Contractor's Audit number 94-MRA-01 conducted in Charlotte, North Carolina from April 25 through 29, 1994 in order to evaluate the adequacy and effectiveness of the M&O audit process. The observation of this audit consisted of observing the audit team and audited organization during the audit process, reviewing the audit team's qualifications, implementation of the audit plan, checklists and related procedures, attending all audit team meetings, and management briefings.

The purpose of the audit was to evaluate the adequacy and effectiveness of implementation of selected elements of the M&O Quality Assurance (QA) Program at the offices in Charlotte, North Carolina. The following elements were included in the scope of this audit: Organization; QA Program; Design Control; Implementing Documents; Document Control; Corrective Action and QA Records.

The following personnel participated in the audit:

- G. L. Keener, Audit Team Leader, M&O
- R. B. Berlien, Auditor, M&O
- H. C. Dameron, Auditor, M&O
- P. G. Delozier, Technical Specialist, M&O
- B. M. Franks, Observer, M&O
- D. A. Klimas, Observer, Yucca Mountain Quality Assurance Division (YMQAD)/Quality Assurance Technical Support Services (QATSS)
- D. C. Threatt, Observer, Headquarter Quality Assurance Division/QATSS
- R. E. Powe, Observer, YMOAD/OATSS

The following observations are provided relative to the effectiveness of the audit process:

The audit was performed utilizing the audit plan developed in accordance with M&O Quality Administrative Procedure (QAP)-18-2 and approved by the M&O QA Audits Manager. The audit team was designated by the QA Audits Manager as required and team members were determined to be independent of activities being audited. One Technical Specialist was used during the audit and was indoctrinated and trained in the audit process as required.

The Office of Civilian Radioactive Waste Management (OCRWM) surveillance team considers that the audit was effective in determining the adequacy and effectiveness of implementation of the M&O QA Program in the Charlotte, NC offices for the Monitored Retrievable Storage (MRS) and Multi-Purpose Canister (MPC) design process.

The M&O Audit Team Leader was well prepared and conducted the audit in a professional manner assuring that all aspects of the audit plan purpose and scope were thoroughly evaluated. In addition, the Audit Team Leader effectively addressed recommendations from OCRWM OQA for improving the M&O audit process. The Audit Team members were observed utilizing prepared checklists and properly documenting evaluations and objective evidence. The Technical Specialist performed an in-depth review of technical requirements flow down from the System Requirements Documents to the Design Procurement Specifications for the MPC and Transportation Cask and assured that the technical documents were developed in accordance with the Technical Document Preparation Plan.

The OCRWM surveillance team reviewed the qualification and training records of the audit team members to determine that the auditors and technical specialist had been properly trained and qualified prior to beginning the audit process. An audit team member's qualification records were not in compliance with the M&O procedure QAP-18-1, "Certification of Audit Personnel." Evidence to support qualification as an auditor was not properly documented on the required auditor qualification form. This condition was corrected during the audit by Revision 2 to QAP-18-1 allowing acceptance requirements for auditor training qualification from outside sources that are equivalent to the qualification requirements of OCRWM and to eliminate the requirement to participate as an auditor-in-training on two M&O audits prior to qualification as an auditor.

As a result of the audit, the audit team identified nine deficiencies, seven of which were corrected during the audit. The following represents a brief description of the two deficiencies that resulted in the issuance of M&O Corrective Action Reports (CARs):

M&O CAR 94-OC-004

Verification of education was not completed prior to performing work subject to Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 0, requirements; verification of experience was not completed within the required fifteen days after the manager/supervisor signed the individual's position description and individuals were not current on reading assignments on Procedure Change Notices.

M&O CAR 94-OV-021

M&O QAP-17-1, "Record Source Responsibilities for QA Records" and QAP-17-2, "Receipt and Handling of QA Records and Records Packages," do not meet all QARD requirements. QAP-17-1 does not address reauthentication of record/record package corrected after submittal to the Local Record Center (LRC) and QAP-17-2 does not provide controls for the protection of QA Records removed from the LRC.

The following is a brief description of the seven deficiencies corrected during the course of the audit which were isolated in nature and required only remedial actions.

1. Original Description Forms (DFs) for TBDs and TBVs were not forwarded to the LRC as required.

M&O procedure Charlotte Local Procedure CLP-3-2, "TBV/TBD Monitoring," was revised to delete the requirement for submittal of original forms.

2. Completed DFs had not been submitted to the LRC as required.

All completed DFs were submitted to the LRC prior to the completion of the audit.

3. A copy of the monthly TBV/TBD Status Report was not sent to all required originators.

All originators were given a copy of the TBV/TBD Status Report.

4. Delegation letters were improperly designated as Non-QA Records and were not forwarded to the LRC as required.

The delegation letters were corrected and sent to the LRC.

5. The "Comment Due Date" was not recorded on the Document Review Record (DRR) sheet for the MPC and Transportation Cask specifications as required but was recorded on the Interoffice Correspondence that accompanied the DRRs.

The "Comment Due Date" was recorded on the DRRs as required.

6. Three record packages were maintained in temporary storage longer than one year without an extension request as required by procedure.

The record packages were sent to the Central Records Facility.

7. There was no list established identifying the current status of each controlled local procedure.

A list was established identifying the current status of CLPs.

(Block 10 Continued) SURVEILLANCE CONCLUSIONS

The audit plan used by the M&O Audit Team thoroughly addressed all aspects of the audit including an evaluation of the adequacy of procedures and determination of the continued effectiveness of implementation of corrective action resulting from prior audits and surveillances. The audit checklists addressed all scheduled criteria to the extent necessary to determine effectiveness of implementation. In addition, the audit plan and checklist addressed recommendations for improving audit effectiveness made by OCRWM OQA personnel as a result of observations of prior M&O audits.

The OQA personnel performing the observation/surveillance concluded that the M&O Audit Team conducted a thorough and effective audit in determining that the Charlotte M&O organization was effectively implementing the M&O QA Program in the areas of Organization; QA Program; Design Control; Implementing Documents; Document Control; Corrective Action and QA Records. All M&O Charlotte personnel contacted during the audit were cooperative and expressed interest in meeting QA Program requirements. This observation is supported by the diligent efforts to correct any and all deficiencies that were able to be corrected before the end of the audit.