ENCLOSURE 4

OCRWM OQA

OBSERVATION REPORT

OF

M&O

AUDIT

94-VIA-02

U. S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
HEADQUARTERS QUALITY ASSURANCE DIVISION
OBSERVATION REPORT

M&O CONTRACTOR
AUDIT NO. 94-VIA-02
OF THE M&O QUALITY ASSURANCE PROGRAM

CONDUCTED AT VIENNA, VIRGINIA
JANUARY 17-21, 1994

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Observer

1.0 INTRODUCTION

The OCRWM Office of Quality Assurance observed the M&O Contractor Quality Assurance Audit number 94-VIA-02 of the M&O QA Program. The audit was observed by representatives from the Headquarters Quality Assurance Division and the Yucca Mountain Quality Assurance Division.

The audit was conducted during the period of January 17-21, 1994, in Vienna, Virginia.

The scope of the M&O audit was to evaluate the adequacy and effectiveness of implementation of Elements IV, V, VI, VII, and XVI of the M&O Quality Assurance Program.

2.0 OBJECTIVE

This report addresses the evaluation of the adequacy and effectiveness of the M&O audit process in determining the ability of the M&O Contractor to implement QA Program controls.

3.0 AUDIT PARTICIPANTS

W. Farmer, M&O	Audit Team Leader
P. Chomentowski, M&O	Auditor
G. Keener, M&O	Auditor
D. Jennings, M&O	Auditor
D. Threatt, QATSS/HQAD	Observer
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4.0 REVIEW OF AUDIT PROCESS

Overall, the OCRWM Observers consider that the M&O audit process was marginally effective in evaluating the adequacy and effectiveness of implementation of the M&O QA Program except in the area of Procurement Controls in which the audit was determined to be ineffective. Weaknesses were noted in the use of the audit checklists (See Recommendation 5.2a) and in the review of objective evidence (See Recommendation 5.2b). A followup surveillance, 94-VIS-02, was conducted by the M&O during the week of January 31, 1994 to address the concerns identified by the Observers.

The elements audited included Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; and Corrective Action. Corrective Action Reports from previous audits and surveillances were reviewed in preparation for this audit.

The audit process was observed to determine the ability of the audit team to adequately assess the implementation and effectiveness of the M&O QA Program. Evaluation of the M&O audit process was based on direct observations made during interviews; discussions with the auditors and auditees; and reviews of the audit plan, checklists, and audited documents.

The OCRWM observers reviewed personnel records to determine that the audit team had been qualified to perform the audit. Although it was determined that the audit team was qualified, it was noted that during OCRWM surveillance HQ-SR-94-02 that for one member of the audit team, the auditor qualification records were not completed according to the requirements of the M&O procedure.

The audit was performed using checklists based upon the M&O Quality Administrative Procedures. The checklists were used in conducting some portions of the audit and the M&O procedures were used to conduct the audit when checklists were not being used (See Recommendation 5.2a).

The M&O audit team determined that the implementation of the audited M&O QA Program Elements was effective with the exception that the M&O procurement process was determined to be marginally effective.

The audit team identified six deficiencies as a result of the audit. Two deficiencies were identified in the area of Procedures, two deficiencies were identified in the area of Document Control, one deficiency was identified in the area of Procurement, and one deficiency was identified in the area of Corrective Action. The following M&O Corrective Action Reports (CARs) were issued as a result of the deficiencies.

M&O CAR 94-QV-C-007

The M&O procedures require a Document Identifier (DI) on documents to be controlled and also require that Document Control Center (DCC) staff review the document to ensure that it contains the required information. Contrary to these requirements, the Technical Document Preparation Plan (TDPP) for the CRWMS Interface Specification and the TDPP for Systems Requirements Documents were submitted to the DCC by the originator without the required DI and were not returned to the originator by the DCC.

M&O CAR 94-QV-C-008

For CARs, not classified as "Significant", QAP-16-1 requires that the interfacing manager(s) investigate the reported condition, document the results of the investigation, and propose a remedial action. Contrary to this requirement, several M&O CARs did not document the interfacing manager's investigation of the reported condition.

NOTE: This condition was identified during OCRWM Surveillance HQ-SR-94-02 and documented on OCRWM CAR HQ-94-004.

M&O CAR 94-QV-C-009

The QARD states that the content of implementing documents shall contain a sequential description of work to be performed. The M&O procedure for preparation of procedures states that the process steps are to be, "preferably sequential, if appropriate".

NOTE: This condition was identified during OCRWM Surveillance HQ-SR-94-02 and documented in the Verification Report for OCRWM CAR HQ-93-013.

M&O CAR 94-QV-C-010

The QARD requires that the content of implementing documents contain the identification of lifetime and nonpermanent quality assurance records generated by the implementing document. The M&O procedure for preparation of procedures does not contain this requirement.

M&O CAR 94-QV-C-011

The M&O QAP-3-13 requires Document Identifiers for certain document types. Several documents reviewed did not contain the required Document Identifiers.

M&O CAR 94-QN-C-015

The M&O QAP-7-1 requires that a designated Plan Preparer prepare and document a plan for the procurement process of quality-affecting procurements. A Purchase Requisition (HD 3153) was submitted to the QE Manager for signature without an approved procurement plan.

The following deficiency was identified as a result of the followup surveillance (94-VIS-02) evaluating the procurement process.

M&O CAR 94-QV-C-012

The QA requirements associated with the transition of the work of Sandia National Laboratory to the M&O were not fully implemented. Approval of the SNL Quality Assurance Plan by the M&O was documented, but the basis for approval was not included. Deficiencies identified during the M&O evaluation of the SNL program were not documented as required by M&O procedures. M&O procedures do not effectively address the procurement transition process, therefore, procedural actions required in the approval of suppliers were not performed.

Deficiencies Corrected During the Audit:

1. A Purchase Requisition/Statement of Work for HVAC modification of the Central Records Facility records vault was not reviewed by the QA organization. The Purchase Requisition/Statement of Work was subsequently sent to QA for review and was determined to be nonquality-affecting.

2. No records existed to show that two Procurement Department personnel had been trained in the latest revision of QAP-4-1 and QAP-7-1. Further investigation found that the I&T Matrices were in the possession of the affected individuals and had not been placed in the training files.

3. No action had been taken on CAR 93-QV-C-086 since issuance on 8/31/93. Timeliness of CAR process was previously identified by CARs 94-QN-C-010 and 94-QV-C-003 the deficiency will be addressed with closure of these CARs.

5.0 OBSERVER COMMENTS

5.1 A positive observation was noted relative to the audit process and areas audited in that, regardless of the difficulty in maintaining the audit schedule due to inclement weather, the audit team kept the auditee personnel and the audit observers well informed of the progress of the audit and the status of audit results.

5.2 The following represent areas that the observers feel that the audit process could be improved upon:

a) During the audit, that the auditors did not always have the checklist in their possession during interviews. The auditors frequently used the procedures and asked questions related to the procedural processes. While this can be effective in determining compliance with the procedure, it does not provide confidence in the effectiveness of the process and the effectiveness of the QA program in meeting QARD requirements. It is recommended that the M&O audit checklists be restructured to better address the process being audited and that the checklists be used consistently throughout the conduct of the audit to ensure continuity and completeness of the audit.

b) In some cases, the auditors relied extensively on interviews to determine compliance with the QA program and did not sufficiently examine objective evidence. In evaluating the procurement process, the auditor interviewed several personnel and relied primarily on statements made by the interviewees, with limited consideration of objective evidence. It is recommended that, in future audits, M&O audit personnel be instructed to pursue more in-depth examination of objective evidence as a basis for evaluation of QA program effectiveness.

c) The M&O review of the procurement process only identified a missing form and a missing procurement plan. No further action was determined necessary by M&O audit personnel based on the explanations provided by the audited organizations. After completion of the audit, the Observers discussed concerns regarding the procurement process with M&O QA personnel who performed a followup surveillance (94-VIS-02) to further investigate procurement activities. M&O CAR 94-QV-C-012 was issued as a result of the surveillance. Following the above recommendation to thoroughly evaluate objective evidence in lieu of auditee explanations with regard to requirements would help to ensure the accuracy of audit results and not require that observers identify problem areas to the audit team.