

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

**AUDIT REPORT
OF
MANAGEMENT AND OPERATING CONTRACTOR
LAS VEGAS, NEVADA**

**AUDIT NUMBER YM-ARP-95-02
JANUARY 9 THROUGH 13, 1995**

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Approved by: DC Anne For Date: 3/17/95
Donald G. Horton
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1.0 EXECUTIVE SUMMARY

As a result of performance based Quality Assurance (QA) Audit YM-ARP-95-02, the audit team determined that the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O) is satisfactorily implementing an effective QA program in accordance with the U. S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management QA Requirements and Description Document (QARD), DOE/RW-0333P, Revision 1 and the M&O implementing procedures for Section 5.0, "Implementing Documents," Section XV, "Nonconformances," and Section XVII, "QA Records." Section XVI, "Corrective Action" was determined not effective with respect to the areas listed below.

In addition to the above programmatic areas covered during this audit, the performance based portion evaluated the corrective action process in accordance with the approved audit plan. The performance based evaluation of process effectiveness and product acceptability was based on four key areas included in the corrective action process as follows: 1) Identification, 2) Evaluation, 3) Corrective Action, and 4) Verification. The corrective action process area was determined to be ineffective due to a lack of effective implementation of corrective action; inadequate evaluation of deficiency impact; inadequate objective evidence of justification for closure of Corrective Action Requests (CAR), and inadequate verification of implementation for corrective actions.

The evaluation of the process implementation effectiveness for the specific areas reviewed resulted in one deficiency documented in CAR, YM-95-023, regarding the M&O procedure process and the amendment of an existing CAR, HQ-95-003, documenting an inadequate corrective action process. There were two deficiencies identified by the audit team and corrected prior to the postaudit meeting. These conditions are described in Section 5.5.2 of this report. Additionally, there were seven recommendations resulting from the audit, which are detailed in Section 6.0 of this report.

2.0 SCOPE

This audit of the M&O was conducted to evaluate the effectiveness of the M&O's controls for the M&O corrective action process.

The QA program elements evaluated during the audit, in accordance with the approved audit plan, are as follows:

QA PROGRAM ELEMENTS/REQUIREMENTS

- 5.0 Implementing Documents
- 15.0 Nonconformances
- 16.0 Corrective Action
- 17.0 QA Records

PERFORMANCE BASED

The corrective action process/activities evaluated during the audit, in accordance with the approved audit plan, were as follows:

- 1) Identification
- 2) Evaluation
- 3) Corrective Action
- 4) Verification

TECHNICAL AREAS

None.

3.0 AUDIT TEAM AND OBSERVERS

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

| <u>Name/Title/Organization</u> | <u>QA Program Elements/Requirements, Processes, Activities or End-products</u> |
|--|--|
| Steven P. Nolan, Audit Team Leader (ATL) Yucca Mountain Quality Assurance Division (YMQAD) | 15.0 Control of Nonconformances |
| Stephen R. Dana, Auditor, YMQAD | 16.0 Corrective Action Process |
| Kenneth O. Gilkerson, Auditor, YMQAD | 5.0 Implementing Documents and 16.0 Corrective Action Process |
| Frank J. Kratzinger, Auditor, YMQAD | 17.0 QA Records |
| Walter Coutier, Auditor, Headquarters Quality Assurance Division | 16.0 Corrective Action Process |

Susan Zimmerman, Observer, State of Nevada

John Buckley, Observer, U.S. Nuclear
Regulatory Commission (NRC)

Bruce Mabrito, Observer, NRC

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at the M&O office in Las Vegas, Nevada, on January 9, 1995. A daily debriefing and coordination meeting was held with M&O management and staff, and daily audit team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at the M&O office in Las Vegas, Nevada, on January 13, 1995. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

PROGRAMMATIC:

The audit team concluded that, in general, the M&O programmatic controls are satisfactorily being implemented for Sections 5.0, "Implementing Documents," 15.0, "Nonconformances," and 17.0, "QA Records."

The programmatic controls for the above activities were found to be satisfactory based on the use of trained personnel working effectively; documentation that substantiated the quality of the products; and interviews conducted with cognizant M&O personnel.

QA Program Element 16.0, "Corrective Action" was found to be unsatisfactory. See "Performance Based" section below.

PERFORMANCE BASED:

As a result of the performance based evaluation, the M&O process for corrective action is considered ineffective for the specific areas reviewed due to the deficiencies identified in the amended CAR HQ-95-003, and objective evidence reviewed during the course of the audit. These included the lack of effective implementation of corrective action; inadequate evaluation of deficiency impact; inadequate objective evidence of justification for closure of CARs, and inadequate verification of implementation for corrective actions.

The process for M&O corrective action requires improved controls in both Vienna, Virginia, and at the Las Vegas, Nevada facility in these areas to ensure effective implementation.

There were two deficiencies identified by the audit team and corrected prior to the post audit meeting. These conditions are described in Section 5.5.2 of this report. Additionally, there were seven recommendations resulting from the audit which are detailed in Section 6.0 of this report.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions taken as a result of this audit.

5.3 QA Program Audit Activities

A summary table of audit results is provided in Attachment 2. The details of the audit evaluation, along with the objective evidence reviewed, are contained within the audit checklists. The checklists are kept and maintained as QA Records.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of Deficiencies

The audit team identified two deficiencies during the audit for which one CAR, YM-95-023, has been issued and the other has been incorporated into amended CAR HQ-95-003. The CARs have been transmitted to you under a separate letter, Ltr YMQAD: RBC-1886 and Ltr Clark to Robertson dtd 2/14/95.

5.5.1 Corrective Action Requests

CAR YM-95-023

Quantitative and qualitative criteria have not been established in some M&O procedures.

CAR HQ-95-003

The corrective action process is not always being adequately implemented in the areas of effective corrective action, evaluation of deficiency impact, adequate objective evidence to substantiate closure of CARs, and verification activities concerning correction actions.

5.5.2 Deficiencies Corrected During the Audit

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

REQUIREMENT:

1. Quality Assurance Procedure (QAP)-17-1, Revision 3, Paragraph 5.8.2, "Corrections that change the technical content or the intended purpose or use of a record that are made after an approval process must be re-approved by the originating organization."

ADVERSE CONDITION:

Reference: Document 94-3118, Records Package of the Readiness Review for Start of Construction of the Exploratory Studies Facility Using the Tunnel Boring Machine, Revision 0, dated November 21, 1994.

The approval sheet for the subject reference final report (Page 2 of 419) contains cut-and-paste, tape-over approval signatures for several responsible individuals.

In addition, the General Manager approved the document on November 11, 1994; four days prior to the approval by another team member.

ACTIONS TAKEN:

Original signature sheets were located for responsible individuals. The team leader and team members re-signed a new approval sheet on January 11, 1995. One team member, who was out of the country, faxed a letter attesting to his signature and approval on January 11, 1995. The General Manager then approved the signature sheet on January 12, 1995. The revised documentation was submitted to, and received by the Local Records Center (LRC), as a supplement to the records package on January 13, 1995. The actions taken and the associated documentation was verified by the auditor as satisfactory to resolving the identified issue.

REQUIREMENT:

2. **M&O QAP-2-1, Revision 4, Paragraphs 5.3.2,
"Managers/Supervisors shall ensure that personnel under their supervision either have training or have read the latest revision of a procedure before doing work according to that procedure."**

ADVERSE CONDITION:

One individual was identified as one of three responsible personnel for CAR 94-QN-C-035 issued May 23, 1994. There is no objective evidence that this individual had received training or read the latest revision (Revision 1, July 30, 1993) to M&O QAP-16-1, Corrective Action, until January 3, 1995. The previous record for training to QAP-16-1 is for Revision 0, Procedure Change Number 2, dated June 14, 1993.

ACTION TAKEN:

A training self-study record dated February 1, 1994, was located for the individual and presented to the auditor. This training record provided adequate documentation that the individual was current to M&O QAP-16.1, Revision 1, during the time frame that he was involved in CAR 94-QN-C-035.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by the M&O management.

1. **M&O should generate a letter from the head of the engineering department/division providing names of individuals that have demonstrated competency in dispositioning Nonconformance Reports (NCRs) by discipline or area of expertise.**
2. **A performance based surveillance should be performed regarding the Nonconformance System i.e., Yucca Mountain Administrative Procedure (YAP)-15.1Q as it crosses all organizational boundaries. This surveillance should address whether project controls in place are effective and are being implemented per the requirements.**
3. **Procedure QAP-17-2, Revision 1, contains at least two paragraphs, 5.1.7 (compare authenticators to list) and 5.6 (duplicate check of records), that are not required to be documented for objective evidence unless the results of the actions are negative.**

It is recommended that a type of checklist or revised batch control cover sheet be used to document that these actions were performed.

4. Procedure QAP-17-2, Revision 1, Paragraph 5.2.4 states that, "If QA Records Package Segments are stored in the LRC for more than one year, the LRC staff shall request the Record Source to fill out a new transmittal in order to extend the period of storage."

On July 29, 1994, the LRC sent out a letter requesting a new transmittal for four Record Package Segments which exceeded the yearly time limit. During the audit, it was discovered that there had been no response to these request letters.

In order to close this loop, it is recommended that the procedure be revised to include the requirement that if a response is not received within 30 days of the request letter, the QA Records Package Segment will be returned to the Record Source.

5. M&O should consider addressing the following items associated with the records package submitted for the Readiness Review of the Tunnel Boring Machine.
 - a. The document identifier (BABFBA000-0717-5705-00001, Revision 00, dated November 15, 1994) does not consistently appear on all pages of the record submittal.
 - b. The Open Item List (Page 263) for open item PH1-10-4, includes Kiewit as having responsibility; the open item does not.
 - c. Open item PH1-11-3 does not include the DOE as having responsibility; the Open Item List does.
 - d. Open item PH1-21-8 was closed September 19, 1994. The Open Item List shows a closure date of September 14, 1994.
6. The M&O should consider training in the corrective action process for QA and line organization personnel that addresses:
 - a. The methodology of adequately investigating the extent and impact of an adverse condition.
 - b. What is considered sufficient objective evidence to support the evaluation, cause determination, and closure of an adverse condition.

- c. What information is necessary to provide and support an acceptable response to an identified adverse condition.
7. QARD, Revision 1, Section 5.2.4, M&O procedure QAP-5-1, Revision 3, and M&O procedure QAP-5-2, Revision 3, require that "...when work cannot be accomplished as described in the implementing document, or accomplishment of such work would result in an undesirable situation, the work shall be stopped. Work shall not resume until the implementing document is changed to reflect the correct work practices." A literal translation of this requirement could cause the M&O to have to shut down many of its activities due to various procedural and process problems that have been identified in recent audit and surveillances. The M&O should consider the format for expedited changes as described in Section VI of the QARD subsection 6.2.7.

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

| <u>Name</u> | <u>Organization/Title</u> | <u>Preaudit Meeting</u> | <u>Contacted During Audit</u> | <u>Postaudit Meeting</u> |
|--------------|---|-------------------------|-------------------------------|--------------------------|
| Abend, G. | M&O/QA Specialist | X | X | X |
| Arth, F. | M&O/QA Tech. Specialist | X | X | |
| Baredine, T. | M&O/Imaging Dept. Supervisor | | | X |
| Bartley, C. | M&O/QA Tech. Specialist | X | X | X |
| Beall, K. | M&O-SAIC/Mgr. FOS | X | X | |
| Belke, W. | NRC/Observer | | | X |
| Bennett, R. | M&O/Quality Control | | X | |
| Blaylock, J. | YMQAD-DOE | | X | |
| Bryant, A. | M&O/Training Specialist | | X | |
| Buckley, J. | NRC/Observer | X | | X |
| Chaffin, N. | M&O/Records | | X | |
| Chandler, D. | M&O-SAIC/Support Ops. | X | X | X |
| Diaz, M. | YMQAD/Audit Supervisor | X | | |
| Foust, L. | M&O/Asst. General Mgr. | | | X |
| Franks, D. | M&O/QA Surveillance Mgr. | X | X | |
| Geer, T. | M&O/MGDS Sr. Mgr. | X | | |
| Gibson, D. | M&O/Records Clerk | | X | |
| Greene, H. | YMQAD/QA Division Mgr. | X | | X |
| Hayes, J. | M&O/Quality Control - Field | X | | |
| Heath, C. | M&O/Deputy AGM-PGM Integration | | X | |
| Horton, D. | OQA/Director | | | X |
| Horton, S. | OQA/QA Special Asst. | | | X |
| Jenkins, D. | M&O/QA Engineer | X | X | X |
| Jerome, K. | M&O/Records | | X | |
| Johnson, K. | M&O-IRG/QA Mgr. | | X | X |
| Justice, J. | M&O/Training Specialist | | X | |
| Justice, R. | M&O/Quality Engineering Support Mgr. | X | X | X |
| Kali, G. | M&O/Media Specialist | | X | |
| Klimas, D. | YMQAD/Sr. QA Specialist | | X | X |
| Leonard, W. | M&O/Project Engineer | | X | |
| Mabrito, B. | NRC/Observer | X | | X |
| Malone, M. | M&O-IRG/QA Specialist | X | X | X |
| Maudlin, R. | YMQAD/Sr. QA Specialist | X | | |
| McDaniel, M. | YMQAD/Sr. QA Specialist | X | | |
| Mueller, T. | M&O/Records Analyst | X | X | X |

ATTACHMENT 1
Personnel Contacted During the Audit
(Continuation)

| <u>Name</u> | <u>Organization/Title</u> | <u>Preaudit Meeting</u> | <u>Contacted During Audit</u> | <u>Postaudit Meeting</u> |
|------------------|---------------------------------------|-------------------------|-------------------------------|--------------------------|
| Penovich, M. | M&O/Training Supervisor | X | | X |
| Petrie, W. | M&O/QA Specialist | | | X |
| Ruth, R. | M&O/QA Mgr. | | X | X |
| Sandifer, R. | M&O/Deputy - MGDS Ops. | | X | X |
| Segrest, A. | M&O/MGDS Mgr. | | X | |
| Spence, R. | YMQAD-DOE/Director | | | X |
| Therien, J. | YMQAD/Programs | | X | |
| Tiesenhausen, E. | Clark County - Nevada/Engineer | | | X |
| Tunney, D. | M&O-IRG/Sr. QA Specialist | X | X | X |
| Verden, J. | M&O/Records Mgr. | X | X | X |
| Wagster, R. | M&O/Project Engineer | X | X | |
| Willis, J. | M&O/QA Engineering Mgr. | X | X | |
| Worcester, K. | M&O/Records Processing Coordinator | | | X |
| Yunker, J. | M&O/Mgr. Regulatory Evaluation | X | | X |
| Zimmerman, S. | State of Nevada/Observer | X | | |

LEGEND:

AGM - PGM = Assistant General Manager - Project General Manager
 Asst. = Assistant
 FOS = Field Operations Support
 IRG = Integrated Resources Group
 Mgr. = Manager
 MGDS = Monitored Geologic Disposal System
 Ops. = Operations
 SAIC = Science Applications International Corporation
 Sr. = Senior
 Tesh. = Technical

| QA ELEMENT/ACTIVITIES | PROCESS STEPS | DETAILS (Checklist) | CAR | CDA | RECOM-MENDATION | ADE-QUACY | COM-PLIANCE | OVER-ALL |
|--------------------------------------|---|---------------------|-----------|-------|----------------------------|-----------|-------------|---|
| 16.0 - M&O CORRECTIVE ACTION PROCESS | 1. Identification | Pages 1-4 of 19 | N | N | N | | SAT | I N E F F E C T I V E |
| | 2. Evaluation | Pages 5-18 of 19 | HQ-95-003 | No. 2 | No. 6 Checklist Item 16-20 | | UNSAT | |
| | 3. Corrective Action | Pages 9-17 of 19 | HQ-95-003 | N | No. 6 | | UNSAT | |
| | 4. Verification | Pages 16-19 of 19 | HQ-95-003 | N | No. 6 | | UNSAT | |
| 5.0 - IMPLEMENTING DOCUMENTS | QAP 5.1, Revision 3, Preparation of M&O Quality Administrative Procedures | Pages 2-7 of 32 | YM-95-023 | N | No. 7 | | Marginal | S A T |
| | QAP 5.2, Revision 1, Preparation of M&O Implementing Line Procedures | Pages 2-7 of 32 | N | N | No. 7 | | SAT | |
| 15.0 - CONTROL OF NONCONFORMANCES | YAP-15.1Q, Revision 1, Control of Nonconformances | Pages 8-12 of 32 | N | N | Nos. 1 and 2 | | SAT | S A T |

ATTACHMENT 2

| QA ELEMENT/ ACTIVITIES | PROCESS STEPS | DETAILS (Checklist) | CAR | CDA | RECOM-MENDATION | ADE-QUACY | COM-PLIANCE | OVER-ALL |
|-------------------------------|---|----------------------------|------------|--------------|------------------------|------------------|--------------------|----------------------|
| 17.0 - QA RECORDS | QAP 17.1, Revision 3, Record Source Responsibilities | Pages 13-16 of 32 | N | No. 1 | No. 5 | | SAT | S A T |
| | QAP 17.2, Revision 1, Receipt and Handling of QA Records and Records Packages | Pages 17-19 of 32 | N | N | Nos. 3 and 4 | | SAT | |
| | QAP 17.5, Revision 1, Indexing Quality Assurance Records | Pages 20-21 of 32 | N | N | N | | SAT | |
| | QAP 17.6, Revision 2, Storage, Removal, and Retrieval of QA Records | Pages 22-24 of 32 | N | N | N | | SAT | |
| | NLP-17.4, Revision 3, Microfilming Program Records | Pages 25-30 of 32 | N | N | N | | SAT | |
| | NLP-17.5, Revision 2, Storage and Retrieval of QA Records by Security Archives | Pages 31-32 of 32 | N | N | N | | SAT | |