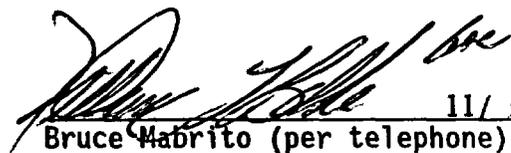


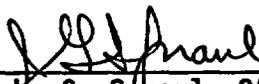
U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT 94-10
OF THE
U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
AUDIT YMP-94-01
OF THE
CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND
OPERATING CONTRACTOR DESIGN PACKAGE 2C ACTIVITIES


11/4/94
William L. Belke
High-Level Waste Projects &
Quality Assurance Section
High-Level Waste & Uranium
Recovery Projects Branch
Division of Waste Management

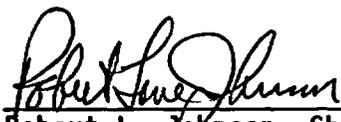

11/4/94
Bruce Habrito (per telephone)
Center for Nuclear Waste
Regulatory Analyses


11/4/94
Thomas C. Trbovich (per telephone)
Center for Nuclear Waste
Regulatory Analyses

Reviewed and approved by:


11/4/94
John G. Spraul, QA Team Leader
High-Level Waste Projects &
Quality Assurance Section
High-Level Waste & Uranium
Recovery Projects Branch
Division of Waste Management

Reviewed and approved by:


11/10/94
Robert L. Johnson, Chief
High-Level Waste Projects &
Quality Assurance Section
High-Level Waste & Uranium
Recovery Projects Branch
Division of Waste Management

ENCLOSURE

1.0 INTRODUCTION

During July 25-29, 1994, members of the U.S. Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD) audit of the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O). The limited-scope, performance-based audit, YMP-94-01, conducted at the M&O offices in Las Vegas, Nevada, evaluated the effectiveness of selected M&O design processes, and the quality of the resultant end products, specifically concentrating on Design Package 2C, "Topopah Spring North Ramp." A State of Nevada representative also participated as an observer of this audit.

This report addresses the effectiveness of the audit and the adequacy of implementation of the M&O design control process.

2.0 OBJECTIVES

The objectives of the audit were to evaluate the effectiveness of the M&O design controls in meeting program requirements and management commitments and expectations in the development and preparation of design documents and issuance of acceptable design packages for construction.

The NRC staff's objectives were to gain confidence that the M&O organization was properly implementing the design control requirements of their QA program in accordance with the OCRWM Quality Assurance Requirements and Description document (QARD-DOE/RW-0333P) and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B) and to determine if the audit was performed in such a manner as to provide continued confidence in the DOE audit process.

3.0 MANAGEMENT SUMMARY AND CONCLUSIONS

Even though it was scheduled very soon after a full scope DOE QA System Evaluation audit of the M&O, the NRC staff has determined that M&O Audit YMP-94-01 was useful and effective in identifying additional design control problem areas. The audit was organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team qualifications were verified and personnel were found to be knowledgeable of program QA requirements. The audit team assignments and the checklist items were adequately described in the audit plan. The team included a technical specialist.

The NRC staff agrees with the preliminary audit team finding that M&O design controls are ineffective. Fifteen preliminary Corrective Action Requests (CARs) were discussed by the audit team leader at the post-audit meeting, and several others were resolved during the audit. Many of the preliminary CARs are significant and need to be addressed with consideration on how they affect the overall design of the Exploratory Studies Facility (ESF) and other M&O design activities. As a consequence of the number and significance of these findings, M&O management decided late in the audit to withdraw Design Package 2C from the DOE review and approval process. A full-scope audit of the M&O (HQ-94-02), an internal M&O surveillance, and the Design Package 2C 90% design

review have previously identified additional design control and design product deficiencies. These deficiencies were identified after the M&O undertook its Design Control Improvement Plan (Revision 1 is dated September 28, 1993). Apparently the improvements proposed in the Design Control Improvement Plan had not yet been implemented or are not adequate to address the problems recognized in Fiscal Year 1993.

The NRC staff expects to be kept advised of the corrective action process, will participate in closely monitoring the corrective actions of the M&O as observers, and may perform its own independent audits/surveillances at a later date to assess implementation of the M&O QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

William L. Belke	Observer	
Bruce Mabrito	Observer	Center for Nuclear Waste Regulatory Analyses (CNWRA)
Thomas Trbovich	Observer	CNWRA

4.2 DOE

Kenneth O. Gilkerson	Audit Team Leader (ATL)	YMQAD/Quality Assurance Technical and Support Services (QATSS)
William Sublette	Technical Specialist	OCRWM/Technical and Management Support Services (T&MSS)
Frank Kratzinger	Auditor	YMQAD/QATSS
Neil Cox	Auditor	YMQAD/QATSS
Robert Howard	Auditor	YMQAD/QATSS
John Pelletier	Auditor	YMQAD/QATSS
Richard Peck	Auditor	YMQAD/QATSS
Richard Powe	Auditor	YMQAD/QATSS

4.3 State Government

Susan Zimmerman	Observer	State of Nevada
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5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This audit of M&O was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 6) and QAP 16.1, "Corrective Action" (Revision 6). The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Scope of the Audit and Observations

5.1.1 QA Programmatic Elements

Audit YMP-94-01 was a limited-scope, performance-based audit, which evaluated the effectiveness of selected processes and the quality of the resultant end

products associated with M&O activities performed under QA program element 3.0, "Design Control," specifically concentrating on Design Package 2C.

As identified in the audit plan, evaluation of the M&O design process effectiveness and product acceptability was based on:

- proper implementation of the critical process steps
- accomplishing performance objectives (e.g., meeting project milestones without sacrificing product quality, while maintaining safety, quality, and cost-conscious attitudes during performance)
- use of trained and qualified personnel working effectively
- documentation that substantiates quality of the products
- acceptable results and quality of the end products.

5.1.2 Technical Areas

The audit of the M&O included technical evaluation of Design Package 2C, which covered the following: the mining specifications and drawings, structural specifications and drawings, mechanical specifications and drawings, instrumentation/electrical specifications and drawings, and the Determination of Importance Evaluation (DIE) and Basis For Design (BFD) subsurface general specifications.

5.1.3 Observations

The NRC staff observed the majority of the audit team evaluations. There was no technical specialist on the NRC team.

5.2 Timing of the Audit

The NRC staff believes that this audit occurred too soon after the overall QA System Evaluation audit (HQ-94-02) conducted in June, 1994, which also covered the design control activities. Due to schedule delays, this performance-based audit, which was scheduled first, actually followed the QA System Evaluation audit by approximately one month. Thus, the M&O staff had insufficient time to address the deficiencies or initiate appropriate corrective actions after the QA System Evaluation audit. However, the additional deficiencies that were identified in this audit may clarify and provide additional focus on corrective action needs. The NRC staff concern over the timing of this audit is presented as an Observation in Section 5.8.1 of this report.

5.3 Examination of the Design Control QA Programmatic Element

The NRC staff observed that each of the auditors reviewed a representative sample of documentation related to design control and interviewed appropriate M&O personnel. The auditors observed were well prepared and knowledgeable of the QA program requirements. The ATL was especially effective in managing the audit team and in the daily caucuses with M&O management. Checklists, based on M&O implementing procedures, were used effectively; and auditors pursued issues beyond the checklists when appropriate. The audit team was divided into multiple sub-teams, which conducted the evaluation of specifications and drawings (design output documents) which were traced back through the process

steps used to create the final product. These steps included flowdown of upper-tier requirements, development of design documents (for example, DIES, BFD, and design analyses), discipline reviews and checks, interdisciplinary reviews and checks, 90-percent design review and checks, design verification reviews and checks, and preparation of final approval documents. In addition, training and qualification of personnel and use of scientific investigation and site characterization data were verified.

The NRC staff observations regarding the audit and the implementation of each part of the design control element are discussed below.

5.3.1 Mining Specifications and Drawings

The auditor and technical specialist conducted an effective evaluation; reviewing documentation and conducting interviews with M&O staff. Six specifications and eleven drawings were selected for review. The technical specialist identified a lack of flowdown and traceability of several 10 CFR Part 60 requirements, and a CAR was initiated. A similar condition was identified by the NRC On-Site Representative in May 1993, and this was subsequently documented in an August 20, 1993, letter from J. Holonich to D. Shelor. Also, this condition was identified in Comments 128, 129, 130 and 132 of the NRC Staff Site Characterization Analysis of the DOE Site Characterization Plan, NUREG-1347, July 1989. The NRC staff is concerned about this repetitive condition and will be following the response and corrective action.

The NRC staff believes that this condition may be attributed to the complex document hierarchy associated with the ESF Technical Baseline. It appears that anytime a revision is made to a top-tier document, all other documents (specifications, drawings, procedures, and instructions) must be checked and/or revised for that revision. With the number of documents involved and the numerous changes occurring in the ESF process, this could present the potential for a large margin of error whereby requirements do not always get accurately incorporated and translated into the relevant documents. This is identified as an Observation in Section 5.8.1 of this report.

The ATL and the audit sub-team made acceptable adjustments to the audit schedule when it was learned that one of the M&O lead discipline engineers was not available due to travel. The auditor and technical specialist were able to interview others and work around the situation; however, such absences of key technical personnel can cause audits to be less effective and are indicative of an oversight in management of staff. This is listed as a Weakness in Section 5.8.2 of this report.

Based on the review of objective evidence and interviews with cognizant personnel, the audit team determined that the performance of activities associated with the design control process for the mining design was unsatisfactory. A potential cause was that many M&O engineers have not had experience in a highly regulated environment and, therefore, were not as concerned with documentation of assumptions or analyses. The NRC agrees with the audit team's conclusion and found that the audit of this area was effective.

The audit sub-team issued CARs YM-94-062, YM-94-063, YM-94-073, and YM-94-074 in this portion of the audit. They are described in Section 5.9 of this report.

5.3.2 Structural Specifications and Drawings

Three specifications, four drawings, five check prints and five design analysis documents were selected for review by the auditor. Specification deficiencies were identified with the discipline and interdiscipline checks, "Q" control (indicating use on important to radiological safety and/or waste isolation areas) for structural steel set attachments (hanger brackets, pipe supports, etc.), adequacy of design input assumptions, and flowdown of upper-tier requirements to the output documents.

The auditor and technical specialist had difficulty in clearly understanding why certain structural decisions or selections were made in Design Package 2C, and in some cases decisions were simply not documented. The rationale for engineering decisions should be documented in a manner such that peers reviewing the flow of documents, inputs and outputs, and verification checks can readily understand why decisions were made and how they were justified, without the original engineer being present to answer questions. More detailed procedural requirements for reviews and checks to clearly state the sequence and methods by which such verifications are made are needed in order to fully support the licensing process.

Based on the detailed review of the objective evidence, the performance of activities associated with design control processes for the structural discipline was judged unsatisfactory by the audit team. The NRC staff agrees with this conclusion and considers that the audit in this area was effective.

The audit sub-team issued CARs YM-94-064, YM-94-065, and YM-94-072 in this portion of the audit. They are described in Section 5.9 of this report.

5.3.3 Mechanical Specifications and Drawings

The auditor conducted a thorough evaluation of drawings and specifications and, when questions arose, interviewed the appropriate personnel. Twelve specifications and ten drawings were selected for review. None of the design work was graded as Important to Waste Isolation or Important to Safety and, therefore, did not come under the controls of the QA program. This area was found to be satisfactory, and the audit was judged effective.

In addition to the drawings and specification reviews, mandatory comments (that is, those requiring response and resolution) on the Document Review Sheets from the M&O 90% review of Design Package 2C were reviewed to determine whether the comments were adequately addressed and properly resolved. The design reviewers had identified missing requirements, incorrect information, incorrect calculations, inadequate translation of requirements into inputs, and lack of detailed explanations in Design Package 2C. The comments were found to have been answered and acceptably resolved. The NRC staff requested the auditor to further review the mandatory comments and determine whether the M&O had performed any type of analysis to determine why negative mandatory

comments had resulted from the 90% review. (This would be analogous to a "root cause" analysis.) There was no documented objective evidence that this had been done by the M&O. NRC staff believes that had the M&O responded to the 90% review comments by also conducting a thorough root cause analysis, many of the recent findings from the audit would not have resulted.

The NRC staff is concerned with the number of mandatory comments that surfaced during the 90% design review of Design Package 2C and with Design Packages 2A and 2B. The M&O should have recognized that these were indicative of potentially significant problems in the area of design control. However, the design effort proceeded without recognizing a problem existed or making any attempt to determine why it existed. The NRC staff recommends that for future reviews, a conscientious attempt should be made to analyze and determine the extent and significance of design review comments before advancing to the next phase of design. This has been noted as a Weakness in Section 5.8.1 of this report.

The audit sub-team issued CAR YM-94-071 in this portion of the audit. It is described in Section 5.9 of this report.

5.3.4 Instrumentation/Electrical Specifications and Drawings

The auditor conducted a thorough review of drawings and specifications in his evaluation of this area. Only one specification, "Grounding" (for the grounding of electrical and instrumentation equipment in the area covered by Design Package 2C), was identified as quality affecting and was reviewed by the auditor. No difficulties were encountered and few minor discrepancies were identified. This discipline was judged by the audit team to be satisfactorily implemented and the audit of this area was effective.

5.3.5 DIE/BFD Subsurface General Specifications

The Subsurface General Construction Specification, 01501, was reviewed by the auditors. Several discrepancies were noted: (1) the Tunnel Boring Machine (TBM) Maintenance & Operating Manual was used for design inputs and was not identified as a design document, (2) the TBM Manual was not under configuration control, (3) the DIE did not identify the TBM proposal as a design input, and (4) there were differences between the DIE and Waste Isolation Evaluation (WIE) documents. The review of the specification by the auditors was thorough and detailed enough to make a determination of whether procedural implementation was adequate. The auditors held discussions with M&O staff to determine the full meaning of the term "standard mining practices" which was referred to throughout the general specification. No adequate definition of the term with quantifying acceptance and test criteria could be located, and this was the subject of a CAR. Another CAR was issued when the auditors determined that although references are made in the Construction Tunneling Services TBM Maintenance and Operating Manual to "Q" requirements, the Manual itself was not issuance controlled and was not under configuration control. This area was judged unsatisfactory, which is concurred in by the NRC staff. The auditors conducted an effective evaluation.

The audit sub-team issued CARs YM-94-066, YM-94-067, YM-94-068, YM-094-069, YM-94-070, YM-94-075, and YM-94-076 in this portion of the audit. They are described in Section 5.9 of this report.

5.4 Conduct of Audit

Audit YMP-94-01 was conducted in a professional manner, and the auditors adequately evaluated activities and objective evidence. The audit was clearly able to determine that the M&O organization has ineffectively implemented design controls over Design Package 2C.

The audit included interviews which were observed by the NRC staff, with the points of contact. The objectives of the in-depth interviews were to determine if the selected processes were effective and if the quality of the end product, Design Package 2C, was acceptable based upon paragraph 5.1.1 above.

In comparison to previous audits of other DOE contractors observed by the NRC staff, the M&O QA organization did not have a strong presence early in the audit process. This was not corrected until NRC observers raised a concern during one of the ATL meetings with M&O management. Additionally, there did not appear to be solid discipline integration between the technical and QA functions at the M&O. For example, when there was a comment or potential finding connected to a technical issue (such as the mandatory comments identified in Section 5.3.3 of this report), the technical organization would respond without coordinating with the QA organization. It would be prudent to have the QA organization involved in both technical and programmatic issues to assist in resolution, cause determination, and prevention of recurrence. Again, such technical/QA integration is not a QA requirement, but such interaction may have strengthened the M&O responses to the audit team.

5.5 Qualification of Auditors

The qualification records of the ATL and auditors were reviewed by the NRC staff observers and were found to be acceptable in compliance with the requirements of QAAP 18.1, "Qualification of Audit Personnel."

5.6 Audit Team Independence

The audit team was composed of YMQAD/QATSS personnel and a technical specialist from OCRWM/T&MSS. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence.

5.7 Review of Previous Audit Findings

The ATL assigned some of the audit sub-teams to follow up on the previously identified CARs issued during Audit HQ-94-02 of the M&O program. The sub-teams were instructed to look for similar conditions during this performance-based audit, and several such conditions were identified.

5.8 Summary of NRC Staff Findings

The NRC staff agrees with the preliminary YMQAD audit team finding that the overall implementation of the Design Control Programmatic Element is ineffective. The NRC staff did not observe any deficiencies in the audit process.

5.8.1 Observations

The NRC staff is concerned that this audit was conducted despite several outstanding and significant deficiencies resulting from the DOE QA System Evaluation audit conducted in June 1994 and a recent M&O internal surveillance. There appeared to be no attempt to analyze these deficiencies and comments from a root cause perspective and to implement effective corrective actions. The attitude of the M&O management appeared to be one of "meeting a planned audit schedule" rather than considering the overall effect on quality and how these deficiencies impact the overall design and construction of the ESF (see Section 5.3.3).

There appears to be a cumbersome document hierarchy with numerous implementing procedures associated with the ESF Technical Baseline. When a revision is made to a top-tier document, it necessitates a review of all related documents. This becomes more complex and opens the possibility for errors when a given design is in process that must be continually updated in conjunction with procedural revisions. The NRC recommends that this process be reviewed with consideration being given to eliminating redundancy and making the process, wherever possible, more "user friendly" (see Section 5.3.1).

5.8.2 Weakness

Absence of key M&O technical personnel during the audit to provide information in the geotechnical area caused some delay and rescheduling during the auditing process. This weakness is a repetitive occurrence as similarly noted in NRC Observation Audit Reports 90-08, 11/27/90 (Fenix and Scisson); 92-14, 9/10/92 (Raytheon); and 93-04, 2/17/93 (EM-343) (see Section 5.3).

5.8.3 Good Practices

The audit team was thoroughly prepared and understood the programmatic and technical aspects associated with performance-based auditing. The audit team expressed potential findings in a professional manner and described its effect relative to the completeness of design. The ATL was especially effective and knowledgeable during the daily briefings with M&O management in completely expressing the importance of potential findings.

At the pre-audit meeting, the ATL emphasized that the practice of volunteering information by individuals other than the auditee should be discontinued. During previous audits of DOE and DOE participants, personnel other than the individual specifically being audited (escorts, for example) frequently volunteered information. This sometimes defeated the purpose of the audit

whereby the auditor, during the interview, attempts to determine a particular individual's knowledge of the QA requirements of the area being audited.

5.9 Summary of YMQAD Audit Findings

At the post-audit meeting, the ATL explained the areas of concern and the 15 preliminary CARs. The CARs are summarized as follows:

1. CAR YM-94-062 Errors and inconsistencies in design specifications, drawings, and calculations.
2. CAR YM-94-063 Design output documents (specifications) have been submitted for M&O technical baseline as approved documents. However, two required signatures were missing on 10 of 29 specifications.
3. CAR YM-94-064 The notes of one drawing specified that utility bracket attachments are non-QA controlled activities, but by so indicating them as non-QA, there was no application of quality requirements, nor any required inspection controls — even though a Q-listed item was being impacted.
4. CAR YM-94-065 No objective evidence existed for discipline (structural) checks for Design Package 2C in the areas of design analysis, specifications, and drawings for specific items. For both the specifications and drawings concerning the structural discipline, it was found that the design analyses had not been completed or checked. The check copy of the electrical cable tray support design analysis was not available for review to the auditors. The audit team was informed that it was not considered a QA record by the M&O and could, therefore, be discarded. The audit team is concerned that any OCRWM-related documentation that could substantiate the design process would be considered disposable.
5. CAR YM-94-066 Not all of the controls identified in the Test Interference Evaluations have been incorporated into the DIE. No evaluation has been performed to determine the test interference impacts resulting from not adhering to the controls specified.
6. CAR YM-94-067 The North Ramp DIE identified a functional transition zone between the North Ramp Tunnel, which is on the Q-list because of its importance to radiological safety, and the alcoves for ground support which had not been identified as "Q." The "TS North Ramp Alcove Ground Support Analysis" identified all alcove ground supports as "Q." Also the refuge chamber specification is not identified as "Q." However, it contains requirements for alcove ground support.
7. CAR YM-94-68 There was no objective evidence that the WIE comparing Drill and Blast with Mechanical Evacuation Techniques was prepared, reviewed, or approved in accordance with the specified implementing procedures.

8. CAR YM-94-69 The TBM proposal and operations/maintenance manual were used as design inputs and were not being controlled as specified by the QARD. Additionally, changes to the manual are not being controlled.
9. CAR YM-94-70 The M&O procedure, "Development of Waste Isolation Fluctuations," does not implement the QARD as written. The procedure allows use of unqualified data and computer codes without them being identified and tracked.
10. CAR YM-94-71 The BFD is to contain a traceability matrix of all the output documents. Two of the mechanical discipline documents were omitted from the BFD.
11. CAR YM-94-72 There is a lack of documentation which should describe the rationale for making assumptions and selecting data in the Structural Steel Sets Analysis for "rock raveling values" and for "rock conditions," as well as for selecting conservative seismic mean peak horizontal acceleration.
12. CAR YM-94-73 The design of the ESF starter tunnel was not validated in accordance with the QARD, yet it was used as input to the design of the Design Package 2C. There is no plan to use design validation data for making real time design modifications to the ground support system.
13. CAR YM-94-74 There was a lack of adequate flowdown and traceability of 10 CFR Part 60 requirements to the Exploratory Studies Facility Design Requirements (ESFDR) - that is, quantitative criteria were not provided through to the ESFDR to meet the requirements of 10 CFR 60.141(d) and inconsistencies between the ESFDR matrix and 10 CFR 60 are apparent.
14. CAR YM-94-75 The DIE and General Specifications require QA controls for implementing "standard mining practices," but they do not specify what these practices are, identify a specific mining standard that identifies these practices, or provide acceptance or testing criteria to confirm that the standard practices are met.
15. CAR YM-94-76 Contrary to the QARD requirement that acquired software be documented sufficiently to demonstrate the ability of the software to meet the needs of the affected organization, the WIE group is utilizing a software program which has not been verified or validated.