

NOV 1 1992

Mr. John P. Roberts, Acting Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Dear Mr. Roberts:

SUBJECT: OBSERVATION AUDIT OF THE YUCCA MOUNTAIN SITE CHARACTERIZATION
PROJECT OFFICE

I am transmitting the U.S. Nuclear Regulatory Commission Observation Audit Report No. 92-17 for the U.S. Department of Energy, Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD), Quality Assurance (QA) Audit No. YMP-92-24 of the Yucca Mountain Site Characterization Project Office (YMPO). This audit was conducted at Las Vegas, Nevada, and at the Nevada Test Site during September 28 through October 2, 1992. The audit scope included eight QA programmatic elements; it did not include any technical areas.

The NRC staff evaluated the YMQAD QA audit to gain confidence that YMQAD and YMPO are properly implementing the requirements of the OCRWM QA program. The NRC staff based its evaluation of the YMQAD audit process and the YMPO QA program on direct observations of the auditors; discussions with the audit team, YMPO, and YMPO contractor personnel; and review of the audit plan, audit checklists, and pertinent YMPO documents.

The NRC staff has determined that YMQAD Audit No. YMP-92-24 was useful and effective. Part of the audit included an in-depth review of the YMPO configuration management process reflecting the increased activity related to site work, the Exploratory Studies Facility design effort, and the corresponding technical and quality-related documents. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. 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 agrees with the preliminary YMQAD audit team findings that overall the YMPO QA program has adequate procedural controls in place and that implementation in the areas audited is satisfactory. The audit team did, however, point out the need for the YMPO to improve the configuration management process because this area was found to be marginally acceptable. Two of the programmatic elements were reviewed by the audit team but were not audited due to lack of implementation. Four preliminary Corrective Action

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Mr. John P. Roberts

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OCRWM should closely monitor YMPO QA program implementation to ensure that the deficiencies identified during this audit and earlier audits and surveillances are corrected in a timely manner and future implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess the YMPO QA program.

A written response to this letter or the enclosed report is not required. If you have any questions, please call Ken Hooks on (301) 504-2447.

Sincerely, */s/*

Joseph J. Holonich, Director
Repository Licensing and Quality Assurance
Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

- cc: R. Loux, State of Nevada
- T. J. Hickey, Nevada Legislative Committee
- C. Gertz, DOE/NV
- M. Murphy, Nye County, NV
- M. Baughman, Lincoln County, NV
- D. Bechtel, Clark County, NV
- D. Weigel, GAO
- P. Niedzielski-Eichner, Nye County, NV
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November 5, 1992

1.0 INTRODUCTION

During September 28 through October 2, 1992, the U.S. Nuclear Regulatory Commission staff observed the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Yucca Mountain Quality Assurance Division (YMQAD), Quality Assurance (QA) Audit No. YMP-92-24 of the Yucca Mountain Site Characterization Project Office (YMPO) at Las Vegas, Nevada, and at the Nevada Test Site. The audit scope included eight QA programmatic elements; it did not include any technical areas.

2.0 OBJECTIVES

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

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the YMPO QA program on direct observations of the auditors; discussions with the audit team, YMPO, and YMPO contractor personnel; and review of the audit plan, audit checklists, and pertinent YMPO documents. The staff has determined that YMQAD QA Audit No. YMP-92-24 was useful and effective. Part of the audit included an in-depth review of the YMPO configuration management process reflecting the increased activity related to site work, the Exploratory Studies Facility (ESF) design effort, and the corresponding technical and quality-related documents. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. 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 agrees with the preliminary YMQAD audit team findings that overall the YMPO QA program has adequate procedural controls in place and that implementation in the areas audited is satisfactory. The audit team did, however, point out the need for the YMPO to improve the configuration management process because this area was found to be marginally acceptable. Two of the programmatic elements were reviewed by the audit team but were not audited due to lack of implementation. Four preliminary Corrective Action Requests (CARs) were issued by the audit team, none of which are significant in terms of the overall YMPO QA program.

Additionally, the YMQAD audit team identified ten minor deficiencies requiring only remedial actions which were corrected during the audit. This timely resolution precluded the need for the audit team to write CARs for these deficiencies.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John W. Gilray	Observation Audit Team Leader	Center for Nuclear Waste Regulatory Analyses
Bruce Mabrito	Observer	

4.2 DOE

John Martin	Audit Team Leader (ATL)	Science Applications International Corp. (SAIC)
Robert H. Klemens	Auditor	SAIC
Amy Arceo	Auditor	SAIC
John R. Matras	Auditor	SAIC
Sam Horton	Auditor	SAIC
Tom Vandell	Auditor	MAC Technical Services Co.
Neil Cox	Auditor	SAIC
Donald Horton	Observer	OCRWM Headquarters

4.3 Clark County, Nevada

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

The audit was conducted in accordance with OCRWM QA Administrative Procedures (QAAPs) 18.2, "Audit Program," Revision 5, and 16.1, "Corrective Action," Revision 4. The NRC observation of the YMQAD 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 YMQAD audit was to determine whether the YMPO QA program meets the requirements imposed by the OCRWM QARD and to assess the extent and effectiveness of implementation of the program. The audit scope included eight programmatic elements; it did not include any technical areas.

(a) Programmatic Elements

The audit was based on the requirements in the OCRWM QARD and applicable documents pertaining to QA controls. The checklists covered QA program controls for QA Programmatic Elements 3.0, 4.0, 5.0, 6.0, 7.0, 15.0, 17.0 and 20.0 (which correspond to 10 CFR 50 Appendix B Criteria III, IV, V, VI, VII, XV, and XVII). Two of the eight programmatic elements (7.0 and 15.0) were reviewed by the audit team but were not audited due to lack of implementation.

(b) Technical Areas

No technical areas were included in the scope of this audit.

5.2 Timing of the Audit

YMPO activities associated with Programmatic Elements 3.0, 5.0, 6.0, 17.0, and 20.0 were last audited on October 28 through November 1, 1991, during YMQAD QA Audit No. YMP-91-I-01. The NRC staff believes the timing of this audit was appropriate to verify corrective actions from the previous audit and for the staff to evaluate the YMPO QA program.

5.3 Examination of Programmatic Elements

The audit checklists covered the QA program controls for the eight programmatic elements listed below:

- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Plans, Procedures, Instructions, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 15.0 Control of Nonconforming Items
- 17.0 Quality Assurance Records
- 20.0 Scientific Investigation Control

The NRC staff observed the audit team's evaluation of Programmatic Elements 3.0 and 17.0. Only those elements which were observed by the NRC staff will be discussed in this report.

(a) Programmatic Element 3.0 - Design Control

The audit of the Design Control programmatic element involved a detailed investigation by the auditor to cover the 104 separate items in the audit checklist. The auditor was persistent and conscientious in tracking down information and went beyond the audit checklist items when it appeared there might be a deficiency in other parts of the YMPO QA Program.

The YMPO Configuration Control Board Register was requested by the auditor and was utilized throughout the audit. There was an acceptable sampling inspection of documents which were in the YMPO Configuration Management System.

The following YMPO procedures were used as the basis for this portion of the audit: Quality Management Procedure 03-09, "Project Change Control Board Process"; Administrative Procedure (AP)-3.3Q, "Change Control Process"; AP-3.5Q, "Field Change Control Process"; AP-3.6Q, "Configuration Management"; AP-5.19Q, "Interface Control"; AP-5.20Q, "Hold Control"; and AP-5.24Q, "Preparation and Submittal of As-Built Drawings and Specifications." A total of 21 Change Requests, 22 Field

Change Requests (FCRs), 4 job packages (JPs), 7 Document Change Proposals, 6 project level documents, and 2 Interface Memorandums of Understanding were reviewed by the auditor. The auditor initially identified several nonconformances, however the audited organization took steps promptly to locate the required objective evidence or issued Intermediate Change Notices to procedures which corrected the nonconformances.

Based upon the observation of this audited QA program element, it was determined that the auditor conducted a detailed investigation of the design control criterion by asking appropriate questions, requesting sufficient objective evidence, and utilizing the audit checklist. Three preliminary CARs were written by the auditor concerning this program element. One identified a weakness in the tracking of to-be-determined data. This was contrary to the requirements of AP-3.6Q, Revision 1. The second CAR focused on the lack of control of as-built drawings and notification to the architect/engineer that such drawings had been accepted by the Configuration Control Board. This was contrary to the requirements of AP-5.24Q, Revision 0. The third CAR dealt with the lack of objective evidence to show that a technical evaluation was performed on a FCR. This was contrary to the requirements of AP-3.5Q, Revision 1.

The auditor also reviewed the overall hierarchy of design and technical requirements documents and identified those that affect controls and inputs to the ESF design. In this regard, four types of documents were identified: Exploratory Studies Facility Design Requirements, the Reference Information Base, the Technical Direction documents, and the DOE-accepted Architectural Engineering Basis for Design. Through discussions with the YMPO design organization, the auditor identified the applicable quality-related procedures which describe how the design and technical requirements documents are to be prepared and used. In general, the auditor concluded that there were sufficient documented "flow down" requirements to enable effective traceability of the ESF design outputs to documented upper tier YMPO design and technical requirements.

The audit of this programmatic element was effective, and the NRC staff agrees with the audit team finding that QA program implementation is generally acceptable.

(b) Programmatic Element 17.0 - Quality Assurance Records

During this portion of the audit, the auditor and observer reviewed records at the Nevada Test Site, Test Site Document and Records Center (which included a concrete and steel vault in the building which was acceptable for storage of QA records). The auditor interviewed the Job Package Records Coordinator and reviewed a list which identified a total of 19 JPs (of which 15 were approved and stored in the vault). The auditor selected three representative JPs (JP92-3, "Drilling of VSP Drillhole UZ-16"; JP92-5, "Midway Valley Investigations Phases I and II"; and JP92-12, "Quaternary Faulting Within the Site Area") and reviewed these documents in detail against the requirements of AP 6.22Q "Job

Package Completion and Records." Due to the incomplete status of the JPs, the auditor could not verify all of the Programmatic Element 17.0 audit checklist items.

The auditor found the JPs in compliance with the procedure, considering their incomplete status. In the interviews, the auditor always started the conversation by asking the individual to identify the procedures to which the person worked. This proved to be an excellent technique by which to start the interview process. There were no nonconformances identified by the auditor at the Test Site Document and Records Center.

An adequate sampling of the records at the YMPO offices was accomplished. The auditor identified illegible pages in one study plan and in one JP. A preliminary CAR was written concerning lack of legibility of several documents, a missing page in a document, and a draft document which was not stamped "draft".

The auditor worked in a professional manner, was competent and thorough, utilized the audit checklist effectively, and performed a useful and effective audit. The NRC staff agrees with the audit team finding that QA program implementation is acceptable.

5.4 Conduct of Audit

The audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA aspects of the YMPO program. The audit checklists included the important QA controls addressed in the QARD that were applicable to the YMPO program. In general, the team was persistent in its interviews and challenged responses when necessary. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between YMPO management and the ATL to discuss the potential findings. The auditors who identified concerns were included in these meetings to more clearly explain their concerns.

5.5 Qualification of Auditors

The qualifications of the QA auditors on this audit team have been reviewed by the NRC staff and found acceptable, meeting the requirements of OCRWM QAAP 18.1, "Qualification of Audit Personnel."

5.6 Audit Team Preparation

The QA auditors were well prepared in the area they were assigned to audit and knowledgeable of the QARD and implementing procedures. Audit plan YMP-92-24 was complete and included (1) the audit scope, (2) a list of audit team personnel, (3) a list of the audit activities, (4) the audit notification letter, (5) the past audit report, and (6) the audit checklists.

5.7 Audit Team Independence

The audit team members did not have prior responsibility for performing the activities they investigated. The audit team members had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence.

5.8 Summary of NRC Staff Findings

The NRC staff did not identify any observations relating to deficiencies in either the audit process or the YMPO QA program implementation. The staff noted that this was a particularly important and timely audit in that it was an in-depth review of the YMPO configuration management process reflecting the increased activity related to site work, the ESF design effort, and the corresponding technical and quality related documents.

5.9 Summary - YMOAD Audit Findings

The audit team identified 10 remedial deficiencies which were corrected during the audit and wrote 4 preliminary CARs against the YMPO program:

(a) Lack of document control tracking of to-be-determined data, contrary to AP 3.6Q, Revision 1. [See Section 5.3(a).]

(b) Lack of control of as-built drawings and notification to the architect/engineer that such drawings had been accepted by the Configuration Control Board, contrary to AP 5.24Q, Revision 0. [See Section 5.3(a).]

(c) Lack of objective evidence to show that a technical evaluation was performed on a FCR, contrary to AP 3.5Q, Revision 1. [See Section 5.3(a).]

(d) Record packages having illegible pages, contain draft material not properly stamped, and having missing pages, contrary to QARD Revision 3, Section 17.3, AP 1.18Q, Revision 1 and AP 1.10, Revision 5. [See Section 5.3(c).]

None of the deficiencies identified in these preliminary CARs is significant in terms of the overall YMPO QA program, since all can be corrected and steps taken to preclude recurrence.