U. S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 92-11

FOR THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AUDIT NO. YMP-92-15 OF YUCCA MOUNTAIN SITE

CHARACTERIZATION PROJECT OFFICE

John W. Gilray (by telecon)
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management

Reviewed and Approved by:

Kenneth R. Hooks

Repository Licensing and Quality Assurance Project Directorate

Division of High-Level Waste Management

1.0 INTRODUCTION

From May 4-7, 1992, the U.S. Nuclear Regulatory Commission staff observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) Quality Assurance (QA) Audit No. YMP-92-15 of the Yucca Mountain Site Characterization Project Office (YMPO) conducted in Las Vegas, Nevada. The audit was performed by auditors from the DOE/OQA Yucca Mountain Quality Assurance Division (YMQAD).

This report addresses the effectiveness of the DOE/OQA audit and the adequacy and effectiveness of implementation of QA controls in some programmatic areas of the YMPO QA program.

2.0 OBJECTIVES

The objective of the DOE/OQA audit was to evaluate the implementation and effectiveness of the YMPO QA program in meeting the applicable requirements of DOE/RW-0214, Quality Assurance Requirements Document (QARD) and associated implementing procedures. In addition, the audit served to follow-up on Corrective Action Request (CAR) YMP-92-007 identified during Audit No. YMP-91-I-01 which was held in October 1991. The NRC staff's objective was to gain confidence that DOE/OQA and YMPO are properly implementing the requirements of the OCRWM QA program in accordance with the QARD and Title 10, Code of Federal Regulations, Part 60 (10 CFR 60), Subpart G.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/OQA audit process and the YMPO QA program on direct observations of the auditors, discussions with the audit team and YMPO and contractor personnel, and reviews of pertinent audit information (e.g., audit plan, checklists, and YMPO documents).

The NRC staff observed only that portion of the audit dealing with procurement document control. In this area, the NRC staff agrees with the preliminary DOE/OQA audit team findings that the remedial and corrective actions associated with Corrective Action Request YM-92-007 are satisfactory, and no other activities associated with this area have taken place since the February 1992 audit. The audit team did not issue any preliminary Corrective Action Requests as a result of this audit.

The NRC staff determined that DOE/OQA QA Audit No. YMP-92-15 was useful and effective. 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 audit team did not include any technical specialists and no evaluation was made of the technical adequacy of work products.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John W. Gilray

Observer

4.2 DOE

Richard E. Powe	Audit Team Leader	Science Applications International Corp.
		(SAIC)
Sandra D. Bates	Auditor	SAIC
Neil D. Cox	Auditor	SAIC
Robert H. Klemens	Auditor	SAIC
Anthony E. Cocoros	Auditor	MAC Technical Services
		Co. (MACTEC)

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE/OQA audit was conducted in accordance with OCWRM Quality Assurance Administrative Procedures (QAAP) 18.2, "Audit Program," Revision 5, and 16.1, "Corrective Action Requests," Revision 4. The NRC staff observation of the DOE/OQA audit was based on the NRC procedure "Conduct of Observation Audits" issued October 6, 1989. NRC staff findings are classified in accordance with this procedure. NRC staff findings may also include weaknesses (actions or items which are not deficiencies, but could be improved), good practices (actions or items which enhance the QA program), and requests for information required to determine if an action or item is deficient. Written responses to weaknesses identified by the NRC staff will be requested when appropriate. In general, weaknesses and items related to requests for information will be examined by the NRC staff in future audits.

5.1 SCOPE OF AUDIT

The DOE/OQA audit scope was to determine whether the YMPO QA program meets the requirements and commitments imposed by the OCRWM QARD by verifying compliance with requirements and the extent and effectiveness of implementation of the program. Technical areas were audited for compliance to procedural controls only, since technical specialists were not included on the audit team.

(a) Programmatic Elements

The programmtic portion of the audit utilized checklists based on the requirements in the QARD and associated implementing procedures. The checklists covered QA program controls for seven criteria of Title 10, Code of Federal Regulations, Part 50, Appendix B.

(b) <u>Technical Areas</u>

Technical products were not evaluated during this audit.

5.2 TIMING OF THE AUDIT

The last full scope audit of all elements of the YMPO QA program was in November 1991, and a limited scope audit of the YMPO QA program was performed in February 1992. The NRC staff believes the timing of this audit, May 4-7, 1992, was appropriate.

5.3 EXAMINATION OF PROGRAMMATIC ELEMENTS

The audit checklists covered the QA program controls for the seven programmatic elements/criteria listed below.

- 1.0 Organization
- 2.0 Quality Assurance Program
- 4.0 Procurement Document Control
- 7.0 Control of Purchased Items and Services
- 11.0 Test Control
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action

The NRC staff observed the audit team's evaluation of the programmatic element dealing with procurement document control. Therefore, only this portion of the audit is discussed in detail below.

(a) <u>Procurement Document Control (Criterion 4)</u>

The auditors used an audit checklist to evaluate implementation of the requirements stated in YMPO Quality Management Procedure (QMP) 04-02 Rev. 0, Interim Change Notice (ICN) 1 (Criterion 4), and QMP-07-04 Rev. 1, ICNs 1 and 2.

The auditors also used the checklist to verify the status of CAR YMP-92-007 which was written as a result of the October, 1991, audit. CAR YMP-92-007 deals with the lack of an approved quality procedure which "...describes the procurement process for the preparation, review, approval and issuance of Management Agreements, Memoranda of Understanding or other similar documents such as guidance letters/technical letters which utilize existing open contracts maintained by the DOE Field Operations Offices to perform YMPO Project specific work."

Since the issuance of this CAR, the YMPO has developed a detailed procedure (QMP-04-03, "Technical Directives") describing the controls for preparing, issuing and revising technical directives to contractors The effective date for implementing this procedure was May 15, 1992.

In the interim, the YMPO was controlling technical directives through a detailed guidance letter dated November 22, 1991. This audit (YMP-92-15) included a review and evaluation of the 26 technical directive letters issued since November 22, 1991, using detailed checklists prepared from the controls addressed in the November 22, 1991, letter. The audit team determined that the technical directive letters were being prepared and controlled in accordance with the guidance letter. No adverse findings were identified. The audit team further concluded that the remedial and preventive actions taken to date are satisfactory and that the CAR YMP-92-007 can be closed after successful verification that QMP-04-03, "Technical Directives" has been effectively implemented.

The audit of Criterion 4 relative to evaluating the corrective procurement measures associated with CAR YMP-92-007, was conducted in a thorough and professional manner. The auditors did an effective job of examining the evidence associated with procurement document control and the status of CAR YMP-92-007.

The audit team determined that no procurement activities, other than those associated with the corrective actions for CAR YMP-92-007, have taken place since the audit in February 1992. The portion of the audit observed by the NRC staff was comprehensive and effective.

5.4 EXAMINATION OF TECHNICAL PRODUCTS

The NRC staff did not include any technical specialists on the NRC audit observation team since assessment of technical adequacy and qualification of technical products was not planned for this audit.

5.5 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 OCRWM QARD that are applicable to the YMPO program. The audit team used the checklists effectively during the interviews with YMPO and contractor personnel and review of documents. In general, the team was persistent in its interviews, challenging responses when necessary.

5.6 QUALIFICATION OF AUDITORS

The qualifications of the OCRWM auditors are acceptable based on certification in accordance with OCRWM QAAP 18.1.

5.7 AUDIT TEAM PREPARATION

The QA auditors were well prepared in the areas they were assigned to audit and knowledgeable of the OCRWM QARD and implementing procedures. Audit Plan YMP-92-15 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.

5.8 AUDIT TEAM INDEPENDENCE

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

5.9 REVIEW OF PREVIOUS FINDINGS

The YMPO response to CAR YMP-92-007 was reviewed during this audit and the audit team determined that remedial and preventive actions taken to date were satisfactory.

5.10 SUMMARY OF NRC STAFF FINDINGS

(a) Observations

The NRC staff did not identify any Observations relating to deficiencies in either the DOE/OQA audit process or the area of YMPO QA program implementation.

(b) Weaknesses

• The NRC staff did not identify any areas of weakness during this audit.

(c) Good Practices

The audit team was well prepared and was familiar with the QA program requirements.

5.11 SUMMARY - DOE/OQA AUDIT FINDINGS

At the formal exit briefing on May 7, 1992, the audit team identified no new CARs against the YMPO QA program in the areas audited. The DOE/OQA audit team determined that, in the areas audited, the YMPO QA program has adequate procedural controls in place and that implementation in those areas where there had been activity since the last audit was satisfactory.