U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 92-04

FOR THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT OFFICE

AUDIT NO. YMP-92-05 OF LAWRENCE LIVERMORE NATIONAL LABORATORY

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1.0 INTRODUCTION

From December 3-5, 1991, a member of the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management, Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance (QA) Audit No. YMP-92-05 of Lawrence Livermore National Laboratory (LLNL), which was conducted in Livermore, California.

This report addresses the effectiveness of the DOE/YMPO audit and the adequacy QA controls in six programmatic areas of the LLNL QA program.

2.0 OBJECTIVES

The objective of the DOE/YMPO audit was to evaluate the implementation and effectiveness of the LLNL QA program in meeting the applicable requirements of DOE/RW-0214, Quality Assurance Requirements Document (QARD), Rev. 3. The NRC staff's objective was to gain confidence that LLNL is properly implementing the requirements of their QA program in accordance with the QARD and Title 10 Code of Federal Regulations (10 CFR), Part 50, Appendix B.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/YMPO audit process and the LLNL QA program on direct observations of the auditors, discussions with the audit team and LLNL and contractor personnel, and reviews of pertinent audit information (e.g., audit plan checklists and LLNL documents). The NRC staff has determined that DOE/YMPO QA Audit No. YMP-92-05 was useful and effective for the limited amount of quality affecting work included in the scope of the audit. 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 their assignments and checklist items were adequately described in the audit plan. No technical activities were included in the scope of the audit, and the audit team did not include any technical specialists.

The NRC staff agrees with the preliminary DOE/YMPO audit team findings that the LLNL QA program has adequate procedural controls in place for the areas that were audited, and that program implementation is adequate for three of the six criteria audited (Criteria 1, 2 and 15). The audit team found implementation of one criteria marginally effective (Criteria 18), and the other two criteria were considered indeterminate due to a lack of quality affecting activities being conducted in these areas (Criteria 11 and 16).

DOE/YMPO should closely monitor the LLNL program to ensure that the one preliminary deficiency identified during this audit is corrected in a timely manner and future implementation is carried out in an effective manner. 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 LLNL QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

James T. Conway	Observer	

4.2 DOE

Richard L. Maudlin	Audit Team Leader (ATL)	MAC Technical Services Co. (MACTEC)
Richard L. Weeks	Auditor	Science Applications International Corp. (SAIC)
A. Edward Cocoros	Auditor	MACTEC
Mario R. Diaz	Auditor	DOE/YMPO

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE/YMPO audit was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program," Revision 4 and 16.1. "Corrective Action Requests," Revision 3.

The NRC staff observation of the DOE/YMPO 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. The 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/YMPO audit scope was to determine whether the LLNL QA program meets the requirements and commitments imposed by the OCRWM QARD and the LLNL QA Program Plan (QAPP) by verifying compliance with requirements and the extent and effectiveness of implementation of the program.

(a) Programmatic Elements

The programmatic portion of the audit utilized checklists based on the requirements in the QARD and LLNL's QAPP and other applicable documents. The checklists covered QA program controls for 6 of the 18 Title 10 Code of Federal Regulations (10 CFR) Part 50, Appendix B criteria (six of 18 QAPP sections), since this was one of DOE's limited scope audits (begun in fiscal year 1992).

(b) Technical Areas

Technical products from LLNL were not evaluated during this audit.

5.2 TIMING OF THE AUDIT

Although LLNL has performed little quality-affecting support activities for the YMP since the last audit in June 1991, the NRC staff believes the timing of this audit was appropriate in order to evaluate LLNL's capability to do so in the future.

5.3 EXAMINATION OF PROGRAMMATIC ELEMENTS

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

1.0 Organization
2.0 Quality Assurance Program
11.0 Test Control
15.0 Control of Nonconforming Items
16.0 Corrective Action
18.0 Audits

The NRC staff observed the audit team's evaluation of selected programmatic elements of the QAPP. Only those elements of the QA program which were observed (programmatic elements/criteria 1 and 18) will be addressed in detail in this report.

(a) Organization (Criterion 1)

The auditor used the published audit checklist which consisted of requirements from Procedure 033-YMP-QP 1.0 "Organization," Revision 1. The auditor interviewed the Yucca Mountain Project (YMP) Leader, Deputy Project Leader (DPL), Energy Program Assurance Manager, YMP Quality Assurance Manager (QAM), three Technical Area Leaders (TAL), and the YMP Administrator to verify his/her cognizance relative to functional duties and responsibilities. The auditor utilized the checklist requirements as the basis of his investigation and appeared to be thorough in his evaluation of the YMPO quality system.

It was verified that the YMP Leader has responsibility and authority for the overall management of the project. The DPL acts as the designee for the YMP Leader for assigned tasks. TALs are responsible for implementing the YMP QA program as it pertains to their specific technical areas. The YMP QAM has the responsibility, authority, and organizational freedom to assure that the QA program is established, executed, and maintained. The QAM is fully dedicated to QA activities and utilizes qualified contractor personnel when

work activities warrant additional staff. The YMP Administrator is responsible for records management and document control, training coordination, and action item tracking.

It was verified that the YMP leader communicates with the QAM regarding the effectiveness and adequacy of the YMP QA program via weekly staff meetings and the QA Action Item List which is issued weekly by the QA organization.

Based on the depth of questioning and satisfactory completion of the audit checklists, the auditor adequately reviewed and evaluated the LLNL organizational structure for compliance to the QARD and the QAPP. The audit of this area was effective, and Criterion 1 is adequately implemented. The audit team found Criterion 1 to be effectively implemented.

(b) Audits (Criterion 18)

The DOE auditors used their audit checklist as the basis for reviewing LLNL internal audit reports and discussions with LLNL QA organization personnel. The auditors were thorough in their interviews of LLNL personnel, use of the checklists, and in reviewing the objective evidence. The auditors looked at the LLNL audits, auditor qualifications, audit schedules, supplier audits, and management reviews of the audit findings.

Seven internal audits were performed since the last DOE audit of LLNL in June 1991. Each audit package contained a records package transmittal form, notification and audit plan, audit report, audit checklist, and an audit planning worksheet. On three of the reports, it was noted that several findings were identified as observations when they should have been documented as findings. Although the LLNL QA organization indicated that this situation existed because there were no quality-affecting activities ongoing for the areas that were audited, the audit team indicated that a CAR would be generated in this area.

The LLNL program of audits, as represented by the sample observed during this audit, appears to be well planned and implemented. The audit of this area was thorough and effective, and with the exception of the potential CAR, Criterion 18 is adequately implemented. The audit team categorized Criterion 18 as marginally effective due to the recurring deficiency identified in the potential CAR.

(c) Conclusions

The audit of the LLNL QA program effectively evaluated the degree of compliance to the LLNL QAPP and associated procedures for the limited amount of work included in the scope of this audit. The auditors utilized appropriate checklist questions and in-depth interviews to obtain the required information in evaluating the LLNL QA program.

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 part of the scope of this audit and the audit team did not include any technical specialists

5.5 CONDUCT OF AUDIT

The overall conduct of 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 LLNL program. The audit checklists included the important QA controls addressed in both the OCRWM QARD and the LLNL QAPP. The audit team used the comprehensive checklists effectively during the interviews with LLNL and contractor personnel and review of documents. In general, the team was persistent in its interviews, challenging responses when necessary. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between LLNL management and the ATL to discuss the potential findings. The auditors who identified findings were included in these meetings to more clearly explain the deficient conditions. The findings were well substantiated and reflected significant rather than trivial issues.

5.6 QUALIFICATION OF AUDITORS

The qualification records of the ATL and the three auditors on the team were previously reviewed by the NRC staff and were found acceptable in meeting the requirements of QMP-02-02, "Qualification of Quality Assurance Program Audit Personnel," Revision 2.

5.7 AUDIT TEAM PREPARATION

The QA auditors were well prepared in the areas they were assigned to audit and knowledgeable in the LLNL QAPP and implementing procedures. Overall, Audit Plan YMP-92-05 was complete and included: (1) the audit scope; (2) a list of audit team personnel; (3) a list of all the audit activities; (4) the audit notification letter; and (5) the QA checklists.

5.8 AUDIT TEAM INDEPENDENCE

The audit team members did not have prior 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 LLNL personnel.

5.9 REVIEW OF PREVIOUS FINDINGS

Responses to CARs YM-91-055 thru -062, which were identified in the June 1991 audit, were evaluated by a DOE/YMPO individual in November 1991. Acceptable corrective action was implemented for all the CARs with the exception of CAR YM-91-056 which was not closed and will remain open until the issuance of OCRWM's revised QARD.

5.10 SUMMARY OF NRC STAFF FINDINGS

(a) Observations

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

(b) Weaknesses

None were identified.

(c) Good Practices

The audit team was well prepared and familiar with the QA program requirements and relevant implementing procedures and conducted a thorough audit in a professional manner.

Personnel qualification records were well documented and adequate to facilitate reviews and audits.

There is a strong commitment and support for an effective QA program at the management level. Both the YMP Leader and the DPL have a good knowledge of the QA requirements and demonstrated a positive attitude toward an effective QA program.

LLNL staff and contractor personnel appear familiar with procedural and QA program requirements.

The efforts of LLNL management as well as the technical staff and contractor personnel facilitated the smooth and effective conduct of the audit.

5.11 SUMMARY - DOE/YMPO AUDIT FINDINGS

At the formal exit briefing on December 5, 1991, the audit team identified one potential CAR written against the LLNL QA program. In addition, during the audit, LLNL was able to resolve seven remedial deficiencies prior to the post-audit conference. The CAR issued to LLNL can be summarized as follows:

- Several audit reports identified a number of findings as "observations" when they should have been documented as CARs.