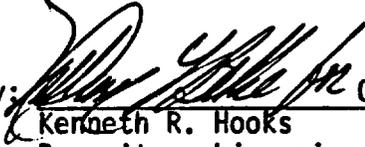


U. S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 91-8
FOR THE OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. 91-01 OF
LAWRENCE LIVERMORE NATIONAL LABORATORY


07/25/91
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07/29/91
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1.0 INTRODUCTION

From June 3-7, 1991, the U.S. Nuclear Regulatory Commission (NRC) staff observed the U.S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance (QA) Audit No. 91-01 of Lawrence Livermore National Laboratory (LLNL) conducted in Livermore, California. LLNL, a participant in the Yucca Mountain Site Characterization Project (YMP), is responsible for the development of a waste package which includes the definition of the package environment, waste package material development and testing, and waste package design, performance analysis, and testing. LLNL also provides assistance to other YMP participants in areas of specialized expertise.

This report addresses the effectiveness of the DOE/YMPO audit and, to a lesser extent, the adequacy of the LLNL QA program.

2.0 OBJECTIVES

The objectives of the DOE/YMPO audit were to evaluate the implementation and effectiveness of the LLNL QA program. The NRC staff's objective was to gain confidence that DOE and LLNL are properly implementing the requirements of their QA programs by evaluating the effectiveness of the DOE audit and determining whether the LLNL QA program is in accordance with the requirements of the DOE/Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD).

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 personnel, and reviews of pertinent audit information (e.g., the audit plan checklists, and LLNL documents). The NRC staff has determined that, overall, Audit No. 91-01 of LLNL achieved its purpose of determining the effectiveness of the LLNL QA program implementation for the areas that were audited. The audit was conducted in a professional manner. The audit team was well prepared, and their checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary DOE/YMPO audit team findings that the LLNL QA program was effectively implemented for the areas that were audited, considering the limited amount of work being conducted under the QA program, with the exception that Audits (Criterion 18) was not effectively implemented. However, LLNL should initiate timely corrective actions for the weaknesses identified by the DOE/YMPO audit team and NRC staff.

One Observation (Level 3) was noted by the NRC staff in the QA Program area (Criterion 2). Changes are being made to the NRC accepted LLNL QA Program Plan (QAPP) and are not being transmitted to the NRC staff. This subject has been discussed between DOE and NRC at several of the NRC/DOE QA meetings, and it was agreed that DOE would transmit all changes to the NRC accepted DOE QA programs to the NRC as an "information copy."

The NRC staff is also concerned about what appears to be inadequate communication of QA issues to the respective LLNL individuals and organizations as observed at the audit entrance meeting and in the calibration area.

DOE/YMPO should monitor the LLNL program to ensure that deficiencies identified during this audit are corrected 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 adequacy and effectiveness of the LLNL QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

| | | |
|------------------|----------|-------------------------------------------------|
| William Belke | Observer | |
| Robert D. Brient | Observer | Center for Nuclear Waste Regulatory Analyses |

4.2 DOE

| | | |
|---------------------|------------------------------|----------------------------------------------------|
| Frank J. Kratzinger | Audit Team Leader | Science Applications International Corp. (SAIC) |
| Amelia I. Arceo | Auditor | SAIC |
| James Blaylock | Auditor | DOE/YMPO |
| Edward A. Cocoros | Auditor | MAC Technical Services Co. |
| Neil D. Cox | Auditor | SAIC |
| Mario R. Diaz | Auditor | DOE/YMPO |
| Ken T. McFall | Auditor | SAIC |
| Richard L. Weeks | Auditor | SAIC |
| Richard E. Powe | Lead Technical Specialist | SAIC |
| David Stahl | Technical Specialist | SAIC |

4.3 State of Nevada

| | |
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| Susan Zimmerman | Observer |
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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, Revision 3, "Audit Program," and OCRWM QAAP 16.1, Revision 3, "Corrective Action Requests."

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 Observations are classified in accordance with the procedure guidelines. 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.

The NRC staff expects DOE to respond in writing to all Observations. 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 or surveillances.

5.1 SCOPE OF AUDIT

The audit scope was to determine the effectiveness of the LLNL QA program implementation.

(a) Programmatic Elements

The audit team utilized checklists developed from requirements in the Yucca Mountain Project Administrative Procedures (Quality) (AP-Qs), LLNL QAPP, and applicable implementing procedures. The checklists covered QA program controls for 14 of the Title 10 Code of Federal Regulations (10 CFR) Part 50 Appendix B criteria. The 14 criteria evaluated were 1, 2, 3, 4, 5, 6, 7, 8, 12, 13, 15, 16, 17, and 18. The remaining four criteria were examined to verify that LLNL was inactive in these areas since they were previously identified as not applicable to the LLNL scope of work. The NRC staff accepted this position and found the other fourteen programmatic elements addressing the 10 CFR Part 50 Appendix B criteria acceptable in its review of the LLNL QAPP (ref. Linehan/Stein letter dated October 4, 1989).

(b) Technical Areas

Although no NRC technical observers participated in this audit, the technical portion of the audit was observed to a limited extent while the programmatic evaluations took place. As explained in the discussion of Criterion 3, Scientific Investigation and Design Control (Section 5.3(c)), virtually no quality affecting technical products had been developed by LLNL in the technical areas audited since the previous audit. As a result, the technical portion concentrated on discussions with the technical staff to evaluate the first three of the review criteria identified in the audit plan:

1. Technical qualifications of scientific investigators.
2. Understanding of procedural requirements as they pertain to scientific investigation activities.
3. Adequacy of technical procedures.

The fourth review criterion, development and review of technical products, could not be sufficiently evaluated.

The interviews and objective evidence were sufficient to determine that QA controls were effectively implemented for the limited amount of quality-affecting technical work conducted in the following Work Breakdown Structure (WBS) areas;

- W.B.S. 1.2.2.3.1.1 Waste Form Testing - Spent Fuel
- W.B.S. 1.2.2.3.4.2 Thermodynamic Data Determination

The other two areas had insufficient activity to determine effectiveness:

- W.B.S. 1.2.1.4.5 Geochemical Modeling and Database Development
- W.B.S. 1.2.2.2.2 Hydrologic Properties of Waste Package Environment

5.2 TIMING OF THE AUDIT

Although LLNL has performed little quality-affecting support activities for the YMP since the last audit in 1990, 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 fourteen elements listed below.

- 1.0 Organization
- 2.0 Quality Assurance
- 3.0 Scientific Investigation and Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification & Control of Items, Samples, and Data
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage
- 15.0 Control of Non-Conforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

The NRC staff observed the DOE/YMPO audit team's evaluation of selected programmatic elements of the LLNL QAPP. Only portions of some elements were observed. Therefore, some programmatic deficiencies identified by the audit team were not observed by the NRC staff. Such deficiencies will not be discussed in detail in this report.

(a) Organization (Criterion 1)

Interviews were conducted by the DOE/YMPO auditors with the LLNL YMP Technical Project Officer (TPO), Associate Project Leader, Assistant Project Leaders, and support staff to obtain their description of the LLNL YMP activities and QA organization. These interviews were based on checklist questions derived from the LLNL QAPP, implementing procedures, Work Breakdown Structures, and Scientific Investigation Plans. As a result of the statements made during these interviews, a special meeting was requested with LLNL and DOE/YMPO staff by the NRC staff to determine the extent of ongoing work activities and how they related to the audit process.

The results of this meeting indicated that LLNL is involved in a substantive amount of technical work activities pertaining to the YMP. It was the NRC staff's understanding that these activities essentially are graded for QA and then designated as either "scoping" or "quality-affecting." Project activities designated as "quality-affecting" are subject to the QA audit process. Those project activities designated as "scoping" are not subject to the QA audit process although QA is applied with a graded approach. This appears somewhat confusing to the NRC staff since the data that is acquired from these scoping activities conducted may possibly be used for licensing purposes. The NRC staff commented that it may be beneficial for LLNL to consider subjecting scoping activities to the QA audit process to preclude having to repeat or requalify the data acquired from these activities for future application to the YMP.

The LLNL QA organization for the YMP consists of one full-time dedicated individual namely, the QA Manager. When conditions or work activities warrant additional staff, LLNL utilizes appropriately qualified contractor personnel. During this audit, the LLNL QA organization did not appear to be as involved and available as in past audits. This appeared to hinder and delay the auditing process. (See Section 5.5, Conduct of Audit).

For the limited amount of activity in this area, the auditors effectively reviewed and evaluated this criterion for compliance with the LLNL QAPP. The LLNL QA program under this criterion is adequate.

(b) Quality Assurance Program (Criterion 2)

The auditors examined over 40 personnel qualification records for compliance with the LLNL procedures. The qualification records were examined for education, experience, indoctrination and training, and personnel proficiency evaluation. The NRC staff was able to directly examine the files including those of the TPO and other management-type personnel. The files contained a computerized print-out of the training the individual received, the date completed, and whether the

individual was exempt from certain training. A signed statement by management verified the individual was suitably trained for a particular activity. Documentation attested to the annual management review of the individual's proficiency. Additionally, the personnel qualification files contained the individual's resume, detailed position description, and the security check validating the individual's education and prior employment. The LLNL personnel files were exceptionally well documented and organized in order to facilitate reviews and audits.

Two potential Corrective Action Requests (CARs) were identified by the DOE/YMPO auditors; one concerning the QA records for management assessment, the other concerning the recall system for the completion of training.

Section 2 of the LLNL QAPP requires that changes to the LLNL QAPP be submitted to the DOE/YMPO for approval. Changes to the LLNL QAPP are allowed to be issued without DOE approval for interim use provided they are marked as such. The NRC staff observed that this area of the LLNL QAPP was adequately implemented in accordance with the established procedural controls.

However, with respect to this area, the NRC staff identified an Observation (Level 3) concerning failure to submit QAPP changes to the NRC. In the QAPP section of the audit books distributed for this audit, the Table of Contents was noted as Revision 8 dated 3/28/91. The NRC staff accepted Revision 0 of the LLNL QAPP (ref. October 24, 1989 letter from J. Linehan to R. Stein). The QAPP section indicated 18 changes had been made to the LLNL QAPP since NRC had accepted this document. A review of NRC correspondence indicated that these changes have not been received by the NRC staff.

In the NRC staff acceptance letters for the DOE and DOE project participant QA plans, it was requested that DOE submit changes to NRC for review, evaluation, and acceptance if such changes downgrade the commitments that the NRC has previously accepted. This subject has also been discussed with DOE on several occasions at the NRC/DOE QA meetings. DOE agreed to send the NRC staff changes that downgrade the QA program for review, evaluation, and acceptance. Those changes that do not downgrade the QA plans (e.g., minor clarifications or editorial changes) would be sent to the NRC staff as an "information copy." This has not been done with the LLNL QAPP as exemplified by the numerous changes to the LLNL QAPP. This Observation will be carried as an open item on the NRC/DOE Open Items List.

Other than the aforementioned Observation, based on the satisfactory completion of the audit checklist, the auditors adequately reviewed and evaluated this criterion for compliance to the OCRWM QARD and LLNL QAPP. LLNL implementation of QA program requirements concerning personnel qualifications is adequate.

(c) Scientific Investigation and Design Control (Criterion 3)

The procedural audit of Criterion 3 was conducted, for the most part, simultaneously with the technical and software QA audits. The majority of the technical activities audited were found to be non-quality affecting, i.e., preliminary or scoping work. The Thermodynamic Data Determination task had on-going quality affecting work; one publication associated with this work was completed and was reviewed by the Technical Specialist. The other objective evidence reviewed consisted of review packages for Technical Implementing Procedures (TIPs) and for publications. The Technical Specialist obtained lists of documents for each of the four technical activities, and evaluated a sample of approximately 25%. Several laboratories were visited and scientific notebooks were reviewed, generally with very positive results. No peer reviews had been performed in the past year. No checklist items evaluated existing data qualification, which initiated an Audit Observation Inquiry. The reply indicated that current technical activities audited do not include data qualification within the scopes of work. The NRC staff found this reply acceptable.

The LLNL technical staff were knowledgeable of QA requirements and their responsibilities. To the extent that limited quality affecting activities had been conducted, the audit was effective and LLNL implementation appeared to be adequate.

Software Quality Assurance

The LLNL Software Quality Assurance (SQA) Plan has been in effect for several months; however, only two of the planned seven implementing procedures have been developed. During this portion of the audit observed, the auditor discussed the status of codes VTOUGH and EQ 3/6 with their respective investigators and developers. Both codes had been "frozen" and placed under configuration control since the last audit. Software documentation is being developed, but it is limited due to funding constraints.

The audit of this area was effective. Due to the lack of activity, implementation of the SQA Plan was indeterminate.

(d) Procurement Document Control and Control of Purchased Items and Services (Criteria 4 & 7)

LLNL Quality Procedures (QP) 4.0 and 4.1 implement the requirements of Criteria 4 and 7, consequently, the audit checklist likewise consolidated these criteria. Since the previous DOE/YMPO audit, four procurement documents had been initiated, three purchase orders for personal services for Peer Review services, and one for QA auditing services, all of which will be performed under the LLNL QA program.

The auditor reviewed documentation associated with all four of the procurement activities. No supplier qualification was involved since all activities were to be performed under the LLNL QA program. Criterion 4 was adequately implemented; however, the lack of activity in Criterion 7 precluded any determination of effectiveness. The audit of both criteria was effective.

(e) Document Control (Criteria 6)

The portion of the audit of this criterion observed by the NRC staff involved verification of proper document distribution. The auditor and auditor-in-training selected seven document recipients to determine that the correct documents and current revisions were issued. After identifying a single discrepancy between a distribution list and actual issuance, the sample size was increased to 12, with no other problems identified. The auditors utilized worksheets to facilitate recording the results of reviewing the large number of documents, which is considered good practice. The audit was effective and implementation of document controls appeared adequate.

(f) Identification & Control of Items, Samples, and Data (Criterion 8)

The auditor was able to review sample controls for uranium oxide tests (samples prepared from reagents), rock core samples (from the Sample Management Facility in Nevada), and metallic specimens. The application of these criteria was limited primarily to identification, since no special handling or storage needs had been identified by LLNL. To the extent that controls applied, Criterion 8 was adequately implemented. The audit of this criterion was effective.

(g) Control of Measuring and Test Equipment (Criterion 12)

To determine the adequacy of measuring and test equipment (M & TE), the auditor reviewed the calibration records for 14 of the 38 pieces of M & TE on the LLNL current M & TE Master Status List.

LLNL uses their onsite Electronics Services Group (ESG) and Engineering Management and Analysis Section (EMA) for calibration of electronic and mechanical equipment respectively. The EMA has been certified to perform calibrations while the ESG was noted as not being certified. In place of the ESG, LLNL utilizes two outside certified vendors (Simco and Tektronics) for electrical equipment calibrations. The onsite LLNL calibration service group and section are treated as vendors and are certified as such.

The EMA staff were knowledgeable and competent in the calibration procedures, equipment, and associated documentation requirements. The laboratory notebooks were found to be extremely well documented and the instruments were currently calibrated. On the second day of the audit, the NRC staff requested documentation verifying that the EMA, Simco, and Tektronics calibration facilities had been certified. Approximately one hour prior to the exit meeting, LLNL provided documentation to the NRC staff that verified the EMA, Simco, and

Tektronics calibration facilities had been certified. The NRC staff discovered in this documentation, that the ESG had also been approved and certified (ref. 4/19/91 letter from R. Hamati to L. Jardine). The NRC staff brought this to the attention of the auditor since it was understood, from the start of the audit, that the ESG was not certified and therefore, not included in the audit process.

The auditor and audit team leader indicated that the ESG would probably be recommended for a special surveillance in the near future. Based on the above, it appears to the NRC staff that there may be a problem in communicating important QA matters to involved individuals and organizations in a timely manner. The LLNL internal March 1990 QA audit of the ESG documented numerous audit findings and concluded that the QA program for the ESG was ineffective. In view of this conclusion, it would appear to the NRC staff that when the ESG was found acceptable, involved individuals would have been informed in a timely manner. Should DOE decide to perform a special surveillance of the ESG, the NRC staff believes this extra burden of resource expenditures could have been avoided if effective communication existed.

The NRC staff is concerned about the length of time it took for the LLNL QA organization to respond to the relatively straightforward Audit Observation Inquiry (3 days), the timing of the response (about 1 hour prior to the audit exit meeting), and the apparent lack of communication to alert LLNL personnel and the DOE/YMPO audit team that the ESG was now qualified to perform electronic calibrations. The audit and implementation of this criterion appeared marginal.

(h) Quality Assurance Records (Criterion 17)

A very limited portion of this criterion was observed. The auditors evaluated an adequate sample of records and used detailed checklists to complete this portion of the audit. The LLNL records personnel were familiar with the QA requirements and responsibilities.

The NRC staff noticed that the QA records were being stored in one-hour fire rated record file containers. The LLNL QAPP requires records to be stored in two-hour fire rated containers for alternate single record facilities. The NRC staff questioned the auditors and LLNL records personnel on why this condition exists and whether it had been found acceptable by DOE. The auditors and LLNL records personnel were aware of this condition which was documented during the August 6-9, 1990, DOE/YMPO surveillance. Standard Deficiency Report (SDR)

567 was issued which noted this as a surveillance finding. In response to the SDR, a letter was produced from the LLNL Fire Department which stated that in the event of an uncontrolled fire in the trailer in which the record containers were housed, the trailer would be completely consumed in 30 minutes and therefore, leave the one-hour record containers relatively undamaged. The SDR also referenced documentation for DOE to approve this alternative which was unavailable during this audit.

The NRC staff also questioned whether LLNL had obtained approval from DOE for exceptions pertaining to record protection against natural disasters such as winds, fires, or floods. The DOE auditors agreed to look into this matter and furnish the NRC staff with the information after completion of the audit. The information was furnished to the NRC staff the week following the LLNL audit, and the DOE auditors decided that insufficient information had been furnished by LLNL to effectively close SDR 567. Therefore, another CAR (replaces SDR) was issued to keep this item open. The audit of this criterion was effective and the implementation appeared to be adequate.

(i) Audits (Criterion 18)

From the observer's standpoint, this was the area for which the most QA implementation and activity had occurred. The auditors were extremely thorough and methodical 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 potential CARs were written as a result of the auditor's findings which included: (1) insufficient lead auditor qualification; (2) no procedure for implementing an Adverse Audit Finding Report resulting from an audit finding; (3) no objective evidence available for technical specialist training; (4) two criteria not audited during 1990; (5) audit observations should have been treated as audit findings; (6) audit reports not transmitted to management; and (7) the written exam for the lead auditor did not meet the LLNL QAPP requirements.

The DOE/YMPO auditors were well prepared, knowledgeable, and made good use of their checklists. An adequate evaluation was conducted in this area. The NRC staff observed that there was little interface from the LLNL QA organization until the last day of the audit. Based on the numerous potential CARs, the NRC agrees with the DOE/YMPO conclusion that LLNL implementation in this area is ineffective.

(j) 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 being conducted under the LLNL QA program. The auditors utilized appropriate checklist questions and in-depth interviews to obtain the required information in evaluating the LLNL QA program. The daily caucuses held by the audit team provided good interaction between the technical and programmatic auditors.

5.4 Examination Of Technical Products

The NRC staff did not include any technical specialists on the NRC audit observation team since there was minimal technical work selected and available for this audit. The NRC staff did not make a determination of the overall technical adequacy for the audit. (See Section 5.3(c))

5.5 Conduct of Audit

The auditors used detailed checklists and extended their investigations beyond the checklists when appropriate. The technical evaluations of the technical activities and the programmatic evaluations of Criterion 3 were conducted simultaneously, effectively integrating these two aspects of the audit. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between LLNL management and the Audit Team Leader to discuss the potential findings and comments. 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.

A difference between this and previous YMP audits observed by the NRC staff was the lack of a presentation by the auditee during the Pre-audit Conference. Previous auditees had used such presentations to familiarize the auditors and observers with the organization and activities, and to identify escorts and contacts for individual criteria and activities. Some delays were encountered during the audit in establishing contacts, which may have been avoided had individuals been identified. Up until the time of the audit exit conference, discussions were ongoing between LLNL and the audit team in efforts to resolve findings. These last minute deliberations might have been avoided had appropriate LLNL personnel, specifically the QA staff, been more active participants during the auditing investigations. The LLNL QA Manager and contractor support staff were notably absent during many of the auditing activities, including one TPO meeting. The NRC staff was not able to evaluate the capabilities of the LLNL QA organization due to the limited amount of contact during the audit.

5.6 Qualification of Auditors

The qualifications of the QA auditors on the team were previously accepted by the NRC staff (ref. NRC Observation Audit Report for USGS dated August 22, 1988) or were acceptable based on QMP-02-02, the DOE procedure for qualifying auditors. The technical specialists appeared knowledgeable of the LLNL QA program requirements.

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. The technical specialists were generally familiar with the technical activities of LLNL as described in the Work Breakdown Structures and Scientific Investigation Plans.

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 Audit Findings

- (a) Audit Plan 91-01 overall was complete and included: (1) the audit scope; (2) a list of audit team personnel and observers; (3) a list of all the audit activities; (4) the audit notification letter; (5) the LLNL QAPP, and past audit report; and (6) the programmatic and technical checklists. All seven SDRs (536 through 541 and 544) resulting from the May 1990 QA audit had been closed prior to this audit. Corrective actions were reported to NRC as being reviewed and found effective prior to this audit. During this audit, SDR 567 resulting from DOE Surveillance Report YMP-SR-035, had to be reissued as CAR YM-92-056 due to insufficient information furnished for closeout.
- (b) The NRC had no observations resulting from the May 1990, June 1989, or October 1988 audits.
- (c) Based on discussions between the State of Nevada and NRC observers, the State of Nevada observations from previous audits appeared to have been resolved prior to this audit.

5.10 Summary of NRC Staff Findings

(a) Observations

Since NRC accepted the LLNL QAPP (ref. October 24, 1988 letter from J. Linehan to R. Stein), several changes have been made to it. These changes have not been furnished to the NRC staff as previously agreed

to by DOE. NRC will carry this as an open item on the NRC/DOE Open Items List until satisfactory resolution (Level 3). (Refer to Section 5.3(b) for details).

(b) Weaknesses

- o A substantive amount of LLNL's activities appear to be conducted under a graded QA approach and designated as "scoping." These activities could produce data that may be used for licensing purposes but at present, are not subject to the QA auditing process. Should this data be used for licensing, it would have to be requalified. It may be beneficial for LLNL to consider subjecting "scoping" activities to the QA process to preclude having to repeat or requalify this data (Refer to Section 5.3(a)).
- o It is the NRC staff's evaluation that there is insufficient QA involvement in the LLNL YMP activities to effectively communicate QA issues to involved personnel. During the audit, it was understood that the ESG was not qualified to do electronic equipment calibrations and therefore, not included as part of this audit. Just prior to the conclusion of the audit, documentation was produced as a result of an NRC Audit Observation Inquiry indicating the ESG was qualified on April 19, 1991. Also, the QA organization did not appear to be as involved and available to the auditors as they normally have been in previous audits. (Refer to sections 5.3(a) and 5.3(g)).
- o At the entrance meeting prior to starting the audit, there was no presentation from LLNL staff to give an overview of the organization, ongoing work, and establish contacts for the auditors. (Refer to Section 5.5)
- o Corrective actions and closeout of all previously issued SDRs/CARs were supposedly verified prior to this audit. The NRC staff looked at only one of the previously closed out SDRs and noted the closeout of the corrective action was not entirely accurate. The NRC staff recommends that DOE/YMPO audit teams increase their attention to the closeout and corrective action aspects of prior SDRs/CARs.

(c) Good Practices

- o The EMA calibration facility was well developed and implemented in an effective manner. EMA personnel were knowledgeable and the laboratory notebooks were maintained in a neat, orderly manner.
- o Personnel qualification records were well documented and accurate to facilitate reviews and audits.

5.11 Summary - DOE/YMPO Audit Findings

The audit team identified 10 potential deficiencies which required corrective action during the audit and one after the audit. CARs were issued in the following areas:

| <u>PROGRAMMATIC ELEMENT</u> | <u>ADVERSE CONDITION (SUMMARY)</u> |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------|
| 2 | QA records for management assessment missing and/or not attached to package and also marked as a non-QA record; |
| 2 | Training and retraining times not being met; |
| 3 | Independent review of Site Investigations required by LLNL QAPP not in implementing procedure; |
| 17 | QA records stored in one-hour container instead of the two-hour container required by the LLNL QAPP; |
| 18 | No implementing procedure for Adverse Audit Finding Report; |
| 18 | Insufficient lead auditor qualification; |
| 18 | No objective evidence of a technical specialist being trained; |
| 18 | Audit reports not distributed to management; |
| 18 | Audit observations should have been audit findings; |
| 18 | Criteria 5 and 13 omitted from an internal audit of LLNL; and |
| 18 | Lead auditor examination did not meet LLNL QAPP requirements. |