

U. S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 90-3
FOR THE YUCCA MOUNTAIN PROJECT OFFICE
AUDIT NO. 90-02 OF LAWRENCE LIVERMORE NATIONAL LABORATORY

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1.0 INTRODUCTION

From May 14 through 18, 1990, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers on the U.S. Department of Energy (DOE)/Yucca Mountain Project Office (YMPO) Quality Assurance (QA) Audit No. 90-02 of Lawrence Livermore National Laboratory (LLNL), which was conducted in Livermore, California. LLNL, a participant in the Yucca Mountain Project (YMP), is responsible for the development of a waste package which includes the definition of the package environment, material development and testing, 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 objective of the DOE/YMPO audit was to determine the effectiveness of the LLNL QA program in meeting the applicable requirements of the Nevada Nuclear Waste Storage Investigations (NNWSI) Project Quality Assurance Plan NNWSI/88-9 Revision 4 (88-9 QA Plan) for the YMP. 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/YMPO audit and determining whether the LLNL QA program is in accordance with the requirements of the 88-9 QA Plan and 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 reviews of the pertinent audit information (e.g., audit plan, checklists, and LLNL documents). Due to the limited amount of YMP work being conducted by LLNL under the QA program, the NRC staff has determined that, overall, DOE/YMPO Audit No. 90-02 of LLNL was marginal in achieving its purpose of determining the effectiveness of the LLNL QA program. The audit was conducted in a professional manner, and the programmatic and technical portions of the audit were generally effective and well integrated. The audit team was well qualified in the QA and technical disciplines, and their assignment and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary finding of the audit team that LLNL has an adequate QA program for the areas that were audited; QA and technical personnel were trained and qualified; and the LLNL YMP QA program has sufficient controls in place to continue developing scientific

investigation plans, activity plans, and technical procedures. DOE must closely monitor the LLNL program to ensure that future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audit at a later date to determine the adequacy and effectiveness of the LLNL QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

James T. Conway	Observer
Kien C. Chang	Observer
Robert D. Brient	Observer (Center for Nuclear Waste Regulatory Analyses)

4.2 DOE

Gerald Heaney	Audit Team Leader	SAIC
Samuel C. Matthews	Lead Technical Specialist	SAIC
Amelia I. Arceo	Auditor	SAIC
Anthony E. Cocoros	Auditor	DOE/YMPO (MACTEC)
Sidney L. Crawford	Auditor	SAIC
Mario R. Diaz	Auditor	DOE/YMPO
Richard L. Maudlin	Auditor	DOE/YMPO (MACTEC)
John E. Shaler	Observer	SAIC
Robert Constable	Auditor-in-Training	DOE/YMPO
Richard Weeks	Auditor-in-Training	SAIC
Thomas Higgins	Auditor-in-Training	SAIC
Diane Harrison-Giesler	Auditor-in-Training	DOE/YMPO
James J. George	Auditor-in-Training	CER Corporation
David Stahl	Technical Specialist	SAIC
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5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE audit was conducted in accordance with procedures YMPO Quality Management Procedure (QMP) 18-01, "Audit System for the Waste Management Project Office," Revision 3, and YMPO QMP 16-03, "Standard Deficiency Reporting System," Revision 1. 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 following guidelines:

(a) Level 1

Failure of the audit team to independently identify either:

- Flaws in completed and accepted work important to safety or waste isolation which renders the work unuseable for its intended purpose. Denotes failure of the QA program to verify quality, or
- A breakdown in the QA program resulting in multiple examples of the same or similar significant deficiencies over an extended period of time in more than one work activity (technical area), or
- Multiple deficiencies of the same or similar significant deficiencies in a single work activity (technical area). Failure of the audit team to adequately assess a significant area of the QA program or its implementation, such as technical products, applicable 10 CFR Part 50, Appendix B criteria, or quality level classifications, without prior justification, such that the overall effectiveness of the QA program being audited is made indeterminate.

(b) Level 2

Failure of the audit team to independently identify an isolated significant deficiency.

(c) Level 3

Failure of the audit team to independently identify deficiencies that have minor significance, or failure of the audit team to follow applicable audit procedures.

Level 1, 2 and 3 NRC staff observations require a written response from DOE to be resolved.

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 or surveillances.

5.1 Scope of Audit

The audit scope was to verify that the LLNL QA program meets the requirements of the LLNL QA Program Plan (QAPP), Revision 3 dated December 20, 1989 and to verify the adequacy of implementation of the QA program. In addition, discrepancies identified during previous audits/surveillances that remain open were evaluated to determine whether LLNL had taken effective corrective actions (CAs).

(a) Programmatic Elements

The programmatic portion of the audit utilized checklists based on

the requirements in the 88-9 QA Plan, the YMPO Administrative Procedures (APs), the QAPP, and LLNL Quality Procedures (QPs). The checklists covered QA program controls for fourteen of the eighteen 10 CFR Part 50 Appendix B criteria.

Criteria IX, X, XI and XIV of 10 CFR Part 50, Appendix B (Sections 9.0, 10.0, 11.0 and 14.0 of the 88-9 QA Plan and the QAPP) were not included in the scope of the audit since LLNL currently is not performing activities in these areas. However, the NRC staff has accepted the eighteen programmatic elements addressing Appendix B criteria in their review of the QAPP (ref. Linehan/Stein letter dated June 19, 1989).

(b) Technical Areas

Three technical activities were selected by DOE/YMPO to be reviewed during the audit. The activities included Waste Package Performance Assessment, Waste Form, and Metal Barrier Selection and Testing (MBST). The technical checklists were developed from information contained in LLNL monthly Project Status Reports, Scientific Investigation Plans (SIPs), and Technical Procedures (TPs). The technical specialists were instructed to include the following areas in their evaluations:

- Technical qualifications of scientific personnel.
- Understanding of procedural requirements as they pertain to scientific investigation activities;
- Adequacy of technical procedures; and
- Development of SIPs, study plans, work supporting the Site Characterization Plan and any related work products.

The audit included the requirement to determine whether LLNL had taken effective corrective actions to resolve findings identified during previous DOE audits and surveillances.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate. LLNL had made a number of improvements in their QA program in the last year, and even though implementation was limited, it was beneficial to assess the adequacy of the improvements to date.

5.3 Examination of Programmatic Elements

The DOE/YMPO programmatic checklists covered the QA program controls for the fourteen elements listed below:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Scientific Investigation Control 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 and Control of Items, Samples and Data
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage
- 15.0 Control of Nonconformances
- 16.0 Corrective Action
- 17.0 Records
- 18.0 Audits

The NRC staff observed the audit team's evaluation of selected programmatic elements of the QAPP. Only portions of some elements were observed; the details of program deficiencies identified by the DOE/YMPO audit team members which were not part of the portion observed will not be discussed in this report.

(a) Organization (Criterion 1)

The DOE auditors utilized the published audit checklists and were thorough in reviewing objective evidence presented. The auditors utilized in-depth questioning and interviewed the LLNL YMP Leader and the LLNL YMP QA Manager to obtain their description of the LLNL organizational structure and the responsibilities of persons and organizations performing quality affecting activities. The QA organization currently consists of eleven personnel and five of these are contractor employees. Two of the contractor employees from Kaiser Engineers perform all the external audits of vendors.

Based on the depth of questioning and satisfactory completion of the audit checklists, the auditors adequately reviewed and evaluated the LLNL organizational structure for compliance to the 88-9 QA plan and the QAPP.

(b) Quality Assurance Program (Criterion 2)

The evaluation of personnel qualification, indoctrination and training included review of a significant number of qualification and training files and an interview with the QA Manager. The auditors were well prepared and utilized prepared tables for recording the results of record reviews. Some audit questions were not answered during interviews with the training and QA staff, and they had to be resolved by the LLNL YMP QA Manager.

It was noted that since December 1988 all readiness reviews were performed in accordance with YMPO AP 5.13Q per direction from the DOE/YMPO. LLNL QP 2.6 "Readiness Reviews" will be written to make it a line-management func-

tion and not a QA verification function, and future readiness reviews will be performed to this procedure. Only one peer review has been conducted in the area of MBST under the QA program to AP 5.13Q. The report "Selection Criteria for the Yucca Mountain Project Waste Package Container Material" was dated December 1988.

Procedure QP 2.5 "Acceptance of Data Not Generated Under the Control of the YMP QAPP" has not been implemented to date. The QA Manager indicated that a matrix of potential data that was not collected under an approved QA program was sent to DOE/YMPO in March 1989.

LLNL management assessments of QA program effectiveness are conducted on an annual basis. The last assessment was reported in May 1989. The 1990 assessment will be completed by July 1, 1990. The DOE/YMPO auditors indicated a surveillance of this activity may be scheduled. The effectiveness of the QA program is based on assessment of reviews of audit, nonconformance, surveillance, QA, and project reports and interviews with personnel.

Based on the extent of the checklist and depth of the evaluation, the audit of Criterion 2 appeared to be effective, and the implementation by LLNL appeared to be adequate.

(c) Scientific Investigation-Control (Criterion 3)

The observed auditing of Criterion 3 was conducted simultaneously with the technical audit of the MBST activities. Both involved interviews with the Task Leader and Principal Investigators, review of procedures, Activity Plans and records, and observation of laboratory areas. The Activity Plans that were reviewed included "Parametric Studies of Linear-Sweep Polarization to Determine Pitting Potentials, Metal Degradation and Microstructure: Measurement of Plane-Strain Fracture Toughness and Measurement of Threshold Stress Intensity for Stress Corrosion Cracking".

Material tests on the six candidate container materials (austenitic alloys 304L, 316L and Alloy 825 (high nickel); and copper based alloys CDA 102 (oxygen free copper), CDA 613 (Cu-7Al) and CDA 715 (Cu-30Ni)) are expected to resume by the end of this year. Tests will also be done on other potential candidate materials.

It was noted that the LLNL Software QA Plan had been approved by the DOE/YMPO. The Plan is applicable for the development and use of PANDORA (DOE's waste package performance code). LLNL is currently developing another document which will supersede all previous procedures for the implementation of the Software QA Plan. A Software Quality Manager, who is responsible for the computer codes, reports directly to the YMP Leader.

A potential deficiency was identified involving inconsistencies among planning documents and the actual intentions of the investigators.

LLNL technical staff appeared to be cognizant of QA program requirements and their responsibilities. The auditor and technical specialists utilized detailed checklists and were thorough in their investigations. Based on the depth of the programmatic and technical reviews, the audit of Criterion 3 and MBST activities was effective. In general, LLNL compliance appeared to be adequate.

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

The evaluation of these criteria included a review of procurement documents and interviews with LLNL Resource Management staff. Possibly due to budget cutbacks and the preliminary status of LLNL activities, very few Quality Level 1 or 2 procurements have been made.

The Resource Planning Control Manager generates a procurement package which contains a Procurement Document Review Form signed by the Task Leader, YMP Leader, and the QA Manager following their review and approval of the package. A qualified supplier's list (QSL) documented the evaluation and acceptance of seven suppliers.

It was noted that six candidate container materials for the MBST activity were purchased from William & Company, a material supplier, and subsequently machined into finished test coupons by Metcut Research Associates. Neither company was on the QSL, and the purchase orders (POs) were handled as "commercial items". There was no documented evidence that LLNL had upgraded (i.e., inspection, testing) the coupons for which the results of the tests will be used in Quality Level 1 MBST activities. This was identified as a potential deficiency relating to procurement and quality verification of test coupons.

Due to the limited number of records available for review, this part of the audit can be considered only marginally effective in evaluating implementation; however, auditors were thorough and LLNL controls appear adequate. LLNL staff seemed competent and cognizant of their QA programmatic responsibilities.

(e) Instructions Procedures, Plans and Drawings (Criterion 5) and Document Control (Criterion 6)

The NRC staff observed DOE's evaluation of these programmatic elements which require that activities affecting quality be performed in accordance with instructions, procedures, plans or drawings appropriate to the circumstances, and the documents should be controlled. The auditors used checklists which contained general requirements from the QAPP and specific requirements from the QA implementing procedures. The checklist questions were adequate to audit these criteria.

Based on a review of a number of SIPs and TPs, the auditors determined

that this portion of the program was satisfactory. The audit of these two criteria was thorough and effective, and the LLNL QA program appeared to be effective and properly implemented in these areas.

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

The calibration program at LLNL uses two calibration facilities, one for mechanical and the other for electrical equipment, located within the laboratory. The LLNL Electronic Services Group (ESG) and Engineering Measurements & Analysis (EMA) Section - are both treated as vendors by the LLNL YMP. The EMA Section is on the QSL since the LLNL YMP has approved the description of their QA program and implementing procedures and performed an audit of their activities. To date, ESG has not been approved by LLNL YMP, but ESG is currently generating a QA program description and procedures to meet the requirements of the LLNL YMP QA program. With regards to electrical equipment, ESG utilizes two outside calibration service vendors - SIMCO and Tektronics. Both these vendors have been surveyed and accepted by the QA organization of LLNL YMP.

A visit was made to the EMA facility and included a review of the calibration description document, procedures, and observation of the calibration laboratory. Two potential observations were made by the auditor involving a recall date error and a calibration performed by a vendor who had not been qualified under the LLNL YMP QA system.

The audit and LLNL implementation appeared to be effective based on the extent of the checklist and of the records reviewed.

(g) Control of Nonconforming Items (Criterion 15)

Evaluations included review of a significant portion of nonconformance records and interviews with the QA Manager and staff. The auditors initially identified some conditions as deficient; however, the Lead Auditor and the QA Manager were able to resolve the questions before completion of the audit. At first the auditors were provided with records that did not accurately reflect nonconformance status, and based their initial findings on the incorrect records. Apparently LLNL QA staff did not understand or were not aware of the records needed by the auditors.

Based on the results of the reviews and resolution of the misunderstandings, the audit was effective, but not particularly efficient. A possible weakness in the depth of the LLNL QA staff may be suggested by their inability to resolve the potential findings without intervention of the QA Manager. LLNL nonconformance controls appear to be adequate.

(h) Corrective Action (Criterion 16)

The QA program handles most CA through the nonconformance process includ-

ing responses and CA for audit findings. As a result, only two CA reports were generated in the last year or so. The auditors interviewed the QA Manager to come to an understanding of this somewhat uncommon approach.

Due to the very limited number of CA activities available to evaluate, the effectiveness of the audit of CA implementation was considered indeterminate.

(i) Records (Criterion 17)

The auditors reviewed the list of record packages for activities affecting quality and randomly selected specific packages for review of compliance to LLNL QP 17.0 "QA Records". The record packages were reviewed in detail for compliance to the required forms for transmittal and approvals.

The extent of questioning and the number of record packages reviewed allowed the auditors to conduct an effective evaluation of the processing of QA records. The LLNL QA program appeared to be effectively implemented in this area.

(j) Audits (Criterion 18)

The DOE auditors used their audit checklist as the basis for reviewing LLNL internal audit and surveillance reports and for discussions with LLNL QA organization personnel. The status of CAs and plans for future surveillances and audits were reviewed. It was noted that some observation items from previous audits were not monitored. This could cause QA problems if corrections addressing the problem areas are not made. There seems to be inconsistencies between DOE QA requirements and LLNL requirements on the need to follow up observation items. It was the understanding of LLNL QA record staff that recording of follow-up actions is not required for observation items.

The LLNL program of audits and surveillances, as represented by the sample observed during this audit, appears to be well planned and implemented and generally effective. The audit of this area was thorough and professional in nature, emphasizing the use of objective evidence to support statements made by LLNL QA personnel.

(k) Conclusions

The programmatic audit of the LLNL QA program evaluated the degree of compliance to the 88-9 QA Plan, the QAPP and applicable implementing procedures. The audit 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.

The audit of the elements observed was conducted in a professional manner;

however, the overall effectiveness of the audit was marginal due to the limited degree of implementation and limited technical activities and products available to evaluate. In general, the LLNL YMP QA program is adequate, and effective to the degree that it has been implemented.

5.4 Examination of Technical Products

The audit team technical specialists reviewed, to varying degrees, the technical areas listed below by Work Breakdown Structure (WBS) Number and title:

<u>WBS Number</u>	<u>Title</u>
1.2.1.4.2 Sub-activity (I-20-20a)	- Waste Package Performance Assessment Develop Scenario Identifications
1.2.2.3.1 Sub-activity (D-20-45)	- Waste Form Low-Temperature Oven Method for Spent Fuel Oxidation Testing
1.2.2.3.2 Sub-activities (E-20-15)	- Metal Barrier Selection and Testing Establishment of Selection Criteria
(E-20-18a)	- Use of Linear-Sweep Polarization to Determine Pitting Potentials
(E-20-18c)	- Parametric Studies of Metal Degradation and Microstructure: Measurement of Plane-Strain Fracture Toughness
(E-20-18d)	- Parametric Studies of Metal Degradation and Microstructure: Measurement of Threshold Stress Intensity for Stress Corrosion Cracking

The NRC staff reviewed copies of three SIPs, six Activity Plans, and twelve TPs prior to the start of the audit, with the understanding that these documents were used by the audit team technical specialists in their preparation for the audit. The NRC staff observed the audit team's evaluation of selected technical areas. QA auditors and technical specialists working together as a team were involved in the reviews observed by the NRC staff. Only portions of the examinations of some technical products were observed; the details of program deficiencies identified by the audit team members which were not part of the portion observed will not be discussed in this report.

Although formal testing has not started in each of the three technical areas, laboratory notebooks and test log books for the six sub-activities were examined by the audit team members. Selected portions of the contents in these books were discussed between the audit team members and LLNL technical personnel.

The technical portion of the audit was thorough and effective, and integration of the technical portion with the programmatic portion was good. The LLNL technical personnel were qualified and generally understood the QA requirements in their areas. The technical checklists were adequately prepared, and the questions pertained to important technical design issues. Specific questions were asked focusing on the design items important for site characterization or waste isolation.

5.5. Conduct of Audit

The overall conduct of the QA and technical portions of the LLNL audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA and technical aspects of the LLNL program. The audit checklists included the important QA controls addressed in the 88-9 QA Plan that are applicable to LLNL. The audit team used the comprehensive checklists effectively during the interviews with LLNL personnel and review of documents. In general, the team was persistent in their interviews, challenging certain LLNL responses when necessary. The integration of the technical and programmatic portions of the audit was effective.

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 YMPO procedure for qualifying auditors.

5.7 Audit Team Preparation

The QA auditors and technical specialists were well prepared in the areas they were assigned to audit and knowledgeable in the QAPP and LLNL implementing procedures. Audit Plan 90-02 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 QAPP, and past audit report; and (6) the QA and technical 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 appeared to have 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) No deficiencies were identified in the June 1989 QA audit. At the time of the audit, four Standard Deficiency Reports (SDRs) remained open from previous DOE/YMPO audits and surveillances of LLNL. CA for SDRs 38, 90, 479, and 480 was considered to be properly implemented by the audit team, and these SDRs will be closed.

- (b) The NRC had no observations resulting from the 1989 audit, and all NRC observations from previous audits were effectively resolved during the June 1989 audit.
- (c) Although the State of Nevada commented in writing on the June 1989 audit, they did not have any observations requiring resolution.

5.10 Summary of NRC Staff Findings

(a) Observations

- o The NRC staff did not identify any observations relating to deficiencies in either the DOE/YMPO audit process or the LLNL QA program.

(b) Weaknesses

- o The overall audit was marginal in achieving its purpose of determining the effectiveness of the LLNL QA program due to limited implementation of the QA program. Few programmatic records and technical products were available upon which audit conclusions could be based.
- o A large number of audit questions could only be resolved by the LLNL QA Manager, which may suggest a lack of delegation of activities by the QA Manager to his staff, or a lack of depth and experience in the LLNL QA organization.
- o LLNL administrative procedures do not address the resolution of comments for all reviewers of technical documents. The internal review procedures for this process appear to be questionable.
- o Although DOE has verbally agreed to evaluate earlier observations, the DOE audit procedure(s) does not explicitly require that previous NRC and State of Nevada findings be reviewed to determine the scope of the audit.
- o LLNL completed a Peer Review Report on "Selection Criteria for the Yucca Mountain Project Waste Package Container Material" in December 1988. To date, neither the report nor information on the peer review process has been made available to the NRC staff.
- o The YMP Leader noted that LLNL does not receive copies of the DOE/YMPO Audit Reports for other participant programs. Receipt of these reports would enable LLNL to be aware of and look for deficiencies common to other participant programs.

(c) Good Practices

- ° Improved performance in coordinating the QA programmatic and technical evaluations simultaneously to allow the integration of these two aspects of the audit.
- ° The audit team was well prepared and conducted a thorough audit in a professional manner.

5.11 Summary - DOE/YMPO Audit Team Findings

During the course of the audit, the audit team identified approximately 14 deficiencies in the LLNL QA program and prepared draft SDRs describing these deficiencies. In addition six observations and six recommendations were noted by the audit team. Seven of the potential SDRs remained unresolved at the time of the exit briefing on May 18, 1990. A summary statement of each of the seven deficiencies follows:

- (a) The establishment of minimum qualifications for Readiness Review Board (RRB) members was not clearly documented. In addition, there was no objective evidence that the RRB approved a required Review Record Memorandum.
- (b) Record packages for several approved and issued TPs and the Waste Form Scientific Investigation Plan could not be found within the Local Record Center.
- (c) POs were issued as commercial grade items without addressing QA requirements.
- (d) POs were issued with numerous differences in requirements from the related purchase requisitions.
- (e) APs and related TPs describing technical activities were inconsistent.
- (f) LLNL implementing procedures do not require follow-up for observations generated as a result of surveillances and audits.
- (g) LLNL CA implementing procedures do not include time limits for the evaluation of deficiency documents.