

U. S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT NO. 90-1  
FOR THE YUCCA MOUNTAIN PROJECT OFFICE  
AUDIT NO. 89-7 OF LOS ALAMOS NATIONAL LABORATORY

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## 1.0 INTRODUCTION

From November 13 through 17, 1989, 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. 89-7 of Los Alamos National Laboratory (LANL), which was conducted in Los Alamos, New Mexico. LANL, a participant in the Yucca Mountain Project (YMP), is responsible for nuclide migration, geochemistry, mineralogy, and petrology studies, and is the lead organization for the coordination and scheduling of the exploratory shaft testing program.

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

## 2.0 OBJECTIVES

The objective of the DOE/YMPO audit was to determine the effectiveness of the LANL QA program in meeting the applicable requirements of the Nevada Nuclear Waste Storage Investigations (NNWSI) Project Quality Assurance Plan NNWSI/88-9 Revision 2 (88-9 QA Plan) for the YMP. The NRC staff's objective was to gain confidence that DOE and LANL are properly implementing the requirements of their QA programs by evaluating the effectiveness of the DOE/YMPO audit and determining whether the LANL 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 LANL 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 LANL documents).

The NRC staff found that, overall, DOE/YMPO Audit No. 89-7 of LANL was effective. The programmatic portion of the audit was generally effective, but some of the technical portions of the audit were ineffective. Integration of the technical and programmatic portions of the audit was not as effective as in some recent DOE/YMPO audits.

In general, the NRC staff agrees with the preliminary DOE/YMPO audit team findings that the LANL QA program is inadequate in the areas of procedures, training, technical reviews, and audits and surveillances. The audit team identified approximately twenty potential deficiencies in the LANL QA program, of which twelve remained unresolved by the time of the exit meeting on November 17, 1989. Some of these deficiencies were further examples of deficiencies previously identified and thought to be corrected, which raises questions about the effectiveness of both the LANL corrective action program and the DOE surveillance program.

The extent and type of the deficiencies identified and the persistent problems in the LANL QA program are of concern to the NRC staff. DOE

must closely monitor the LANL program to ensure that future implementation is carried out in an acceptable 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 LANL QA program.

#### 4.0 AUDIT PARTICIPANTS

##### 4.1 NRC

Kenneth R. Hooks	Observer
Tilak R. Verma	Observer
John W. Bradbury	Observer
Jeffrey Pohle	Observer (Part Time)
Michael R. Gonzalez	Observer (Center for Nuclear Waste Regulatory Analyses)

##### 4.2 DOE

James Blaylock	Audit Manager	DOE/YMPO
Stephen R. Dana	Audit Team Leader	SAIC
Dean B. Eppler	Lead Technical Specialist	SAIC
Amelia I. Arceo	Auditor	SAIC
Joseph R. Caldwell	Observer	DOE/YMPO (MACTEC)
Paul L. Cloke	Technical Specialist	SAIC
Sidney L. Crawford	Auditor	SAIC
Mario R. Diaz	Auditor	DOE/YMPO
Janet A. Docka	Observer	DOE HQ (Weston)
Jane Hadden	Auditor-in-Training	DOE HQ.(KOH Systems)
Frank J. Kratzinger	Auditor	SAIC
W. R. (John) Marchand	Observer	DOE HQ (Weston)
Kenneth T. McFall	Auditor-in-Training	SAIC
Martha J. Mitchell	Observer	SAIC
Deborah Mogar	Audit Assistant	SAIC
Martha Pendelton	Observer	SAIC
Frederick J. Ruth	Auditor	SAIC
Carolyn Rutland	Technical Specialist	SAIC

##### 4.3. State of Nevada

Susan Zimmerman	Observer	
Maurice Morgenstein	Observer	Mifflin & Associates
Donald Shettel	Observer	Mifflin & Associates

#### 5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE audit was conducted in accordance with procedures WMPO QMP 18-01, "Audit System for the Waste Management Project Office," Revision 3, and

WMPO 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 Observations 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

During the audit entrance briefing the LANL personnel stated that all work for the YMP is being done as QA Level 1. The YMP work has been done under the LANL Quality Assurance Program Plan (QAPP), LANL-YMP-QAPP R4.4 since August 31, 1989; there are only minor changes between R4.4 and R4.3, which became effective February 10, 1989.

### (a) Programmatic Elements

The programmatic portion of the audit utilized checklists based on the requirements in the 88-9 QA Plan, the YMP Administrative Procedures (APs), LANL YMP QAPP R4.4 and LANL Quality Assurance 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 LANL-YMP-QAPP R4.4) were not included in the scope of the audit since LANL currently has no activities (i.e., engineered items) to which these criteria apply. The NRC staff has accepted this position and found the other fourteen programmatic elements addressing Appendix B criteria acceptable in their review of the LANL QAPP (ref. Linehan/Stein letter dated November 1, 1989).

### (b) Technical Areas

The technical areas selected to be reviewed during the audit included all in which there was any significant activity. The technical checklists were developed from information contained in LANL monthly Project Status Reports, LANL Detailed (technical) Procedures (DPs) and LANL Study Plans (SPs). The SPs reviewed as part of the basis for this audit are under review by DOE, but none had been released to the NRC.

The audit team technical specialists were instructed to review the following personnel and procedural-type elements common to all the technical (subject) areas:

- Technical qualifications of LANL Scientific Investigations and Design Personnel (technical staff);
- LANL technical staff understanding of technical and QA procedural requirements as they pertain to scientific investigation and design control activities;
- Adequacy of technical procedures; and

- Development of SPs and work supporting the Site Characterization Plan (SCP).

The audit plan did not include the requirement to determine whether LANL had taken effective corrective actions to resolve discrepancies identified during previous DOE audits and surveillances since all such deficiencies had been closed or were in the closure process, with the exception of software QA. However, as required by QMP-18-01, Rev. 3 the nature and frequency of previously identified deficiencies were considered in establishing the audit scope. The DOE/YMPO Audit Team Leader stated during the pre-audit briefing for the observers that NRC and State of Nevada findings from the previous DOE/YMPO audit of LANL (October 3 through October 7, 1988) and the NRC findings from the NRC audit of LANL (June 8 through June 12, 1987) were reviewed as input to the scope of this audit.

The LANL Software Quality Assurance Plan had not been approved by YMPO at the time of this audit so this area was not included in the scope of the audit. The YMPO program for QA Level Assignments was under revision, as discussed at the September 7, 1989 DOE/NRC bi-monthly QA Meeting, and this area was also excluded from the audit scope.

The scope of the audit was acceptable in that it appeared to cover all the 10 CFR Part 50, Appendix B criteria for which LANL had responsibility and in which there was any activity at the time, and the technical areas in which there was activity.

During the course of the audit, the NRC observers determined that sufficient work was being done on computer software that software QA should have been included in the scope of the audit. A LANL proposal that a stop work be issued against LANL/YMP software activity was issued immediately prior to the start of the audit and was being evaluated by LANL personnel (LANL memorandum H.P. Nunes to Distribution dated November 10, 1989, stop Work Order No. SW/LA-001, Re Software Quality Assurance Plan and Implementing Procedures).

## 5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was generally appropriate. LANL had taken a number of corrective actions to improve their QA program in the last twelve months, and 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 LANL QAPP. Only portions of the audits of some elements were observed; the identification of program deficiencies by the DOE/YMPO audit team members may not have been part of the portion observed and may not be discussed in this report.

(a) Organization (Criterion 1)

The LANL Yucca Mountain Project organization was discussed in detail during interviews conducted by the auditors with the LANL Technical Project Officer (TPO) and LANL QA Project Leader (QAPL). The technical and QA staff responsibilities were identified along with the required subcontractor interfaces. The information obtained during these discussions provided the necessary input to satisfy the respective audit checklist items.

The auditors' questioning and procedure reviews were conducted satisfactorily and provided sufficient information to adequately assess the organizational structure for compliance to the 88-9 QA Plan. Potential deficiencies were identified relative to the lack of written procedures to describe subcontractor interfaces and potential conflict of interest by the QA Liaison (QAL) assigned to the technical staff. QALs are assigned QA responsibilities, however, they report directly to the technical staff, who also evaluate the QALs performance.

(b) Quality Assurance Program (Criterion 2)

Interviews were conducted by the auditors with the Los Alamos Technical Associates (LATA) Project Manager, the LANL TPO, and the LANL QAPL to discuss the QA program activities and organization. LATA (subcontractor to LANL) handles the responsibility for implementing much of the LANL QA program, including such activities as audits, surveillances, nonconformance control, corrective action requests, etc.

A potential deficiency was identified as a result of formal management assessments not being conducted in 1988 and 1989. Consequently, required input for trending purposes was not available.

Another potential deficiency concerned position descriptions for project personnel which lacked adequate details of education and experience requirements and personnel records which contained improper verification of education and experience. As an example, the number of years credited for experience totaled higher than what was actually accounted for in one personnel file. Verification of education was not documented and authenticated but was based on assumption. The auditors' evaluation was performed in a satisfactory manner based on the level of questioning and the number of records reviewed.

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

The auditors had a good knowledge and understanding of the requirements documents and procedures utilized in preparing the audit checklist for auditing this criterion. The auditors followed their checklist and then asked follow-up questions. The programmatic auditors accompanied different technical specialists and assessed the adequacy and implementation of Criterion 3 for the following technical activities:

- (i) 8.3.1.3.2.2 - History of Mineralogic and Geochemical Alteration of Yucca Mountain
- (ii) 8.3.1.3.5.1 - Dissolved Species Concentration Limits
- (iii) 8.3.1.3.4.1 - Sorption
- (iv) 8.3.1.3.4.2 - Biological Sorption and Transport
- (v) 8.3.1.2.3.1 - Testing of C-Well Sites with Reactive Tracer

The auditors asked follow-up questions from the questions asked by the technical specialists. Scientific and laboratory notebooks were checked for procedural details and documentation of results for these technical activities. The audit team conducted a very effective assessment of the adequacy and implementation of this program element of the LANL QA program.

Several DPs and SPs reviewed by the NRC observers during the course of this portion of the audit did not have any substantial technical comments resulting from the internal LANL technical reviews that were done on these documents. The completion of technical reviews was indicated either by signature from the reviewer or by some editorial comments along with the signature. Several of the DPs were found to be technically inadequate by the DOE/YMPO audit team during this audit. In addition, documentation of external reviews of these DPs and SPs contained technical comments which appeared straightforward and subject to identification in the internal technical review.

(d) Instructions, Procedures, Plans, and Drawings (Criterion 5)

The auditors had a good knowledge and understanding of those LANL QPs which describe the requirements for writing DPs and SPs. It was apparent that the pertinent QPs controlling the development of

procedures had been reviewed prior to developing the audit checklists, based on the checklist questions regarding certain aspects of the procedures and the procedure development process.

A sample of QPs and DPs was reviewed to determine compliance with the requirements for developing procedures, especially regarding proper description and identification of acceptance criteria and QA records.

(e) Document Control (Criterion 6)

The auditors were well prepared, and used the audit checklist effectively in directing discussion with LANL and LATA personnel. QPs and record packages were reviewed, including controlled distribution lists for QPs and DPs. A sample of project manuals was reviewed for compliance with project procedures to replace/annotate obsolete procedures. The audit process and the LANL QA program appeared effective in this programmatic element, although a QA program deficiency concerning removal of obsolete procedures was identified by the auditors.

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

The auditors had a good knowledge and understanding of the requirements documents and procedures that were utilized in preparation of the audit checklist. The auditors seemed well prepared and utilized their audit checklist in an effective manner. Follow-up questions were asked to get a complete assessment of the adequacy and effectiveness of the LANL QA Program under Criterion 8. The programmatic specialists accompanied the technical specialists and assessed the adequacy and effectiveness of this criterion for the following technical activities:

- (i) 8.3.1.3.5.1 - Dissolved Species Concentration Limits
- (ii) 8.3.1.3.4.1 - Sorption
- (iii) 8.3.1.3.4.2 - Biological Sorption and Transport
- (iv) 8.3.1.3.2.2 - History of Mineralogic and Geochemical Alteration of Yucca Mountain

The auditors conducted a very effective assessment of the adequacy and implementation of the QA requirements under this program element of the LANL QA program. Several deficiencies were identified during the course of the audit.

(g) Control of Nonconformance (Criterion 15)

Records for nonconformance control were reviewed by the auditors to verify implementation of procedure requirements. The reports were selected by the auditors on a sampling basis. Discussions were also held with the LATA QA personnel responsible for these activities.

The records review and subsequent interviews identified weaknesses relative to proper identification of nonconformances, inadequate controls for Nonconformance Report (NCR) revisions, and insufficient information for NCR closeout. Procedures governing these activities were inadequate and contained significant voids in control of the process. Trending of NCRs had not been accomplished for the third quarter of calendar year (CY) 1989 although required by the trending procedure. The effective date for this procedure was June 1989. Lack of a procedure for revising NCRs and failure to trend NCRs were identified by the auditors as potential deficiencies.

The auditors were well prepared and thorough, and the audit of this programmatic element was effective.

(h) Corrective Action (Criterion 16)

The auditors made a very thorough and in-depth review of the corrective action system, in particular Corrective Action Reports (CARs) issued during 1989 and the requirements of administrative procedure TWS-QAS-QP-16.1, R.1. The auditors identified a number of areas in which the CARs were generally deficient, due at least in part to inadequate guidance in the governing procedures. A potential deficiency concerning the general inadequacies of the corrective action program was identified by the auditors.

(i) Records (Criterion 17)

The auditors were knowledgeable of the LANL QAPP and procedural requirements concerning records, and used the audit checklists effectively in guiding the discussion with LANL and LATA personnel. Record packages sent to files were reviewed in detail, questions were appropriate and followup was good. This portion of the audit was professional and effective. The LANL/LATA controls for records were generally adequate, and the personnel were knowledgeable and competent.

(j) Audits (Criterion 18)

Audits and surveillance reports were reviewed by the auditors to verify implementation of procedure requirements. The reports were selected by the auditors on a sampling basis. Discussions were also held with the LATA QA personnel responsible for these activities. The auditors conducted extensive interviews with both the LATA QA supervisors and the lead auditors to evaluate the LANL audit program. The questions and reviews of additional audit reports provided sufficient information to answer the checklist items.

The auditors identified weaknesses relative to performance and reporting of audits. The audit checklists reviewed were incomplete and did not indicate the status of the checklist items. The

checklists also lacked documentation of the objective evidence reviewed in reaching the audit conclusions. Based on the discussions held with the LATA QA auditing staff, there appeared to be a lack of appreciation of the merits of documenting objective evidence and identifying the status of the checklist items (i.e., satisfactory and unsatisfactory).

#### 5.4 Examination of Technical Products

The audit team technical specialists reviewed, to varying degrees, the technical areas listed below by SCP section number and title:

<u>SCP Section</u>	<u>Title</u>
8.3.1.3.2.1	Mineralogy, Petrology, and Chemistry of Transport Pathways
8.3.1.3.2.2	History of Mineralogic and Geochemical Alteration of Yucca Mountain
8.3.1.2.3.1	Characterization of the Site Saturated-Zone Ground Water Flow Study (Activity 7, Testing of C Well Sites with Reactive Tracer)
8.3.1.3.3.2	Kinetics and Thermodynamics of Mineral Evolution
8.3.1.3.4.1	Sorption
8.3.1.3.4.2	Biological Sorption and Transport
8.3.1.3.5.1	Dissolved Species Concentration Limits (Solubility Determination)
8.3.1.8.1.1	Probability of a Volcanic Eruption Penetrating the Repository
8.3.1.8.5.1	Characterization of Volcanic Features

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 some, but not all, of the reviews observed by the NRC staff. Only portions of the examinations of some technical products were observed; the identification of program deficiencies by the audit team members may not have been part of the portion observed and may not be discussed in this report.

##### (a) Mineralogy, Petrology, and Chemistry of Transport Pathways

The technical specialists reviewing this activity had obviously reviewed the SP, pertinent DPs and Project Status Reports (PSRs) in preparing for the audit. The audit checklist was used to guide discussion with the LANL technical personnel, and the technical specialists performed a limited review of some documentation.

No programmatic auditors were present during this portion of the audit, and the relationship of items to the QA program requirements was not explored in any depth by the technical specialists. Programmatic aspects of this technical area were reviewed by the

programmatic auditors after the technical specialists completed their review. Integration of the programmatic and technical portions of the audit for this activity was ineffective.

(b) History of Mineralogy and Geochemical Alteration of Yucca Mountain

The audit checklist was used by the technical specialists as the basis for discussions with LANL technical personnel. Efforts to qualify existing data were discussed; there did not appear to be much ongoing effort in this area.

The technical specialists were joined by auditors partway through this portion of the audit, and questions related to the application of Criterion 8 to this technical area were explored in detail. The remainder of this portion of the audit included review of SP internal review documentation, identification of acceptance/rejection criteria in DPs, and a review of physical storage and record keeping for samples.

(c) Testing of C-Well Sites with Reactive Tracer

The auditors reviewed some selected procedures in concert with certain work products (including lab notebooks). It should be noted that, in this instance, the selection of work activities and products available to be reviewed was limited due to the fact that the study plan is not final. All procedures are not yet completed and ongoing work is considered to be primarily "research and development".

There are six proposed procedures for field experiments (three procedures for single-well experiments and three procedures for multiple-well experiments) that are "to be determined." The LANL principal investigator (PI) indicated that LANL will essentially copy the United States Geological Survey (USGS) field procedures for the conservative tracer study whenever these procedures are available. Discussions centered primarily on the geochemical aspects of the laboratory investigations, although the technical specialists did ask general questions as to how the relationship between laboratory and field derived parameters could be established.

The technical specialists had only five checklist questions, none of which appeared technical. They left the interview shortly after asking their questions, which took less than one hour. No findings were identified by the technical specialists. The auditors continued their review, and the observers stayed another hour and questioned the investigators. The technical and programmatic aspects of this portion of the audit were not effectively integrated.

(d) Kinetics and Thermodynamics of Mineral Evolution

The technical checklist contained only four questions, of which two were programmatic. Discussions focused mainly on explaining

the technical basis of the study to the observers who had not seen the study plan. Lab notebooks were not reviewed by the technical specialists until later in the week. However, this technical activity has not gotten past the most preliminary stages, i.e., literature searches, laboratory set-up, etc. The technical auditors made no findings while the NRC observers were present.

(e) Sorption

The technical specialists were persistent in tracking down concerns; two separate sessions were needed to cover all of their concerns. The technical specialists reviewed the notebooks thoroughly to determine whether documentation was adequate to permit duplication of the work. The review appeared to be thorough and effective. It appeared the main function of the technical specialists was to determine that technical information was properly and legibly entered into lab notebooks, and to determine if qualified technical personnel could follow the logic of the notebook and duplicate the work. In this respect the audit was effective.

(f) Biological Sorption and Transport

The technical auditors utilized the study plan and the LANL monthly reports to develop their technical checklist for auditing this technical activity. The technical auditors seemed to have a good knowledge and understanding of the study plan, technical procedures and the status of this activity. The technical auditors also seemed knowledgeable on the QA requirements for the technical work conducted under this study. The PI and his technical staff seemed technically qualified and understood the QA requirements for doing their technical work. Several scientific and laboratory notebooks were reviewed and checked for technical data and procedural details. Two potential deficiencies were identified by the technical specialists. The audit of this technical activity was effective.

(g) Dissolved Species Concentration Limits

The technical audit checklist for this activity was developed in part from the LANL PSRs. The technical specialists had a good knowledge and understanding of the technical work being conducted under this activity. The LANL PI and his staff were questioned to ascertain the status of the SP and technical procedures for this activity. Several laboratory and scientific notebooks were reviewed for procedural details and data records.

The PI in responding to the technical specialists' questions indicated that it had been more than a year since he had seen the SP; therefore, the PI was not always certain about the contents of the SP for this activity. In one case, when the technical specialists asked a question regarding a particular technical procedure listed in the SP, the PI responded that LANL/YMP does not

use that particular procedure anymore. The technical specialists thought that it was a weakness that the SP was not kept up-to-date.

The PI and his staff seemed very well qualified and knowledgeable about their technical work. This portion of the audit was performed in a professional and comprehensive manner.

#### (h) Characterization of Volcanic Features

The technical specialists had only five checklist questions prepared for this technical area. The LANL PI stated that the audit was focusing on only a small portion of the study, a part which might not impact the results of the study. The PI recognized that the method was in the developmental stage, as "bugs" are still being ironed out. No findings were identified by the technical specialists. The audit process, limited to a one-hour discussion, was inadequate to evaluate the QA program aspects.

#### 5.5 Conduct of Audit

The audit team members were generally well prepared and most demonstrated a sound knowledge of the QA and technical aspects of the LANL program.

The audit checklists included the important QA controls addressed in the 88-9 QA Plan that are applicable to LANL. In general, the audit team used the checklists effectively in their interviews with LANL personnel and review of documents. Some of the technical portions of the audit were inadequate, and integration of the technical and programmatic portions of the audit was sometimes ineffective.

#### 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. In general, the technical specialists appeared knowledgeable in the technical areas which they reviewed, but not all appeared knowledgeable of the LANL QA Program requirements.

#### 5.7 Audit Team Preparation

The QA auditors were generally well prepared in the areas they were assigned to audit and knowledgeable in the LANL QAPP and implementing procedures. The technical specialists were familiar with the technical activities of the LANL personnel as described in the SPs and monthly PSRs. Audit Plan 89-7 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 LANL QAPP, and past audit report; and (6) the programmatic 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 had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence from LANL personnel.

## 5.9 Review of Previous Audit Findings

The NRC staff reviewed the status of the SDRs and NRC and State of Nevada observations from the October 3 through October 7, 1988 DOE/YMPO audit of LANL and the NRC findings from the June 8 through June 12, 1987 NRC audit of LANL.

### (a) SDRs from DOE/YMPO Audit of October 3 through October 7, 1988

The DOE/YMPO Audit 88-06 of the LANL QA program had eighteen SDRs. During the pre-audit briefing for the observers, the Audit Team Leader stated that all these SDRs were either closed, or in the closure cycle, with the exception of SDR No. 222 dealing with software QA.

### (b) NRC Staff Findings from DOE/YMPO Audit of October 3 through October 7, 1988

The NRC staff made five observations in the Observation Audit Report for DOE/YMPO Audit 88-06; all the observations concerned the activities of the DOE/YMPO audit team. Observation 1 requested that the basis for not including certain criteria of 10 CFR Part 50 Appendix B in the audit should be addressed in the audit plan. Although this was not done, the basis was discussed in the pre-audit briefing for the observers, and is directly deducible from the LANL QAPP. The other four observations were resolved by the performance of the audit team during Audit 89-7. Although none of the five observations had been formally resolved in writing by DOE at the time of this audit, the NRC staff considers them to be closed.

### (c) State of Nevada Observations from DOE/YMPO Audit of October 3 through October 7, 1988

The State of Nevada made nine observations concerning DOE/YMPO Audit 88-06. Three of these observations concerned the audit process, and appear to the NRC staff to be resolved by the performance of the audit team during Audit 89-7. Three of six State observations related to the Los Alamos QA program appear to the NRC staff to be resolved; the observations concerning inadequate training, difficulty in tracing data and ineffective use of the corrective action system do not appear to have been resolved.

(d) NRC Audit Findings from its 1987 Audit of LANL QA Program

The NRC audit of the LANL QA program performed June 8 through June 12, 1987 identified twenty-two concerns, of which seventeen were findings or deficiencies requiring resolution by DOE. These concerns were addressed by LANL in seventeen CARs; DOE reported in a letter from G. Appel to J. Linehan dated August 14, 1989 that all CARs had been closed by verification of corrective actions.

During the course of Audit 89-7, at the specific request of the NRC observers, the DOE/YMPO audit team reviewed those findings and deficiencies which could reasonably be incorporated in the scope of the audit to verify that the corrective actions taken by LANL were effective. Similar deficiencies were identified by audit team members in the areas of inadequate training records, acceptance/rejection criteria in procedures, and inadequate documentation of supplier surveys/evaluations.

5.10 Summary of NRC Staff Findings

(a) Observations

- No NRC staff observations relating to deficiencies in the audit process were identified. Apparent deficiencies in the LANL QA program identified by the NRC staff were also identified and presented as potential deficiencies or observations by the DOE/YMPO audit team.
- The NRC staff observed that the DOE surveillance process for verifying corrective actions resulting from previously identified deficiencies appears inadequate. Several corrective actions which were verified by DOE surveillances, solely on the basis of procedural changes and training, appear to have been ineffective in resolving the root causes of the deficiencies (Section 5.9(d)). If this finding had been against the audit process it would have been classified as a Level 1 or Level 2 Observation. The NRC staff recommends that DOE evaluate the results of the CY 1989 audits for reoccurrence of deficiencies assumed to have been corrected by the DOE contractor organization and DOE.

(b) Weaknesses

The NRC staff identified the following weaknesses in the audit process:

- Some portions of the technical audit were inadequate; in particular, there was insufficient probing for the data and documents forming the bases for the SPs and objective evidence of the use of DPs in the technical process. This may be indicative of inadequate training of some technical specialists in QA requirements and audit process (Sections 5.4(c) and (h)).

- The integration of the technical and procedural portions of the audit was highly variable, ranging from excellent to inadequate (Sections 5.3(c) and (d) and 5.4(a) and (c)).
- The technical portion of the audit appeared in some instances to be driven by schedule or some other external forcing function (Section 5.4(c)).
- The LANL SPs associated with the technical areas included in the audit scope were not available to the NRC or State of Nevada observers prior to the start of the audit.
- The NRC staff believes that software QA should have been included in the scope of the audit. Significant work was being done by LANL in computer analyses in support of the SPs, although the LANL software QA plan has not been approved by DOE (Section 5.1 (b)).

The NRC observers noted the following weaknesses in the LANL QA program which were not explicitly discussed by the Audit Team Leader in the exit meeting:

- The technical review process for documents such as DPs and SPs is inadequately documented to provide objective evidence of the adequacy of the reviews (Section 5.3(c)).
- LANL management assessments of the effective implementation of the LANL QA program are nonexistent (Section 5.3(b)) or inadequate, based on the number and type of deficiencies identified in this audit and the ineffectiveness of the LANL corrective action system.

#### 5.11 Summary - DOE/YMPO Audit Team Findings

During the course of the audit, the audit team identified approximately twenty deficiencies in the LANL QA program and prepared draft SDRs describing these deficiencies. Twelve of these potential SDRs remained unresolved at the time of the exit briefing on November 17, 1989. A summary statement of each of the twelve deficiencies follows:

- (a) The responsibility of subcontractors for interface control is not clearly defined by procedures.
- (b) A review of training records identified one individual who was certified to four QPs that have not been issued.
- (c) Some position descriptions do not adequately identify required indoctrination and training for the positions.
- (d) A review of personnel records identified two individuals who did not meet the minimum education requirements established in their position descriptions, and no justification or rationale was documented.

- (e) Some SPs were revised subsequent to completion of the technical review and were not re-reviewed.
- (f) Some DPs do not adequately address acceptance/rejection criteria for covered activities.
- (g) Obsolete/superseded revisions of procedures had not been removed from controlled copies of some manuals, or marked as superseded, as required by procedure.
- (h) NCRs have not been analyzed, as required, for trends adverse to quality.
- (i) NCRs have been revised without any procedural description of the revision criteria or process.
- (j) CARs are generally inadequate; the actions to be taken to prevent recurrence are not identified, the methods of verification of corrective action are not identified, the CARs have not been analyzed for trends adverse to quality.
- (k) The response to Audit Report No. 89-2 took 63, days and no CAR was issued.
- (l) LANL Audit Plans do not identify the organizations to be audited; many audit checklists are inadequate.

The potential deficiencies of the LANL QA Program implementation in the areas of adequacy of position description and the lack of trend analyses are similar to deficiencies identified in several other contractor programs during CY 1989, and may be generic deficiencies throughout the DOE contractor programs. The NRC staff recommends that DOE/YMPO evaluate the results of the CY 1989 audits for generic deficiencies, repeated failures of corrective action programs, and adverse program trends.