U. S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT

FOR THE

YUCCA MOUNTAIN PROJECT OFFICE

AUDIT NO. 88-08 OF

LOS ALAMOS NATIONAL LABORATORY

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NRC OBSERVATION REPORT OF DOE/YMPO AUDIT OF LANL (#88-08)

Summary

From October 3, 1988 through October 7, 1988 the Nuclear Regulatory Commission (NRC) staff participated as observers of the Department of Energy/Yucca Mountain Project Office (DOE/YMPO) audit (#88-08) of Los Alamos National Laboratory (LANL). The purpose of this observation was to evaluate the effectiveness of the YMPO audit and to determine whether DOE and its contractor are properly reviewing and implementing their quality assurance (QA) programs. The NRC staff based their conclusions on direct observations of the auditors, discussions with the audit team, and review of the pertinent audit information (e.g., the audit plan and checklist).

The staff has concluded that the overall audit was acceptable in that it resulted in identifying significant weaknesses in LANL's QA program. In particular, the LANL QA program lacked clear procedures of how to implement the QA program and lacked a well defined QA training program. As a consequence, the QA program was not being effectively implemented. The NRC staff believes that the deficiencies identified in this audit are of such a magnitude that a follow-up audit of LANL should be performed soon after they have corrected these deficiencies and have upgraded their QA program to meet the DOE/YMPO 88-9 requirements document. The NRC staff has identified some shortcomings in the audit process (noted in the report) that should be corrected in order to enhance the effectiveness of future audits.

1.0 Introduction

From October 3, 1988 through October 7, 1988 the Nuclear Regulatory Commission (NRC) staff participated as observers in the Department of Energy/Yucca Mountain Project Office (DOE/YMPO) quality assurance (QA) audit of Los Alamos National Laboratory (LANL). LANL is the prime contractor responsible for nuclide migration, geochemistry, mineralogy, and petrology studies. LANL also acts as the lead technical organization for the coordination and scheduling of the exploratory shaft testing program.

The DOE/YMPO audit (#88-08) was conducted at LANL, Los Alamos, New Mexico, to determine the effectiveness of LANL's QA program in meeting the requirements of NNWSI NVO-196-17, Revision 5 and to verify implementation of this QA program as it relates to the Yucca Mountain Project. The remainder of this report will address the adequacy of the DOE/YMPO audit (#88-08). The NRC staff's evaluation of the DOE/YMPO audit team is based on direct observations of the auditors, discussions with the audit team, and review of the audit plan, checklist and background material.

2.0 Scope and Purpose of NRC Staff Participation

The purpose of the staff observation was to evaluate the effectiveness of the YMPO audit and to determine whether DOE and its contractor are properly reviewing and implementing their QA programs in accordance with DOE requirements and 10 CFR Part 50, Appendix B. Observation audits enable the staff to provide recommendations to DOE on their audit program and the implementation of their contractor's QA programs. These observations of DOE/YMPO audits and the subsequent recommendations should assist DOE in meeting the NRC's QA requirements.

3.0 Audit Team Members

The DOE/YMPO audit team members, the NRC observers, and other observers are listed below.

NRC

John Bradbury	Observer	
James Donnelly	Observer	
John Gilray	Observer	
Thomas Trbovich	Observer	Center for Nuclear Waste Regulatory Analysis, San Antonio, Texas

DOE

William Camp	Audit Team Leader	SAIC, Las Vegas, Nevada
Wendell Mansel	Lead Auditor	SAIC, Las Vegas, Nevada
Mae Cotter	Auditor	SAIC, Las Vegas, Nevada
John Friend	Auditor	SAIC, Las Vegas, Nevada
Fredrick Ruth	Auditor	SAIC, Las Vegas, Nevada

James Ulseth	Auditor	SAIC, Las Vegas, Nevada
Everett Bryant	Auditor	SAIC, Las Vegas, Nevada
Catherine Hampton	Auditor Trainee	YMP, Las Vegas, Nevada
Dean Eppler	Lead Technical Specialist	SAIC, Las Vegas, Nevada
Duane Chesnut	Technical Specialist	SAIC, Las Vegas, Nevada
Paul Cloke	Technical Specialist	SAIC, Las Vegas, Nevada
Steven Mattson	Technical Specialist	SAIC, Las Vegas, Nevada
Carolyn Rutland	Technical Specialist	SAIC, Las Vegas, Nevada
Keith Schwartztrauber	Technical Specialist	SAIC, Las Vegas, Neveda
Royce Monks	Observer	YMP, Las Vegas, Nevada
Robert Waters	Observer	YMP, Las Vegas, Nevada
Roxanne Edwards	Observer	YMP, Las Vegas, Nevada
Jay Jones	Observer	OCRWM, Washington, DC
Kathleen Mihm	Observer	OCRWM, Washington, DC
Karl Sommer	Observer	OCRWM, Washington, DC

State Observers

Susan Zimmerman	Observer	State of Nevada, Reno, Nevada
Frank Dickson	Observer	State of Nevada, Reno, Nevada
Maurice Morganstein	Observer	State of Nevada, Reno, Nevada

4.0 Staff Observations

As observers, the NRC staff evaluated the effectiveness of the audit and audit team. The audit areas that were observed and evaluated included:

(1) scope of the audit;
(2) timing of the audit;
(3) technical products;
(4) conduct of the audit;
(5) qualification of the auditors;
(6) audit team preparation
(7) conduct of meetings; and
(8) team coordination

4.1 Scope of Audit

The NRC staff noted that the audit plan did not address the following 10 CFR Part 50, Appendix B criteria:

9.0 Control of Special Processes
10.0 Inspection
11.0 Test Control
14.0 Inspection, Test and Operating Status

When this concern was brought to the attention of the audit team leader it was explained by the audit team that these particular criteria are not applicable to LANL's scientific investigative work. Indirectly, these controls are addressed in other sections of LANL's QA program, particularly in Section 3 which pertains to scientific investigations. This policy has been previously discussed with the NRC and found acceptable. It is recommended however, that when an Appendix B criteria is not included in the audit that the audit plan specifically identify this and describe the rationale for not including the criteria in the scope of the audit.

4.2 Timing of Audit

DOE/YMPO's last audit of LANL was conducted on March 30 through April 3, 1987. As a result of the increased level of QA and technical activities at LANL and as a result of the preliminary findings from this 88-08 audit, the staff believes that this audit was essential. However, based on the number of problems identified by the audit team and the LANL QA organization, DOE/YMPO should have either increased the frequency of their audits or instituted a more effective surveillance program of the ongoing LANL QA and technical activities in order to identify and correct problems in a more timely manner.

4.3 Technical Products

The NRC technical staff witnessed portions of the audit in the following technical areas:

1) Hydrothermal Geochemistry 86/4.1.3-HG, Rev. 0
2) Biological Sorption Transport 86/4.1.5-MB, Rev. 1
3) Sorption 86/4.1.5-SP, Rev. 0
4) Solubility Determination 86/4.1.4, Rev. 0
5) Dynamic Transport Process 86/4.1.6-DTP, Rev. 0
6) Retardation Sensitivity Analysis 86/4.1.7, Rev. 0
7) Reactive Tracer Testing 86/4.1.1/C-Wells, Rev. 0

Due to the scheduling of the audit interviews concurrently, the NRC staff was not able to witness all of the technical discussions (checklist questions and responses). The NRC technical staff selected which interviews to observe based on 1) the possible significance of the area to repository performance or site characterization, 2) the familiarity of the observer with the auditor (as from previous audits), and 3) the familiarity of the observer with the technical area. The areas tracked extensively by the NRC staff were Dynamic Transport Process, Solubility Determination, and Sorption. Portions of Reactive Tracer Testing and Biological Sorption Transport interviews were observed. The interviews for Hydrothermal Geochemistry and Retardation Sensitivity Analysis were not observed.

The choice of the technical areas audited was appropriate. These technical areas are key to some of the geochemical aspects of site characterization and performance assessment. The rest of the key geochemical areas were audited in 1987.

Objectives for the technical phase of the quality assurance audit were included as part of the audit notebook. A list of questions (Appendix A) were provided to serve as a basis for the checklist questions. Not all of the objectives of the audit were met. For example, the question "Were the procedures in place technically adequate for the intended application?" was not addressed. Sorption ratios from batch experiments were not shown in this audit to be adequate for modeling the repository. Another question not addressed was "Were there sufficient technical procedures for the activity under review?" The checklist questions referred to existing procedures, not all of the alternative procedures that might be considered to characterize the site. The types of questions in Appendix A are better addressed in a peer review and not a QA Audit. The scope of the audit would be too large if these questions were considered.

The review of technical products by the DOE technical auditors was adequate. Questions from the checklist provided a basis for discussion. However, the technical auditors sometimes expanded the questioning when appropriate to determine how the activity fit into the overall site characterization program.

It was noted by the DOE technical auditors that the technical products (milestones) from certain activities are not so detailed as to allow one to track results back to specific experiments on specific samples. These details are contained in laboratory notebooks.

The auditors were thorough in their review of laboratory notebooks. They spent considerable time tracing results back through the notebooks. They noted that, in some isolated cases, portions of some laboratory notebooks were illegible. However, for the most part, laboratory notebooks were immaculate.

The DOE technical audit team members were generally prepared as indicated by the substance of some of the checklist questions and the discussions they held with the principle investigators. One exception, however, was their failure to consider the information form the NRC "mini" audit in June 1987. (Also discussed in Section 4.6.) The "mini" audit reviewed some of the same detailed procedures as contained in this audit. It was found in the "mini" audit that the detailed procedures did not contain a section on acceptance criteria as required in the LANL QA Program. The NRC technical observer did not hear any discussion of this finding by the technical auditors at this DOE audit.

The audit team appeared well-coordinated and improved through the course of the audit. For example, it was noted by the DOE programmatic auditors that J-13 groundwater had been supplied over a number of years to LANL in 55 gallon drums. Five drums had been used since the beginning of the sorption/solubility work. However, the information in the laboratory notebooks did not specify from which drum water was taken. The technical auditors looked into this possible area of concern. Discussion in the caucus concerned the effect on quality if the drums were not differentiated. Various points of view were presented and a decision was made concerning the action to be taken by the audit team.

4.4 Conduct of the Audit

Based on an overall evaluation by the NRC staff of the performance of the DOE/YMPO audit team, the NRC staff concludes that the conduct of the audit was effective and acceptable with the exception of some select areas of weakness. Both the QA and technical audit team members demonstrated the necessary skills in their investigations and evaluations of LANL's activities and QA documentation associated with the Yucca Mountain Project. As a result of this effort, numerous QA programmatic and several technical deficiencies were identified along with an effectiveness statement provided for each area audited. Of particular interest was the constructive and productive dialogue and interchange of audit findings, concerns and information that was exhibited between the QA and technical audit team members during the daily audit caucuses. Furthermore, when it appeared that the LANL staff was imposing constraints on the audit scope during the early stages of the audit, the DOE/YMPO audit team leader, through discussions with the LANL Technical Project Officer (TPO), was successful in getting a clear policy statement to members of the LANL staff that the DOE/YMPO audit teams have the freedom to audit any areas of activity pertaining to the Yucca Mountain Project. This action improved the cooperation of the LANL staff.

The staff observed in one instance that an auditor did not adequately follow-up a concern when it was observed by the staff that one of the LANL employees apparently lacked basic knowledge of their own QA manual. The NRC staff is concerned since this individual is one of the more experienced QA professionals for the LANL/YMPO and should have been thoroughly familiar with the QA manual which they developed. In this specific instance, the auditor was unaware of the apparent lack of knowledge. The NRC staff informed the audit team of this concern and noted that this problem could be an indication of other more serious problems (i.e., inadequate staff numbers, lack of or poor training, etc.) The NRC staff recommends that when such instances are encountered, that appropriate follow-up action be taken to determine if corrective action is necessary and if such concerns are symptoms of a much larger problem.

Other areas of weakness are addressed in section 4.2.1, 4.2.2, 4.2.5, and 4.2.7 of this report. Again these weaknesses should not overshadow the overall success and effectiveness of the audit but are addressed in order that corrective measures may take place to enhance the overall audit process.

4.5 Qualification of the Auditors

As part of its effort to more efficiently observe the DOE audit program, the staff has conducted a review of the SAIC QA auditors who could be used on DOE/YMPO audit teams and the procedure used to qualify them. The results of this review are contained in the staff observation report covering the DOE/YMPO audit of the U.S. Geological Survey (John J. Linehan (NRC) letter to Ralph Stein (DOE) dated August 22, 1988). Based on this review, the staff concluded that the DOE/YMPO QA auditors available for audits were acceptably qualified to perform QA audits. In addition, as a result of its review of QMP-02-02, "Qualification of Quality Assurance Program Audit Personnel," the staff concluded any new auditors qualified using this procedure would also be acceptable. Since the qualifications of the auditors on the team were reviewed by the staff or were qualified using QMP-02-02, the staff finds the team qualified.

The qualifications of the technical auditors were reviewed by the NRC technical observer. Those qualifications were found to be adequate for the technical areas audited. All technical auditors had PhDs in related fields and experience ranging from 3 to 30 years.

4.6 Audit Team Preparation

In general, the staff believes that although the audit team was prepared for the audit, there were areas where the team could have exhibited better preparation. The audit team was familiar with the YMPO and LANL requirements documents, had prepared an audit plan, and followed their implementing procedure QMP-18-01 in conducting audits. The audit team did not, however, insist on obtaining the LANL QA program implementing procedures for review prior to conducting the audit. LANL's rationale for not wanting to send these procedures to the audit team was that the procedures were being revised to meet the YMPO 88-09 QA requirements document. Consequently, the audit team was not familiar with the QA program implementing procedures and some audit time had to be directed to the review of these procedures while at Los Alamos. In addition, the checklists were therefore prepared against the LANL QA Program Plan during the pre-planning phase rather than against the QA program implementing procedures. As a result, some of the QA programmatic checklist questions were superficial in nature. The staff believes the audit could have been more effective if the QA program implementing procedures were available to the audit team during the preparation stage of the audit.

Also, the staff believes that insufficient attention was given to the audit findings identified by NRC in their June 1987 audit of LANL. The NRC's audit report could have been a useful aid in assisting the audit team in identifying previous weaknesses in LANL's QA program which could be reaudited to determine the extent of effective corrective action. Through discussions with the audit team members, it was apparent that some of them were not aware of the NRC audit report. For future audits, the NRC staff recommends that information of this type. be utilized by the audit team to enhance the overall effectiveness of the audit.

4.7 Conduct of Meetings

The overall conduct of the preaudit and postaudit conference by the audit team was acceptable. During the preaudit conference, the scope of the audit was clearly defined, requirements documents were identified, and questions or comments were encouraged. At the postaudit conference, the deficiencies were explained well and the LANL personnel were given the opportunity to respond. Likewise, the observers were afforded the opportunity to make comments during the preaudit, postaudit and daily caucus meetings. This is consistent with QMP-18-01 and standard auditing practice.

The daily caucuses were conducted in a very effective manner. Productive dialogue took place between the QA and technical members of the audit team. This allowed members to consider whether concerns were symptomatic of a generic or larger problem. Also, members were able to identify perceived QA weaknesses and direct their attention and evaluation in these areas. This was particularly evident in the areas of record control, traceability of test samples and data, and in the control of technical notebooks.

4.8 Audit Team Coordination

The staff found the coordination and direction of the audit team members during the first two days somewhat disorganized. For example, at the beginning of each day, the audit team was assigned several LANL staff members as escorts. At the same time and same location, LANL management was attempting to meet with the audit team leader for the daily briefing. As a result of the large number of people in one room, with different objectives, execution of assignments and utilization of resources were not very effective. The staff recommends that, in the future, the briefing meetings be conducted in a separate room away from other audit team members.

4.9 Summary of Observations

Based on the information contained in the previous sections, the NRC staff has identified areas where improvements in the overall audit process could be achieved. For each observation provided the staff has identified the report section where it is discussed in more detail. DOE/YMPO should review the NRC staff observations and provide a response describing how these will be considered in future audits.

<u>Observation 1</u>

For future audits, all elements of 10 CFR 50, Appendix B should be included and addressed in the audit plan. When certain elements of Appendix B are not part of the audit, the basis and justification for not including these in the audit should be addressed in the audit plan. (Section 4.1)

Observation 2

When the lack of necessary knowledge is detected in the audited organization's staff, this should be followed up with further investigation to determine the extent of the problem and whether the concern is symptomatic of a much larger problem. (Section 4.4)

Observation 3

The QA implementing procedures should be available and utilized by the audit team during the preparatory stages of the audit. (Section 4.6).

Observation 4

Past audit reports, regardless of the organization conducting the audit, should be available and utilized by the audit team during the preparatory stages of the audit. (Section 4.6)

Observation 5

The briefing meetings between the audited organization's management and the audit team leader should be conducted in a separate location in order to minimize distractions and lost auditing time. (Section 4.8)

5.0 Preliminary Findings of the DOE/YMPO Audit Team

As a result of the audit, the DOE/YMPO has identified 19 preliminary SDRs of which 17 are QA program related and 2 technical related; 13 preliminary observations of which 9 are QA program related and 4 technical related; and 12 recommendations of which 7 are QA program related and 5 technical related. The following is a summary of the more important preliminary SDR findings.

- Lack of QA program implementing procedures describing how to carry out the QA program controls.
- Lack of controls for computer software programs.
- Lack of timely corrective actions to identified deficiencies.
- Lack of QA training program procedures, position descriptions, and minimum training requirements not described.

APPENDIX A

Attachment 1

AUDIT PLAN 88 - 4 Rev.1,13May8

OBJECTIVES FOR THE TECHNICAL PHASE OF THE QUALITY ASSURANCE AUDIT

In order to provide a unified approch to the conduct of the technical phase of a Quality Assurance audit the following questions are provided. The intention is to have these questions serve as the basis for the questions developed in the technical checklist(XX-2).

- Were there sufficient technical procedures for the activity under review
- Were the procedures in place technically adequate for the intended application
- Did the prime or critical methodologies employed consider existing/accepted approaches and technologies
- Where controversial methodologies were employed was an adequate peer review performed
- Was the background/credentials of those individuals engaged in the task/activity appropriate to the desired/intended outcome of the activity
- Was the level of effort/rigor employed commensurate with the stated objectives of the task/activity
- Where concerns exist as to the efficacy of an activity is a further technical review indicated
- Where the interim analysis or interpretation of data supports reported results is the analysis/interpretation appropriate for the proposed activity/task
- Were the design calculations, design methods , and design analyses employed for an activity appropriate to the maturity of the design

ENCLOSURE 3