

U. S. NUCLEAR REGULATORY COMMISSION
AUDIT OBSERVATION REPORT
FOR THE
YUCCA MOUNTAIN PROJECT OFFICE
AUDIT NO. 88-05 OF
LAWRENCE LIVERMORE NATIONAL LABORATORY

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1. INTRODUCTION

From October 24, 1988 through October 28, 1988, members of the U. S. Nuclear Regulatory Commission (NRC) staff observed a U. S. Department of Energy/Yucca Mountain Project Office (DOE/YMPO) audit of the Lawrence Livermore National Laboratory (LLL). LLL is the DOE/YMPO contractor responsible for the development of the waste package to be used in a tuff environment. The purpose of the audit, as stated in the DOE/YMPO audit plan, was to evaluate the effectiveness of implementation of the LLL Quality Assurance Program Plan (QAPP) and its associated procedures. The audit was conducted using YMPO procedures QMP-18-01, "Audit System for the Waste Management Project Office," and QMP-16-03, "Standard Deficiency Reporting System."

In addition to the quality assurance (QA) aspects of the audit, the DOE/YMPO team also evaluated the ongoing technical work being done at LLL. Although no purpose for the technical evaluation was given in the audit plan, the guidance used by the technical specialists on the DOE/YMPO team was presented in "Objectives for the Technical Phase of the Quality Assurance Audit." This guidance is used by the DOE/YMPO technical specialists to evaluate the scientific investigation plans (SIPs) and their implementing procedures, to determine if they are technically acceptable.

The QA portion of the audit covered all 18 criteria in Part 50 to the Code of Federal Regulations, Title 10 (10 CFR Part 50), Appendix B, and the technical evaluations covered eight SIPs. The SIP subjects that were covered include: (1) waste package environment (SIP B-2.2.2); (2) waste form testing (SIP D-2.2.3.1); (3) metal barrier testing (SIP E-2.2.3.2); (4) integrated testing (SIP G-2.2.3.4); (5) design fabrication and prototype testing (SIP H-2.2.4); (6) performance assessment (SIP I-2.2.5); (7) geochemical modeling (SIP J-2.3.8); and (8) engineered barrier design testing (SIP S-2.6.9.2.5).

2. SCOPE AND PURPOSE OF STAFF PARTICIPATION

The purpose of the staff observation was to determine if DOE conducted the audit in a manner such that the NRC staff could gain confidence that DOE and its contractors were properly implementing their programs in accordance with internal DOE requirements and 10 CFR Part 50, Appendix B. Observation audits enable the staff to provide guidance to DOE on its audit program and implementation of its contractors' QA programs, as they are being developed. Staff observations will help DOE meet the NRC's QA requirements.

With respect to the technical portion of the audit, the staff observations allow it to evaluate whether DOE is reviewing ongoing activities with the depth and rigor necessary to ensure that the work is acceptable. These observation audits also allow the staff to provide DOE with guidance on where additional work may be needed in its site characterization and design work.

3. AUDIT TEAM MEMBERS

The NRC observation audit team consisted of a team leader and four observers. The DOE audit team was comprised of staff from Science Applications International Corporation (SAIC), the DOE contractor for overseeing

implementation of the DOE waste management program, DOE/San Francisco and DOE/HQ. NRC team members, DOE team members, and other observers on the audit are listed below.

3.1 NRC Team

Joseph J. Holonich, Team Leader, (NRC)
Linda K. Riddle, Observer, (NRC)
Tin Mo, Observer, (NRC)
Kien Chang, Observer, (NRC)
Robert Engelhardt, Observer, (NRC/Center for Nuclear Waste Regulatory Analysis)

3.2 DOE Audit Team

Stephen Hans, Team Leader, (SAIC)
John Friend, Lead Auditor, (SAIC)
Catherine Thompson, Auditor, (SAIC)
James Ulseth, Auditor, (SAIC)
James Clark, Auditor, (SAIC)
Mae Cotter, Auditor, (SAIC)
Florencio Ramirez, Auditor, (DOE/San Francisco)
Norman Frank, Auditor, (DOE/HQ)
Karl Sommer, Auditor, (DOE/HQ)
Paul Cloke, Lead Technical Specialist, (SAIC)
David Stahl, Technical Specialist, (SAIC)
Keith Kersh, Technical Specialist, (SAIC)
Martha Mitchell, Technical Specialist, (SAIC)
Keith Schwartztrauber, Technical Specialist, (SAIC)
U-Sun Park, Technical Specialist, (SAIC)

3.3 Additional Participants

Nancy Voltura, Observer, (DOE/YMPO)
Catherine Hampton, Observer, (DOE/YMPO)
Susan Zimmerman, Observer, (State of Nevada)
Thomas Devine, Observer, (State of Nevada)
Don Shettel, Observer, (State of Nevada)
Chris Pflum, Observer, (SAIC)
Hal Cleary, Observer, (Weston)

4. STAFF OBSERVATIONS

In its participation as observers, the NRC staff observed and evaluated the following areas to determine whether the audit and audit team were effective:

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

The acceptability of each aforementioned area is based on direct staff observations of members of the audit team and the review of supporting documentation.

4.1 Scope of Audit

As stated in Section 1. of this report, the QA portion of the audit covered all 18 criteria in 10 CFR Part 50, Appendix B. In addition, the technical specialists investigated those SIPs identified in Section 1., which covered ongoing technical work at LLL. Although the scope of governing requirements and sample size of SIPs were adequate to cover the LLL program, the team could not conduct a detailed evaluation of the implementation. This is because no ongoing work was classified as QA Level I; therefore, many QAPP implementing procedures and the technical procedures still were in preparation. The team identified this as a concern and issued a standard deficiency report (SDR) on the lack of procedures that implement the latest approved version of the LLL QAPP. In the technical area, DOE technical specialists identified the concern about the QA level classification of the LLL work and recommended that LLL evaluate the level assignments to ensure that the work has had the proper QA level assignment. The need to evaluate the QA level assignments is discussed in Section 4.3 of this report.

One important SIP area not covered by the technical specialists was related to the exploratory shaft facility (ESF). Presently, the only ongoing LLL ESF work is in G-tunnel at the Nevada Test Site (NTS). The G-tunnel work investigates the practicality of experiments for use in the ESF. Although the team originally intended to cover the G-tunnel work, YMPO made a decision not to visit the NTS. Even though the experiments are not being run at the waste repository and are assigned a QA Level III, the results from the G-tunnel work will directly influence the types of and methods for conducting experiments in the ESF. Data and information obtained from the ESF are important to waste isolation because they will be used to determine the acceptability of the site. Therefore, the determination of the types and methods of experiments should be made in a rigorous, controlled manner. Hence, the team should have investigated the G-tunnel work to ensure that the QA level assignments were proper.

The staff reviewed the checklists that the auditors and technical specialists used to determine if they comprehensively covered the Appendix B criteria and SIPs that were investigated. Based on its review, the staff observed that the checklists contained questions that were not sufficiently detailed to cover Appendix B completely. However, the staff did observe, during the audit, that auditors and technical specialists complemented the checklist questions with more detailed questions. The approach of using the checklist questions as guides to the areas that needed to be audited, and then asking more detailed questions during the audit, worked well.

Based on the above information, the staff concluded that the overall audit scope was acceptable, with the exception of the need to investigate the G-tunnel work.

4.2 Timing of Audit

Based on the status and importance of activities, the staff observed that the scheduling of the audit was appropriate. At present, all of the ongoing LLL work has been given a Level QA III assignment. The audit identified several significant deficiencies in the LLL QA program. Identifying these deficiencies before the start of QA Level I work will allow LLL to correct the problems before Level I work is begun.

4.3 Examination of Technical Products

As observers, the staff found that the technical specialists on the team performed acceptable investigations. They were part of the overall team and participated in both the technical and QA areas. This, along with the team coordination by the team leaders, resulted in an integrated review by the entire team. Several examples of issues identified by the technical specialists that are both technical and QA-related concerns include:

- (1) ineffective controls for software QA;
- (2) the need for a procedure to control raw data; and
- (3) a problem with interfaces between LLL and other project participants.

Based on its review of the backgrounds of the technical specialists and its observations during the audit, the staff found that the technical specialists were knowledgeable in the areas being investigated. Many of the specialists had undergraduate and graduate degrees, as well as experience in the appropriate fields. In addition, during the audit, the technical specialists asked questions that were relevant to the subject areas, and the conclusions were based on sound technical bases.

The technical specialists used checklists to conduct their audits. Copies of the checklists were provided in the audit plan and were completed by the specialists as the audit progressed. As with the QA auditors, the technical specialists used the checklist as a guide and asked more detailed questions during the audit.

Because of the limited amount of ongoing technical work and the fact that a portion of the ongoing work is still being developed, the technical specialists could not examine the technical products to the degree necessary. For example, the specialists could not check calculations because none was available for review. Similarly, many of the technical procedures were still in preparation and could not be evaluated. Areas reviewed by the specialists included laboratory notebooks, technical reviews by LLL personnel, the classification of work by LLL, and the disposition of nonconformance reports (NCRs) by LLL.

Based on its observations, the staff concluded that the DOE technical specialists performed an acceptable investigation. During the audit, the staff observed that the technical specialists reviewed the laboratory notebooks to ensure that the information recorded was sufficient to reconstruct the test or reproduce the data by an independent investigation. In the area of work classification and QA level assignments, the technical specialists identified several issues. One issue was the fact that all ongoing LLL work was given a

QA Level III assignment. Some of the data generated under QA Level III activities could be used to develop computer codes that would be used in QA Level I work. At present, LLL does not have any means of identifying data that can be used, indirectly, in QA Level I work. Without this identification method, LLL can not know what ongoing work may need to be upgraded to Level I.

The second issue that the DOE team raised complements this first issue. It deals with the lack of a plan by LLL for upgrading work from QA Level III to Level I. Because there is no procedure in place to control any necessary upgrades, LLL does not have a controlled approach for ensuring that upgrades are properly controlled. A third issue that the team raised is the need for LLL to revisit all the QA level assignments to ensure that the ongoing work is properly classified. Because these three issues do not result in any requirements violations, the DOE team will report these to LLL as recommendations.

The final area of technical examination covered the QA controls placed on computer software. Based on its review of the checklist and observations, the staff concluded that the technical specialist conducted a thorough investigation. As a result of his investigations, the technical specialist identified several concerns, the principal one being the lack of an effective QA program for computer software. All the findings that the team identified, including software QA, are summarized in Section 5. of this report.

As a result of its observations and based on the above information, the staff concludes that a complete and thorough technical examination was conducted.

4.4 Conduct of Audit

In conducting the audit, the DOE team was persistent and thorough in its investigations. Additional, detailed questions were asked during the audit, to help establish the bases for conclusions. Often, the auditors requested supporting information to help form a complete record of objective evidence to support conclusions. As problems were identified, additional investigations were performed. An example of this can be found in the audit of Criterion XVII, "Quality Assurance Records." As problems were identified by the auditor for this criterion, the team leader expanded the investigation of the records area. Subsequently, the team found several major deficiencies that, when viewed as a whole, show a lack of records control.

Most of the findings that the team reported represented significant deficiencies in the implementation of the LLL QA program. Examples of major deficiencies reported are:

- (1) lack of an effective training program;
- (2) lack of controls for the LLL records management system;
- (3) lack of procedures controlling interfaces between LLL and other participants;
- (4) the fact that LLL had not implemented the latest version of its QAPP as required; and
- (5) the inability of LLL to audit its subcontractors because of problems with the DOE Memorandum of Understanding between national laboratories.

The total number of findings that the team reported were 21 SDRs and 16 observations. SDRs are findings that result from LLL not meeting the necessary requirements, whereas observations are issues that, if left uncorrected, would become SDRs. Besides making findings on the LLL program, the team also identified two findings on YMPO. The YMPO findings were the direct result of two findings on LLL and were: (1) the lack of project-wide interface controls between participants, and (2) the fact that a peer review of LLL work was not conducted in accordance with procedures.

During their investigations, the auditors asked detailed questions and obtained a sufficient amount of objective evidence to support the findings. At the daily team caucus, the team leader would review the individual findings to determine if the findings were isolated problems or system discrepancies.

Although the team attempted to review past findings to ensure that any closure considered the root cause, the team found that most of the previous findings had not been corrected. Based on this, the team issued an SDR identifying the lack of a corrective actions program as required by Criterion XVI, "Corrective Actions."

The audit team was comprised of six technical specialists and eight QA auditors. As discussed previously, the technical specialists not only were able to evaluate the technical areas of work, but were also knowledgeable in QA and able to identify potential QA problems. In most cases, the checklists for both the auditors and technical specialists contained a sufficient amount of evidence to be able to reconstruct the audit. In its review of the checklists, the staff found one checklist that did not contain enough information to support the findings. This concern was discussed with the lead auditor, who stated that none of the checklists had received management review, and that all checklists would be reviewed to ensure that sufficient information was documented to support the findings. Although management review may ensure that all the checklists are consistent with respect to the amount of documentation, because the auditors are the individuals who perform the investigations, it is important that they record the appropriate information on the checklists at the time of the audit. With the one exception, all the QA and technical checklists that the staff reviewed contained the necessary documentation, including requirements, as well as the information needed to support the findings.

Based on its observations and the above information, the staff concluded that the DOE team conducted a complete and thorough audit.

4.5 Auditor Qualifications

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 audit teams and the procedure used to qualify them. The results of this review are contained in the staff observation report covering the DOE 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 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. Because all of the SAIC auditors on the team were either reviewed by the staff or were qualified using QMP-02-02, the staff found them qualified. The staff reviewed the qualifications of the three auditors from DOE/HQ and from DOE/San Francisco during the audit, and also found them acceptable.

4.6 Audit Team Preparation

Overall, the staff observed that the audit team was prepared for the audit. This is based on a review of the audit plan provided to the staff and observations during the audit. In general, the audit plan was complete and included the information necessary to support the audit. This included: (1) the audit scope; (2) a list of audit personnel and observers; (3) a list of audit activities; (4) a copy of the notification letter; (5) copies of the LLL QAPP, SIPs, and procedures; (6) a schedule for the audit (this was provided separately); and (7) copies of the checklists (the technical checklist was provided separately). Both the QA auditors and the technical specialists were knowledgeable of the necessary requirements. This was repeatedly demonstrated, during the audit, when the auditors and specialists could easily cite requirements, appropriate NRC guidance endorsed by YMPO, and applicable industry standards. All team members attended the preaudit conference, the daily caucus, and the post-audit conference. The audit was conducted following YMPO procedures QMP-18-01, "Audit System for the Waste Management Project," and QMP-16-03, "Standard Deficiency Reporting System."

4.7 Conduct of the Meetings

With the exception of the post-audit conference, team meetings were acceptable. In the pre-audit conference, the team leader, lead auditor, and lead technical specialists clearly presented the purpose and scope of the audit. During the daily caucus, the team members reported potential findings, and the team leader used this as an opportunity to question the members to ensure that the findings were warranted and to determine the nature of the findings, e.g., isolated discrepancies versus systematic problems. In addition, the team leader used the daily caucus to coordinate the audit activities and to help assign auditors to new areas as issues were identified.

At the post-audit conference, the lead auditor reported the team findings to LLL. At this meeting, the lead auditor reported the findings by reading them directly from his notes. When doing this, he used initialisms and shortened phrases unfamiliar to many of the LLL technical people. For example, he noted a problem with "c of c," which means certificate of compliance. Without adequately explaining the findings, the lead auditor may have frustrated the technical audience. Because proper QA begins with the people performing the work, it is important that people know and understand problems and understand why they are important. Not doing so may lead to a view of QA that is counterproductive to the proper implementation of technical work.

During the daily meetings, observers were allowed to present additional information. Such an opportunity was not available at the pre-audit or post-audit conferences; however, the staff did not request it.

4.8 Audit Team Coordination

The team leader, lead auditor, and lead technical specialist conducted the audit team coordination during the audit, in an acceptable manner. As noted above, a daily caucus was held and served as the main avenue of team coordination. As team members identified issues, the team leader would note if the issue indicated that a concern existed in another area, and he would ask the auditor or specialists in that area to evaluate the set of circumstances. Team coordination led to the finding that there was no procedure controlling interfaces between LLL and other participants.

A technical specialist originally identified this issue; however, once the issue was found and determined to be in Criterion III, "Design Control," the auditor for this criterion was asked to investigate if other problems existed. As a result of this investigation, the auditor found that LLL did not have sufficient controls for interface among its subcontractors. This also led to a finding on the lack of YMPO interface controls between project participants.

4.9 Audit Team Independence

None of the audit team had any direct responsibility for performing the activities they investigated. This conclusion is based on the fact that primarily individuals from SAIC made-up the team, and none of the team members was responsible for reviewing, approving, or implementing the LLL program. Members of the team did have sufficient authority to make the audit meaningful and effective. However, the staff cannot determine if there is sufficient organizational freedom until it evaluates how DOE responds to the two findings that the team identified on YMPO.

5. PRELIMINARY AUDIT TEAM FINDINGS

Based on its audit, the DOE team has identified the preliminary findings discussed in Sections 5.1, "Standard Deficiencies," and 5.2, "Observations."

5.1 Standard Deficiencies

- Position qualification requirements do not contain position descriptions, qualification summaries, and resumes.
- The training program is not effective and various requirements have not been satisfied.
- Comment resolutions for QA procedures are not properly documented.
- The peer review conducted by LLL is not in compliance with YMPO requirements.
- Interface procedures have not been developed to control interfaces between LLL and other project participants.
- There is no evidence that purchase award documents have been reviewed against originals.
- Procedures that implement the latest approved LLL QAPP have not been implemented.
- The master list of documents and the QAPP table of contents are not maintained up to date; interim change notices and instructional memoranda are not included.
- Computer files that identify who received copies and revision numbers are out dated and have not been maintained since January 1988.
- There is a lack of definition of key reviewers. In addition, there is no evidence of approval by key reviewers of removing controlled copies holders from distribution. There is also no evidence of the QA deputy collecting documents.

- There was no evidence of a bid evaluation and selection of procurement sources available for review during the audit.
- SDR 90 issued in 1987 on the calibration program cannot be closed because the corrective action is not complete.
- The use of the four specific YMPO classified dispositions are not included in the procedure. YMPO approval is required if "repair" or "use as is" are the dispositions. No exception to the YMPO requirements was noted during the audit.
- Corrective actions are not being performed in a timely and effective manner. Examples include the material and test equipment calibration program, training, internal and external audit follow-up.
- The LLL records management system is not effective. Specific examples include: (1) a lack of controls on legibility, identification, completeness, and reproducibility; (2) no effort to obtain the "best available" copy was in place; (3) records are not sufficiently protected from fire or transmitted to YMPO from LLL within the required time limit; (4) there is a lack of acceptable dual storage and no access control to records; and (5) there is also a lack of film verification controls for microfilmed records, a lack of controls of one-of-a-kind records, and no procedure for nor a master records list.
- There is a lack of effectiveness evaluations resulting from LLL internal audits.
- There is a lack of definition of technical specialists used during LLL QA audits.
- There is a lack of audits of subcontractors, specifically Battelle Pacific Northwest and Argonne National Laboratories.
- There is a lack of training and qualification for LLL auditors.
- There is a lack of compliance with LLL procedures regarding QA level assignments.

In addition to the SDRs issued on LLL, the team also identified two SDRs on YMPO. These were: (1) the lack of procedures to control interfaces between participants, and (2) the fact that a peer review was conducted without following the appropriate requirements.

5.2 Observations

- Specific training needs are not identified for LLL personnel.
- A peer review of alternate materials for barrier selection should be required.
- Position descriptions in the personnel qualifications records are inconsistent.
- There is no data base to identify training needs.
- The software QA program is hampered by the QA organization's lack of involvement.

- The purchase documents are not forwarded to YMPO for QA Level I purchase orders.
- Acceptance criteria in the procedures are not specific enough.
- Review comments should be retained and documented.
- There is a lack of procedures to define the effective date of issued procedures.
- LLL has an unacceptable practice for changing records, i.e., white-out, no signature, no initials or dates.
- Validation of the certificate of compliance is not addressed in the QAPP.
- The trend analysis does not include NCRs or audit findings.
- There is a lack of a method to revise NCRs.
- There is a need for a procedure for disputes between QA and line management.
- There is no formal system to follow-up SDRs.
- There is a lack of procedural control of NCR data, i.e., date and form.
- There is no record of training of lead auditors before the audits.