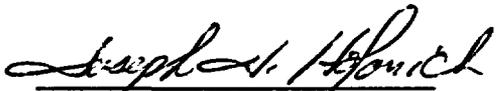
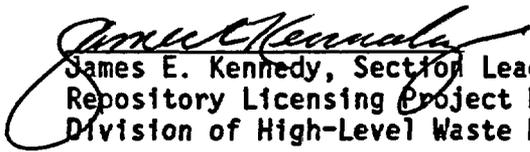


U. S. NUCLEAR REGULATORY COMMISSION
AUDIT OBSERVATION REPORT
FOR THE
NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT
AUDIT NO. 88-06 OF
SANDIA NATIONAL LABORATORY



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1.0 Introduction

From July 25, 1988 through July 29, 1988, members of the Nuclear Regulatory Commission (NRC) staff observed a Department of Energy/Yucca Mountain Project Office (DOE/YMPO) audit of Sandia National Laboratory (SNL). SNL is the DOE/YMPO contractor responsible for the development of the repository systems, data management and analysis, conceptual repository design, and system performance assessment. The purpose of the audit, as stated in the DOE/YMPO audit plan, was to verify implementation of the SNL 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 SNL. 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" which was referenced by the audit plan and was to be used by the DOE technical specialists to conduct their investigations. After reviewing this guidance, it appears that the purpose of the DOE/YMPO technical evaluation was to determine the acceptability of the work breakdown structures (WBSs) and their implementing procedures.

The QA portion of the audit covered all of the 18 criteria given in Part 50 to the Code of Federal Regulations, Title 10 (10 CFR 50), Appendix B. Although SNL had indicated that Criteria IX, "Control of Special Processes," and XIV "Inspection, Test, and Operating Status," were not applicable to a QA program at this time, the audit team included this criteria to determine if SNL was performing work that would be covered by these criteria.

With respect to the technical evaluations that were performed during the audit, the technical specialists covered 13 WBSs in their reviews. The WBS subjects that were covered include: (1) the reference information base (WBS 1.2.1.3.3); (2) rock mass analysis (WBS 1.2.4.2.1.1); (3) laboratory properties (WBS 1.2.4.2.1.3); (4) code development and certification (WBS 1.2.4.6.1); (5) preclosure safety (WBS 1.2.4.6.3); (6) seismic design (WBS 1.2.4.1.2); (7) the site and engineering properties data base (WBS 1.2.1.3.1); (8) flow and radionuclide transport (WBS 1.2.1.4.1); (9) surface facilities (WBS 1.2.4.3.1); (10) underground design (WBSs 1.2.4.3.3, 1.2.4.3.4, and 1.2.4.3.5); and (11) design analysis (WBS 1.2.4.6.2).

2.0 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 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. These observation audits and the subsequent recommendations will assist DOE in meeting 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.

3.0 Audit Team Members

The NRC observation audit team consisted of a team leader and four observers. The DOE/YMPO audit team was comprised of staff from Science Applications International Corporation (SAIC), the DOE contractor for overseeing implementation of the DOE waste management program, and DOE/YMPO. The NRC team members, the DOE/YMPO audit team members, and other observers on the audit are listed below.

NRC Team

Joseph J. Holonich, Team Leader, (NRC)
William Belke, Observer, (NRC)
James P. Donnelly, Observer, (NRC)
John J. Peshel, Observer, (NRC)
Naïem Tanious, Observer, (NRC)

DOE Audit Team

Henry H. Caldwell, Team Leader, (SAIC)
Gerard Heaney, Lead Auditor, (SAIC)
Catherine Thompson, Auditor, (SAIC)
James Ulseth, Auditor, (SAIC)
Steven Dana, Auditor, (SAIC)
Wendell B. Mansel, Auditor, (DOE/YMPO)
William Camp, Auditor, (SAIC)
William Sublette, Lead Technical Specialist, (SAIC)
Forrest D. Peters, Technical Specialist, (SAIC)
David Cummings, Technical Specialist, (SAIC)
Barry Dial, Technical Specialist, (SAIC)
John P. Tinucci, Technical Specialist, (SAIC)
Steven Woolfolk, Technical Specialist, (SAIC)
Tom Watson, Technical Specialist, (HARZA)
U-Sun Park, Technical Specialist, (SAIC)

Additional Participants

Anthony Bacca, Observer, (DOE/YMPO)
David Brown, Observer, (DOE/HQ)
Susan Zimmerman, Observer, (State of Nevada)
James Grubb, Observer, (State of Nevada)
Frank Kendorski, Observer, (State of Nevada)
Steven Leedom, Observer, (DOE/YMPO)
Royce Monks, Observer, (DOE/YMPO)
Stanley H. Klein, Observer, (SAIC)
Jay Jones, Observer, (DOE/HQ)

4.0 Staff Observations

4.1 Summary of Staff Participation

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) review of technical products;
- (4) conduct of the audit;
- (5) qualification of the auditors;
- (6) preparation;
- (7) conduct of meetings; and
- (8) team coordination;

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

4.2 Observations

4.2.1 Scope of the Audit

The audit plan states the purpose of this audit was "to evaluate the Sandia National Laboratories (SNL) Quality Assurance Program through verification of the implementation of the SNL Quality Assurance Program Plan Revision 0, and its implementing procedures." Consequently, the applicable 18 criteria of 10 CFR 50, Appendix B and 13 WBS elements were evaluated. Except for portions of Criterion I, all of the 10 CFR 50, Appendix B QA criteria included in the audit were addressed by the team. This is supported by the audit plan and audit checklist utilized during the audit. As noted in Section 1.0 of this report, Criteria IX and XIV were not examined since SNL has concluded that these criteria are not applicable to its QA program. Nonetheless, the audit checklist did include questions to verify that no work had been performed in these areas. This approach was acceptable to the NRC staff since it goes beyond mere acceptance of SNL's statement.

With respect to Criterion I, the checklist questions did not address the SNL QA organizational structure (e.g., whether the QA organization's duties and responsibilities were clearly defined and independent, and what was the reporting level). The audit team justified not examining Criterion I by noting that the SNL QAPP was written to meet the QA organizational requirements in NVO-196-17 Rev. 4; however, SNL will soon be updating the QAPP to meet NNWSI-88-9 Rev. 0 (formerly NVO-196-17, Rev. 6). The audit team was under the impression that SNL will restructure their QA organization during their QAPP update to NNWSI-88-9 Rev. 0; therefore, it would be inappropriate to audit the present QA organizational structure since it would change in the near future. The NRC staff believes that questions applicable to any QA organization could have been asked to determine the overall structure, independence, and reporting level of the SNL QA organization. It is the NRC staff's position that such an approach be taken for similar situations encountered during future audits.

One primary area of NRC staff concern was the audit team's focus on only procedural compliance, irrespective of whether desired results were being produced. The audit plan supports this approach since it states that the purpose of this audit was to verify that SNL is complying with their implementing procedures. An example of this approach is found in checklist question 10-1 which states, "Verify that the QA Coordinator has established a schedule of surveillances," which is a requirement in SNL procedure QAP 10-1 Rev.0. This question alone leaves many important areas unaddressed such as (1) were technical specialists utilized during the surveillances; (2) were surveillances of in-process tests or experiments conducted; and (3) were planned surveillances actually performed. A review of the other checklist questions within Criterion X revealed that the aforementioned areas were not addressed. If a surveillance schedule exists, the requirement is met; however, this does not ensure adequate review and oversight through the conduct of surveillances. It should be noted that the staff did not observe this specific audit area, but did review the completed checklist. There was no indication that the additional questions needed to evaluate the overall QA program had been asked. Realizing that the checklist is a guide, and the auditors do have flexibility in auditing style, the auditor for this area may have asked the additional questions necessary to evaluate the overall surveillance program. However, based on the information contained in the checklist, and the fact that no overall conclusions were presented at the daily caucus nor in the final DOE/YMPO report to SNL, the staff is concerned that the level of detailed questioning needed for a complete evaluation was not performed. In future audits, the DOE/WMPO auditors should ask those questions necessary to evaluate the total program, clearly document the responses, and discuss any findings.

Another example where it appeared that the audit team was concentrating solely on procedural compliance was in the area of records control. The SNL QAPP states that an access list designating those individuals who have access to the records file shall be maintained. An SDR was generated by the audit team indicating that such a list did not exist. Although issuance of the SDR was in accordance with the audit objective and governing YMPO procedures, the NRC staff, based on its observations, is concerned that the audit team appeared to overemphasize the lack of a list rather than focusing on whether or not access to the records management center was being controlled. In subsequent discussion with the audit team, the staff was told that the checklist was expanded to include effectiveness questions. The staff requested a copy of the completed checklist to determine if the additional questions addressed the effectiveness of the SNL QA program. Based on its review of the expanded checklist, the staff concludes that the additional questions did address the effectiveness of the QA program. These two examples indicate that there is inconsistency between the investigations of individual auditors. It is the position of the staff that DOE ensure an evaluation of the overall QA program should remain the primary focus of all auditors. This is because procedural compliance is only part of acceptably implementing a QA program.

With respect to the scope of the technical evaluations, the staff reviewed the questions given in "Objectives for the Technical Phases of the Quality Assurance Audit," and has concluded that DOE needs to expand the areas covered. In particular, at least two additional objectives must be considered in future audits. These are:

- (1) expand the technical reviews to include an investigation to determine if QA levels of items and activities are properly assigned; and

- (2) provide a systematic investigation to determine whether the requirements of 10 CFR 60 are being adequately addressed.

With respect to the first item, the staff observed that the QA level assignment for the ESF Title I design and the prior activities conducted to initiate the advanced conceptual design (ACD) of the repository were QA level III. The QA level assignment (QALA) was determined using the "QA Level Decision Tree" given in Appendix C of the SNL QAPP. The QA level assignment for the ESF Title I design and the design work related to the ACD should be reviewed with sufficient rigor to ensure that the QALAs are correct. The audit team should have investigated the QA level assignment for the technical activities in order to determine if the appropriate steps had been followed and to determine if the resultant assignments were acceptable.

In the second area, future audits should include investigations on whether ongoing activities are meeting the requirements given in 10 CFR 60. This is based on the fact that ongoing activities will eventually lead to a final design for the repository that will be used by DOE to support a license application. Since the final design must meet the requirements of 10 CFR 60, work activities that support the repository should be conducted such that the ultimate requirements are considered at all stages of design not just during the final design.

As noted in Section 1.0 of this report, the technical evaluations covered 13 WBSs dealing with various phases of data collection activities. Based on its observation of these WBSs and the other WBSs being performed by SNL, it is the staff position that the technical evaluations should include WBSs dealing with ESF related activities. This is based on the fact that ESF related activities are of immediate importance to the repository program since construction of the ESF is scheduled to start in June 1989. Examples of WBSs that the staff believes should have been included in the audit are:

- (1) WBS-1.2.6.1.1, Exploratory Shaft Management, Planning, and Design,"
- (2) WBS-1.2.6.9.1, "Exploratory Shaft Test Plan," and
- (3) WBS-1.2.5.2.2, "Site Characterization Plan."

4.2.2 Timing of the Audit

The NRC staff believes the timing of the audit was appropriate based on the status and safety importance of the activities presently being performed by SNL. For example, SNL is performing the performance assessment analyses for the exploratory shaft facility (ESF) studies. Realizing that ESF Title II design is scheduled for completion in March 1989, SNL's ESF activities are at a crucial stage and the timing of the audit was appropriate.

4.2.3 Review of Technical Products

Prior to the audit, each technical specialist prepared a checklist based on the technical products that were covered by their review. These included the WBSs that were evaluated, the implementing procedures, and findings from previous audits. The questions on the technical checklist were complete and thorough and were consistent with achieving the objectives stated in "Objectives for

the Technical Phase of the Quality Assurance Audit." However, as noted in 4.2.1, the scope of the technical evaluations should be expanded to include additional areas of investigation.

All of the technical specialists used the checklist for conducting their investigations. Although the checklist questions served as a guide for the technical specialists, the specialists amended them to expand the audit into more detailed areas. By asking additional questions that were not on the checklist, the specialists were able to ask the necessary questions needed to completely understand the subject area and make findings based on sufficient information.

Overall, the staff found that the technical specialists were well prepared for the evaluations and the reviews that were conducted were acceptable. However, in at least one instance, the staff did observe an area where the lead technical specialist expressed some concern with the questions on the checklist. As a result of his concerns, the lead specialist eventually discarded the checklist questions and developed his own. This action raises two concerns to the staff. First, since it is the responsibility of the lead technical specialist to review and approve the technical checklist questions, the staff is concerned that the dissatisfaction expressed by the lead specialist during the audit may indicate that a complete review of the questions was not performed. Second, since the specialist did not think the questions were adequate, the staff is concerned that the specialist did not conduct a sufficient amount of preparation for the audit. Had the specialist conducted adequate preparation, he should have noted any problems with the checklist questions before the audit began.

The technical specialists were persistent and thorough in questioning the activities being investigated under the audit. Generally, the technical specialists integrated their review activities with other members of the QA audit team. When a potential programmatic problem was uncovered, the lead technical auditor and the audit team leader were notified. The questioning of SNL personnel on data traceability, management, and control was one of several cases in which members of the QA audit team assisted in the technical investigation. Another example of team integration dealt with the identification of a programmatic concern by a technical specialist. In this instance, the technical specialist found that white out had been used on documents that were considered QA records. This concern was identified to the QA auditor responsible for the programmatic review of this area, and additional investigations were conducted.

There was, however, one instance where the staff observed that an observer had identified more technical issues than the technical specialist on the team. The area of concern dealt with the evaluation of the WBS covering laboratory properties. In that area, the staff observed that one of the observers from the State of Nevada made several technical findings as a result of his observation of the investigation. The findings that were made by the Nevada observer include:

- (1) entries in the logbook for QA level II data were inadequately recorded;
- (2) procedure used for the activity contained subjective color descriptions such as a bluish-green tint instead of reference numbers that are used to describe color standards; and

(3) calculations were not checked by SNL personnel.

It is the staff position that findings of this nature are an important part of the technical evaluation and should have been made by the technical specialist. When findings of this nature are made by observers, the staff becomes concerned that the technical specialists are not conducting the detailed investigations necessary to meet their stated objectives. This is not to say that similar conclusions would not be made by the specialist on the DOE/YMPO team. However, based on the evidence observed, the staff could not determine if such conclusions would have been made.

Finally the staff found that the technical discussions were frank, open, and mostly within the scope of the audit. In most cases, the questioning resulted in findings or observations that represented problems requiring corrective actions by SNL. However, the staff is concerned that the depth of investigations dealt more with the subcontractors and not SNL. This is based on the fact that the technical specialists centered their reviews on areas that were the responsibility of the SNL contractors. For example, in their review of qualifications, the technical specialist requested the qualifications of the individuals from the contracting organizations. Only after the staff raised the question of the qualifications of SNL personnel did the technical specialist also request the SNL qualifications. Although it is important to ensure that the individuals performing the actual design work are qualified, it is just as important to determine if the individual participating in technical decisions related to the contract is equally qualified since the principal investigator from SNL is often required to make decisions on the technical work.

4.2.4 Conduct of the Audit

Overall, the conduct of the audit was acceptable. The auditors were persistent and thorough in their investigations, the SDRs and observations were based on a sound foundation of facts, the results were recorded on well developed checklists, and specific SDRs were examined to determine if there was a systematic discrepancy or an isolated flaw.

In the area of persistent investigations, the auditors performed well. An example of this was observed during the audit team's review of the Reference Information Base (RIB). The RIB is the primary source of data used in the design of the ESF and its adequate control is essential in these earlier stages of ESF design. The RIB contains actual values (e.g., dry thermal conductivity) for many key parameters which are needed for future testing and design work. These values originate from prior investigative work and must undergo a formal review and approval cycle before being "baselined" in the RIB for project wide use. The transfer of data from the source documents to the RIB was reviewed in detail to verify that the data had been correctly transferred. Likewise, the source documents were thoroughly reviewed to identify the quality status (i.e., Quality Level I, II, III, or Unqualified) of the data contained within these documents. The traceability of RIB data - from data acquisition to input into the RIB - was scrutinized in sufficient detail. Considering the importance of this data base for the near term ESF design activities, the audit team was correct in concentrating their efforts in this area.

With respect to documenting the SDRs, the violated requirement or implementing procedure was recorded, document numbers and dates were recorded, and the auditor who identified the problem was stated. An example of this was observed during the audit team's review of SNL's training program. Upon review of one auditor's checklist, the following was documented: (1) the SNL training requirement; (2) the names of the SNL personnel whose training files were reviewed; (3) when training was completed; and (4) the procedure to which they were trained. This approach clearly documents the objective evidence needed to support potential SDRs and should be continued.

In the training area, the NRC staff noted a specific example where the auditor attempted to determine if a potential SDR was a systematic problem or an isolated flaw. The auditor noted a potential problem that no objective evidence existed that SNL personnel were being trained when procedures or requirements changed. The auditor discussed this with the QA lead auditor and it was agreed that the sample size should be expanded. The original concern was substantiated based on the expanded sample. Consequently, a preliminary SDR was issued in the training area.

The audit team followed most of the requirements in its procedure for generating SDRs. The NRC observers noted several instances where the QA lead auditor would allow SNL to correct minor deficiencies immediately, thus eliminating the potential SDR. This is consistent with the process given in QMP-16-03. The problem would be noted in the audit report but the formal SDR submittal, corrective action response, and follow-up verification would not take place. This approach appears satisfactory to the NRC staff since it allows the audit team to focus on more serious problems and does not tie up resources during the follow-up verification activities.

Although the YMPO team provided an acceptable amount of objective evidence on the SDR forms and followed some parts of the procedure, team members did not indicate what severity level (1, 2, or 3) the proposed SDR was. In Sections 5.2.1.1 and 5.2.1.2 of QMP-16-03, the instructions for documenting deficiency conditions on an SDR clearly require that the severity level be identified by DOE/YMPO matrix support personnel. Because the audit team was instructed by DOE/YMPO not to assign a severity level, the team conducted the audit without following the necessary procedures. One of the main reasons for having documented procedures is to ensure that the audits are conducted in a consistent, nonambiguous manner. If DOE/YMPO continues to provide oral instructions that are contrary to established procedures, adherence to established requirements cannot be documented. Therefore, in future audits, the audit teams should follow the procedure or an approved interim change notice.

During the audit, the staff asked several questions of audit team to attempt to gain assurance that the team was conducting an acceptable audit. For example, the staff requested objective evidence to substantiate whether personnel performing reviews of work plans were qualified. Although the YMPO audit team response indicates, in part, that a technical review was performed and that the individual was qualified, the response does not indicate what the basis was to establish how the individual was qualified. Additionally, a sample of one individual does not in itself substantiate whether there are any trends or whether technical reviewers are qualified. Based on the lack of a sufficient sample size, it is the staff's position that the audit in this area did not determine if the technical reviewers are qualified.

Another staff inquiry requested the methodology on how peer reviews were being conducted since it appeared to the staff that the reviews were technical reviews not peer reviews. The audit team response indicates that it was a technical review, but certain of the SNL technical reviewers consider this a peer review. There are distinct differences between a peer review and technical review as delineated in the NRC Generic Technical Position, NUREG-1297. This confusion could leave certain reservation as to whether personnel are knowledgeable in the activities they are performing and applicable NRC regulations and guidance. Understanding applicable NRC regulations and guidance is an important step in implementing an acceptable QA program. The YMPO team should not only ensure that SNL personnel are following procedures, but should also ensure that the SNL personnel know of and understand NRC as well as YMPO requirements and guidance.

For at least two responses to staff inquires, the YMPO audit team did not provide sufficient information for the staff to make a determination of acceptability. In the first area, the staff asked for information describing how previous audit findings were determined by the audit team to be acceptably closed. From the information provided in the response, the NRC staff cannot make a determination as to whether the YMPO team coverage in this audit area was sufficient. Similarly, the NRC staff requested information to determine if Level II work done by SNL had the potential to be used in licensing. Again, the lack of information in the YMPO response precludes the NRC staff from making a determination of whether the audit was sufficient in investigating this area.

Lastly, the staff requested information pertaining to why the SNL Technical Procedures (TP) have not received a documented review by the SNL QA organization to determine if the procedures include appropriate QA criteria. The response was that an SDR will be generated. The staff is concerned that the YMPO audit team did not investigate this area in sufficient detail. The response that an SDR will be generated leads the staff to conclude that the YMPO team did not consider this issue until the staff raised it. Based on the information and examples previously discussed, the staff has concluded that the YMPO team did not perform a sufficiently detailed audit. This is a concern that the staff has repeatedly raised. DOE/YMPO management needs to ensure that future audit teams conduct thorough investigations of all audited areas.

Another, major concern of the NRC staff was the use of unqualified data for ESF design and analysis activities. This unqualified data is contained in the RIB, a YMPO approved baseline document. Yet, no SDR was generated by the audit team. According to the audit team leader, no SNL or YMPO requirements, as presently applicable, have been violated. However, NUREG-1298 "Qualification of Existing Data for High-Level Nuclear Waste Repositories," which was recently endorsed by DOE, states that all data used in support of the license application that is important to safety or waste isolation must be qualified to meet the QA requirements of 10 CFR 60, Subpart G. The SNL QAPP has not been updated to include DOE's endorsement of the NUREG. The NRC staff believes that some ESF design and analysis work will likely be important to waste isolation and may therefore be needed in licensing. The ESF design and analyses are rapidly proceeding; yet, the quality of the data used in that has not been determined. The NRC observers would expect future audits to identify any obvious departure from NRC requirements or positions regardless of whether a contractor's QAPP has not been updated to include a recent commitment. This concern could possibly be addressed by modifying procedures QMP-16-03 and QMP-18-01. Regardless of the approach, immediate DOE management attention is necessary.

4.2.5 Qualification of the Team Members

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 all of the auditors on the team were reviewed by the staff or were qualified using QMP-02-02, the staff finds that the team is qualified.

4.2.6 Audit Team Preparation

With respect to audit team preparation, the team was thoroughly familiar with the SNL QAPP and its implementing procedures as well as the requirements in the governing YMPO QAPP. This conclusion is supported by the development of a detailed audit plan and checklist. The checklist questions addressed the detailed SNL procedures which implement individual QAPP criteria. Likewise, in the case of at least one auditor, it was verified that checklist questions which could be answered during a desk audit were completed prior to the conduct of the audit. This allows more on-site review of QAPP implementation rather than programmatic compliance. Another example of adequate audit team preparation was in the area of Criterion XII, "Control of Measuring and Test Equipment." An SDR had been issued during a June 1987 audit with respect to SNL using the Primary Standards Laboratory (PSL) for calibration services. Subsequently, the YMPO Director issued a letter in September 1987 which terminated the use of the PSL for any future calibration services. The auditor who reviewed this area was well aware of the previous SDR and YMPO mandate. Checklist questions 12-1 and 12-2 clearly indicate this since one question references the YMPO Director's letter and the other paraphrases the previous SDR. As a whole, the audit team was well prepared and knowledgeable in the SNL QAPP and implementing procedures.

However, the NRC staff observed both positive and negative points with respect to the audit team's awareness of applicable requirement documents generated outside of SNL. For example, during the course of observing Criterion III, "Scientific Investigation Control and Design Control," there was much discussion as to whether the QA Level assignment to a particular design element should be QA Level I, II or III. Part of the discussion was related to the decision of how or why a particular QA level would be assigned. The proper assignment of Quality Levels is important since this designation (I, II, or III) governs what QA controls are applied to a particular item or activity. In future audits, team members should exercise better preparation and be aware of DOE/YMPO requirements and NRC guidance endorsed by DOE related to the area being audited.

On the other hand, it was observed during the audit team's daily caucuses that several of the auditors were aware of the data qualification methods described in NUREG-1298. One auditor identified an SNL attempt to qualify some older data using the methodology continued in NUREG-1298. Knowledge of NRC guidance

and understanding how organizations are implementing the guidance are important parts of conducting a thorough audit. This type of preparation and investigation should continue.

4.2.7 Conduct of Meetings

The overall conduct of the entrance meeting held July 25, 1988, was well organized, clear, and effectively performed. The audit scope, objective, and schedule were clearly discussed by both the lead QA auditor and lead technical specialist.

Daily status meetings were held with SNL upper management to brief them on the status of the audit. Potential SDRs were identified by the audit team leader and SNL was given the opportunity to respond. This approach is consistent with most audit methodologies. It was observed by the staff that there were several times during these meetings that the lead QA auditor was not completely prepared. Often, once an SDR was reported, SNL would ask for additional information because the lead auditor did not have the requested information, he would have to go to other team members following the meetings to get it. It is important that the audited organization understand the context of a finding so that it can take the necessary corrective actions. After the first few meetings, the lead auditor realized this was a problem and requested that the meetings be scheduled later in the morning so that he could be better prepared. Prior to the daily meetings with the audited organization, the audit team should be sufficiently prepared to discuss the issues presented.

Daily team caucuses were also held to discuss the auditors' daily investigations. Consequently, potential SDRs were discussed and coordinated between other auditors if applicable. This practice allows the identification of quality trends and helps minimize duplication of effort. In short, these caucuses were conducted satisfactorily and helped with team coordination.

Lastly, during the July 29, 1988 status meeting (which was basically a preliminary exit meeting) each SDR identified to date was discussed and the affected QAPP criteria identified. The presentation was clear, to the point, and additional clarification was provided upon request. In addition, all the observers were afforded the opportunity to present additional information or make comments. This is consistent with the DOE/NRC agreement concerning the role of observers.

4.2.8 Audit Team Coordination

The overall coordination of the audit team was performed well. Considering the large number of auditors and observers this was a formidable task. The QA lead auditor identified several areas where the SNL QA program had not been updated to the latest YMPO requirements document (NNWSI 88-9) and directed the audit team to focus on these areas and evaluate whether problems existed. In addition, the lead auditor questioned the auditors to ensure that potential SDRs were based on objective evidence. Furthermore, the auditors worked well together. For example, one auditor recorded the names of several SNL personnel whose qualifications needed to be reviewed. Consequently, this information was provided to another auditor who was checking personnel qualifications.

4.3 Staff Conclusions

Based on the information contained in the previous sections, the NRC staff has the following conclusions on the DOE/YMPO audit and audit team. For each conclusion, the staff has identified the report section where the conclusion is discussed in detail. DOE/YMPO should review the staff conclusions and provide a response describing how these will be considered in future audits.

1. The QA organizational structure of the audited organization should be evaluated to determine whether its duties and responsibilities are clearly defined, if it is sufficiently independent, and whether it reports to a sufficient management level. (Section 4.2.1)
2. DOE/YMPO audit results should address the overall QA program not just transmit SDRs to the audited organization. (Section 4.2.1)
3. The audit team should focus more on QA program effectiveness - not solely procedural implementation. (Section 4.2.1)
4. The technical specialists should use their checklist as their main source of information to guide the investigation. As stated in item 6, the specialist should ensure that sufficient details are investigated to satisfy the objectives of the audit. (Section 4.2.3)
5. DOE/YMPO should expand the scope of the technical evaluations to include a review of QA level assignments, and an evaluation of whether the requirements of 10 CFR 60 are being adequately considered during all phases of the design process. (Section 4.2.1)
6. The technical specialists should evaluate technical work being performed on all aspects of the ESF design, not just data-related activities. (Section 4.2.3)
7. The technical specialists should ensure that their investigations are sufficiently detailed so that the stated objectives can be met. (Section 4.2.3)
8. Future DOE/YMPO audit teams should ensure that appropriate emphasis is given to evaluating the technical qualifications of individuals in the audited organization and not solely its subcontractors. (Section 4.2.3)
9. The audit of technical reviewers was not sufficient to determine their qualifications. (Section 4.1.4)
10. The audit teams should follow documented procedures or interim change notices. (Section 4.2.4)
11. The DOE/YMPO audits should be able to determine if personnel at the audited organization understand and implement NRC requirements. (Section 4.2.4)
12. DOE/YMPO should provide sufficient information to support its positions. (Section 4.2.4)

13. DOE/YMPO should ensure that its audit teams are performing thorough investigations. (Section 4.2.4)
14. Unqualified data is being used in the ESF design; yet, no SDR was generated by the audit team. This is contrary to DOE's recent commitment to NUREG-1298. This area should be reexamined to determine what corrective action is appropriate. (Section 4.2.4)

5.0 Preliminary Findings of the DOE/WMPO Audit Team

5.1 Introduction

As a result of the audit, the DOE/YMPO team has several preliminary findings that it reported to SNL during the daily status meetings. Because many of these issues were minor in nature and could be closed by SNL before the audit ended, some of the issues identified below may not become a final finding of the team. Since DOE/YMPO would not provide draft copies of its SDRs, observations, and recommendations to the staff, the only method of identifying findings was the daily SNL briefing. In future audits, the DOE/YMPO teams should provide the staff with draft copies of all preliminary findings so that the staff will have a better understanding of what issues will be addressed in the DOE/YMPO audit report.

5.2 Preliminary Findings

- The SNL QAPP discusses different ways to do Level I and II design review but the department operating procedures (DOPs) do not reflect this difference.
- There are insufficient controls to ensure that computer codes maintain their integrity once a modification is made to the program.
- The deficiency identification memorandum (DIM) files are incomplete with respect to all correspondence concerning a particular DIM.
- A nonconformance report (NCR) was written on the use of the PSL; however, the PSL control records could not be found to trace any calibrations performed by the PSL.
- DOP 4-1 references DOP 4-2 which no longer exists.
- An access list is required to limit access to the records management center. However, the list presently in use contains the names of all SNL personnel assigned to the NNWSI project.
- Records are dated by using the date when the record is received in the record management center. It is important to have the actual date of document not the date it was received in the records center. Hence, the DOE/YMPO team recommended that undated documents be returned to the originator to determine their dates.
- Individuals in the record management center are altering records without returning them to the originator for correction.

- The audit report for the MACTech audit conducted April 1, 1988 was not issued within the 30 days required in the SNL QAPP.
- SNL personnel are not being trained to revisions of procedures.
- The SNL familiarization program is not being completed in a timely manner. Some programs for SNL personnel go more than a year.
- SNL personnel are recording data on a document form that is not part of the procedure. Although this form is better than the one presently in the procedure, SNL should change the procedure to include the better form.
- There was no evidence that NCRs had been distributed to the appropriate SNL personnel.
- The SNL QA organization has not reviewed the input and output documents for surface design activities.
- For some DIMs, there is no evidence that a review was conducted for QA Level II design activities.
- There is no catalog of training tools, manuals, tapes, etc. as required by the SNL QAPP.
- Position descriptions do not identify minimum education requirements.
- SNL QA personnel are not certified via project procedure DOP 2-6.
- There are no verification and validation records available for the computer codes used by Bechtel.
- SNL technical reviewers are not certified to do reviews.
- The SNL audit schedule for fiscal year 1988 only goes to August.
- There is no trend procedure in place.
- There is no evidence of technical reviews of work plans as required by the SNL QAP.
- The quality assurance level assignment sheets for revised work plans did not receive QA reviews.
- The experience summaries for SNL personnel do not elaborate on the particulars of experience.

Appendix A

As part of its effort to prepare for its role as observers, the NRC staff, along with the other observers, received copies of the binders used by the audit team. The binders are titled, "NNWSI WMPO Audit 88-06, Sandia National Laboratories, Volume I and II," and are available to the public at the NRC Public Document Room (PDR). The information contained in these binders serves as background for the audit, and portions are reviewed by the staff as part of its evaluation of the audit process. The information that was provided is listed below.

- (1) WMPO Quality Assurance Audit Plan, Audit 88-06
- (2) Audit 88-06, Audit Plan Attachments
 1. QMP-18-01, "Audit System for the Waste Management Project Office"
 2. QMP-16-03, "Standard Deficiency Reporting System"
 3. WMPO Quality Assurance Audit Task Organization
 4. Objectives for the Technical Phase of the Quality Assurance Audit
 5. WMPO Audit Observer Inquiry
 6. State and Tribal Representative Participation
 7. NRC Procedure for Observation Audits
 8. HQ Observation of WMPO Quality Assurance Audits
- (3) WMPO Audit 88-06 Team Assignments
- (4) SNL Quality Assurance Program Plan (QAPP)
- (5) Copies of the WMPO audit checklist
- (6) Blank SDRs
- (7) WMPO Audit Report on 87-5 for SNL and the SNL response to Audit 87-5.
- (8) Copies of the following monthly SNL status reports
 - A. December 1987
 - B. March 1988
 - C. April 1988
 - D. May 1988
- (9) Copies of the following work breakdown structures (WBSs)

WBS Number	WBS Title
1.2.1.3.1.S	Tuff Date Base
1.2.4.3.2.S	Surface Facilities
1.2.1.3.3.S	Reference Information Base
1.2.1.4.1.S	Flow and Radionuclide Transport

WBS Number**WBS Title**

1.2.4.1.2.S
1.2.4.3.4.S
1.2.4.3.5.S
1.2.4.6.1.S

Design Basis
Underground Excavation
Underground Service Systems
Repository Performance Code
Development/Certification
Design Analysis
Preclosure Safety Analyses
Rock-Mass Analysis
Laboratory Properties

1.2.4.6.2.S
1.2.4.6.3.S
1.2.4.2.1.1.S
1.2.4.2.1.3.S

- (10) Copies of the procedures for implementing the QAPP and the WBSs. Because of the large amount of procedures that were made available to the staff, their numbers and titles are not repeated here. However, copies of the procedures are contained in NNWSI WMPO Audit 88-06, Sandia National Laboratories, Volume II, which is available for inspection in the NRC PDR.