



Department of Energy
Washington, DC 20585

APR 10 1989

Mr. John Linehan, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High Level
Waste Management
Office of Nuclear Materials
Safety and Safeguards
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Linehan:

At the July 7, 1988, meeting between the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC), on Quality Assurance (QA), the DOE committed to provide the NRC with responses to comments made in NRC's audit observation reports (Open Item QA-G-1). In addition, two specific NRC audit observation reports from 1986 were identified (Open Items QA-G-1a and 1d). With the exception of item b), responses to the audit observation comments are enclosed.

- a) DOE Audit of USGS conducted in March 1986 -- A response to NRC observation of the USGS audit was contained in a memo dated September 22, 1986, from D. Vieth to J. Knight. The NRC was sent a copy of the response.
- b) DOE Audit of Pacific Northwest Laboratory (PNL) conducted in September 1986 -- The PNL audit concerns no longer merit responses because the work scope at that time involved the Deaf Smith County Site. Since the Salt Repository Project has been terminated DOE considers responses to those NRC observations unnecessary.
- c) YMP Audit #88-04, U.S. Geological Survey at Denver CO conducted in June 1988;
- d) YMP Audit #88-05, Lawrence Livermore National Laboratory, conducted in October 1988;
- e) YMP Audit #88-06, Sandia National Laboratory conducted in July-August 1988;
- f) YMP Audit #88-07, Reynolds Electrical and Engineering Co. (REECO) conducted in August 1988;
- g) YMP Audit #88-08, Los Alamos National Laboratory conducted in October 1988.

Responses to audits 88-01 (Fenix & Scisson), 88-02 (Holmes & Narver), and 88-03 (USGS, Menlo Park, CA) were sent to you on December 29, 1988.

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We believe that this letter and the enclosures close the referenced Open Items relative to all audits conducted prior to, or during calendar year 1988.

Should you have any questions on this matter, please call me on 586-1464.

A handwritten signature in black ink, appearing to read "Gordon Appel". The signature is written in a cursive style with a large, sweeping initial "G".

Gordon Appel, Chief
Licensing Branch



Department of Energy
Nevada Operations Office
P. O. Box 14100
Las Vegas, NV 89114-4100

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James P. Knight, Director, Licensing & Regulatory Division, DOE/HQ (RW-23),
FORS

REPORT OF OBSERVATIONS MADE DURING SCIENCE APPLICATIONS INTERNATIONAL CORPORATION (SAIC) QUALITY ASSURANCE (QA) AUDIT OF NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNWSI) PROJECT ACTIVITIES AT THE U.S. GEOLOGICAL SURVEY (USGS)/ DENVER, MARCH 10-14, 1986

Reference letter, Susan G. Bilhorn to John L. Linehan, dated June 2, 1986.

The purpose of this letter is to document the Waste Management Project Office's (WMPPO) comments regarding some of the observations reported in the above referenced letter. The comments are as follows.

1. In the section titled "The Audit," paragraph 1C states "Coordination between SAIC and USGS prior to the audit was lacking. Audit interviews had not been arranged (schedules and individuals) prior to the preaudit meeting, therefore, last minute arrangements and adjustments were necessary."

The following coordinating actions had been taken prior to the audit.

a. The audit plan was transmitted to USGS on April 22, 1986, outlining the purpose, scope, audit schedule, and the requirements to be audited.

b. A specific request had been made of the USGS QA Manager to provide the number of persons that would support the audit team units during the auditing of the various QA elements. We were advised that due to the uncertainty of personnel availability the assignments would be made during the preaudit meeting.

c. Three telephone conversations had been held with the USGS QA Manager to coordinate specifics prior to the audit.

d. Historically last minute arrangements and adjustments are associated with the start of an audit.

2. Paragraph A under Conclusions states "The audit was highly compliance-oriented in spite of the inclusion of technical team members and reviews of technical activities (see Enclosure 1 as illustration). This differs from the NRC approach to inspections and audits (such as IDI's) which focus more on the quality of technical work than on compliance with QA procedures."

By definition in NQA-1, Criteria 18, an audit is a planned activity performed to determine compliance with established procedures, instructions, drawings, and other applicable documents. The other seventeen criteria of NQA-1 were designed to provide assurance that technical activities are accomplished and reviewed by competent trained personnel--not QA auditors. WMPPO audits have been and will continue to be highly compliance oriented.

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3. Paragraph 3 under Concerns states "The conditions which merit issuance of a stop work order on repository activities during prelicensing have not been defined. Also, the method, authority, and responsibility for recommending a stop work order based on audit findings are not in place, especially for audits conducted by a contractor, such as SAIC."

The conditions meriting the issuance of a stop work order are judgmental and would be difficult to define. QMP-18-01 "Audit System for the Waste Management Project Office (WMPO/NV)," paragraph 4.3 charges the lead auditor with the responsibility for immediately reporting any significant conditions affecting quality to the WMPO Director for appropriate action. Presumably if the conditions warrant stop work, a stop work order will be issued. QMP-18-01 is currently being revised to define the method, authority, and responsibility for recommending a stop work order.

4. Paragraph 4 under Concerns states "A potential problem with independence from cost and scheduling was apparent regarding audits conducted by contractors such as SAIC. In spite of the uncertainty associated with a first time recommendation of a stop work order, I believe that the SAIC audit team gave undue attention to what they thought SAIC management and NNWSI would want to hear. In addition, the lead auditor was concerned about contacting the NNWSI QA Manager to discuss the situation. I consider that if contracting organizations such as SAIC are to function as 'extensions of project staff' in the area of QA, that they should feel free to act with project authority and exhibit the necessary independence from cost and scheduling."

The WMPO fails to understand how the actions of the audit team and audit team leader relate to potential problem with independence from costs and scheduling. As stated, the uncertainty associated with a first time recommendation of a stop work order which required the understanding of the protocol for a stop work order may have resulted in the lead auditors concerns, however, cost and scheduling should not have been a concern. Enclosure 1, WMPO organization chart, is structured such that the QA Support Contractor (SAIC/QASC) Manager, who is responsible for providing auditor assistance for the conduct of audits and reports to the WMPO Director which provides the independence required to perform QA functions. In addition, if disputes in QA arise the QASC Manager, who supports the WMPO Project Quality Manager (PQM), has access to the DOE/NV Manager through the PQM, thereby providing complete independence from cost and scheduling.

5. Observation Number 1 states "NNWSI and DOE/HQ attribute the term 'technical audit' to NRC (initiated by NRC at the site visit, December 1984). NNWSI has been pushed, therefore, to conduct such audits but has been given little direction as to the definition or intent of the term. This has generated numerous interpretations and much confusion. The NRC's intent should be clarified."

This observation very aptly presents the WMPO's uncertainty as to the NRC intent relative to the execution of technical audits. The WMPO has received various versions of the NRC intent, all of which have been verbal. These covered such actions as a review for compliance to technical procedures, a

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vertical slice through a design process amounting to a design review, a peer review of publications, or a review for adequacy of experiments. Until such time as the NRC clarifies the position formally, the WMPO will conduct technical audits by:

- a. Reviewing for compliance to technical procedures.
- b. Reviewing technical documents for adequacy of peer reviews.

6. Observation Number 2 states "NRC staff have noted that the scope of the audits conducted by DOE projects have been too optimistic in that they attempt to cover all 18 criteria in less than 4 days. MNWSI has apparently interpreted this to mean that they need only evaluate the criteria which most directly affect the quality of work performed by each contractor and not audit against all 18 criteria stated in the requirements. The intent was, however, that the adequacy of QA be evaluated as necessary to determine compliance with the requirements. In order to conduct an adequate evaluation, audits may need to be longer or divided into parts. In addition, regular surveillance and review should indicate areas which need greater or lesser attention during audits."

The audit plans for each of the WMPO FY 1985 and 1986 audits to date have addressed all 18 criteria. The degree of evaluation of each element has been a function of the amount of activity required to adequately evaluate the QA element. Where there had been little activity the effort expended was not as extensive as in areas of greater activity. Where there had not been any activity, these elements were not audited. It is difficult to audit an activity for compliance to requirements if no work has been performed on the activity, or when an activity does not involve all 18 criteria. The WMPO will continue to audit all active QA elements of the 18 criteria during each audit. The number of elements that can be adequately audited in a time period is a function of the number of auditors assigned. To date the WMPO feels that a sufficient number of auditors have been assigned and that each of the audits has adequately evaluated all of the appropriate QA elements. The WMPO's audit policy is to follow up audits with surveillances to further probe and conduct in depth reviews of areas noted to require additional attention.


Donald L. Vieth, Director
Waste Management Project Office

WMPO:JB-2077

Enclosure:
As stated

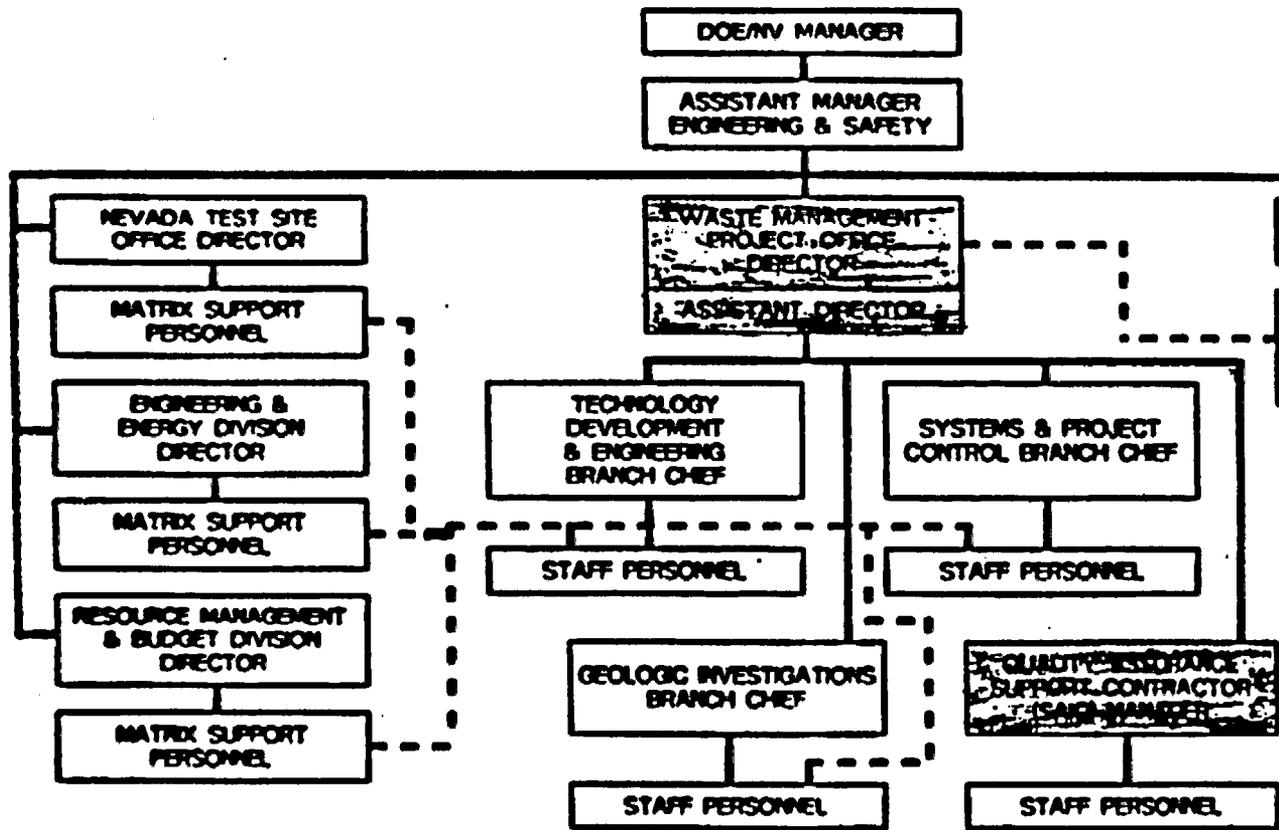
cc:
V. J. Cassella, DOE/HQ (RW-221), FORS
W. J. Purcell, DOE/HQ (RW-23) FORS
Paul Prestholt, NRC/HQ
Dale Hedges, NRC/HQ
S. H. Klein, SAIC, Las Vegas, NV
A. E. Cocoros, SAIC, Las Vegas, NV
James Blaylock, WMPO, DOE/NV

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— Administrative Responsibility, Authority and Accountability
- - - Matrix Support Functional Responsibilities and Accountabilities



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS #1.2.9.3
"QA"

MAR 07 1989

Ralph Stein, Associate Director, Systems Integration and Regulations,
HQ (RW-30) FORS

PROPOSED RESPONSES TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVATION
AUDIT REPORT FOR YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) AUDIT
NO. 88-04 OF THE U.S. GEOLOGICAL SURVEY (USGS)/DENVER

The Project Office has evaluated recommendations made by the NRC staff
concerning the Project Office audit of USGS/Denver, Audit No. 88-04.
Proposed responses are enclosed.

If you have any questions regarding these responses, please contact me at
(702) 794-7913 or FTS 544-7913.

James Blaylock
James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:JB-2418

Enclosure:
Response to Audit 88-4

cc w/o encl:
L. H. Barrett, HQ (RW-3) FORS
S. J. Klein, SAIC, Las Vegas, NV
H. H. Caldwell, SAIC, Las Vegas, NV
J. E. Clark, SAIC, Las Vegas, NV
B. A. Tabaka, SAIC, Las Vegas, NV

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NRC OBSERVATIONS AND RESPONSES FOR AUDIT 88-04

NRC Recommendation 1:

Describe what is intended in QMP-18-01 as it relates to determining the effectiveness of implementation of QA programs.

Response:

Determination of "effectiveness of implementation" is an assessment of the degree to which the objectives of the QA program have been fulfilled. The initial premise is that the approved QA program is responsive to requirements; i.e., the requirements are correctly interpreted, and commitments and methods described in the program represent adequate control measures if successfully implemented.

The second premise is that supporting policies, practices and procedures have been instituted to implement the approved QA program. During the scientific investigation stage, the effectiveness of that implementation is gauged by the demonstrated capability to control data production processes and produce the desired results of the QA program — accurate, precise, reproducible data and conclusions that enjoy the confidence of producers and end-users alike.

While achievement of accurate, precise, reproducible data is possible without the logical program implementation sequence established by the two premises stated above, the confidence factor cannot be assured in such a case. Therefore, audits conducted by the Project Office utilize "effectiveness" criteria closely related to and representative of the logic engendered in the two premises.

The Project Office considers effectiveness of implementation evidenced by the following as a minimum:

- o Active and supportive awareness (among quality achievers) of the intent and purpose of the QA program.
- o No breakdowns (e.g., the presence of recurring, longstanding uncorrected, or internally unidentified problems) have occurred in the control measures established to meet requirements.
- o Feedback mechanisms detect, correct and preclude recurrence of anomalies.
- o Performance of technical and quality-affecting activities is observed to be in accordance with prescribed requirements.
- o End-products have a pedigree as a result of controlled input sources and compliant intermediary processes. (Intermediary processes include but are not limited to: data collection, data reduction and analysis, equipment calibrations, sample/material identification and storage, information transmittals, technical reviews, and document issuance.)

ENCLOSURE

Recommendation 2:

Include an evaluation of the overall QA program in future audits.

Response:

The Project Office has recognized the need to formulate an overall assessment of the participants' QA programs, and has included such a summary evaluation in subsequent audits. The evaluation is presented in the Executive Summary of the audit report as a statement of overall program effectiveness.

Recommendation 3:

Increase the frequency of audits of the USGS until its QA program is totally in place.

Response:

It is the Project Office position that since the USGS is under a Stop Work Order as a result of Audits 88-03 and 88-04, no further audits will be conducted until the USGS QA program incorporates the requirements of the latest Yucca Mountain Project QAP. However, surveillances will be performed to verify corrective action completion on deficiencies identified during previous audits. The surveillances will also provide input for scheduling the next full-scope QA Program audit.

Recommendation 4:

In the area of technical investigations, ensure that adequate coverage of SIPs and procedures is included in the checklist.

Response:

This concern was noted and has been addressed in subsequent audits. In the Los Alamos and Lawrence Livermore audits, technical checklists have included questions that more thoroughly investigate SIPs and their related technical procedures. Preaudit training of technical specialists has emphasized placing increased focus on the technical methods employed to execute the SIPs, rather than on programmatic concerns.

Recommendation 5:

Include the evaluation of the documentation of deviations from SIPs and procedures that occur because of prototype testing.

Response:

Questions relating to deviations from approaches and methods outlined in the SIPs (and their procedures) have been included in subsequent technical checklists. In tracing the conduct of SIPs during the audit, the technical specialists compare documentation of actual SIP performance to the activities prescribed in the SIPs. When changes have occurred, the impact of the change will be discussed and evaluated.

Recommendation 6:

Conduct better preparatory activities to ensure that all necessary areas are audited to minimize confusion during entrance activities.

Response:

The Project Office regards this observation and the resulting recommendation as a misperception of the significance of the described events.

Regarding the issue of belated expansion of the audit scope to include software, initial input from the USGS was that software was not being used at Denver. Upon confirmation to the contrary, checklist questions were developed and brought to Denver in a timely manner, as is the standard procedure for expanding audit scope when any new area must be further investigated. Audit team preparation need not consider every possible contingency when adjustments to scope are a normal practice.

Regarding the escort matching concern, it is both expected and accepted to have initial logistical challenges when security controls are involved — especially when escorts are necessary. The ever-increasing numbers of audit observers was a major factor in the "confusion" cited in the observation, but the auditees (and the audit team) made effective adjustments to overcome the initial difficulties.

Recommendation 7:

Allow observation by NRC staff of all DOE/WMPPO audit-related meetings.

Response:

It is now the Project Office policy and practice to invite all observers to all meetings conducted during audits.

CC: L. Barrett
G. Appel (orig)



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS 1.2.9.3
"QA: N/A"

MAR 06 1989

Ralph Stein, Associate Director, Systems Integration & Regulations, HQ
(RW-30) FORS

PROPOSED RESPONSE TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVATION OF
YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) AUDIT 88-05

The Project Office has evaluated the NRC comments for U.S. Department of
Energy/Project Office Audit 88-05 of Lawrence Livermore National Laboratory.
The enclosure contains the proposed response.

If you have any questions regarding this response, please contact
James Blaylock of my staff at (702) 794-7913 or FTS 544-7913.

Carl P. Gertz, Project Manager
Yucca Mountain Project Office

YMP:JB-2256

Enclosure:
Response to Audit 88-05

- cc w/o encl:
- Gordon Appel, HQ (RW-331) FORS
- L. H. Barrett, HQ (RW-3) FORS
- H. H. Caldwell, SAIC, Las Vegas, NV
- J. C. Friend, SAIC, Las Vegas, NV
- B. A. Tabaka, SAIC, Las Vegas, NV



NRC OBSERVATION REPORT FOR AUDIT 88-05

The purpose of this letter is to transmit the response to comments generated by members of the Nuclear Regulatory Commission (NRC) during observation of the U.S. Department of Energy/Yucca Mountain Project audit (No. 88-05) of Lawrence Livermore National Laboratory. The audit was conducted during the week of October 24, 1988. The NRC Audit Observation Report (Letter, Linehan to Stein, dtd. 11/25/88) identified no comments that require a response. However, the Project Office has reviewed the NRC comments and will consider them for incorporation into future audits.



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS 1.2.9.3
"QA"

MAR 07 1989

Ralph Stein, Associate Director, Systems Integration and Regulations,
HQ (FW-30) FORS

PROPOSED RESPONSES TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVATION AUDIT REPORT FOR YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT NO. 88-06 OF SANDIA NATIONAL LABORATORIES (SNL)

References: (1) Letter, Linehan to Stein, dtd. 11/4/88
(2) Letter, Holonich to File, dtd. 11/20/88

The Project Office has evaluated the conclusions made by the NRC staff in the referenced letters concerning Project Office QA Audit 88-06 of SNL, which was conducted at the SNL facilities in Albuquerque, New Mexico, on July 25 through August 3, 1988. Proposed responses are enclosed.

If you have any questions regarding these responses, please contact me at (702) 794-7913 or FTS 544-7913.

James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:JB-2462

Enclosure:
Response to NRC Observation Report

cc w/encl:

Gordon Appel, HQ (FW-331) FORS
L. H. Barrett, HQ (FW-3) FORS
N. E. Carter, SAIC, Las Vegas, NV
S. H. Klein, SAIC, Las Vegas, NV
Stephen Metta, SAIC, Las Vegas, NV
J. E. Shaler, SAIC, Las Vegas, NV
O. D. Smith, SAIC, Las Vegas, NV
J. W. Estella, SAIC, Las Vegas, NV
H. H. Caldwell, SAIC, Las Vegas, NV
Gerard Heaney, SAIC, Las Vegas, NV
W. R. Sublette, SAIC, Las Vegas, NV
D. L. Mogar, SAIC, Las Vegas, NV



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YUCCA MOUNTAIN PROJECT OFFICE RESPONSE
TO NRC STAFF CONCLUSIONS CONTAINED IN
NRC OBSERVATION REPORT FOR QA AUDIT NO. 88-06

NRC CONCLUSION 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.

Response:

The NRC observation contained in paragraph 4.2.1 of the observation report stated that "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 Project Office offers the following clarification. The audit team did not have the impression that the SNL QA organizational structure would change in the near future. The SNL organizational structure as described in the SNL QAPP, Rev. A, was in need of revision in order to comply with Project requirements. This determination was made during Project Office QA Audit 87-5 of SNL, as described in Observation No. 5 of that audit report. The SNL response to the observation stated that the next revision of the SNL NNWSI QAPP (Rev. B) would carefully consider the suggestions contained in the observation. During the conduct of Audit 88-06, Rev. B was not yet approved. The audit team could not audit to an unapproved document. However, the audit team did review a draft copy of Rev. B to ensure that the commitments from the response to Observation No. 5 were being incorporated. Review of Audit 88-06 checklist item No. 1-7 indicates that SNL is satisfactorily complying with its previous commitments.

In addition, the lead auditor requested that the auditor assigned Criterion 1 review the draft copy of Rev. B to ensure that SNL personnel have the ability to escalate disputes to progressively higher levels of established organizational channels, including the Project Quality Manager. Review of Audit 88-06 checklist item No. 1-8 indicates that SNL is satisfactorily incorporating this provision into Rev. B.

Recommendations were made by the audit team in Audit 88-06 Observation No. 88-06-03 for SNL to develop a procedure for organization that would (1) define the SNL organization, (2) describe responsibilities for quality-related activities, and (3) identify the lines of communication within the SNL organization for resolution of quality-related disputes. An organization procedure separate from the QAPP would expedite the process SNL must take to indicate changes to the SNL organization. Follow-up by the Project Office to the observation response will include a verification that the previous SNL commitments are incorporated into the approved SNL QAPP, Rev. B.

NRC CONCLUSION 2:

DOE/YMPO audit results should address the overall QA program, not just transmit SDRs to the audited organization.

Response:

The Project Office audit report does address the audit results of the effectiveness of the overall QA program, as evidenced in the "Statement of Program Effectiveness" section (refer to paragraph 4.1). The transmitted SDRs and observations alone do not constitute the entire evaluation of a Project participant's QA program.

NRC CONCLUSION 3:

The audit team should focus more on QA program effectiveness, not solely on procedural implementation.

Response:

The audit plan stated that "The purpose of this audit was to evaluate the effectiveness of the SNL QA Program through verification of the implementation of the SNL QAPP, Rev. 0 and its implementing procedures." The audit team focused on verification that QAPP requirements were incorporated into implementing procedures, and verifying the implementation of those procedures. Based upon the results of this verification, the audit team was able to evaluate the effectiveness of the SNL QA Program, stated as the objective in the audit plan. In addition to reviewing these results to help determine the effectiveness of the SNL QA Program, the Lead Auditor requested that each auditor provide input on the effectiveness of each criterion audited. This request was made at two audit team caucus meetings at which the NRC staff observers were present. The audit report contains an entire section (refer to paragraph 4.1) on the effectiveness of the SNL QA Program. The NRC Observation Report does not appear to have considered the Project Office audit report in documenting Conclusion 3.

For the two examples given by the NRC supporting their concern, the following responses are offered:

Example 1:

Checklist item 10-1 states, "Verify that the QA Coordinator has established a schedule of surveillances." The question alone leaves many important areas unaddressed.

Response:

The audit team utilized the audit checklist as a guide. The Project Office agrees that checklist item 10-1 alone would leave many important areas unaddressed. However, the auditor did ask more questions than what the

example was based on. Several of the additional questions addressed these important areas, and were documented in the audit checklist during the audit. The "Statement of Program Effectiveness" section (refer to paragraph 4.1) documented in the audit report, includes the evaluation that SNL has not implemented the requirements in the Project QA Plan for surveillance activities. In addition, this concern was discussed at the audit exit meeting held at SNL on August 3, 1988, which was not attended by any of the NRC observers.

Example 2:

The NRC staff, based on its observations, is concerned that the audit team appeared to overemphasize the lack of a records management center area access list rather than focusing on whether access to the records management center was being controlled.

Response:

An SDR documenting the lack of an access list to the SNL records management center was drafted during the course of the audit. However, the SDR was not issued since the deficiency was corrected during the course of the audit and it was determined that corrective action to prevent recurrence was not required. Evaluation of the overall access control of records was being monitored by the entire audit team throughout the audit. Numerous times at the audit caucus meetings, the lead auditor asked the team if there were any problems in obtaining the appropriate records required to perform the audit. Based upon the fact that the audit team requested and received hundreds of records from the SNL records management center without undue problem or delay, the overall records control (including access) was evaluated to be acceptable. If records retrieval from the SNL records management center would have been a problem for the audit team, the draft SDR would have been issued, since an obvious adverse impact would have resulted from not having controlled access to the SNL records management center.

NRC CONCLUSION 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 objectives of the audit.

Response:

Contrary to the NRC statement contained in their observation report, the lead technical specialist did not discard use of the checklist for WBS element 1.2.4.2.1.3, "Laboratory Properties." Every audit item on the checklist was addressed during the audit by the lead technical specialist. However, before addressing the audit items on the checklist, the lead technical specialist asked a series of questions that were not on the checklist. The objective of these initial questions was to determine the status of the work in the Modified Work Plan for this WBS element. The

initial questions were intended to determine what work had been conducted and whether this work and the QA level at which it was performed were consistent with SNL's Modified Work Plan. This line of questioning was also necessary to determine if unqualified data or QA Level III work was being performed that would eventually be used for, or in support of, advanced conceptual design of the repository.

At the last stages of planning for this audit, the lead technical specialist was assigned to investigate the subject WBS because the original technical specialist could not accompany the audit team to SNL. The lead technical specialist's background was appropriate for auditing this area; however, due to the late change the lead technical specialist did not have time to develop his own checklist, and instead had to use the one developed by the technical specialist previously assigned to audit this WBS.

Every auditor has their own style or approach for developing a checklist that they will feel comfortable using in the performance of the audit. The NRC should recognize the need for a certain amount of individual style and flexibility in the development of the checklist as long as the objectives of the audit are accomplished. This need for flexibility of style was noted by the NRC on page 5 of their Audit Observation Report for the NNWSI audit of SNL: "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." In the case of the lead technical specialist, he asked additional questions that were not on the initial checklist to better evaluate SNL's QA program from a technical perspective.

NRC CONCLUSION 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.

Response:

The scope of the audit's technical evaluations did include a review of the selection of QA level assignments for several of the SNL technical activities audited, as evidenced by review of the audit checklist (refer to audit checklist item Nos. T-56, T-57, T-81, T-82, T-122, T-143, T-207, and T-208 for examples). These technical evaluations resulted in the issuance of SDR No. 173 and Observation Nos. 88-06-09, 10, 11, and 19.

Regarding the NRC's suggestion that future technical evaluations be expanded to "include investigations on whether ongoing activities are meeting the requirements given in 10 CFR 60," this suggestion is accomplished by auditing the controlling investigation plans (i.e: scientific investigation plans, workplans, study plans) which are based on higher level project documents such as the SCP, etc, which address the requirements contained 10 CFR 60.

NRC CONCLUSION 6:

The technical specialists should evaluate technical work being performed on all aspects of the ESF design, not just data-related activities.

Response:

The technical portion of the audit focused primarily on the technical aspects of QA Level I and II data collection activities, design activities, and performance assessment activities. The primary scope of SNL responsibility in support of the Project involves the repository and data management. SNL's ESF-related work is primarily a management support or planning type of activity that has been designated as QA Level III or NA (nontechnical administrative activities - no QA assignment required). The three WBS activity examples listed in the observation report are management support activities.

NRC CONCLUSION 7:

The technical specialists should ensure that their investigations are sufficiently detailed so that the stated objectives can be met.

Response:

Contrary to the statement contained in the NRC observation report, the technical specialists performed a detailed investigation to meet the stated objective of the audit. The NRC stated on the bottom of page 7 and the top of page 8 in their Audit Observation Report for the NNWSI audit of SNL that the State of Nevada "observer had identified more technical issues than the technical specialist on the team." This is an unfair and inaccurate statement. In this instance, the State of Nevada observer began independently reviewing an SNL document while the technical specialist was pursuing another course of questioning with the SNL personnel that was not directly related to the document being reviewed by the State of Nevada observer. While the technical specialist was asking questions, the State of Nevada observer suddenly interjected that he had found what he considered QA problems in the document he had been reviewing independently; his comment was unrelated to the course of questions. The Project Office technical specialist listened to the State of Nevada observer's comments, asked the SNL personnel a few additional questions pertinent to the State of Nevada observer's concerns, and then continued with his original course of questioning. It should be added that the Project Office technical specialist evaluated the State of Nevada's observer's concerns and included some of them as part of Recommendation No. 4 in the audit report. In general, considering the length of time generally available for an audit and the breadth of material to be audited, a technical specialist can only be expected to evaluate the technical quality of a sample of an audited organization's work. The technical specialist cannot be expected to locate and identify every technically-related quality assurance problem. Rather, based on the audit team's evaluation of the samples reviewed, an overall evaluation on program implementation is developed.

NRC CONCLUSION 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.

Response:

The NRC observation report states, "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."

The technical specialists on the audit team were not responsible for verifying the qualifications of the SNL personnel. This verification was assigned to the programmatic auditor assigned Criterion 2. Audit checklist item No. 2-18 is specific in verifying the qualifications of the SNL personnel. The programmatic auditor was to verify that SNL personnel met the position qualifications as defined in SNL position descriptions. This verification could not be accomplished during the audit because the SNL position descriptions did not contain all the information necessary to perform a complete review of SNL qualifications. This deficiency was documented on SDR No. 169, Rev. 0. Follow-up to this SDR will include a verification that SNL personnel meet the qualifications contained in the revised position descriptions.

The audit team openly discussed this deficiency during the audit team caucus meetings, which were attended by the NRC staff. Based on these discussions, the Project Office believes it did ensure appropriate emphasis on evaluating the technical qualifications of individuals within SNL in that the audit team had prepared checklist questions directed at the verification of the qualifications of SNL personnel.

NRC CONCLUSION 9:

The audit of technical reviewers was not sufficient to determine their qualifications.

Response:

As stated in the response to NRC Conclusion 8, a verification of the qualifications of SNL personnel could not be completed during the audit because the basis for establishing qualifications, the position descriptions, did not contain all the information required to perform the review. Follow-up to SDR No. 169, Rev. 0, which documented this deficiency, will include a verification of SNL personnel qualifications.

NRC CONCLUSION 10:

The audit teams should follow documented procedures or interim change notices.

Response:

The audit team utilized Quality Management Procedure (QMP)-16-03, "Standard Deficiency Reporting System," Rev. 0, in processing the final approved SDRs that were issued as a result of the audit. The paragraphs of the procedure that are referenced in the NRC observation report (5.2.1.1.9 and 5.2.1.2) specifically state that Project Office personnel shall identify and document deficient conditions on an SDR form by completing the appropriate blocks on the SDR. These paragraphs of the procedure do not state that the audit team members must indicate the severity level on the SDR, as stated in the NRC observation report. The audit team leader stated throughout the audit that the severity levels for any SDRs generated as a result of the audit would be assigned by the Project Quality Manager in an effort to maintain consistency in assigning severity levels for SDRs. Procedural requirements referenced in the NRC observation report for the issuance of the resultant SDRs were not violated.

The audit team did not have all the SDRs drafted during the audit. There was never any intention to release draft copies of the SDRs even if they had been drafted on the forms. A synopsis of the SDRs, observations, and recommendations resulting from the audit was discussed with SNL management and audit observers on a daily basis in efforts to inform them of the progress of the audit. During the audit exit meeting held at SNL on August 3, 1988, which was not attended by any of the NRC observers, the synopsis of SDRs was presented along with the proposed severity level the audit team was going to recommend to the PQM.

NRC CONCLUSION 11:

The DOE/YMPO audits should be able to determine if personnel at the audited organization understand and implement NRC requirements.

Response:

The NRC observation report identifies a concern regarding terminology used involving the term peer review. The NRC should be aware that a peer review as delineated in the NRC Generic Technical Position (GTP) has not yet been performed at SNL.

Although the practice of calling a 'technical review' a 'peer review' has long been used within SNL, the review of documents such as the SNL Modified Work Plans are considered by the Project Office to be technical reviews. The Project Office has provided guidance for the conduct of peer reviews to the Project participants in the Project QA Plan, NNWSI/88-9, Rev. 2 (refer to Appendix J), which was recently accepted by the NRC. Appendix J contains the NRC requirements specified within the NRC GTP for peer reviews, NUREG-1297.

The Project participants are required to develop implementing procedures to incorporate these and other Project requirements. Upon approval of these implementing procedures, the Project participants will be required to train their personnel to these procedures. This training should alleviate future

confusion with regard to the terminology involving peer reviews and provide all Project personnel with an understanding of NRC as well as Project Office requirements for the conduct of peer reviews.

NRC CONCLUSION 12:

DOE/YMPO should provide sufficient information to support its positions.

Response:

For the two NRC concerns contained in the NRC observation report, the following responses are offered.

Concern 1:

The NRC 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 Project Office team coverage in this audit area was sufficient.

Response:

During the audit, the audit team was responsible for verifying SNL committed corrective actions to only one previously generated SDR (No. 103, Rev. 0) that was generated as a result of a design document review, not a previous audit as implied in the NRC concern. The two commitments that were to be verified were: (1) a design drawing was to be submitted by SNL to the Project Office after review and approval by QA, and (2) SNL Department Operating Procedure 3-1 was to be revised to address QA review and approval of engineering drawings that are design outputs. These actions were satisfactorily verified to be complete. The corrective actions committed in response to the SDR could have been verified prior to the audit. However, the Project Office took the opportunity to verify the corrective actions to this SDR during the audit so that the implementation of the revised procedure could be verified. The approach taken by the audit team provides a more comprehensive verification and greater assurance that an SDR can be closed.

The audit team was not responsible for determining the acceptability of any other SDRs for closure during the audit. Copies of previously closed SDRs from past audits were contained in the audit books distributed to audit team members and observers for information purposes. The Project Office utilizes this practice to help prepare audit team members for the audit by making them aware of the kinds of deficiencies previously identified at SNL. The audit team could therefore determine whether previously committed corrective actions are still effective within the SNL QA Program. The closed SDRs were satisfactorily verified during audit follow-up activities by members of the previous audit team. This explanation was given at the time the audit books were described to the audit observers. Further questions should have been addressed to the Audit Team Leader or Lead Auditor prior to the end of the audit to alleviate any concerns by the observers.

Concern 2:

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.

Response:

Once again, neither the Audit Team Leader nor the Lead Auditor had any knowledge of this concern during the audit. The Project Office maintains the position that any Quality Level I, II, and III work has the potential to be used in licensing. The Project uses an approach to QA that recognizes the differences between engineered items and activities that affect radiological health and safety and waste isolation, and those that do not. The approach is designed to ensure that each item or activity is evaluated and assigned a QA level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, nonradiological health and safety, NRC licensing requirements, the operability and maintainability of the repository, costs, and schedules.

This approach classifies items and activities into one of three QA levels (QA Level I, II, and III), and further selects the QA requirements and measures to be applied to these items and activities consistent with their importance to safety (QA Levels I and II), waste isolation (QA Level I), and the achievement of DOE mission objectives (QA Levels II and III). This will be accomplished by deliberate quality planning and selective application of QA requirements on the item or activity to be performed, with varying degrees of QA applied depending on the item or activity function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.

This approach will ensure that all engineered items important to safety or waste isolation (Q-List) and activities important to waste isolation (quality activities list) are identified and controlled in accordance with a QA program that meets the requirements of 10 CFR 60, Subpart G (QA Level I).

Data or data interpretations generated as a result of activities not controlled in accordance with a 10 CFR 60, Subpart G QA Program (QA Level I), or activities performed before the complete implementation (acceptance by the NRC) of the Project QAPs will not be used in the licensing process as primary information for items and activities important to safety and/or waste isolation unless qualified in accordance with administrative procedures meeting the guidance provided in "Qualification of Existing Data for High Level Nuclear Waste Repositories" (NRC, 1988a) or other method accepted by the NRC.

All Project Office audits concentrate their verification efforts on Quality Level I or II work products and activities to verify that QA requirements are being met.

NRC CONCLUSION 13:

DOE/YMPO should ensure its audit teams are performing thorough investigations.

Response:

The Project Office is concerned that the NRC is questioning the investigation performed by the audit team based on the example presented in the NRC observation report.

The NRC concern stated, "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."

The audit checklist, prepared in advance of the audit, contains questions related to the NRC concern. Specifically, audit checklist item No. 5-8 states, "Verify that TP's are reviewed and approved by the following:

- o Author
- o SNL NNWSI Project PI
- o An independent technical reviewer
- o Division Supervisor of the PI
- o (QA Review - WMPO 88/9)"

The fifth bullet of checklist item No. 5-8 requires the auditor to verify if a QA review of TPs has been performed by SNL.

The auditor responsible for Criterion 5 reported that "Objective evidence could not be provided to demonstrate that SNL QA had performed a QA review of SNL technical procedures." This deficiency is documented on the audit checklist and on SDR No. 178, Rev. 0. The requirement was a significant addition incorporated into the Yucca Mountain Project QA Plan, NVO-196-17, Rev. 5. SNL had not revised their QAPP to meet Rev. 5 at the time of the audit. This discussion took place at the audit team caucus meetings attended by the NRC observers.

NRC CONCLUSION 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.

Response:

The NRC has expressed a concern in the observation report that unqualified data was being used in ESF design and analysis activities. As pointed out in the NRC clarification letter ("Clarification of last paragraph on Page 10 of the Sandia Observation Audit Report," J. J. Holonich to File, dtd. 11/20/88), data contained in the RIB does not necessarily have to be qualified. Only if the data is to be used for licensing does it need qualification. The Project Office has taken the position that unqualified data can be used during the design and analysis activities of the ESF. However, this unqualified data must be identified in the RIB as unqualified and is to be supported with data obtained from ESF testing activities throughout the site characterization phase of the Project. At that time the data will have to undergo the qualification process outlined in NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories," if it is decided to use the data in licensing.

As pointed out by the NRC staff in the observation report (refer to last paragraph on page 8), "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." There were no deficiencies identified as a result of the audit team's investigation.

There have not been any attempts to qualify existing data to date on the Project. The Project Office is presently revising its procedure, "Qualification of Data and Data Interpretation Not Generated Under the NNWSI Project QA Plan," which will be followed by all Project participants when attempts to qualify data begin. The procedure will incorporate the requirements contained in NUREG-1298 and provide a uniform qualification methodology for all Project participants to implement.



Department of Energy

Nevada Operations Office

P. O. Box 98518

Las Vegas, NV 89193-8518

MAR 06 1989

WBS #1.2.9.3

"QA"

Ralph Stein, Associate Director, Systems Integration and Regulations,
HQ (RW-30) FORS

PROPOSED RESPONSES TO THE U.S. NUCLEAR REGULATORY COMMISSION (NRC)
OBSERVATION AUDIT REPORT FOR YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE)
AUDIT NO. 88-07 OF REYNOLDS ELECTRICAL AND ENGINEERING COMPANY (REECO)

The Project Office has evaluated recommendations made by the NRC staff concerning the Project Office audit of REECO, Audit No. 88-07. Proposed responses are enclosed.

If you have any questions regarding these responses, please contact James Blaylock of my staff at (702) 794-7913 or FTS 544-7913.

A handwritten signature in black ink, appearing to read "Carl P. Gertz".

Carl P. Gertz, Project Manager
Yucca Mountain Project Office

YMP:JB-2419

Enclosure:
Response to Audit 88-07

cc w/o encl:

L. H. Barrett, HQ (RW-3) FORS
M. A. Fox, REECO, Las Vegas, NV
R. F. Pritchett, REECO, Las Vegas, NV
H. H. Caldwell, SAIC, Las Vegas, NV
J. E. Clark, SAIC, Las Vegas, NV
B. A. Tabaka, SAIC, Las Vegas, NV



NRC OBSERVATIONS AND RESPONSES FOR AUDIT 88-07

Observation 1

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 included in the audit, the basis and justification should be included in the audit plan.

Response

The Project Office prepares audit plans in accordance with standardized guidelines that do not include written justification why certain QA elements are excluded from the audit scope. Audit plans are prepared for the express purposes of guiding the audit team and informing the audited organization of scheduled activities. The DOE is considering specifying the reasons why specific criteria may not be part of the scope of an audit.

However, since the Yucca Mountain Project QAP (NINWSI/88-9, Rev.1) requires an audit of applicable elements of each contractor's QA Program on an annual basis, the audit report for each scheduled full-scope audit will document the basis for any exclusions of applicable QA elements.

With regard to the staff's concern that Criterion 16, "Corrective Action," was not evaluated in detail, the Project Office again emphasizes that no Nevada Test Site Operations (NTSO) work had been performed in this area. Therefore, there was insufficient objective evidence available to examine existing controls. The other areas evaluated that had no Yucca Mountain Project work did have NTSSO work that could be evaluated for capability.

ENCLOSURE

Observation 2

The audit process should include an evaluation of the quality of the product and/or activity as well as procedural controls.

Response

The Project Office policy concerning audits is to examine procedural controls as well as evaluate the quality of end products or activity. This policy has been in effect in past audits and will remain in effect in future audits.

The Project Office believes that the singular example used to substantiate the NRC staff's concern that programmatic controls were overemphasized may not have had the benefit of capturing the complete discussion since the NRC staff observer did not arrive at the interview concerning surveillances in time to witness the full questioning process. In the situation described, questioning did indeed focus on the certification form for surveillance personnel, but only after it had been established that the form represented the official record of minimum qualifications. This preliminary discussion was missed by the staff observer, as was the retrieval (through prior auditee notification) and review of surveillance documents that led to the qualifications issue. These end-product review actions were witnessed by observers from the Project Office and the State of Nevada, who were present at the interview from its beginning.

Questions on the substance and content of the four retrieved surveillance reports was included in the interview. The adequacy of emphasis on that end-product review is subject to opinion, but the Project Office believes the auditor examined characteristics in the reports sufficiently to conclude that surveillances were ineffective. Factors considered in this decision were the infrequency of REECO surveillances and the superficial depth of REECO surveillance reports. This was indicated by the major deficiencies identified and documented during this audit in areas that had been previously surveilled by REECO.

The audit team attempted to evaluate other products of quality affecting activities (e.g., records, procurements, audits), but those products could not be used as bases for conclusions because they were not associated with QA Level I or II Yucca Mountain Project work. Only the programmatic controls could be evaluated. The NRC staff must consider that there can be no end-product evaluation when there are no end-products of QA Level I or II activities.

Observation 3

DOE/YMPO had previously approved the procedures found inadequate by the audit team. Thus, the YMPO review process appears to be deficient. The staff recommends that the audit teams have available to them a formal mechanism in the audit procedure (such as a corrective action report) by which concerns outside of the program they are auditing can be identified. In this instance, such a mechanism would assure that an apparent problem in the YMPO review process was corrected.

Response

Operating philosophy at the time of the REECO audit limited the issuance of deficiency documents to only the audited organization. The audit team has subsequently employed established policy to issue Standard Deficiency Reports (SDRs) as needed to identify Project Office deficiencies when they impact the effective implementation of quality requirements at the contractor level. As a result of the Lawrence Livermore audit, two (2) SDRs were issued to the Project Office.

Observation 4

The audit team should be better prepared in their awareness of applicable implementing procedures and in their method of determining the scope of quality level I or II work conducted since the last audit and presently ongoing.

Response

The first part of this observation apparently resulted from a staff misinterpretation of the audit team leader's reference to "implementing procedures." During the initial stages of audit preparation, the audit team regarded the REECO quality administrative procedures (NQPs) as the first line of "implementing procedures." The team leader's statement to the staff observer concerning insufficient detail in implementing procedures applied to the NQPs. The lack of specifics in NQPs was noted early in the audit preparation phase; hence, development of audit checklist questions was adjusted to focus on identifying control methods employed by REECO in lieu of NQP-level direction. The staff should note that most checklist questions referenced the REECO QAPP requirements, due to the absence of "implementing" controls in the NQPs.

In the audit preparation stage, checklist development revealed that NQP 12.0, "Control of Measuring and Test Equipment," was particularly lacking in specifics necessary to implement Criterion 12 requirements. This fact was relayed to the staff observer within that context, and was not meant to apply to lower level procedures used to perform M&TE calibration activities. The audit team was fully aware of the existence of the lower level calibration procedures, but checklist questions were focused on evaluating the functional capability of programmatic controls — since no QA Level I or II Project work had been performed.

The NRC observers also expressed concern that audit team preparation was inadequate due to the method used to determine the scope of QA Level I or II activities. The Project Office considers this observation unfounded as the Project Office is not aware of any evidence noted during the audit to substantiate this NCR observation. There was no evidence that audit preparation was inadequate simply because the official record of REECO activities was obtained from REECO rather than through the Project Office. Since the audit team was demonstrably aware of the QA Level I and II ongoing activities, the scoping method presently employed by the DOE Project Office is considered adequate and effective.

Observation 5

During the daily caucuses, a sufficient amount of time should be allotted to gathering and analyzing information so that the facts pertaining to SDRs can be clearly documented.

Response

This concern was noted and has been addressed by revised practices adopted on subsequent audits. In the ensuing audits of Los Alamos and Lawrence Livermore, time schedules were adjusted to allow full discussion of issues at the audit team caucuses in the evenings. Meetings with auditee management are scheduled for the next morning. This system allows more time for research of identified discrepancies and assures adequate information is available to team leads during discussions with auditee management.



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

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MAR 06 1989

Ralph Stein, Associate Director, Systems Integration & Regulations,
HQ (RW-40) FORS

**YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) RESPONSES TO U.S. NUCLEAR
REGULATORY COMMISSION (NRC)/LOS ALAMOS NATIONAL LABORATORY AUDIT 88-08
OBSERVATIONS**

The Project Office has evaluated the NRC comments for U.S. Department of Energy/Project Office Audit 88-08. The enclosure contains the NRC comments and the proposed responses.

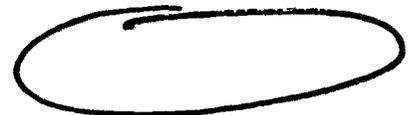
If you have any questions regarding these responses, please contact James Blaylock of my staff at FTS 544-7913 or (702) 794-7914.


Carl P. Gertz, Project Manager
Yucca Mountain Project Office

YMP:JB-1761

Enclosure:
NRC Observations and Responses for Audit 88-08

cc w/encl:
L. H. Barrett, HQ (RW-3) FORS
S. H. Klein, SAIC, Las Vegas, NV
H. H. Caldwell, SAIC, Las Vegas, NV
J. C. Friend, SAIC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV
B. A. Tabaka, SAIC, Las Vegas, NV



NRC OBSERVATIONS AND RESPONSES FOR AUDIT 88-08

The purpose of this letter is to transmit responses to observations reported by members of the Nuclear Regulatory Commission (NRC) observer team during the Department of Energy (DOE)/Yucca Mountain Project Quality Assurance (QA) Audit 88-08 of Los Alamos National Laboratory (Los Alamos). The audit was conducted during the week of October 3, 1988. The NRC Audit Observation Report, (Letter, Linehan to Stein, dtd. 12/22/88) listed five observations regarding the audit team and the conduct of the audit. The observations are summarized below along with the responses:

Observation No. 1

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 them in the audit should be addressed in the audit plan.

Response: During the planning phase of Audit 88-08, a decision was made not to include Appendix B, Criterion IX, Control of Special Process; Criterion X, Inspection; Criterion XI, Test Control; and Criterion XIV Inspection, Test, and Operating Status. These criteria were not included since they did not directly apply to Los Alamos at the time of the audit per the approved Los Alamos QA Program Plan. The audit plan was developed to document what would be audited and did not specify the reasons for omitting certain criteria. The audit report for 88-08 explains in detail why the decision was made not to audit the specific criteria. The DOE is considering specifying the reasons why specific criteria may not be part of the scope of an audit.

Observation No. 2

When the lack of necessary knowledge is detected in the audited organization's staff, it 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.

Response: In reference to the specific case discussed, the auditor, after discussions with the NRC observer, did follow-up on the concern. The auditor developed information that led to the issuance of SDR No. 210, which dealt with the lack of a QA staff training program. Additionally, the auditor contributed information that led to the overall 88-08 decision that the Los Alamos training program was ineffective. Furthermore, the auditor developed information used in the 88-08 Audit Report's executive summary, which states in part, "...the QA Department was understaffed and was frequently unable to respond to the inquiries of the audit team during the course of the audit." Therefore, the larger problem was considered explored and is discussed in Audit Report 88-08.

Observation No. 3

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

Response: During the planning stage of Audit 88-08, a decision was made to only use the Los Alamos QA Program Plan rather than the implementing procedures because the procedures were being revised. It was felt this direction would be more consistent with evaluating the program in place since the previous audit in 1987. Once the audit began, however, it was recognized that enhancing the scope and direction of the audit activities to include the implementing procedures was necessary. At the direction of the Project Office, the audit team redirected their efforts from the approved audit plan to include the implementing procedures. The audit team adjusted their audit plan and added additional checklist questions. The Project Office feels this was an isolated occurrence and will continue to use implementing procedures, as applicable, when developing checklists.

Observation No. 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.

Response: The Project Office agrees that audit reports, regardless of the organization, may be useful in preparing for an audit. During the planning stages of Audit 88-08, the audit team leaders made a decision not to use the NRC "mini" audit as part of this audit. The approach outlined in the NRC audit was not germane to the activity planned by the Yucca Mountain Project. The NRC's concerns are not totally warranted in this instance, since the audit team adequately addressed the three areas that the NRC felt needed improvement at Los Alamos. Those areas were:

1. Procedures

Audit 88-08 identified this as a major area of concern because of a lack of sufficient procedures and inadequacy in existing procedures.

2. Internal Audit Program

Audit 88-08 determined that the internal Los Alamos audit process was ineffective.

3. Documentation and Training of Personnel

Audit 88-08 determined that personnel training and position descriptions were ineffective.

Observation No. 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.

Response: The Project Office agrees totally with this observation and will make every effort to conduct all briefings with the audited organization's management in a separate location.