



Department of Energy
Washington, DC 20585

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

Dear Mr. Linehan:

At the July 7, 1988, meeting between the DOE and NRC on Quality Assurance, the DOE committed (QA-G-1) to provide the NRC with responses to the concerns raised by the NRC observer team at the following:

- a) DOE/YMPO audit (No. 88-01) of Fenix and Scisson conducted during the week of 2/22/88.
- b) DOE/YMPO audit (No. 88-02) of Holmes and Narver conducted during the week of 3/28/88.
- c) DOE/YMPO audit (No. 88-03) of the U.S. Geological Survey conducted during the week of April 25, 1988

Enclosed are the DOE responses. Questions regarding this correspondence should be addressed to myself, at 586-1462.

Sincerely,

Gordon Appel, Chief
Licensing Branch
Office of Civilian Radioactive
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cc: R. Stein, RW-30 w/encl
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NRC OBSERVATION REPORT FOR AUDIT 88-01

1. Effectiveness of the audit would have been improved if a technical specialist would have been added who was knowledgeable in mining, etc...No evaluation of the end product was made.
2. Technical checklist questions are considered to be programmatic by the NRC. Examples were 2-1 and 2-4.

Response To Observation No. 1

The audit team included Technical Specialists. Since the design activity had just been initiated, this was deemed sufficient in view of the limited number of design products that were available for the audit team. Now, a Lead Technical Specialist (LTS) is assigned to audits. The LTS, accompanied by the Team Lead, travels to the site to identify the technical activities to be included in the scope of the audit. Based on this evaluation, the technical specialists with appropriate expertise are identified consistent with the technical activities that were included within the scope of the audit. The LTS then selects the properly qualified TSs and assigns specific areas for checklist preparation.

Response To Observation No. 2

This point is being stressed to the technical specialist team in preparing for the upcoming LANL Audit. Guidelines have been developed to facilitate technical checklist development.

NRC OBSERVATION REPORT FOR AUDIT 88-02

- o Nothing adverse noted.

NRC OBSERVATION REPORT FOR AUDIT 88-03

The purpose of this letter is to transmit responses to concerns reported by members of the Nuclear Regulatory Commission (NRC) observer team during the DOE/WMPO Audit (No. 88-03) of the U.S. Geological Survey (USGS) Yucca Mountain Project (YMP). The audit was conducted during the week of April 25, 1988. The NRC Audit Observation Report, (Letter, Youngblood to Stein, dtd. 5/23/88) listed 15 concerns regarding the audit team and the conduct of the audit. The concerns are summarized below along with the responses:

1. All QA Auditors had a programmatic background: There should be a mix of QA Auditors with programmatic and those with technical backgrounds.

Response: Auditors with technical backgrounds have been audit team members on previous and subsequent audits and will be included in future audits as appropriate. The function of the two technical specialists on the audit was to supplement the technical expertise of the auditors; this is consistent with the practice of using technical expertise to examine the accomplishment of on-going engineering and site characterization activities.

2. Additional audit team preparation was needed in the area of availability of equipment and personnel, (i.e., Seismic Refraction equipment was not at Menlo Park nor was the principal investigator during the audit due to an emergency condition.) The NRC staff thought that preaudit communication between the audit team and the auditee should be improved.

Response: The audit team leader knew in advance that the equipment and the PI would not be available during the audit and attempted to delay the audit. It was determined that the absence of the equipment and the PIs for the two active SIPs was not critical to the overall audit since other activities such as software, procurement, and calibration controls could be successfully audited. In addition, the status of the two active SIPs was investigated during a surveillance in October 1987. Therefore, it was decided by management to conduct the audit as scheduled.

3. 10 CFR 50, Appendix B Criteria II, XVI, XVI and XVII were not audited at USGS-Menlo Park, the reason being, it was judged during the audit planning these criteria would be adequately covered for the USGS in the subsequent audit of USGS headquarters at Denver. The reasons the criteria should have been included in the Menlo Park Audit are:

Criterion II

Auditee personnel did not understand how to process procurement records. This indicates the training program may be ineffective.

Criterion XVI

The NRC Observers questioned the Menlo Park QA representatives on the corrective actions being taken in response to previous SDRs. He stated that since he had not seen the USGS response to the SDR, the corrective actions were not being implemented. This implies that Criterion XVI should have been audited.

Criterion XVII

The fact that procurement records were not sent to Denver and did not have assigned QA Levels indicates a lack of training and/or poor record procedures.

Criterion XVIII

The fact that the USGS internal audits did not find the above deficiencies, indicates that the USGS audit system should have been audited.

Response: Prior to the Menlo Park Audit, it was known that the logical place to programmatically audit Criteria II, XVI, XVII, and XVIII would be at Denver, since objective evidence of implementation of these criteria was maintained there. Through questioning on other criteria at Menlo Park, weaknesses were identified which focused the USGS Denver audit on training, corrective action, records management, and audit investigations at the Denver audit. The audit team did investigate corrective action implementation on previous SDRs and observations (see NRC Observation No. 13). There were no specific questions on the Menlo Park Audit checklist regarding the four cited criteria, but there was follow-up at Denver based on the problems identified at Menlo Park. The Denver audit included these criteria.

Preliminary scoping trips to auditees sites are being conducted to determine what technical work can be audited and which programmatic QA criteria are applicable.

4. Although the two active SIPs were audited, the NRC staff thought that the development process for unapproved SIPs should have been included in the audit.

- o Expanding the scope of the USGS/Denver Audit during the course of the audit. This audit was expanded to include computer software which was discovered to be in use during the course of the audit. The team lead brought in a technical specialist with computer software expertise during the second week of the audit.

10. Time allotted for the audit was insufficient to accomplish the required activities.

Response: Subsequent audits as described in the response to NRC Observation No. 9 have been extended in time as deemed necessary and this policy will continue for future audits.

11. Audit team members were constrained by lack of time from obtaining supporting documentation and facts to justify a team finding, causing inability to respond to a rebuttal by the USGS QA representative.

Response: Every effort is made to obtain the necessary documentation prior to the exit meeting; however, as was the case in this situation, new or additional information may become available at any time.

Subsequent audits have been extended to allow the audit teams more time to investigate observed deficiencies and to fully brief the auditee management on observed deficiencies on a periodic basis.

12. Discussion of issues and potential SDRs should have been discussed prior to the exit meeting.

Response: We agree, since that is the purpose of the periodic caucuses with the auditee management. The purpose of the exit meeting is to summarize the audit results.

13. Audit team did not follow-up on SDRs and observations from previous audits except for a calibration deficiency.

Response: The audit team did investigate the only SDR and observations applicable to the USGS at Menlo Park. SDR No. 72 identified a deficiency in the area of Software QA. Although the corrective action completion date had not yet passed, follow-up was subsequently performed and two SDRs (SDR No. 134 and 140) were written as a result.

One observation from Project Office Audit No. 87/6-7 (Observation No. 3) identified a problem with procurement document control. Follow-up in this area also resulted in an SDR (No. 135). There were three observations from Project Office Surveillance No. SR-88-001:

8. The NRC staff is unable to make a final determination on whether problems exist in the USGS QA Program until a more solid foundation is built on the root cause of deficiencies. The audit team did not perform any root cause analyses as a part of its audit.

Response: The audit team is not responsible for root cause determination on identified deficiencies. The auditee is required to identify the root cause and implement corrective actions accordingly. The recommended actions section of the SDR (Block 10) usually guides the auditee as follows:

1. Identify the action(s) to be taken to correct the specific deficiency.
2. Determine if similar conditions exist.
3. Identify the cause of the condition(s) and what will be done to prevent recurrence.
4. Determine the impact of the deficiency on the work performed.

When responses to SDRs are received, the auditee's determination of root cause is assessed for adequacy.

9. Because team interactions were generally not effective, the team leader could not adjust the scope of the audit or the depth of the investigation.

Response: Audit team interactions for subsequent audits have been generally effective due to DOE/YMP QA Management decisions to modify the audit process by:

- o Adding an overall Team Lead in order for the lead auditor to direct his team more effectively.
- o Appointing a Lead Technical Specialist to improve the direction and coordination of the technical portion of the audit.
- o Extending the audit time for subsequent audits where deemed necessary, (i.e., the USGS/Denver and Sandia Audits).

Response: Because QA is intimately involved in SIP review and approval here at the Project Office, it was decided that the development process would not be audited.

5. Auditors did not vary from checklist questions, thus did not pursue an issue because the checklist requirement had been fulfilled. The main reason was time.

Response: The audit team found sufficient evidence, using only the checklist questions, to conclude that the systems were not being controlled effectively. For example, the procurement checklist produced 23 unsatisfactory answers out of 25 questions. The team felt it was unnecessary to investigate further or extend the auditing process when the deficiencies were so obvious. The same situation existed for the control of M&TE. In the area of software QA, four additional checklist items were added and explored during the audit.

The revised audit procedure emphasizes the responsibility of auditors to investigate to the depth necessary to determine adequate and effective implementation of requirements. In addition, subsequent audit team training has emphasized the fact that audit conduct is not restricted to the audit checklist alone, and checklist questions can be added to the checklist as necessary with approval of the lead auditor.

6. At the first daily caucus there was little if any audit team interaction due to a USGS representative constantly rebutting preliminary findings.

Response: Subsequent audits have not and will not include auditee representatives in the daily caucuses. Auditee management will be kept apprised of preliminary findings once the audit team has completed their daily caucuses.

7. At the audit team caucuses, the team lead (also lead auditor) did not question any of the findings nor was the significance discussed, nor was there any attempt to discover if the findings were systematic deficiencies or just isolated occurrences.

Response: In the areas of procurement control and control of measuring and test equipment, it was concluded by the audit team that the extent of deficiencies indicated that the systems were not being controlled effectively. Furthermore, this fact was stated in the executive summary of the audit report (Letter, Blaylock to Hayes, dtd. 7/21/88).

Observation No. 1 did not require follow-up.

Observation No. 2 from that surveillance is the follow-up on a calibration deficiency referred to in the NRC's report. The follow-up resulted in SDR No. 139.

Observation No. 3 related to procurement activities. Follow-up resulted in SDR No. 136.

SDRs and observations from previous audits and surveillances are reviewed by the audit team during the checklist preparation stage of each audit. Copies of the above referenced documents were included in the auditor's notebooks. In the future, specific reference to the follow-up activities will be made in the audit plan and audit report to increase the visibility of these activities.

14. In the audit area that dealt with the examination of technical products, the staff believes that the technical specialist did not integrate the technical and QA portions of the audit as he should have done. During the audit process, the QA auditor was not involved in the discussions nor is there any evidence that either the QA or technical checklists were used by the appropriate individual on the subteam. This is indicated by the fact that one of the checklist items in the technical area included verification that the procedures used to implement the SIPs contain a discussion of the procedure limitations. As a result of this review, the staff found that NWM-USGS-SP-08, Revision 0 and NWM-USGS-GPP-01, Revision 1, do not discuss any limitations of these procedures. If the checklist were followed, this could have been identified by the auditor.

Response: The site characterization process obtains information (data) that establishes a range of values for a given parameter. Since no pre-established limits are designated for the range of values, acceptance of the data is based on either analysis or statistical criteria. Hence, the "limits" question on the checklist was considered inappropriate by the Technical Specialist and therefore not audited.

15. Several examples of poor team coordination were noted, (i.e., lack of well planned and executed exit meeting as well as daily caucuses).

Response: By adding a team leader to the audit team in subsequent audits, the lead auditor and the lead technical specialist have more time to coordinate the daily schedule, daily caucuses, and the exit meeting.