

LANL BELKE

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AUG 11 1989

MEMORANDUM FOR: John J. Linehan, Director  
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Division of High-Level Waste Management

THROUGH: James E. Kennedy, Section Leader  
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FROM: William L. Belke, QA Project Manager  
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Division of High-Level Waste Management

SUBJECT: NRC REVIEW OF DOE RESPONSES TO NRC's JUNE 8-12, 1987 AUDIT  
OF THE MINERALOGY/PETROLOGY STUDIES AT LOS ALAMOS NATIONAL  
LABORATORY

In June of 1987, the NRC staff conducted an audit of the Los Alamos National Laboratory (LANL) Quality Assurance Program (QAP) against the criteria of Appendix B to 10 CFR Part 50. The audit report was issued on October 9, 1987 and identified 17 deficiencies that DOE needs to respond to before NRC can accept the LANL QAP.

In Section 16.0, paragraph 16.1 of the LANL Quality Assurance Program Plan, it is required that nonconformances and/or conditions adverse to quality be corrected as soon as practical. Likewise, this is also required in Section 16 of Basic Requirement 16 of ANSI/ASME NQA-1-1986. As indicated in the fifth and most recent DOE Surveillance Report (YMP-SR-89-009, dated April 29, 1989), twelve of the original seventeen Corrective Action Reports (CARs) generated as a result of deficiencies cited from the NRC June 8-12, 1987 audit remain open.

The majority of the NRC staff audit findings were defined as "deficiencies" (an item which is an error, inconsistency, or procedural violation with regard to project commitments, specifications, procedures, codes or regulations). Deficiencies do not create an immediate or increased risk to the public health and safety, and consequently are of minor safety concern. Since the majority of the NRC staff findings were not of the substance having an actual or high impact on public health and safety, the findings should have been correctable in a relatively short time frame. However, after two years and five Yucca Mountain Project Office QA Surveillance Report submittals by DOE (88-014, 88-018, 89-002, 89-005, and 89-009), only five CAR's have been completed.

The NRC staff is concerned about whether an effective corrective action program has been established which can implement corrective action in a timely manner, when after two years twelve of seventeen findings of minor safety concern still remain open. This concern was brought to the attention of DOE management by the

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NRC staff at the bi-monthly QA meeting held at NRC Headquarters in Rockville, Maryland, July 11, 1989. It is expected that future NRC audit and surveillance findings will be responded to in a more expeditious manner.

The NRC disposition of the DOE responses is categorized as follows:

1. The response is satisfactory.
2. DOE committed to making changes in the LANL QAPP. For these changes, the NRC staff verified that the necessary changes have been made during its formal review of the LANL QAPP. The LANL QAPP was submitted to the NRC staff by DOE on May 15, 1989, and was acceptable pending satisfactory resolution of eight comments generated by the NRC staff (ref. Linehan/Stein letter dated July 19, 1989).
3. DOE has committed to making changes in procedures at LANL and initiating appropriate corrective action. For these changes, prior to the DOE acceptance audit of LANL, the NRC staff will request DOE to include provisions in their audit process to verify that procedures have been revised and appropriate corrective action implemented to address the deficiencies noted in the audit report. The NRC staff intends to verify this corrective action during subsequent audits, surveillances, and observation audits.

The table below itemizes the current status of the DOE responses to the June 8-12, 1987 NRC audit of LANL.

<u>NRC AUDIT FINDING NO., AND SUMMARY OF NRC AUDIT FINDING</u>	<u>DOE STATUS AND AND RESPONSE</u>	<u>NRC COMMENTS</u>
B-1 (Finding). Procedures do not address how QA Implementation Manager resolves quality-related conflicts. Procedures do not address how stopwork order is implemented.	OPEN-CAR-024 issued. QAPP revised. QP-01.2 issued. Personnel training to new procedures in process.	(3) Acceptable pending NRC/DOE verification of personnel training.
B-2 (Observation). Reporting relationships need to be properly reflected in QAPP.	No response necessary for NRC audit observations. QAPP was revised.	NRC will verify reporting relationships during audit process.
B-3 (Finding). Personnel certified to procedures rather than specific duties. No specific qualifications identified	CLOSED-CAR-025 issued issued and QAPP and QP-02.1 have been revised.	(3) Although DOE closed, the response appears questionable. The emphasis appears to be placed on training to

NRC AUDIT FINDING  
NO., AND SUMMARY OF  
NRC AUDIT FINDING

DOE STATUS AND  
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NRC COMMENTS

for performing the quality-related function of the QA, QAS and QAL.

a specific duty. Training and qualification records should be sampled to determine the adequacy of QP-02.1 for the job description, experience, how certified, specific duty, etc.

B-4 (Finding). No record of management determination of who needs/requires training. No record of annual training evaluation.

OPEN-CAR-026 issued. QAPP and QP-02.1 have been revised to include requirements for training and a documented annual evaluation.

(3) Acceptable pending NRC/DOE verification of personnel training.

B-5 (Deficiency). No identification of the method used to document the QA review and concurrence for procurement requisitions.

OPEN-CAR-027 and CAR-050 issued. QPs 04.1 and 04.3 direct QA to document review results and concurrence of procurement

(3) Acceptable pending NRC/DOE verification of personnel training on procedures. NRC/DOE should take a sample of procurement requisitions to assure QA has participated and documented their review and concurrence.

B-6 (Deficiency). Several of the Detailed Technical Procedures (DPs) did not contain acceptance criteria as required by the QAPP.

OPEN-CAR-027 issued. QP-03.5 to be issued and training on QP-05.2 is in process. A list of procedures that need to include acceptance criteria will be developed.

(3) Acceptable pending NRC/DOE review of QP-03.5 for adequacy and QP-05.2 for implementation. Procedures should be sampled to assure they contain adequate acceptance criteria.

B-7 (Deficiency). The requirement for the identification of equipment and materials does not specify what information should be recorded. The

OPEN-CAR-029 and 050 issued. QP-14 revised and will be reissued as QP-03.5 to include equipment and recording

(3) Acceptable pending NRC/DOE review of the revised procedure for adequacy, understanding and implementation of QP-03.5. NRC believes

NRC AUDIT FINDING  
NO., AND SUMMARY OF  
NRC AUDIT FINDING

DOE STATUS AND  
AND RESPONSE

NRC COMMENTS

meaning of this requirement was also not understood for what should be recorded for sample history.

requirements. Personnel will also be trained in the use of the revised procedure.

the procedure should specify the equipment used, part and/or property number, serial number, and calibration due date. For sample use, it does not appear to clearly address the necessary corrective action for the audit finding.

B-8 (Deficiency). The terms, "State-of-the-art" and "Independent reviewer" are not defined in the QAPP. There were no criteria to determine if the procedures are "state-of-the-art" and if procedures have been developed for technical review of procedures.

OPEN-CAR-030 and CAR-050 issued. QAP-05.2 will be revised to define the two terms, personnel will be trained, and all DPs will have independent technical reviewers.

(3) Acceptable pending NRC/DOE verification of technical reviews of the DPs.

B-9 (Deficiency). QA programs not adequate or appropriate for the services being procured by LANL in that they did not address the appropriate criteria from the LANL QAPP.

OPEN-CAR-031 issued. LANL evaluation of QA programs found them acceptable. Personnel will be trained to QPs 04.1, 04.2, and 04.3.

(3) Acceptable pending NRC/DOE verification of training to QPs. NRC needs to verify the justification of why the LANL evaluation of the QA programs was acceptable.

B-10 (Deficiency). Supplier documents did not contain a summary report of the results of the survey or any subsequent correspondence regarding this supplier.

OPEN-CAR-032 issued. Found this to be an isolated instance and a procedural violation. Personnel will be trained to QPs 04.1, 04.2, and 04.3.

(3) Acceptable pending NRC/DOE verification of personnel training. It should also be verified and determined whether this was an isolated instance by taking a sample of the QA procurement file.

B-11 (Deficiency). Implementing QPs did not address QAPP requirement that annual

OPEN-CAR-033 and CAR-050 issued. QP-04.3 modified to

(3) Acceptable pending NRC/DOE verification of personnel training.

NRC AUDIT FINDING  
NO., AND SUMMARY OF  
NRC AUDIT FINDING

DOE STATUS AND  
AND RESPONSE

NRC COMMENTS

supplier evaluations should be documented.

require QA to reevaluate Vendor' List to determine which suppliers should be reevaluated.

A sample of the Approved Vendor' List and purchase orders should be taken to determine whether this requirement has been implemented.

B-12 (Deficiency). Implementing QPs did not address QAPP requirement that documentation generated by suppliers shall be controlled, handled, and approved in accordance with LANL implementation procedures.

OPEN-CAR-034 and CAR-050 issued. QP-04.1 revised to include QAPP requirement.

(3) Acceptable pending NRC/DOE verification of personnel training. A sample of supplier documents should be taken to verify implementation.

B-13 (Deficiency). Implementing procedures did not address the QAPP requirement to include a means to evaluate supplier performance.

OPEN-CAR-035 issued. QP-04.1 and 04.2 revised to provide a means to evaluate supplier performance with right of access, audits, surveys etc.

(3) Acceptable pending NRC/DOE verification of personnel training to procedures. NRC/DOE should take a sample of procurement documents and associated documentation to verify whether supplier performance has been evaluated.

B-14 (Observation). Inconsistent labeling of box of thin sections.

No response necessary for NRC observations.

NRC will look at sample identification during NRC audits and observation audits.

B-15 (Deficiency). Audits and surveillances not being conducted on a periodic basis and all indicate aspects of the QAPP not being audited. None of 3 surveillances performed were of a technical nature.

CLOSED-CAR-036 issued. Schedules indicate frequencies for audits and surveillances have been increased and indicate they are of a technical nature.

(3) Acceptable. NRC/DOE should look at the scope of the audits and surveillances to determine the depth and nature of the QA and technical aspects.

B-16 (Deficiency). Two completed surveillance reports were not reviewed and signed by the QA

CLOSED-CAR-037 issued. Review of survey files indicate this was an

(3) Acceptable. NRC/DOE could sample completed surveillance reports to

NRC AUDIT FINDING  
NO., AND SUMMARY OF  
NRC AUDIT FINDING

DOE STATUS AND  
AND RESPONSE

NRC COMMENTS

Implementation Manager as required by the QAPP.

isolated case.

determine whether this was an isolated case. The overall effect of a QA review for survey reports should be to determine whether there are any quality trends of an adverse nature as a result of surveillances.

B-17 (Deficiency). A megadigital thermometer and calibration folder were mislabeled. Audit team recognized this was an isolated case.

CLOSED-CAR-038 issued. Corrected at time of audit.

(1) Response is satisfactory.

B-18 (Deficiency). Calibration card for the lab weight not present in the QA support file as required by the implementing procedure. Also, the procedure for the weights did not require the card to be sent to the file.

CLOSED-CAR-039 issued. QP-12.1 revised and the card system has been eliminated

(3) Acceptable. NRC/DOE should take a sample of the M&TE and verify the revised procedure is being properly implemented.

B-19 (Deficiency). Informal inspections of storage areas being conducted but such inspections were not documented.

OPEN-CAR-040 and CAR-050 issued. QP-13.1 revised to require documentation for storage area inspections.

(3) Acceptable pending NRC/DOE verification of personnel training to revised procedure. A sample of storage area inspections should also be taken to verify they are being documented.

**ORIGINAL SIGNED BY**

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