

STEIN LETTER

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SEP 06 1989

Mr. Ralph Stein, Associate Director  
for Systems Integration and Regulations  
Office of Civilian Radioactive Waste Management  
U.S. Department of Energy, RW-24  
Washington, D.C. 20545

Dear Mr. Stein:

SUBJECT: NRC STAFF REVIEW OF DOE RESPONSES TO THE NRC JUNE 8-12, 1987 AUDIT  
OF LANL

In June of 1987, the U.S. Nuclear Regulatory Commission (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 the U.S. Department of Energy (DOE) needs to resolve before NRC can accept the LANL QAP. DOE Surveillance Report YMP-SR-89-009 dated April 29, 1989 indicates that twelve of these deficiencies remain unresolved.

The NRC staff is concerned about the effectiveness of the DOE and LANL corrective action programs when, after two years, twelve of seventeen findings still remain open. Given that the timeliness of corrective actions is one measure of a QA program's effectiveness, the NRC staff believes that future findings in all audits and surveillances must be handled more quickly than in this case.

Another NRC staff concern, based on the lack of timely resolution of these deficiencies, is the amount of paperwork associated with the DOE responses to the NRC audit findings. The five DOE QA Surveillance Report submittals contain 400-450 pages to address the seventeen NRC audit findings. More timely audit responses might occur if less documentation were used. Based on the NRC's previous experience, corrective action reports often consist of two or three pages to close out procedural related audit findings. The NRC staff recommends that DOE evaluate whether the process of responding to audit findings could be enhanced by reducing the amount of documentation required.

With respect to the adequacy of the responses provided by DOE, Enclosure 1 lists the staff comments on each DOE response to a finding. Most corrective actions on findings will need to be verified as having been implemented by the upcoming

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DOE audit of LANL in October 1989. Evidence of satisfactory implementation will be a basis for the staff to close out the findings.

Should you have any questions, please contact Bill Belke on (301) 492-0445.

Sincerely,

**ORIGINAL SIGNED BY**

John J. Linehan, Director  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High Level Waste Management

Enclosure: As stated

- cc: R. Loux, State of Nevada
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SUMMARY OF NRC REVIEW OF DOE RESPONSES  
TO LANL AUDIT FINDINGS

NRC Audit Finding No., and Summary of NRC Audit Finding	DOE Status and Response	NRC Comments
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.	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 for performing the quality-related function of the QAIM, QAS and QAL.	CLOSED-CAR-025 issued and QAPP and QP-02.1 have been revised.	Acceptable pending NRC/DOE verification of personnel training. 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.	Acceptable pending NRC/DOE verification of personnel training.

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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.	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-028 issued. QA-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.	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 meaning of this requirement was also not understood for what should be recorded for sample history.	OPEN-CAR-029 and CAR 050 issued. QP-14 revised and will be reissued as QP-03.5 to include equipment and recording requirements. Personnel will also be trained in the use of the revised procedure.	Acceptable pending NRC/DOE review of the revised procedure for adequacy, understanding and implementation of QP-03.5. NRC believes 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.

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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.	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.	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.	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 supplier evaluations should be documented.	OPEN-CAR-033 and CAR-050 issued. QP-04.3 modified to require QA to require QA to reevaluate Vendor's List to determine which suppliers should be reevaluated.	Acceptable pending NRC/DOE verification of personnel training. A sample of the Approved Vendor's List and purchase orders should be taken to determine whether this requirement has been implemented.

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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.	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.	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 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.	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.

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B-16 (Deficiency). Two completed surveillance reports were not reviewed and signed by the QA Implementation Manager as required by the QAPP.	CLOSED-CAR-037 issued. Review of survey files indicated this was an isolated case.	Acceptable. NRC/DOE could sample completed surveillance reports to 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.	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.	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.	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.