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LPDR
Wm-10 (2)

Department of Energy

Richland Operations Office

P.O. Box 550

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WM DOCKET CONTROL CENTER 87-QSB-49

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Mr. A. N. Kugler, Project Manager
KE/PB
P. O. Box 23210
Oakland, California 94673

Dear Mr. Kugler:

DOE-RL QUALITY SYSTEMS DIVISION (QSD) FOLLOW-UP VERIFICATION OF AUDIT KE/PB 4-85 DATED APRIL 29 - MAY 1, 1986, ON EVALUATION OF ALL 18 CRITERIA AND AUDIT KE/PB 8607 DATED APRIL 15-17, 1986, ON A PROGRAM CONTROL SYSTEM AFFECTING DESIGN

Results of follow-up verification are as follows:

AUDIT 4-85

85/4-01 **FINDING:** The KE/PB Quality Assurance (QA) program applied to Basalt Waste Isolation Project activities lacks the clarity, traceability, and content necessary to demonstrate that the requirements of NOA-1 are satisfied.

EVALUATION OF SUBSEQUENT ACTION: The QA program procedures were completely reviewed. New procedures were generated and implemented. Essentially, a new program was installed at KE/PB. This audit finding has been verified by DOE-RL QSD and finding is closed.

85/4-02 **FINDING:** Several key design control requirements of NOA-1 Requirement 3 and Supplement 3.5-1 are not covered by implementing procedures.

EVALUATION OF SUBSEQUENT ACTION: Design control procedures 6.1 and 6.6 were revised to address the review and approval of design inputs. Also, procedure 6.2, paragraph 3.2.2, seventh bullet was revised to provide for control of simple programs by verification by alternate calculations. Item closed.

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85/4-03 **FINDING:** NQA-1 requirements for QA records are not satisfied in that requirements and responsibilities for records handling are not clearly defined and detailed instructions for retention and transmittal of records are not provided in the KE/PB QA program.

EVALUATION OF SUBSEQUENT ACTION: Since this finding is identical to audit finding 8607-1, this audit finding will be considered closed and QAF 8607-1 will remain open. Further action is not required.

85/4-04 **FINDING:** The KE/PB QA program for control of documents that specify quality requirements or prescribe activities affecting quality does not satisfy NQA-1 requirements for preparation, review, approval, or change of these documents.

EVALUATION OF SUBSEQUENT ACTION: Document control procedure 6.8 was revised to satisfactorily address the finding. Audit finding closed.

85/4-05 **FINDING:** Organizational relationships, responsibilities and authorities are not sufficiently defined to demonstrate compliance to NQA-1 requirements.

EVALUATION OF SUBSEQUENT ACTION: Procedure 1.2 was revised to provide interfaces and responsibilities. Audit finding closed.

85/4-06 **FINDING:** NQA-1 requirements for preparation, review and approval of procedures and instructions for prescribing and performing activities affecting quality are not fully addressed in the KE/PB QA program.

EVALUATION OF SUBSEQUENT ACTION: Procedure 2.3 was rewritten to address procedure preparation. Audit finding closed.

85/4-07 **FINDING:** NQA requirements for procurement controls are not satisfied by the KE/PB QA program.

EVALUATION OF SUBSEQUENT ACTION: Procedure 2.5 rewritten to address procurement control. Audit finding closed.

AUDIT 8607

8607-1 **FINDING:** NOA-1 requires retrievability of records accumulated at various locations and also requires collections, storage and maintenance of design documentation and records to approved procedures.

EVALUATION OF SUBSEQUENT ACTION: Review of the problem indicated deficient condition has not been corrected. Audit finding remains open.

8607-2 **FINDING:** NOA-1 requires control/segregation of nonconforming items. Contrary to the requirements, neither the QA plan nor procedures addressed this requirement.

EVALUATION OF SUBSEQUENT ACTION: Procedure 6.20 "Preparation, Disposition, and Control of Nonconformance Reports" issued and implemented August 29, 1986. Audit finding closed.

Quality Concerns and Recommendations

QC 8607-A Identification and correction of conditions adverse to quality not correct in procedure CS 16.1 Rev. 1.

Procedure CS 16.1 Rev. 2, dated August 29, 1986, states that a stop-work order shall be initiated when the Corrective Action Report (CAR) fails to resolve the deficiency. Item closed.

QC 8607-B There is no provision in QA program to address 10 CFR 60.73 "Reporting of Deficiencies."

Procedure 16.2 does not address above requirement. Due to the significance of this concern, it was required that KE/PB respond to this item. Item remains open.

QC 8607-C Actions to prevent recurrence not addressed in procedure 16.4.

Procedure 2.2 has been revised August 24, 1986, to address this concern. Item closed.

QC 8607-D Seven (7) surveillance reports were selected at random for review of the follow-up process. Three (3) surveillances did not have evidence of follow-up.

The three offending Surveillance Reports (SR10, SR29, and SR88) were corrected by KE/PB and a review performed to assure no other similar deficiencies in SRs. The auditor verified on October 8, 1986, that the three SRs had been corrected. Item closed.


Mr. A. N. Kugler

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The KE/PB Project Manager is the representative responsible for action items. Open items are to be responded to within 30 days of receipt of this letter.

Questions concerning these audits may be directed to Mr. T. J. Marcella at (509) 376-9945.

Sincerely,


Dallas W. Cooper
Contract Administrator

MAC:JHR
QA65A7.R5(K05)

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