



Department of Energy  
Washington, DC 20585

JUL 16 1986

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Mr. John Linehan, Acting Branch Chief  
Repository Projects Branch  
Division of Waste Management  
Nuclear Regulatory Commission  
Washington, D.C. 20555


Dear Mr. Linehan:

Thank you for your letter of June 6, 1986, to W. J. Purcell which transmitted NRC staff comments on recent DOE audits. We appreciate the NRC participation in the DOE audit process and your evaluations and comments.

As part of our internal review we asked our BWIP project to do an analysis of the NRC staff comments related to the audit performed at Kaiser. We also met with other members of the audit team to have benefit of their firsthand knowledge of the audit.

Based on our review, we have concluded that many of the NRC staff's comments were well founded. We have met with senior BWIP management, and have reached agreement on a number of changes that we believe will improve our program. Attachment A to this letter lists the issues and the improvements that we will be implementing. We look forward to your reaction to these improvements and to NRC participation in future BWIP audits to confirm the effectiveness of these actions.

There are, however, several areas in which we disagree with observations made regarding the Kaiser audit. Some areas concern factual errors; others relate to an apparent incomplete understanding of the purpose and scope of the audit. Attachment B to this letter provides our review on these matters. In the future we encourage NRC observers to interact more extensively with the audit team both during and following an audit.

  
James P. Knight, Director  
Siting, Licensing and Quality Assurance  
Division, OGR

Attachments A & B

WM Record File

101.2

WM Project 10

Docket No. ✓

PDR

LPDR ✓ (B)

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## ATTACHMENT A

### ISSUE A-1: Untimely revisions to checklists.

SOLUTION: The time/resources budget has been revised to ensure that audit checklists are completed and approved not later than two weeks prior to audit start. See A-11 for the approval process.

### ISSUE A-1d: Audit plan too brief.

SOLUTION: Future audit plans will be accomplished in two stages. The initial stage will identify audit scope (i.e., activities to be audited and QA program elements the audit will address), initial identification of audit team members, and tentative times for the opening meeting and post-audit conference. The second stage will be the final plan, incorporating results of detailed analysis of previous audit results, DOE surveillances, statements of work (as applicable), applicable auditee procedures, etc. The final plan will also include the approved checklist and audit team member assignments.

### ISSUE A-1e: Audit team members inadequately trained.

SOLUTION: All regularly assigned auditors are scheduled to complete a comprehensive (30 hour) in-house refresher audit course and examination prior to the next audit. Any new personnel entering the program with audit assignments will be required to complete that course before performing the audit function. Individuals from outside the DOE-RL BWI QS audit function who participate as audit team members, and technical or management team members, will be required to complete an eight hour course covering BWI QS audit procedures, practices and techniques prior to participation.

**ISSUE A-2:** There were no members of the team who were capable of evaluating the technical adequacy of work performed.

**SOLUTION:** No future audits of technical activities will be conducted without participation of appropriate specialists to evaluate technical indicators of control effectiveness. The Branch Chief(s) of the technical branch(es) responsible for the areas to be audited will select and assign the technical participants for the audit team. The technical participant(s) may be personnel of the affected Branch or, subject to workload, may be competent specialists drawn from contract sources. Selection criteria in such cases will include independence from the work to be audited.

**ISSUE A-2e:** Training evaluation was not adequately covered in the audit program.

**SOLUTION:** Indicators of training effectiveness have been developed and incorporated in the effectiveness indicator data base since the audit in question.

**ISSUE B-2:** Funding for implementation of appropriate records management and document control at KE/PB.

**SOLUTION:** Funding for this and other KE/PB QA program upgrades was already underway at the time of the audit and transaction has now been completed. Implementation will be completed by the time of SCP issuance.

**ISSUE B-3:** KE/PB program does not include audits.

**SOLUTION:** The upgraded KE/PB QA program does include an auditing program. As practiced at KE/PB, surveillances were formatted and conducted as limited-scope audits. For purposes of identifying detailed program deficiencies and noncompliances and causing corrective action, they were an effective substitute for formal audit at KE/PB's low level of support.

**ISSUE C-1:** Audit preparation was rushed.

**SOLUTION:** The DOE audit schedule will be revised to permit more deliberate and comprehensive preparation of audits.

**ISSUE C-2:** Training of auditors needs strengthening.

**SOLUTION:** See Part A-1e.

ISSUE C-3: NRC observers to the DOE BWIP audits should be trained in "auditing for effectiveness."

SOLUTION: A comprehensive program for observer support has been designed to ensure that each observer has all the pre-audit information and material this office can furnish to enable the observer to achieve his or her observation objectives. The planned support will include a one hour formal orientation on the DOE BWI QS process, and the observer's pre-audit package will include additional familiarization material.

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## Attachment B

1. The NRC observer apparently misunderstood the scope of the audit. As stated in the audit plan and the notification letter, the scope was to evaluate the quality program elements for design control. The audit was not intended to determine total QA Program effectiveness at RKE/PB.
2. The NRC observer criticized the audit team leader for not having a copy of the 1985 audit report with him during this audit, but apparently did not understand that the 1985 audit was a desk audit, did not address implementation, and would serve no useful purpose in this audit.
3. The NRC observer reported that MAC, the contractor who conducted this audit for BWIP, was under contract to Rockwell. In fact, MAC is under contract to PNL, not Rockwell.
4. The NRC observer reported that the DOE-HQ representative expected to observe the audit but found out the day of the audit that he was to be an audit team member. In fact this person has stated that he knew more than a week before the audit that he would participate in the audit as an auditor.
5. The NRC observer stated that none of the auditors were aware of RKE/PB's current work efforts and implied that the 20 minute briefing by RKE/PB was for this purpose. The opening briefing was for the benefit of the NRC observer, not the audit team. Members of the audit team were familiar with RKE/PB's work.
6. The NRC observer felt that it was not apparent that DOE knew about the change to the audit scope; in fact the DOE-BWIP Quality Systems Branch Chief authorized the change.
7. The NRC observer also critiqued the audit for poor use of available time and criticized the auditors for taking time to annotate their checklists. We feel that intelligible, self-contained checklist entries are important.
8. The NRC observer criticized the audit saying it concentrated on superficial paperwork issues. We feel that documentation is a primary source of evidence that required actions have been taken.

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9. The NRC observer criticized some aspects of the audit for concentrating on procedural compliance. We feel procedural compliance is an essential element of an effective QA Program.
10. The NRC observer noted that the audit of procurement activities was accomplished with only an interview; this is incorrect. The audit folder contained copies of documents that the auditor examined to verify the information obtained during the interview.
11. The NRC observer expressed his opinion that the RKE/PB QA staff is not sufficient; we feel the staff size is commensurate with the low level of design effort at RKE/PB that has existed for the past several months.

