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JUN 25 1986

Mr. August N. Kugler
KE/PB
P. O. Box 23210
Oakland, CA 94673

Dear Mr. Kugler:

BASALT WASTE ISOLATION PROJECT (BWIP), KE/PB DESIGN CONTROLS, QUALITY ASSURANCE AUDIT 8607, APRIL 15-17, 1986.

Results of the recent DOE/RL QA Audit of the KE/PB design controls and associated quality assurance activities are hereby transmitted for your action. Apologies are extended for the late transmittal of this report.

Design evaluation was restricted to Study 10 "Conceptual Repository Design" because that project was 90-100 percent complete and offered a wide range of design packages for sampling. Audit scope was limited to those QA program control systems that directly affected design.

Formal controls affecting design during the time of Study 10 activity were incomplete and inadequate. Informal controls, however, were determined to be effective. The quality assurance program was an area of both fault and praise. A total of two (2) adverse findings and four (4) quality concerns were written and these are included in the enclosed audit report.

Commendable practices are also recognized in this audit report for (1) completion of 29 quality related procedures which adhere to the QA program requirements of NQA-1, 1983, (2) initiation and completion of a formal training program which included 20 of the 29 procedures as subject matter, and (3) upgrading procurement practices to require contractor and consulting services adherence to KE/PB's quality assurance program.

WM Record File 101.2

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The audit report, adverse finding sheets, quality concerns, and recommendations are enclosed. Acceptable responses to the adverse findings have been received and are quoted at the appropriate points in the attached report.

Sincerely,

R. P. Saget

R. P. Saget, Chief
Quality Systems Branch
Basalt Waste Isolation Division

BWI:JMH

Enclosure
04E6.H10

cc w/encl: D. Hedges, NRC
E. Sulek, Weston
J. P. Knight, DOE/HQ
C. Newton, DOE/HQ
R. T. Johnson, Rockwell
G. Jackson, Rockwell

Encl. to 6/25/86 Ltr. rec'd 7/1/86 to Kugler BWIP QA Audit 8607

101.2

04E6.H1

AUDIT REPORT NO: DOE/BWID 8607
AUDIT SUBJECT: RKE/PB DESIGN CONTROL/EXPLORATORY SHAFT & REPOSITORY DESIGN
AUDIT DATES: APRIL 15-17, 1986

INTRODUCTION

o Audit Scope

This audit addressed the adequacy and effectiveness of design control and supporting quality assurance functions related to RKE/PB's Exploratory Shaft Liner and Repository Design efforts. Design evaluation was restricted to Study 10 "Conceptual Repository Design" because that project was 90% to 100% complete and offered a wide range of design packages for sampling. Quality assurance controls were limited to those program requirements that affected the design effort. Design controls were determined to be effective. The quality assurance program had some areas of ineffectiveness. A total of two (2) adverse findings and four (4) concerns were written and are included herein. Commendable practices were recognized for the turnaround of three (3) functions that had been considered deficient in previous audits.

The term "formal controls" is used throughout this report to denote control by approved procedures, in contrast to control by "good practice", prudent management, etc.

o Mission of the Audited Activity

RKE/PB has a contract with DOE-RL to perform architectural engineering studies for the Basalt Waste Isolation Project (BWIP). In this capacity their primary mission has been Study 10 "Conceptual Design of the Repository" and Study 11 "Exploratory Shaft Liner Design."

Study 10 - Conceptual design of the repository work around plan and design review

Study 11 - Exploratory shaft liner design technical criteria and methodology

o Current Status of the Audited Activity

Study 10 - 90% design review completed - review report issued

Study 11 - RHO-RL technical review complete - comments incorporated

o Attachments

Attachment (1) to this report contains necessary administrative information such as attendance at entrance and exit meetings and contacts made during the audit. Attachment (2) discusses the audit rationale of "Auditing for Effectiveness" and explains the approach, assumptions and basic methodology of this program. Attachment (3) is a tabular summary of audit findings for this audit and Attachment (4) is a recounting of the two (2) Quality Audit Findings (QAFs).

COMMENDABLE PRACTICES

Commendable practices were recognized for the 1) expeditious completion of twenty-nine (29) technical and quality procedures initiated to comply with NQA-1, 2) initiation of a formal training program and completion of training for 20 of the 29 procedures, and 3) improvements to procurement practices relative to subcontracting and consulting services.

FOLLOW UP RESULTS

Because no previous audits of RKE/PB's BWIP activities were performed by DOE/RL, follow-up for the purpose of closing findings or corrective action assessment was not required during this audit. However, a follow-up for Audit 8607 will be conducted to assure that planned corrective action has been implemented and to assess whether corrective action has been effective.

FINDINGS

o **AUDIT ITEM 1 (1.3) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL FUNCTIONAL RESPONSIBILITY.**

Purpose

To ensure that line management functions achieve quality objectives, and that QA management verifies that work conforms to established requirements.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. Functional managers fail to recognize or discharge their (QA Program) control responsibilities.

b. Personnel demonstrate uncertainty concerning who is responsible for making quality assurance program controls work or believe QA is responsible for controls.

c. Controls or control systems are not working effectively.

Findings:

1) None of the above indicators of system deficiency were found in the audit sample and interviews by the audit team. 2) There are formal controls in place for this activity and these controls are effective.

Functional responsibilities are outlined in organizational chart form and delineated in applicable procedures, both of which are updated on an "as required" basis.

o AUDIT ITEM 2 (1.6) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL INTERFACES THAT AFFECT MULTIPLE ORGANIZATIONAL RESPONSIBILITIES.

Purpose

To ensure the integrity of interfacing work.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. A responsible individual or organization does not have relevant information issued by an interfacing organization or organizational unit.

b. Duplicate or conflicting activity is occurring in two or more interfacing organizations or organizational units without recognition of the duplication or conflict.

c. A record exists of one or more instances in which:

   1) Action was taken or not taken because of late or no receipt of directions from an interfacing authority, or
   2) A decision had to be rescinded or significantly altered because the deciding authority lacked relevant or timely information from an interfacing organization.

Findings

1) None of the above indicators of system deficiency were found in the audit sample evaluated by the audit team. 2) There are formal controls in place for this activity and these controls are effective.

o AUDIT ITEM 3 (2.5) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL INDOCTRINATION AND TRAINING.

Purpose

To ensure that the proficiency of personnel performing activities important to safety, waste isolation or site characterization is achieved and maintained, and that those activities are performed the way management believes them to be.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. There is evidence that personnel responsible for quality verifying functions have not received indoctrination and instructions pertaining to their work.

b. Personnel are not cognizant of program requirements.

c. No evidence exists to indicate that personnel training needs are considered or identified by management.

d. Program fails to provide training in new/revised procedures before documents are issued.

Findings:

1) None of the above indicators of system deficiency were found in the audit sample taken by the audit team. 2) There are formal controls in place for this activity and these controls are effective.

All personnel requiring training in related technical procedures and quality related policies have received that technical training and quality indoctrination, including outside consultants. Records documenting this fact are maintained by a training coordinator.

o AUDIT ITEM 4 (3.1) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DESIGN INPUT.

Purpose

a. To ensure that the design is based on correct requirements & constraints.

b. To ensure that site characterization results and conceptual design bases reflect correct requirements and constraints.

c. To provide tangible evidence that data needs were based on correct requirements and constraints.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. A document contains incorrect requirements or constraints.

b. There is a lack of a controlled document listing or other type list of design inputs (requirements, constraints & objectives).

c. Presence of inputs from an unauthorized source.

Findings

1) None of the above indicators of system deficiency were found in the audit sample examined by the audit team. 2) New formal controls are presently in place and it is too early to determine whether they will be effective. Formal controls in effect at the time of design of the sample packages were incomplete and inadequate. However, each package was evaluated by a technical advisor familiar with the RKE/PB design charter and a DOE auditor using NQA-1 indicators of system deficiency. It was concluded that informal controls had been effective.

o **AUDIT ITEM 5 (3.2) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL THE DESIGN PROCESS.**

Purpose

a. To ensure that the design will perform its intended function within the specified constraints.

b. To ensure that design inputs are correctly translated into the required design.

c. To permit verification that the design meets requirements.

d. To make it possible to reconstruct the design analysis.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. Design documents fail to include or reflect approved design inputs.

b. Documentation is inadequate to reconstruct the design process.

c. Documentation is inadequate to support design verification.

Findings

1) None of the above indicators of system deficiency were found in the audit sample examined by the audit team. 2) New formal controls are presently in place and it is too early to determine whether they will be effective. Formal controls in effect at the time of design of the sample packages were incomplete and inadequate. However, each package was evaluated by a technical advisor familiar with the RKE/PB design charter and a DOE auditor using NQA-1 indicators of system deficiency. It was concluded that this activity had been controlled effectively despite inadequacies in the formal controls.

o AUDIT ITEM 6 (3.3) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DESIGN VERIFICATION.

Purpose

To confirm that the design will perform the intended functions within established constraints.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. There is a lack of documented design verification.

b. There is inadequate, inappropriate or missing resolution of design verification comments.

c. Changes are made to correct errors in designs that were previously subjected to design verification.

Findings

1) None of the above indicators of system deficiency were found in the audit sample examined by the audit team. 2) New formal controls are presently in place and it is too early to determine if they will be effective. Formal controls in effect at the time of design of the sample packages were incomplete and inadequate. However, each package was evaluated by a technical advisor familiar with the RKE/PB design charter and a DOE auditor using NQA-1 indicators of system deficiency. It was concluded that this activity was controlled effectively despite the inadequacy of the formal control system then in effect.

o AUDIT ITEM 7 (3.4) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DESIGN CHANGE.

Purpose

To ensure that design changes do not compromise the original design intent.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. A design change is incorporated into released design without review and approval commensurate with that for original design.

b. A design change is made that is not reviewed and approved by organization(s) that reviewed and approved original concept (except where original organization is no longer responsible for the design).

c. A design change makes an unauthorized change to design function or intent.

Findings

1) None of the above indicators of system deficiency were found in the audit sample examined by the audit team. 2) New formal controls are presently in place and it's indeterminate whether they will be effective. Controls in effect at the time of design of the sample packages were incomplete and inadequate. However, each package was evaluated by a technical advisor familiar with the RKE/PB design charter and a DOE auditor using NQA-1 indicators of system deficiency. It was concluded that this control was effective.

o AUDIT ITEM 8 (3.5) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DESIGN INTERFACES.

Purpose

To ensure that all parts of the design are based on the same set of requirements or constraints in effect at any specific time.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. There is a presence of a document that lacks input that should come from interfacing groups or organizations.

b. There is evidence that personnel are unsure of, or unaware of, one or more design interfaces.

c. Different design bases are used by interfacing design groups or organizations.

d. Design is not compatible at one or more design interfaces.

Findings

1) None of the above indicators of system deficiency were found in the audit sample examined by the audit team. 2) New formal controls are presently in place and it's indeterminate whether they will be effective. Controls in effect at the time of design of the sample packages were incomplete and inadequate. However, each package was evaluated by a technical advisor familiar with the RKE/PB design charter and a DOE auditor using NQA-1 indicators of system deficiency. It was concluded that this control was effective.

o AUDIT ITEM 9 (3.6) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DESIGN DOCUMENTATION AND RECORDS.

Purpose

a. To ensure that the design activity can be reconstructed to provide credibility in the formal record.

b. To ensure a correct and complete design data base which can be used in further design activity.

Indicators of System Deficiency

This system or activity is determined ineffective when:

a. There is an inability to identify sources of design inputs.

b. There is a lack of, or incomplete, documentation available for design calculations.

c. There is a lack of, or incomplete, documentation of design reviews and/or resolution of review comments.

d. There is a lack of, or incomplete, documentation of design verification testing or test results.

Findings

1) None of the above indicators of system deficiency were found in the audit sample examined by the audit team. 2) New formal controls are presently in place and it is indeterminate whether they will be effective. Controls in effect at the time of design of the sample packages were incomplete and inadequate. However, each package was evaluated by a technical advisor familiar with the RKE/PB design charter and one of the three DOE auditors using NQA-1 indicators of system deficiency. It was concluded that this control was effective.

o AUDIT ITEM 10 (3.7) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DESIGN DEFICIENCIES.

Purpose

a. To ensure that no known deficiency remains in the design.

b. To ensure prompt corrective action with regard to the design process.

Indicators of System Deficiency

This system or activity is determined to be ineffective when there is evidence of a change to a released design to correct a design error or deficiency without evidence of corresponding reevaluation of the design control system to identify and correct the cause for error or deficiency.

Findings

1) The above indicator of system deficiency was not found in the audit sample examined by the audit team. 2) New formal controls are presently in place and it is indeterminate whether they will be effective. Controls in effect at the time of design of the sample packages were incomplete and inadequate. However, each package was evaluated by a technical advisor familiar with the RKE/PB design charter and one of the three DOE auditors using NQA-1 indicators of system deficiency. It was concluded that this control was effective.

o **AUDIT ITEM 11 (4.1) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL PROCUREMENT DOCUMENT CONTENT.**

Purpose

To ensure that procurement documents contain all the necessary requirements.

Indicators of System Deficiency

This system or activity is determined to be ineffective if a: procurement document (Statement of Work) is observed to lack any of the following: 1) Scope of work, 2) technical requirements, 3) QA requirements, 4) right of access statement, 5) documentation requirements or 6) reporting of nonconformance requirements.

Findings

1) None of the sub-indicators of system deficiency were found in the audit sample by the audit team. There are formal controls in place for this activity and they are effective.

o **AUDIT ITEM 12 (4.2) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL PROCUREMENT DOCUMENT REVIEW.**

Purpose

To ensure that procurement documents adequately and accurately reflect what is intended to be purchased.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. Procurement packages do not include all necessary supporting documents, such as specs, standards, applicable drawings, etc.

b. Purchase Orders (or S.O.W.s) do not accurately reflect the requirements that were stated in the corresponding procurement requisition packages.

c. There is a lack of evidence of technical and QA review of procurement documents prior to contract award (credibility).

Findings

1) None of the above indicators of system deficiency were found in the audit sample taken by the audit team. There are formal controls in place for this activity and these controls are effective.

A document review by Engineering and Quality Assurance was in evidence on all applicable purchase agreements reviewed by the audit team.

o AUDIT ITEM 13 (4.3) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL PROCUREMENT DOCUMENT CHANGES.

Purpose

To ensure that all parts of the design/system/activity are based on the same set of requirements and constraints at any point in time.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. There are procurement document revisions (involving technical or quality requirement changes) for which engineering and QA review is lacking.

b. There is an absence of procurement changes to reflect design changes made (or released) where these changes affect requirements for purchased items or services.

Findings

1) Neither of the above indicators of system deficiency were found in the audit sample taken by the audit team. 2) There are formal controls in place for this activity and these controls are effective.

Changes are accomplished by a modification statement which is approved by DOE prior to issuance of the change.

o AUDIT ITEM 14 (5.1) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL THE PRESENCE OF APPROVED PROCEDURES.

Purpose

a. To specify agreed upon methods and approaches for performing activities.

b. To ensure the ability to reconstruct any activity after the fact.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. There is evidence that a design base or site characterization activity was performed without approved instructions or procedures.

b. The auditee failed to have approved procedures in place.

Finding

Indicator "b" was observed; approved procedures were not in place for some of the quality related functions such as records management and non-conformance/corrective action requirements. This was noted in the two QAF's written for this Audit. Therefore, this control system must be rated ineffective.

o AUDIT ITEM 15 (5.2) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL COMPLIANCE WITH INSTRUCTIONS, PROCEDURES OR DRAWINGS.

Purpose

a. To ensure that work is done the way management believes it is being done.

b. To ensure that methods or approaches can be reconstructed for purposes of program analysis, program improvement, etc.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. The activity failed to comply with functional procedures.

b. Analysis and/or design processes have not been in compliance with approved instructions or procedures.

Findings

1) Neither of the above indicators of system deficiency were found in the audit sample taken by the audit team. 2) The formal controls in place for the design processes are considered effective.

Twenty-nine (29) new procedures covering the compliance requirements for NQA-1 have been written, training has been conducted and implementation has taken place.

- **AUDIT ITEM 16 (6.1) THE SYSTEM OR ACTIVITY NECESSARY TO IDENTIFY DOCUMENTS TO BE CONTROLLED.**

Purpose

a. To ensure that only legitimate data is used in performance of activities important to safety or waste isolation, or to describe system/facilities important to safety or waste isolation.

b. To be sure that all documents used in activities important to safety or waste isolation, or that describe systems/facilities important to safety or waste isolation, are accounted for.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. The auditee has failed to identify or be aware of documents which are to be controlled.

b. A document is found of the type which has been identified as one to be controlled but is not being controlled.

c. Evidence is found that a controlled document is missing.

Findings

1) None of the above indicators of system deficiency were found in the audit sample taken by the audit team. 2) There are formal controls in place for this activity, and these controls are effective.

- **AUDIT ITEM 17 (6.2) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DOCUMENT IDENTIFICATION.**

Purpose

To ensure that only correct and current documents are used or referenced.

Indicators of System Deficiency

This system or activity is determined to be ineffective when documents which are used for design basis or site characterization are found which cannot be easily identified, referenced or tracked.

Findings

1) The above indicator of system deficiency was not found in the audit sample taken by the audit team. 2) There are formal controls in place for this activity and these controls are effective.

Manuals assigned to audited individuals were all found to be current.

o AUDIT ITEM 18 (6.3) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DOCUMENT REVIEW.

Purpose

To ensure that information is adequate and correct when issued.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. Evidence is found of changes made to issued controlled documents when the purpose was to correct substantive errors or deficiencies.

b. There is a lack of documented evidence of review and comment resolution.

Findings

1) Neither of these indicators of system deficiency were found in the audit sample taken by the audit team. 2) There are formal controls in place for this activity and these controls are effective. However, these controls do not provide for minor changes not requiring the same review and approvals as substantive changes, which could cause unwarranted and time consuming delays in implementation. It is recommended that provisions be made for making minor changes without changing the entire procedure.

o AUDIT ITEM 19 (15.2) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL NONCONFORMANCE REPORTING.

Purpose

a. To ensure that nonconforming items are properly identified and reported to an appropriate level of management to assure proper attention.

b. To ensure that nonconforming items and deficiencies are recorded in a manner that requires documented corrective action.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. There is no means by which personnel other than QA can identify and report nonconformances or deficiencies.

b. Items are tagged as nonconforming but no corrective action is being taken for lack of a reporting system.

Findings

1) Indicator "a" was observed; RKE/PB had no provision for persons other than QA to report design deficiencies. See QAF 8607.2.

Corrective Action

Mr. A. N. Kugler, RKE Project Manager of RKE/PB's BWI project, transmitted a response to this finding which stated, in part: "...a procedure will be generated that requires any person with objective evidence of a nonconforming condition to document that noncompliance for evaluation, disposition, and management attention as appropriate... Procedure will be approved and issued by May 17, 1986." This response is considered acceptable.

o AUDIT ITEM 20 (16.1) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL IDENTIFICATION (FLAGGING) AND CORRECTION.

Purpose

To ensure that conditions adverse to quality are identified and appropriate corrective action is taken.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. The audited organization fails to have a program in place to identify and resolve conditions adverse to quality.

b. There is evidence that the audited organization has failed to detect conditions adverse to quality.

c. There is evidence of failure to take appropriate corrective action for identified adverse conditions.

Findings

1) There is a formal program in place, but it reverses the standard practice of using a STOP WORK as last resort when a CAR has failed to produce the required result. (Concern QC 8607-A) 2) Formal controls are in place for this activity but they should be revised to conform to standard practice on the project. (See Concern QC 8607-A.)

Details of this concern are provided in the Concerns and Recommendations section of this report.

o **AUDIT ITEM 21 (16.2) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL EVALUATION OF POTENTIAL IMPACT/SIGNIFICANCE.**

Purpose

a. To ensure that conditions significantly adverse to quality receive prompt, meaningful attention.

b. To ensure that nonsignificant conditions adverse to quality are not permitted to dilute project resources through excessive attention.

Indicators of System Deficiency

The system or activity is determined to be ineffective when:

a. Presence of nonsignificant problems in the formal (cause, preventive action) corrective action system, except when justified by formal decision on the basis of an adverse trend.

b. Evidence that a final judgment as to problem significance or nonsignificance was made at an inappropriate organizational level or in the absence of appropriate technical consultation.

c. Evidence that assigned responsibility for investigations into causes of significant problems, or preventive action planning, is placed at an inappropriate level or with inappropriate disciplines.

Findings

1) None of the above indicators of system deficiency were observed. The system has operated effectively. However, it would be prudent to include provisions concerning "NRC Reportable" problems in the RKE/PB procedural base. (See Concern QC-8607B.) 2) Formal controls are in place for this activity.

Details of this concern are provided in the Concerns and Recommendations section of this report.

o AUDIT ITEM 22 (16.3) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL DETERMINATION OF CAUSE.

Purpose

To ensure that corrective measures address the basic cause so that project objectives are not compromised by defective controls.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. Root cause is not assessed.

b. Root causes are consistently identified as local to the lower tier organizational units where the problems were identified.

c. There is evidence of failure to perform an analysis to determine cause of a significant adverse condition.

Findings

1) None of these indicators of system deficiency were observed during the audit. The control is effective. 2) Effective formal controls are in place for this function.

o AUDIT ITEM 23 (16.4) THE SYSTEM OR ACTIVITY NECESSARY TO PROVIDE ACTION TO PREVENT RECURRENCE.

Purpose

To prevent recurrence of significant problems.

Indicators of System Deficiency

This system or activity is determined to be ineffective if:

a. Corrective action fails to address root cause.

b. Significant problems recur.

Findings

1) None of these indicators of system deficiency relative to significant problems were found during the audit, as no CARs have been written. Effectiveness of the RKE/PB corrective action program cannot be assessed at this time.

However, existing direction for trend analysis could be improved (see Concern QC-8607-C), and it might be prudent to consider procedural direction for investigative actions following determination of root cause for significant problems (e.g., investigation as to what other, as-yet-undetected, significant problems, not necessarily the same as or similar to the observed problem, could have been triggered by that root cause).

o AUDIT ITEM 24 (16.5) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL PROBLEM DOCUMENTATION, REPORTING TO MANAGEMENT.

Purpose

a. To ensure a credible record of the actions taken.

b. To ensure that corrective action decisions are made at the appropriate management level to assure proper emphasis and attention.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. There is failure to document a significant adverse condition.

b. There is failure to notify management of a significant adverse condition.

c. There is failure of management to adequately attend to a significant adverse condition.

d. Incomplete or open corrective action documents are found which have not been addressed.

e. There is failure to identify the appropriate management level required to assess adverse conditions.

Findings

1) None of the above indicators of system deficiency were found in the audit sample taken by the audit team. 2) There are formal controls in place for this activity. However, effectiveness of the system has not been tested, as no significant problems have been identified.

o AUDIT ITEM 25 (16.6) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL CORRECTIVE ACTION FOLLOW-UP.

Purpose

a. To ensure that the specific preventive action was taken.

b. To ensure that a known significant problem does not continue to threaten the integrity of the program.

Indicators of System Deficiency

This system or activity is determined to be ineffective when:

a. A documented significant condition is found which lacks evidence of follow-up.

b. Evidence is found where follow-up action was taken but the adverse condition recurred (i.e., implementation of action was verified, but the problem recurred).

Findings

1) None of the above indicators of system deficiency were found in the audit. 2) There are controls in place for this activity, but the system has not been challenged, and its effectiveness cannot be fully evaluated. It was noted that some non-significant surveillance finding had been corrected without the required close-out QA signature having been entered on the report form. Even though the problems were not significant, and corrective action had been taken, lack of the close-out signature raises a concern over the long-term credibility of the record (Concern QC 8697-D).

o AUDIT ITEM 26 (17.1) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL THE DESIGNATION OF DOCUMENTS OR DOCUMENT TYPES DESTINED TO BECOME RECORDS.

Purpose

To ensure that personnel know what documents/document types to submit for incorporation in the formal record (the collection or set of individual records for the plant or project) and to define the boundaries of the formal record.

Indicators of system Deficiency

This system or activity is determined to be ineffective when:

a. There is failure of personnel to be aware of which documents are to become records.

b. There is failure to designate documents or document types as records.

c. The auditor does not maintain a records index.

Findings

1) Indicators of system deficiency were found during the audit. The system is ineffective. QAF 8607-1 addresses inadequate protection of one-of-a-kind records and failure to ensure that all required "record-type" documentation will be preserved.

There are no procedures to define records or document types. A records index is maintained.

Corrective Action

RKE/PB has submitted an acceptable response to this adverse finding, as follows: "...Procedures will be generated that provide for identification and control of documents for record purposes. The insufficiency in record protection facilities was previously identified by RKE/PB and corrective action is pending concurrence from Rockwell/DOE to upgrade record storage facilities... RKE/PB will request authorization to implement conformance action within 90 days of the date of audit finding." Early follow-up will be performed to verify that suitable action has been taken.

o AUDIT ITEM 27 (17.2) THE SYSTEM OR ACTIVITY NECESSARY TO CONTROL THE IN-PROCESS DOCUMENT PROTECTION PROGRAM.

Purpose

a. To ensure that the formal record is complete.

b. To prevent loss or destruction of documents intended to become part of the formal record.

c. To ensure that records in the long term storage are usable.

Indicators of System Deficiency

The system or activity is determined to be ineffective when:

a. There is evidence of inadequate physical maintenance or records prior to submittal to RMC.

b. Evidence indicates that there is no systematic method of maintaining records.

Findings

1) The control is ineffective; collection and maintenance of documents was not covered by an approved procedure and no effective informal controls were being exercised. Response to this finding is noted above, under Audit Item 26 (QAF 8607-1).

CONCERNS AND RECOMMENDATIONS

o QUALITY CONCERNS (QC) and Recommendations

QC 8607-A - Identification and Correction of Conditions Adverse to Quality (CS 16.1)

Procedure 2.6 states that a CAR must be issued by Quality Assurance to correct the deficiency emanating from a Stop Work Order (Procedure 2.7). The standard practice is for a Stop Work Order to be issued when a CAR fails to resolve the deficiency or requires a lengthy period of time to resolve a deficiency. The priorities seem to be reversed in RKE/PB's procedures.

QC 8607-B - Evaluation of Potential Impact/Significance (CS 16.2)

There is no provision in the QA Program to address 10 CFR 60.73 "Reporting of Deficiencies."

QC 8607-C - Actions to Prevent Recurrence (CS 16.4)
Provisions for performing Trend Analysis have been recorded in procedure 2.2 - however, the details on how Trend Analysis is to be accomplished is sketchy. No direction is given regarding frequency of repetitive problems, or what time frames are involved. Also, repetition categories are limited to 7 catagories plus an "other" classification. To date, no trends have been documented and addressed since no CARs have been initiated. It is recommended that the Trend Analysis Program be expanded, enhanced, clearly defined and proceduralized.

QC 8607-D - Corrective Action Follow-up (CS -16.6)

Seven (7) Surveillance Reports were selected at random for review of the follow-up process. Five (5) of the seven (7) were closed but in three of the five cases, evaluation was not recorded, initialed nor dated making follow-up incomplete. The audit team determined that corrective action was in fact satisfactorily performed but not recorded. It is recommended that those surveillance reports not selected in the random sampling be reviewed to make sure the corrective action has been recorded in all cases.

o GENERAL OBSERVATION

To ensure a posture of design credibility prior to licensing application, it should be recognized that Validation of Design data listed "to date" may have to be accomplished or re-reviewed based on approved guidelines when these guidelines have been issued.

BWIP AUDIT 8607

ATTACHMENTS

ATTACHMENT 1 - Entrance/Exit Meeting Attendance & Audit Contacts

ATTACHMENT 2 - Audit Summary Table

ATTACHMENT 3 - Audit Rationale

ATTACHMENT 4 - QAF Findings

ATTACHMENT 1

Audit 8607 - RKE/PB Design Control/Exploratory Shaft & Repository Design
Entrance/Exit Meeting Attendance & Audit Contacts

NAME		ENT-RANCE	DURING AUDIT	EXIT
O.E. Trapp	RKE/PB Proj. QA & Lic. Mgr.	x	x	x
C.J. Holman	RKE/PB Proj. QA Engineer		x	x
A.N. Kugler	RKE/PB Project Manager	x	x	x
F. Newcomb	RKE/PB Study 10 Proj. Mgr.	x	x	x
R. Stuckgold	RKE/PB Study 10 Proj. Mgr.	x	x	x
D.L. Howard	RKE/PB Dir. Q Services	x		x
M.T. Mooney	RKE/PB Admin Ctrl. Mgr.	x	x	x
W.R. Manis	RKE/PB Doc. Ctrl. Mgr.	x	x	x
B.W. Lawrence	RKE/PB Chief Proj. Eng.	x	x	x
F.F. Hofinger	RKE/PB Chief Des. Eng.	x	x	x
R. Nunes	RKE/PB VP Eng. Services			x
D.F. Hanlen *	RHO/Tech. Advisor	x	x	x
C. Walenga	USNRC/Observer	x	x	
D.J. Brown *	DOE/Weston/Auditor	x	x	x
C.A. Smiroldo *	DOE/MAC - Auditor	x	x	x
J. M. Harty *	DOE/MAC - Auditor (Lead)	x	x	x

* Audit Team Members

ATTACHMENT 2
AUDIT SUMMARY TABLE
Audit 8607 - RKE/PB Design Control - Exploratory Shaft/Repository Design

AUDIT ID		CONTROL SYSTEM	EFFECTIVENESS RESULTS		
ITEM NO.	CONTROL NO.	DESCRIPTION	ASSESSMENT EFFECTIVE	ASSESSMENT INEFFECTIVE	FOLLOW-UP DOC.
1	1.3	Functional Responsibility Control	x		
2	1.6	Interfaces that Affect Multiple Organizations	x		
3	2.5	Indoctrination & Training	x		
4	3.1	Design Input	x		
5	3.2	Design Process	x		
6	3.3	Design Verification	x		
7	3.4	Design Change	x		
8	3.5	Design Interface	x		
9	3.6	Design Documentation and Records	x		
10	3.7	Design Deficiencies	x		
11	4.1	Procurement Doc. Content	x		
12	4.2	Procurement Doc. Review	x		
13	4.3	Procurement Doc. Changes	x		
14	5.1	Presence of Approved Procedures		x	QAF 8607-1 QAF 8607-2 QC 8607 C

ATTACHMENT 2
AUDIT SUMMARY TABLE (cont.)
Audit 8607 - RKE/PB Design Control - Exploratory Shaft/Repository Design

AUDIT ID		CONTROL SYSTEM	EFFECTIVENESS RESULTS		
ITEM NO.	CONTROL NO.	DESCRIPTION	ASSESSMENT EFFECTIVE	INEFFECTIVE	FOLLOW-UP DOC.
15	5.2	Procedure Compliance	x		
16	6.1	Document Identification	x		
17	6.2	Document Numbering	x		
18	6.3	Document Review	x		
19	15.2	Nonconformance Reporting		x	QAF 8607-2
20	16.1	Identification & Correction	*		QC 8607-A
21	16.2	Evaluation of Impact/Signif-icance	*		QC 8607 B
22	16.3	Determination of Cause	x		
23	16.4	Action to Prevent Recurrence	*		QC 8607 C
24	16.5	Reporting to Management	x		
25	16.6	Corrective Action Follow-up	*		QC 8607 D
26	17.1	Documents Destined to Become Records		x	QAF 8607-1
27	17.2	In-Process Document Protection		x	QAF 8607-1

* Concerns written for these controls

ATTACHMENT 3

AUDIT RATIONALE

BACKGROUND

The Basalt Waste Isolation Project (BWIP) is in a state of transition. The former exploratory work was conducted to provide a basis for deciding whether or not the Columbia Plateau basalts warranted formal site characterization. The decision that site characterization should be performed imposed the need to bring the project QA program into conformance with Nuclear Regulatory Commission licensing requirements. Because ultimate licensability of the site, if it is selected, will depend heavily on the effectiveness and credibility of the controls under which site characterization is accomplished, the conforming QA program must be in place and effectively implemented by the time the site characterization plan is submitted for approval.

The primary objective of the DOE BWI Division audit program during this period is to establish a basis for judging the degree to which the QA program transition is succeeding. A secondary objective is to assemble evidence that can be used as an input for determinations as to usability (i.e., credibility) of relevant work performed prior to and during the transition.

To achieve these objectives, DOE audits must address the following questions:

(a) What is the control baseline for the audited activity up to the time of the audit?

(b) Were and/or are the baseline controls effective for work performed up to the time of the audit?

(c) What measures must be taken to bring the observed control baseline into full conformance with the required licensing QA program in time to support Site Characterization Plan submittal?

It is clear that the conventional approach to QA audit, based on evaluation of compliance to an established procedural base, is incapable of addressing either question (a) or question (b), and is only marginally capable of addressing question (c). The approach adopted for the present audit program, therefore, is designed to make a clear distinction between the effectiveness with which existing control measures are being applied, whether formal or informal, and the status of the transition process. The approach that is being used is described in the following sections of this attachment.

DEFINITIONS

Project risk - The risk of occurrence of an event or condition which, if it were to occur, would cause the output of a project activity to be unusable without rework or performance of unplanned additional work.

QA program element - An institutional provision or management control system required to satisfy requirements of the mandated project QA program. Each program element exists for the purpose of preventing, or significantly reducing the likelihood of, a particular kind of project risk.

Program element technical objective - The purpose of a program element as it relates to the technical usability (quality of the output) of affected activities.

Program element credibility objective - The purpose of a program element as it relates to credibility of evidence concerning (a) processes by which the affected project activity is performed, and (b) application of specified controls.

APPROACH

DOE-RL's BWI audit activity is organized in terms of project functional activities and a preestablished list of QA program elements (see DEFINITIONS) derived from NQA-1-1983. Each project functional activity is subject to a discrete subset of QA program elements (i.e, those program elements that address project risks inherent in the activity).

To understand the basic approach of the audit program, it is essential to recognize that QA program elements fall into three categories: (a) Institutional - organization, staff competence/qualification, working conditions, etc., (b) process specification - written procedures or instructions specifying how work is to be performed, and (c) management control systems - precautionary systems designed to reduce the risk of error and/or detect such error if it does occur.

In keeping with DOE's management role in the BWI project, DOE audit of project activities addresses effectiveness of QA program elements, as follows:

1. Category (a) elements: The audit determines whether the required institutional provisions are in place and examines preselected data sources for the presence of evidence that these provisions are or are not producing the desired results. For this category, presence or absence of the provisions determines credibility of the program element in question, while effectiveness indicators tend to involve factors such as frequency of error, rework, output inadequacy, lack of timely attention to deficiencies, etc.

2. Category (b) elements: It is assumed that technical procedures and instructions formalize accepted methods of performing the work in question. It is recognized that the method described may not be the only acceptable way of producing the desired results, but that a responsible technical and management decision has been made to use the prescribed method. Presence of written technical procedures or instructions is a specific requirement of the 10CFR50 Appendix B QA program (ref. Criterion V of Appendix B). Every audit includes a determination that the necessary technical procedures or instructions are or are not in place. If they are not, control system 5.1, Presence of Written Procedures/Instructions, is reported as ineffective.

   Compliance with approved technical procedures or instructions is also required by 10CFR50 Appendix B. Every audit includes a determination of compliance with those procedures that are in place. Lack of compliance is reported as ineffectiveness of control system 5.2, Compliance.

It should be noted that neither (a) presence or absence of approved technical procedures, nor (b) compliance or failure to comply with such procedures, constitutes necessary or sufficient proof of quality or lack of quality of the affected work.

3. Category (c) elements: These QA program elements formalize the precautionary systems which, in the absence of a formal QA program, are generally considered good professional practice in the interest of reducing project risks (e.g., documentation and traceability of inputs, independent review, etc.). DOE's BWI audits determine whether or not the necessary procedures for these formal systems are in place and being complied with and reports the results in terms of effectiveness of control systems 5.1 and 5.2, respectively.

   It should be noted that category (c) elements do not directly affect original work; they are directed at reducing attendant risks. The fact that all outputs from an activity meet applicable requirements may mean either that the controls are working effectively or that the control system is not being challenged.

   Nonetheless, DOE audits of these controls include a search for downstream evidence of system deficiency on grounds that presence of such evidence would not only expose the weakness in the control system, but would also show a deficiency in the affected technical procedure or the work it prescribes.

   In the general case during the current transition phase, some or all formal control systems remain to be implemented (controls 5.1 and/or 5.2 are not yet effective). However, it is important to determine how effective informal controls have been, and audits examine appropriate data sources for evidence bearing on that effectiveness.

EVIDENCE OF EFFECTIVENESS

A program element is considered to be effective if it achieves the intended result (i.e., prevents the target risk(s) from materializing) and ineffective if it does not. In the site characterization effort, every QA program element must not only achieve its risk containment function, but evidence of its application must be thoroughly credible. Both technical effectiveness and credibility are regarded as absolute prerequisites to licensability. Credibility depends on unimpeachable documentation of all activities required by the program element in question. Therefore, DOE audits of BWI project activities search for evidence of questionable control credibility.

Technical effectiveness is addressed on the basis of indicators that (a) a project risk has materialized (i.e., something has gone wrong), and (b) some part of the applicable control system is deficient. The focus is placed on negative indicators because of the inconclusive nature of favorable evidence.

FINDINGS

The baselining function of DOE audits during the transition phase is best accomplished by explicit reporting for every QA program element addressed by an audit. Findings are worded carefully to make it clear whether informal controls (important to the baseline) or formal controls are at issue. A statement that informal controls have been working effectively in the absence of the required formal system does not imply that the formal system is unnecessary; instead, it means simply that at the present stage of the project the work that has been, or is being, accomplished will probably withstand the scrutiny of any planned validation effort.

Such findings are accompanied by an assessment of the effect the lack of formal control may have on the credibility of the technical work in question and of the degree of control that has been, or is being, exercised.

ATTACHMENT 4

- Quality Audit Findings (QAFs) -

QUALITY AUDIT FINDING

9. QAF Control No.
8607-1

1. TO: Name	Title	2. Location
A. N. Kugler	RKE, Project Manager	RKE/PB Oakland, CA

3. Reference/Requirements	4. Audit Or Surveillance Report No.
NQA-1, 1983, Section 17S-1, Paras 5 and 6 and Section 3S-1, Para 7. (Control Subsystems 17.2 and 3.6)	8607

5. Description

NQA-1 requires retrievability of records accumulated at various locations and also requires collection, storage and maintenance of design documentation and records to approved procedures. The intent of these requirements is to ensure that working documentation intended to become a record is protected in such a way that there is a high level of confidence that it will become a record. Contrary to the above, there is no approved procedure for the collection, storage and maintenance of records. Also the existing method of record storage does not satisfy the requirements of a single facility as defined in 17S-1, Para 4.4.1.

6. Lead Auditor (Signature)	7. Issue Date	8. Response Due Date
[signature]	April 17, 1986	May 2, 1986

10. Auditee Corrective Action Commitment

The audit finding is correct. Procedures will be generated that provide for identification and control of documents for record purposes. The insufficiency in record protection facilities was previously identified by RKE/PB and corrective action is pending concurrence from Rockwell/DOE to upgrade record storage facilities for in-process records (prior to final issuance with reports/design documents). Resolution requires participation/authorization of DOE. RKE/PB will request authorization to implement conformance action within 90 days of the date of audit finding.

NOTE: Action Shall Address Root Cause and Include Measures to Prevent Recurrence

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date
Charles E Williams	4/25/86	

ACTION VERIFIED

14. Lead Auditor (Signature)	15. Date

17. Final Distribution

ORIGINAL-Audit/Surveillance Report File

1--Addressee

2--

3--

16. Final Review and Approval (QAF Closed)

Mgr./Branch Chief, Cognizant Branch — Date

QUALITY AUDIT FINDING

INSTRUCTIONS FOR PREPARING THE QUALITY AUDIT FINDING:

BLOCK NO. INITIATOR	ENTRY INFORMATION
1	Name and title of Auditee/Personnel responsible for providing action.
2	Location of audit or surveillance activity.
3	Reference/requirements. Be concise and factual, reference controlling documents relative to "description."
4	Audit or Surveillance Report No.
5	Description of the observed condition. Be concise and factual.
6	Signature of Lead Auditor or person performing surveillance.
7	Date of initiating QAF.
8	Date by which addressee must respond (NOTE: Whenever possible, this will be date of addressee acknowledgement of condition, e.g., at post-audit conference - must be within 30 days of QAF initiation date).
9	QAF Control Number provided by cognizant originating department/branch.

ADDRESSEE

10	Corrective action commitment of action party.
11	Signature of responsible action party.
12	Signature date.
13	Committed completion date for corrective action.

INITIATOR

14	Signature of Lead Auditor or person performing surveillance - signifies corrective action has been verified adequate and complete.
15	Date of verification.

MANAGER/BRANCH CHIEF (COGNIZANT BRANCH)

16	Sign and date signifying final review and closure (NOTE: includes evaluation of need for re-audit, etc.)
17	Distribute as required.

QUALITY AUDIT FINDING

9. QAF Control No.
8607-2

1. TO: Name	Title	2. Location
A. N. Kugler	RKE, Project Manager	RKE/PB Oakland, CA

3. Reference/Requirements	4. Audit Or Surveillance Report No.
NQA-1, 1983, Section 15	8607

5. Description

NQA-1, Section 15 requires the identification, documentation, evaluation, segregation when practical and disposition of nonconforming items. Contrary to this requirement, neither the QA Plan nor procedures address this requirement for deficiencies identified (especially technical deficiencies) by those other than QA performing a surveillance.

6. Lead Auditor (Signature)	7. Issue Date	8. Response Due Date
	April 17, 1986	May 2, 1986

10. Auditee Corrective Action Commitment

The audit finding is correct. A procedure will be generated that requires any person with objective evidence of a nonconforming condition to document that noncompliance for evaluation, disposition, and management attention as appropriate. This procedure will include all requirements of document control and nonconformance reporting invoked by NQA-1, but may use methods of documentation other than NCR forms where appropriate for in-process work functions (i.e., such as errors found in calculation checks). Procedure will be approved and issued by 5/17/86.

NOTE: Action Shall Address Root Cause and Include Measures to Prevent Recurrence

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date
Charles E Williams	4/25/86	

ACTION VERIFIED

14. Lead Auditor (Signature)	15. Date

17. Final Distribution

ORIGINAL-Audit/Surveillance Report File

1--Addressee

2--

3--

16. Final Review and Approval (QAF Closed)

Mgr./Branch Chief, Cognizant Branch — Date

QUALITY AUDIT FINDING

INSTRUCTIONS FOR PREPARING THE QUALITY AUDIT FINDING:

BLOCK NO. INITIATOR	ENTRY INFORMATION
1	Name and title of Auditee/Personnel responsible for providing action.
2	Location of audit or surveillance activity.
3	Reference/requirements. Be concise and factual, reference controlling documents relative to "description."
4	Audit or Surveillance Report No.
5	Description of the observed condition. Be concise and factual.
6	Signature of Lead Auditor or person performing surveillance.
7	Date of initiating QAF.
8	Date by which addressee must respond (NOTE: Whenever possible, this will be date of addressee acknowledgement of condition, e.g., at post-audit conference - must be within 30 days of QAF initiation date).
9	QAF Control Number provided by cognizant originating department/branch.

ADDRESSEE

10	Corrective action commitment of action party.
11	Signature of responsible action party.
12	Signature date.
13	Committed completion date for corrective action.

INITIATOR

14	Signature of Lead Auditor or person performing surveillance - signifies corrective action has been verified adequate and complete.
15	Date of verification.

MANAGER/BRANCH CHIEF (COGNIZANT BRANCH)

16	Sign and date signifying final review and closure (NOTE: includes evaluation of need for re-audit, etc.)
17	Distribute as required.