Department of Energy
Richland Operations Office
P.O. Box 550
Richland, Washington 99352

MAY 06 1986

86 MAY -9 P12:51

General Manager
Rockwell Hanford Operations
Richland, Washington

Dear Sir:

QUALITY ASSURANCE AUDIT 8603, BASALT WASTE ISOLATION PROJECT (BWIP), MARCH 24-28, 1986.

Results of the recent DOE/RL QA audit of the BWIP Performance Assessment (PA) activities are hereby transmitted for Rockwell's action.

The audit was restricted to Performance Assessment activities (Total System PA, Site PA, Repository PA and Waste Package PA) performed by the Site Department, Systems Analysis Department, Engineered Barriers Department, Geomechanics Department and Licensing Department. The scope of the audit was the implementation and adherence to the Quality Assurance requirements of ANS/ASME NQA-1, 1983.

The formal control systems required for an NQA-1 program are not in place for ongoing performance assessment activities; i.e., required written procedures are not yet in place, and personnel have not been trained in QA program requirements. However, the informal (non-proceduralized) controls being exercised by the responsible personnel on the basis of prudence and professional good practice were found to be working effectively. To achieve an acceptable level of QA program implementation, the necessary procedures will have to be issued, training in the procedures will have to be completed, and the licensing implications of prompt, vigorous, corrective action for recognized QA programmatic deficiencies will have to be clearly recognized.

Commendable practices were observed relative to personnel technical knowledge, dedication, cooperation, and eagerness to correct problem areas.

The audit report and adverse finding sheets are enclosed. Please provide responses to the adverse findings not later than May 12, 1986. Responses should identify root causes, describe proposed corrective action, and indicate the date (or Project milestone event) by which each element of corrective action is expected to be implemented.

Very truly yours,

J. D. Davis for

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

BWI:CAS

Enclosure

cc w/encl:
L. R. Fitch, Rockwell
J. Knight, DOE-HQ
E. Sulek, Weston
V. Dale Hedges, NRC
C. Newton, DOE-HQ

1847

Audit Report No: DOE/BWID 8603
Audit Subject: BASALT WASTE ISOLATION PROJECT PERFORMANCE ASSESSMENT
Audit Dates: March 24 - 28, 1986.

SUMMARY:

The Site Department, Systems Analysis Department, Engineered Barriers Department, Geomechanics Department and Licensing Department performing Performance Assessment activities are satisfactorily implementing the Quality Assurance program requirements with the exception of four areas:

1. Indoctrination and Training in the QA program (control subsystem 2.5)

2. Instructions and Procedures (control subsystem 5.1)

3. Corrective Action (control subsystem 16.1)

4. Designation of Records (control subsystem 17.1)

All departments were deficient in the above listed 4 deficiencies except the Licensing Department which was not deficient in Corrective Action (item #3). Licensing was deficient in items 1, 2 and 4.

Three Quality Audit Findings have been initiated to resolve these deficiencies (deficiencies 1 and 4 are combined into one QAF). In addition, there was a quality concern regarding reviews of changes to procurement documents. See Attachment 3 for the Quality Audit Findings and the Quality Concern.

INTRODUCTION

This audit addressed Rockwell's Basalt Waste Isolation Project (BWIP) Performance Assessment activities. The scope of the audit was the implementation and adherence to the Quality Assurance requirements of ANS/ASME NQA-1, 1983, Quality Assurance Program Requirements for Nuclear Facilities. Performance assessment is the quantitative evaluation of suitability of the proposed repository in basalt of the Hanford Site for the disposal of high-level nuclear waste. Performance assessment evaluates occupational and public safety, and the long-term containment and isolation of the radioactive wastes. Performance assessments are made to evaluate compliance with applicable regulations, to support design engineering activities, and to guide future research in characterizing the proposed repository site.
The Audit addressed applicable QA program controls exercised in performing the following activities (WBS numbers in parentheses):

Total System Performance Assessment (L1E)	Post Closure Performance Assessment (L1E1)	Systems Analysis Dept.
	Computer Code Development (L1E2)	Systems Analysis Dept.
	Data Modeling (L1E3)	Systems Analysis Dept.
	Pre-Closure Safety Analysis (L1E4)	Licensing Dept.
Waste Package Performance Assessment (L2F)	Performance, Reliability and Safety Analysis (L2F1)	Engineered Barriers Dept.
Site Performance Assessment (L3J)	Site Data Acquisition and Control (L3J1)	Site Dept.
Repository Performance Assessment (L4G)	Geomechanics Model Development & Analys. (L4G1)	Geomechanics Dept.
	Seal System Model Development & Analysis (L4G2)	Engineered Barriers Dept.

DISCUSSION

The audit was designed to evaluate the degree to which the Performance Assessment activities satisfied the QA control systems or subsystems identified in ANS/ASME NQA-1, 1983. Thirty-four subsystems were identified in the audit checklist against which Performance Assessment implementation of that subsystem was measured. Attachment 1 presents the 34 subsystems, the purpose of each subsystem, the indicators of the control subsystem failure and the audit results for each subsystem.

In all cases,the audit results and deficiencies were applicable to all four Performance Assessment departments with the exception of the Licensing Department, which was not deficient in Corrective Action. In other words, where a deficiency to a subsystem was found in the Systems Analysis Department, the same deficiency was observed in the Site, Geomechanics, Licensing and Engineered Barriers Departments. Conversely, when no deficiency

to a subsystem was observed, it was observed in all four departments. Throughout this report, reference to Performance Assessment applies to Site, Systems Analysis, Geomechanics, Engineered Barriers and Licensing.

Attachment 2 contains necessary administrative information such as the list of audit team members, attendees at the pre - and post - audit meetings and personnel contacted.

COMMENDABLE PRACTICES

1. All RHO personnel interviewed were very knowledgeable in their technical fields and professional in their work habits.

2. The RHO department and group managers were most cooperative and frank about their department's deficiencies or problem areas. In many cases, the managers were already aware of and had corrective actions underway to resolve deficiencies they had identified prior to the audit.

LACK OF PROCEDURES OR INSTRUCTIONS

During the audit, it was noted that some QA requirements of NQA-1 were being implemented but were not described in approved procedures. For example, all departments were aware of the interfaces required in the course of doing their assigned tasks and the audit evidence indicates that these interfaces were proper and practiced. However, these interfaces were not defined as required by Section 1.0 (Organization) of NQA-1. In another example, all departments took action when a deficiency was detected by analyzing and correcting the problem. In interviews with managers, it was also noted that, when applicable, undocumented preventative action was taken to prevent recurrence (i.e., personnel retrained, manuals amended or revised). Although corrective action activities were being satisfied, the process was not defined in approved procedures as required by Section 16 (Corrective Action) of NQA-1. In a third example, the auditors observed that records were well maintained and processed but, again, no approved procedure existed describing the responsibilities and the process of records retrieveability and maintenance as required by Sections 3.0, Para. 7 (Design Control) and 17.0, Para. 5 (Quality Assurance Records) of NQA-1.

Quality Audit Finding (QAF) 8603-2 was issued as a result of this audit citing lack of instructions or procedures as a deficiency. In review of correspondence, audit findings, surveillance findings and in discussions with the involved PA managers, it was observed by the auditors that the managers were a) aware of which procedures were required and which were missing and b) were taking action to prepare and issue those procedures. It should be noted, however, that in the case of Systems Analysis Department an additional QAF was issued because of excessively slow action in procedure development.

Where procedures were lacking the auditors examined:

a. the implementation of the Quality Assurance principles of each control subsystem.

b. the effectiveness of that implementation.

c. the impact on site characterization studies or design bases that lack of an instruction or procedure could have.

If any of these three criteria were negative, the subsystem was judged ineffective. If all three criteria were positive, the subsystem was judged effective and QAF 8603-2 relied upon to correct the specific deficiency which was lack of procedures or instructions. This approach was used when evaluating such control subsystems as 3.1 Design Input, 3.3 Design Verification, 3.5 Design Interface Control, 6.3 Document Review System, 16.1 Identification and Correction of Immediate Conditions, 17.2 Control/Protection of In-Process Documents Prior to Record Package Completion and 17.3 Record Validation.

Therefore, although some instructions or procedures were lacking, it is the conclusion of the auditors that a) the managers were aware of and were ensuring implementation of the intent of the QA requirements of NQA-1, b) that the work being performed is not being compromised because of the lack of these procedures and c) that resolution of the three QAFs issued as a result of this audit will ensure total compliance in the Performance Assessment activities to the QA requirements of NQA-1.

ATTACHMENT 1

SUMMARY OF AUDITED CONTROL SUBSYSTEMS

ATTACHMENT 1

SUMMARY OF AUDITED CONTROL SUBSYSTEMS

Control 2.5, Indoctrination and Training.

Purpose

This control subsystem is to ensure work is performed and controls are exercised as management believes they are being performed and exercised.

Indicators of Control Failure

The indicators of control failure are a) personnel are not cognizant of requirements and procedures, b) no matrix or other mechanism to identify; who needs training, what is needed, and/or scheduling, c) no verification of such records (training, scheduling, etc.), d) program fails to provide training in new/revised procedures before documents are issued, or e) no evidence of Project personnel indoctrinated in RHO QA Program requirements.

Effectiveness

This control subsystem was judged to be ineffective. While many of the organizations audited provided technical training to their personnel, there was little awareness by personnel (with the exception of the managers) of the total Q.A. Program. There was no formal training program in place for indoctrination and training of personnel to the Q.A. Program. See Quality Audit Finding (QAF) 8603-1 in Attachment 3.

Control 3.1, Design Input.

Purpose

This control subsystem is to ensure that site characterization results and design bases are based on correct requirements and constraints. Also, it is to provide tangible evidence that data needs are based on the correct requirements and constraints.

Indicators of Control Failure

The indicators of control failure were a) finding a document which contains incorrect requirements or constraints, or b) finding a document which does not contain tangible evidence that the data needs were based on the correct requirements and constraints.

Effectiveness

No indications of control failure were noted. This control subsystem is judged effective.

Control 3.2, Design Process.

Purpose

This control subsystem is to ensure that design inputs are correctly translated into the required design. It also permits verification that the design meets the requirements and ensures that the design analysis can be reconstructed.

Indicators of Control Failure

The indicators of control failure were a) finding a document which contains inputs which were incorrectly translated from another document or from the original requirements, b) lack of a verification process for the design or study, or c) finding a document in which it is impossible to reconstruct the analysis.

Effectiveness

No indications of control failure were noted. This control subsystem is judged to be effective.

Control 3.3, Design Verification.

Purpose

This control subsystem is to confirm that the design performs the required functions.

Indicators of Control Failure

The indicators of control failure were a) failure of the organization to perform the verification, or b) failure of a document to require a verification that the design performs the required functions.

Effectiveness

No indications of control failure were noted. This control subsystem is judged to be effective.

Control 3.4, Design Change Control

Purpose

This control subsystem is to ensure that changes do not compromise the original design intent.

Indicators of Control Failure

The indicators of control failure were a) failure to review and approve a proposed design change, or b) finding a design change which was incorporated into the final design and which was not reviewed and approved.

Effectiveness

No indications of control failure were noted. This control subsystem is judged to be effective. The activities audited were generally considered to be research and development work and, therefore, design changes were done prior to input to design. Usually, Design Change Control meant change control of a test program rather than of a change to an engineered design already issued.

Control 3.5, Design Interface Control

Purpose

This control subsystem is 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 Control Failure

The indicators of control failure were a) finding a document which required input or review from others but finding no evidence that the input was provided, b) lack of evidence that the status of design information transmitted across design interfaces is controlled, or c) failure to identify the design interfaces.

Effectiveness

No indications of control failure were noted. This control subsystem is judged to be effective. Design interfaces have been established and no compromise of design was noted due to lack of interface control.

Control 3.6, Design Documentation and Records.

Purpose

This control subsystem is to ensure that the design activity can be reconstructed to provide credibility in the formal record. It is also to ensure a correct and complete design data base which can be used in further design activity.

Indicators of Control Failure

The indicators of control failure were a) inability to retrieve design documents and records, b) lack of a procedure describing how design documents are to be maintained, c) failure to retain design documents and records in accordance with procedure, or e) finding a record package which is incomplete.

Effectiveness

No indications of control failure were noted. This control subsystem is judged to be effective. Document packages examined were complete and easily retrieved.

Control 3.7, Design Deficiency Control.

Purpose

This control is to ensure that no known deficiency in the design is used in the design. Also, it is to assure reevaluation of the design control process.

Indicators of Control Failure

The indicators of control failure were a) finding a final design document which was revised to correct a known deficiency without evidence of a reevaluation by those who performed the original evaluation, or b) failure to provide for a method for identifying deficiencies and for preventing the deficiency from being used in the design.

Effectiveness

No indications of control failure were noted. This control subsystem is judged to be effective.

Control 4.1, Control of Content of Procurement Documents.

Purpose

This control subsystem is to ensure that procurement documents adequately and accurately reflect what is intended to be purchased.

Indicator of Control Failure

The indicator of control failure was finding a procurement document (Statement of Work) which does not contain a scope of work, technical requirements, QA requirements, right of access statement, documentation requirements or reporting of nonconformances requirement.

Effectiveness

No indications of control failure were noted. This control subsystem is judged to be effective. Statement of Work documents examined were prepared and reviewed adequately.

Control 4.2, Procurement Document Review.

Purpose

This control subsystem is to ensure procurement documents include all the necessary requirements.

Indicator of Control Failure

The indicator of control failure was finding a Statement of Work or similar procurement document which does not contain evidence of review by authorized individuals.

Effectiveness

No indications of control failure were noted. All purchase requisitions reviewed were approved by authorized individuals. This control subsystem is judged to be effective.

Control 4.3, Control of Changes to Procurement Documents.

Purpose

This control subsystem is 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 Control Failure

The indicators of control failure were a) finding evidence of changes to a procurement document which was not reviewed in a manner commensurate with the original procurement document, or b) lack of a formal program to provide for changes to procurement documents necessary to implement design changes.

Effectiveness

No indications of control failure were noted. All changes to procurement documents examined were reviewed in a manner commensurate with the original procurement document. This control subsystem is judged to be effective. See Quality Concern in Attachment 3.

Control 5.1, Prescription of Activities by Instruction, Procedures and Drawings.

Purpose

This control subsystem is to ensure that agreed upon methods and approaches are specified in writing. Also, it is to ensure the ability to replicate the activity.

Indicator of Control Failure

The indicator of control failure was finding evidence that a design basis or site characterization activity was performed without approved instructions or procedures.

Effectiveness

This control subsystem is judged to be ineffective. The lack of adequate procedures was common in all activities audited. Especially in the Systems Analysis Department, this deficiency has been identified through audits and surveillances since 1982 without resolution. See QAF 8603-2 in Attachment 3.

Control 5.2, Compliance to Instruction Procedures and Drawings.

Purpose

This control subsystem is for the purpose of knowing how the job was done in order to reconstruct or utilize the results of the activity.

Indicator of Control Failure

The indicator of control failure was finding evidence that personnel failed to follow approved procedures or instructions.

Effectiveness

No indications of control failure were noted. This control subsystem is judged to be effective. Of those procedures and instructions which were available for review, no evidence of failure to follow procedures was noted.

Control 5.3, Maintenance of Working Files.

Purpose

This control subsystem is to ensure that the integrity of the record is preserved.

Indicators of Control Failure

The indicators of control failure were a) finding evidence that files which will ultimately be QA files are being maintained in a deleterious manner, b) finding evidence that files which will ultimately be QA files cannot be located or retrieved, or c) no working files available.

Effectiveness

No indications of control failure were noted. Working files were being maintained in a satisfactory manner and could be located and retrieved readily.

Control 6.1, Identification of Documents to be Controlled.

Purpose

This control subsystem is to ensure that only legitimate data is used in site characterization activities. Additionally, it is to ensure that all the documents used in site characterization that affect safety or waste isolation are accounted for.

Indicators of Control Failure

The indicators of control failure were a) failure to identify or be aware of documents which are to be controlled, b) finding evidence of a document which has been identified as one to be controlled but is not, or c) finding evidence that a controlled document is missing.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. No documents received which were designated for control were found in an uncontrolled state.

Control 6.2, Document Numbering System(s)

Purpose

This control subsystem is to provide a method for assuring that the correct document is used or referenced.

Indicator of Control Failure

The indicator of control failure was finding documents used in site characterization or design basis activities which cannot be identified, referenced or tracked.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. All documents audited were clearly identified and traceable.

Control 6.3, Document Review System

Purpose

This control subsystem is to assure document adequacy and accuracy.

Indicators of Control Failure

The indicators of control failure were a) failure to identify the assignment of personnel responsible for preparing, reviewing, approving and issuing controlled documents, or b) no evidence that a document received a review for adequacy, completeness and correction prior to approval and issuance.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. All documents audited were adequately reviewed.

Control 6.4, Approval and Issuance

Purpose

This control subsystem is to provide clear evidence of the authoritative nature of procedural direction.

Indicator of Control Failure

The indicator of control failure was no evidence of a published approval list.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective.

Control 6.5, Document Change Control

Purpose

This control subsystem is to ensure that site characterization results are not compromised either through use of improper information or through failure to provide for timely updates or revisions.

Indicator of Control Failure

The indicator of control failure was finding a controlled document which was revised without evidence of a review and approval by the same organization that performed the original review and approval.

Effectiveness

No indicators of control failure were noted. This control subsystem is considered effective.

Control 6.6, Distribution Control

Purpose

This control subsystem is to ensure that only the correct up-to-date documents are used and available.

Indicators of Control Failure

The indicators of control failure were a) finding source documents or drawings used in performance assessment which are not current, b) finding source or reference documents available for use by department personnel which are out-of-date or uncontrolled, or c) lack of distribution list.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. Of the documents audited, no source documents or reference documents were found to be out of date or uncontrolled.

Control 7.5, Control of Supplier - Generated Documentation

Purpose

This control subsystem is to ensure that purchased items or services have a credible pedigree. Also, it is to make it possible to reevaluate purchased items or services if new information surfaces, or for later problem analysis.

Indicator of Control Failure

The indicator of control failure was inability to produce required documentation which was included in procurement requirements.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. However, it was noted during the audit that there was some confusion concerning responsibilities for obtaining and handling of supplier-furnished documents. This was considered to be due to lack of training and is included in audit finding 8603-1 (Attachment 3).

Control 11.1, Establishment of Test Control Requirements

Purpose

This control subsystem is to ensure that needs for information/ data to be generated by testing meets actual needs to support the site characterization mission.

Indicators of Control Failure

The indicators of control failure were a) finding a test document which failed to provide requirements and acceptance criteria or which was not approved by the organization responsible for the design of the test, or b) test personnel not qualified.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. All Site Department test procedures examined by the auditor provided requirements and acceptance criteria and were approved by the responsible organization. Personnel are trained to each test procedure and attendance rosters maintained. These were reviewed and found satisfactory. In the other PA departments, Performance Assessment relies upon predictive modeling for future planning and/or test design. Therefore, PA tests involved computer data input and analysis. Computer code user's guides were used to define data input requirements and method of operation.

Control 11.2, Test Planning

Purpose

This control subsystem is to ensure that tests are performed when necessary and in proper sequence so that where the type of data or method of testing on one test depends on results of other tests, the necessary results will be available.

Indicator of Control Failure

The indicator of control failure was finding evidence of a test which was performed without the necessary planning or not in the proper sequence.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. For the Site Department, tests are not performed until the test plan is approved by the Site Department Manager. Test plans reviewed by the auditor were approved. For the other PA departments, planning consisted of defined scenarios analyzed by the applicable computer program. No deficiencies in this methodology were observed.

Control 11.3, Test Procedures

Purpose

This control subsystem is to ensure valid test results and replicability of testing.

Indicators of Control Failure

The indicators of control failure were a) finding evidence that a test was performed without procedures or in violation of procedures, b) finding test procedures which lack objectives or provisions for assuring prerequisites have been met or which fail to address instrumentation (if necessary), test monitoring or maintenance of environmental conditions, or c) finding test procedures which failed to provide for the documentation and review of the test results.

Effectiveness

No indicators of control failure were noted. This control is effective. Since the issuance of RHO's Stop Works 86-001 and -002 for Well DC-23GR, the Site Department has prepared detailed test procedures. All future tests will be performed to approved test procedures. DC-23GR test procedures were reviewed and found to be satisfactory. For the other PA activities, test procedures, essentially computer program user's manuals, describe how to input the test data and obtain the analyzed results. The manuals are approved by the Systems Department Manager and controlled. These manuals were judged to be an acceptable means of providing instruction.

Control 11.4, Test Results Evaluation

Purpose

This control subsystem is to ensure that only valid test data is used in site characterization or as design base information.

Indicators of Control Failure

The indicators of control failure were a) failure or lack of evidence that test results were evaluated by the responsible authority, or b) failure to designate those personnel authorized to perform test results evaluation.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. In the Site Department, test results are reviewed by the test engineers and by the Site Department. For the other PA departments, computer data is reviewed by the computer engineer and by the department manager prior to further use or transmittal to the requester.

Control 11.5, Documentation of Testing

Purpose

This control subsystem is to ensure documented evidence that the test was performed as prescribed. Also, it is to ensure credibility of the test activity as reflected in the formal record.

Indicators of Control Failure

The indicators of control failure were a) finding a record of test data results which is incomplete or incorrect, or b) lack of formal documentation of test data.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. For the Site Department, test results were documented in the procedures. All data had been recorded and no information was missing. For the other PA departments, test results were documented in various published reports and supporting documents. The reports appeared to be complete and methodology and results clearly documented.

Control 16.1, Identification (flagging) and Correction of Immediate Condition

Purpose

This control subsystem is to ensure that conditions adverse to quality are identified and appropriate corrective action taken.

Indicators of Control Failure

The indicators of control failure were a) failure to have a program in place to identify and resolve conditions adverse to quality, b) failure to detect a condition adverse to quality, or c) failure to take appropriate corrective action for identified adverse conditions.

Effectiveness

This control subsystem is judged to be ineffective. As noted in subsystem 5.1, RHO QA had identified lack of procedures as a deficiency and had issued an Audit Finding, a Surveillance Report and a Corrective Action Report. Quality Audit Finding 8603-3 (Attachment 3) states that RHO Management has failed to take timely corrective action and has not assured that all necessary procedures are in place.

Control 16.2, Determination of Cause and Action to Preclude Recurrence of Significant Problems.

Purpose

The purpose of this control subsystem is to prevent recurrence of significant problems.

Indicators of Control Failure

The indicators of control failure were a) lack of a program to determine the cause of an adverse condition or to take action to preclude recurrence, b) failure to perform an analysis to determine cause of an identified adverse condition, or c) failure to detect repetitive problems.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. Since this audit covered mostly research and development work and test data is reviewed and failures analyzed prior to design input, prevention of recurrence of significant problems is an immediate reaction to every analysis of the testing activity.

Control 16.3, Documentation, Reporting to Management.

Purpose

This control subsystem is to ensure that a record exists which will provide credibility of the actions taken in the formal record. Also, it is to ensure that corrective action decisions are made at the appropriate management level to assure proper emphasis and attention.

Indicators of Control Failure

The indicators of control failure were a) failure to document a significant adverse condition, b) failure to notify management of a significant adverse condition, c) failure of management to adequately attend to a significant adverse condition, d) finding an incomplete or open corrective action document which is not being addressed, or e) failure to identify the appropriate management levels required to assess adverse conditions.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. No significant adverse conditions were unattended and the proper level of management was involved in the samples examined.

Control 16.4, Follow-Up

Purpose

This control subsystem is to ensure that the specific preventative action was taken. It is also to ensure that a known significant problem does not continue to threaten the integrity of the program.

Indicators of Control Failure

The indicators of control failure were a) finding a documented significant condition which lacks evidence of follow-up, b) finding evidence that follow-up action was taken but that the adverse condition continued to exist, c) lack of status reporting to management, or e) failure to maintain a status or tracking system for adverse conditions.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. As noted in control subsystem 16.2, this audit dealt primarily with research and development activities. Follow up is routinely performed for corrective actions in the testing and analysis work and, as a result, significant problems involve adequate management attention and status reporting to management.

Control 17.1, Designation of Documents or Document Types Destined to Become Records.

Purpose

This control subsystem is to ensure that participants know what documents and document types are to be submitted for incorporation in the formal record and to define the boundaries of the BWIP record.

Indicators of Control Failure

The indicators of control failure were a) failure of personnel to be aware of which documents are to become records, b) failure to designate documents or document types as records, or c) lack of a record index.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged effective. Records are adequately maintained prior to transmittal to RMC.

Control 17.2, Control/Protection of In-Process Documents Prior to Record Package Completion.

Purpose

To ensure that documents submitted for incorporation in the formal record actually survive until receipt by Records Management Center.

Indicators of Control Failure

The indicators of control failure were a) no evidence of proper physical maintenance of records prior to submittal to RMC, or b) evidence that there is no systematic method to maintain records.

Effectiveness

No indications of control failure were observed. This control subsystem is judged to be effective. There was no evidence of poor maintenance of in-process records. A systematic method (procedure) of control used by all departments would ensure consistency, however, individual controls were adequate.

Control 17.3, Record Validation

Purpose

This control subsystem is to ensure that documents incorporated into the formal record are authentic i.e., that they truly record activities and that they are generated by authorized persons or organizations.

Indicators of Control Failure

The indicators of control failure were a) finding documents designated as QA records which lack evidence of validation or authentication, or b) finding authenticated or validated documents which are incomplete or incorrect.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. All records reviewed during the audit were properly authenticated.

Control 17.5, Identification of Records to Items or Activities.

Purpose

This control subsystem is to ensure that the individual record can be put in correct Project context during subsequent use of, or reference to, the formal Project record. Also, it is to provide a means of retrieval access to the body of records associated with a particular item or activity.

Indicators of Control Failure

The indicators of control failure were a) in-process and/or completed records are not retrievable and identifiable to the related activity, or b) inability to reconstruct what was evaluated during documentation of the record.

Effectiveness

No indicators of control failure were noted. This control subsystem is judged to be effective. In-process and completed records were retrievable and the activity documented could be reconstructed from the retrieved records.

ATTACHMENT 2

MEETING ATTENDEES

AND CONTACTS

ATTACHMENT 2

Meeting Attendees and Contacts

NAME	ORGANIZATION/TITLE	ENT-RANCE	CON-TACTS	EXIT
P.R. Dahlberg	RHO Sys. Anal. Dept.	x		
J.T. Baxter	RHO Modeling & Anal. Dept.	x		
J.S. Thies	RHO Mgr. Sys. Anal. Group	x	x	x
B.K. Sandall	RHO BWIP QA	x		x
K.M. Tominey	RHO Mgr. BWIP QAPV	x		
R.R. Ames	RHO Modeling & Anal.	x		
H.J. Dahlke	RHO Modeling & Anal.	x	x	
T.A. Curran	RHO Modeling & Anal.	x	x	x
T.W. Nolan	RHO BWIP QA	x	x	x
J. Graham	RHO Mgr. BWIP Licensing Dept.	x		
D.G. Harrison	RHO BWIP Licensing	x		x
S.C. Yung	RHO Engineered Barriers Dept.	x		
T.B. McCall	RHO Mgr. Engineered Barriers Dept.	x	x	x
R.D. Allen	RHO Engineered Barriers	x	x	x
C. Cejka	RHO Systems Analysis	x	x	x
B. Sagar	RHO Systems Analysis	x	x	
R.G. Baca	RHO Mgr. Sys. Anal. Dept.	x	x	
S.M. Baker	RHO Mgr. Site Dept.	x	x	x
W. Keltner	RHO Proj. Assurance Coord.	x		
E.A. Fredenburg	RHO Mgr. Engineered Barriers	x	x	x
R.J. Johnson	RHO Mgr. BWIP QA	x		
A.J. Knepp	DOE/RL Geo. & Tech.	x	x	

NAME	ORGANIZATION/TITLE	ENT-RANCE	CON-TACTS	EXIT
W.B. Williams*	DOE/MAC Auditor	x	x	x
W.A. Hedzik*	DOE/MAC Auditor	x	x	x
C.A. Smiroldo*	DOE/MAC Lead Auditor	x	x	x
D. Herborn	RHO Licensing		x	x
G.S. Hunt	RHO Mgr. Systems Group			x
R.L. Snow	RHO Site Dept.		x	x
P.M. Rogers	RHO Site Dept.		x	
U.R. Achenbach	RHO Site Dept.		x	
R.C. Arnett	RHO Systems Analysis		x	
H.L. Benny	RHO Engineered Barriers		x	

*Audit Team Members

ATTACHMENT 3

QUALITY AUDIT FINDINGS

AND

QUALITY CONCERN

QUALITY AUDIT FINDING

9. QAF Control No. 8603-1

1. TO: Name L. R. Fitch **Title** Director, Basalt Waste Isolation Project

2. Location

3. Reference/Requirements

NQA-1, Basic, Sec. 2.5 Quality Assurance Program and 17.1 Designation of Documents or Document Types Destined To Become Records.

4. Audit Or Surveillance Report No.

8603 Performance Assessment

5. Description

The QA Program requires that personnel be indoctrinated and trained in applicable procedures to insure that work is performed in accordance with authorized methods and approaches. (Control systems 2.5 and 17.1).

RHO management has failed to provide personnel with training in the QA Program. This was evident by the lack of awareness in the areas of designation of records, transmittal of records to RMC, responsibility for records generated by Statement of Work or Service Agreement, requirements for document control, identification of nonconforming conditions and corrective action, especially to prevent recurrence.

6. Lead Auditor (Signature) Charles G. Smiroldo Jr.

7. Issue Date April 1, 1986

8. Response Due Date April 30, 1986

10. Auditee Corrective Action Commitment

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

11. Responsible Action Manager (Signature)

12. Date

13. Action Completion Due Date

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

9. QAF Control No. 8603-2

1. TO: Name L. R. Fitch **Title** Director, Basalt Waste Isolation Project

2. Location

3. Reference/Requirements

NQA-1, Basic, Sec. 5 Prescription of Activities by Instructions, Procedures and Drawings. .

4. Audit Or Surveillance Report No.

8603 - Performance Assessment

5. Description

The QA Program requires that activities affecting safety or waste isolation be prescribed in instruction or procedures (Control Sys. 5.1). The purpose of this requirement is to specify the agreed upon methods and approaches and to ensure the ability to replicate the activity.

RHO Management has failed to assure that all the necessary procedures are in place for this activity. This problem was previously identified in RHO QA BCAR-85-007. See QAF 8603-3.

6. Lead Auditor (Signature)	7. Issue Date	8. Response Due Date
Charles G. Smerdon Jr.	April 1, 1986	April 30, 1986

10. Auditee Corrective Action Commitment

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

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date

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

9. QAF Control No. 8603-3

1. TO: Name J. A. Thies, MGR **Title** Systems Analysis Group
L. R. Fitch Director, Basalt Waste Isolation Project

2. Location

3. Reference/Requirements

NQA-1, Basic Section 16
Identification (flagging) and Correction of Immediate Condition.

4. Audit Or Surveillance Report No.

8603 Performance Assessment

5. Description

The QA Program requires the identification and prompt corrective action of conditions adverse to quality (Control System 16.1).

RHO Management has failed to take timely corrective action in that RHO QA Audit Finding 82-02-01, Surveillance Finding 84-047 and Corrective Action Request BCAR-85-007 have not been resolved. Some of the required procedures are in draft form and others have not started, indicating inadequate management attention.

6. Lead Auditor (Signature) Charles G. Smeraldo Jr.

7. Issue Date April 1, 1986

8. Response Due Date April 30, 1986

10. Auditee Corrective Action Commitment

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

11. Responsible Action Manager (Signature)	12. Date	13. Action Completion Due Date

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

ATTACHMENT 3

Quality Concern

While auditing procurement activities, it was noted that a deficiency exists in contract change control.

For direct-funded activities, QAP 4-401 sufficiently provides for QA review of changes to contracts. However, work order funded and purchased support activities, addressed in QAPP 4-402, are not rereviewed by QA. Since these procurement documents support BWIP activities and the products resulting from these procurements may be used in Site Characterization studies or design bases, these documents require the same review for changes as direct-funded procurements.

103D6A.S10