



Department of Energy

Richland Operations Office

P.O. Box 550

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86-BQS-05

JUN 5 1986

General Manager
Rockwell Hanford Operations
Richland, Washington

Dear Sir:

QUALITY ASSURANCE AUDIT 8604 - BASALT WASTE ISOLATION PROJECT
APRIL 1-16, 1986.

Results of the recent DOE-RL QA Audit of Rockwell's Peer Review Process as used on BWIP design and R&D activities is hereby transmitted for action by Rockwell.

The audit was limited to controls that could be assessed from documented Peer Review activities from 1985 and 1986, and discussions with selected technical managers and individuals within five project task areas. Rockwell's Peer Review Process was found to be ineffective, as eleven (11) of nineteen (19) controls evaluated were deficient. Seven audit findings (QAF's) have been issued to document the deficiencies.

Issuance of a stop work was recommended by the DOE lead auditor to prevent Rockwell from completing and releasing further documents subject to Peer Review pending issuance and implementation training on approved procedures that comply with ANSI/ASME NQA-1, 1983 and the NRC Review Plan, to assure that documents and generated records will be credible for use in site characterization or design and R&D activities. BWIP peer review Stop Work order was issued by BWI on April 24, 1986, pending resolution of findings 8604-1, 8604-2 and 8605-4 from this audit.

The Audit Report and adverse findings sheets are enclosed. As indicated at the exit meeting and on the Quality Audit Finding (QAF) sheets delivered to you at that time, responses were due May 21, 1986. These responses have not been received to date. Please expedite your responses, which must identify root causes, describe proposed corrective action and indicate the date by which each element of corrective action is scheduled to be implemented. In addition a senior level evaluation shall be submitted that describes the effect of reported control deficiencies on the validity and credibility of work that was done under the deficient controls.

WM Record File 101
WM Project 10
Docket No.

Sincerely,

PDR
LPDR (B)

R. P. Saget

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

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AUDIT REPORT NO. DOE/BWID 8604

AUDIT SUBJECT: Peer Review as Conducted by Rockwell

AUDIT DATES: April 1-16, 1986

INTRODUCTION

This audit addressed (1) adequacy and effectiveness of the controls exercised by Rockwell's technical and engineering groups in the peer review activities they performed, and (2) the effectiveness of the Rockwell audit and surveillance programs as evidenced by the results of the audit and surveillance activities.

The purpose of the Peer Review Process (Design Verification) is to produce a documented, in-depth critical review of documents, materials and/or data that is performed by a group of individuals (or a single individual if fully justified in advance), where interpretation or judgement is the only method of verifying or validating the results or conclusions. This method establishes credibility that the design and R&D activities performed will ensure that the site is correctly and properly characterized.

Several of the indicators of System Deficiency utilized during the audit required technical evaluations to determine control effectiveness in the task areas that were audited. This Technical support was provided by members of the Engineering and Construction and Geoscience and Technology Branches of BWID.

The documents evaluated and work breakdown elements selected for this audit were from tasks L1E1, L3C2, L3C4, L3C6, L4C1, L4C5 and L6K4. Documents were selected from a listing of released items within the task areas, where the control elements evaluated could be assessed with the indicators of system deficiency utilized. Peer Reviews are a special method of performing Design Verification where interpretation or judgement is the only method of verifying or validating the results or conclusions of documents, materials and/or data and establish credibility in using these items in the site characterization. Peer review is often used where there are no recognized standards or the work is beyond the state of the art. The audit method utilized can only prove the effectiveness of the overall system being evaluated if the in-place controls address the potential failures and make provision for correction within the management system. When examples of ineffective controls are discerned through evaluation of practices or review of documents which are a product of those system controls we can then properly conclude that we have uncovered failures in the in-place controls as has been done in this audit. Whether the output from current work will be utilized as a part of the design base or formal site characterization will be determined by Project Management.

Attachment 1 to this report contains necessary administrative information such as the list of audit team members, attendees at the pre- and post-audit meetings, personnel contacts, etc. Details of evidence examined and conditions observed are contained in the audit working file. Attachment 2 is a summary table of findings by program element/control system. Attachment 3 is the audit rationale. Attachment 4 consists of copies of the adverse audit findings (QAFs).

BASELINE ASSESSMENT

The necessary formal control systems for Peer Review Process activities are not in place, and the formal controls currently being exercised are not effective, either at the ANSI/ASME NQA-1, 1983 or the BOARD level. Rockwell's audit and surveillance program was also found ineffective as neither audits nor surveillances had been performed in the task areas since the present procedure was issued in December 1984.

It is recommended that a stop work be issued on the completion and release of any additional documents or data requiring peer review until Rockwell has issued a procedure that complies with the requirements and adequate training has been given to assure that the individuals and organizations involved will comply with the requirements, which will produce credible data and records for design inputs or site characterization.

FOLLOW-UP

There were no previous audits by Rockwell documented in peer review activities since 1982. BWID QA performed a surveillance of the Peer Review Process as documented in Surveillance Report BQA #7 in March 1986 and the unsatisfactory items reported were documented in this audit report. When the adverse audit findings from this report are closed, they will be used to close out Surveillance Report BQA #7.

FINDINGS

(See Interpretation of Effectiveness in Attachment 3, Audit Rationale.)

o CONTROL 2.5, INDOCTRINATION AND TRAINING

Purpose

To assure that individuals involved have been given sufficient indoctrination and training in the technical requirements and systems to obtain valid reviews for use in site characterization activities. To further assure that applicable control elements have been included in training so that results generated will be usable in subsequent design or construction.

Indicators of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed:

- a. Training and orientation for personnel performing Peer Review activities has not been documented.
- b. Training program content did not cover requirements.

- c. Personnel performing peer reviews are not knowledgeable of the processes and requirements to prevent system failure.

Finding

The three indications of system deficiency were observed in the audit sample: The control system is ineffective (Ref. QAF 8604-1)

The Rockwell procedure covering peer review had been circulated as required reading, and some on-the-job training given; however, discussions with individuals showed a lack of knowledge of the specific requirements of the process.

o CONTROL 3.3, DESIGN VERIFICATION (R&D AND DESIGN) - PEER REVIEW

Purpose

To determine that the site is correctly and properly characterized; that a design meets its requirements and will function as intended; and to ensure the credibility of the Peer Review process.

Indicators of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed:

- a. Failure to Peer Review a design or R&D activity that requires use of judgement to determine acceptability.
- b. Evidence of the release of a design or R&D activity document which had been identified for Peer Review, prior to completion of the review; or failure to identify and control un-Peer Reviewed design or R&D activity documents which could cause incorrect characterization.
- c. Evidence that the Peer Reviewer a) performed, or b) supervised, or c) directed or formulated the basis for the design R&D activity being reviewed.
- d. Instances where not all of the disciplines necessary to perform a design or R&D activity participated in peer review.
- e. Only one Peer Reviewer utilized for a design or R&D activity, where two are required in order to provide credibility.
- f. Evidence that the review comment process was not documented for design or R&D activities.

- g. Evidence or instances observed where peer review comments were not appropriately resolved, which would reduce credibility.
- h. Instances where the reviewers were not allocated sufficient time to perform the review of the design or R&D activity.
- i. Evidence that a change to a peer reviewed design or R&D activity was required as a result of an error in work previously reviewed, resulting in additional peer reviews and placing usability of the item in question.
- j. Evidence that a change to a peer reviewed and accepted design or R&D activity was not subsequently peer reviewed, resulting in a loss of credibility.
- k. Any instances where the scope of the required peer review was not documented.

Finding

All indicators of system failure except b, h, i and j were observed in the audit sample; the control system is ineffective (Ref. QAF 8604-2).

The peer review process as implemented by Rockwell does not comply with ANSI/ASME NOA-1 1983 and the BOARD (see Control 5.1). Further, several examples were observed where review comments and evidence of resolution were not retained; reviewers were not independent of the activity that prepared the document; individuals were not knowledgeable of the purpose or requirements for peer review, and did not document the purpose or scope in internal or external peer review requests.

o CONTROL 3.5, DESIGN INTERFACE CONTROL

Purpose

To ensure that all parts of the Peer Review of design and R&D activities are based on the same set of requirements or constraints in effect at any specific time.

Indicators of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed:

- a. Documents for design or R&D activities which required input or review from others, without evidence that the input was provided (credibility).
- b. Evidence that documents for design or R&D activities were submitted to interfacing organizations for peer review without definition of the scope and purpose.

- c. Instances where documents are not submitted to those disciplines necessary to perform a technical review.

Findings

Indications of system deficiency were observed in both b and c above, and the control is ineffective (Ref. QAF 8604-2). These deficiencies are further evidence of the ineffectiveness of Control 2.5 and Control 5.1.

o CONTROL 3.6, DESIGN DOCUMENTATION AND RECORDS

Purpose

To assure the credibility of the design and R&D activities process; to assure a correct and complete data base which can be used in subsequent site characterization; and to assure correct and satisfactory design which can be used in subsequent design or construction.

Indicators of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed:

- a. Evidence that records of the peer review process are not available for an item that was peer reviewed.
- b. Instances where copies of selected design documents cannot be retrieved.

Finding

Although the formal control system is in place the system is not effective (Ref. QAF 8604-2) as the peer review packages submitted to BRMC do not contain the records required to comply with ANSI/ASME NQA-1, 1983 and the BOARD (See Control 5.1).

o CONTROL 4.1, CONTROL OF CONTENT OF PROCUREMENT DOCUMENTS

Purpose

To assure that procurement documents adequately and accurately reflect item or service being procured (credibility).

Indicator of System Deficiency

This system is deemed ineffective if the following indicator is observed:

Procurement documents issued for items or services fail to include a) a statement of work, b) scope of work, c) technical requirements, d) item to be peer reviewed, or e) documentation requirements and purpose of service (credibility).

Finding

The formal control for procurement of peer review services is not effective and does not comply with ANSI/ASME NQA-1, 1983 and the BOARD (Ref. QAF 8604-3). Evidence was observed where peer review was obtained on a blanket purchase order and the scope and purpose was provided verbally.

o CONTROL 4.2, PROCUREMENT DOCUMENT REVIEW

Purpose

To assure procurement documents are independently reviewed to verify all necessary requirements have been specified. The following indicator was evaluated.

Indicator of System Deficiency

Any instance in which a procurement document examined failed to contain evidence of review by authorized personnel (credibility).

Finding

No evidence of the system deficiency was found in the audit sample. The formal control system is in place and effective, and the records are credible.

o CONTROL 5.1, PRESCRIPTION OF ACTIVITIES

Purpose

To specify in procedures the agreed upon methods and approaches to be used to ensure the ability to replicate the activities.

Indicators of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed.

- a. Evidence that a design or R&D activity for site characterization activity performed without approved procedures or instructions.
- b. The scope of what the peer reviewer is to evaluate is not defined.
- c. No clear identification of design and R&D activities requiring peer review.
- d. The procedure or instruction does not prescribe the reviewer selection process and qualification requirements of a peer review group.
- e. The procedure does not describe the responsibilities of the peer reviewer in the peer review process.

- f. The procedure does not prescribe the requirements specified in the NOA-1 and the BOARD.

Finding

Indicators of system deficiency were found in the procedure for items b, c, d, e, f. The formal control system is in place but is ineffective (Ref. QAF 8604-4).

o CONTROL 5.2, COMPLIANCE

Purpose

To know how the work was performed in order to reconstruct or utilize the results of the activity in a credible manner.

Indicator of System Deficiency

This program element is deemed ineffective if evidence shows that personnel failed to follow approved procedures or instructions.

Finding

Indications of system deficiency were observed in the audit sample for a above. Although a formal control system is in place it has not been effectively implemented (Ref. QAF 8604-4).

The procedure requires that a list of documents requiring peer review be developed and maintained. This has not been implemented. The procedure requires the documentation to include a) and abstract, b) scope, extent, purpose, c) selection process for peer reviewers, d) qualification of reviewers, e) comments and f) disposition of comments. In a review of six documents that were subjected to peer review, none of the document packages included b), c) and some cases e) and f).

o CONTROL 5.3, MAINTENANCE OF WORKING FILE

Purpose

To preserve the integrity of the records pending incorporation within the BRMC.

Indicators of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed:

- a. Evidence that documents which will ultimately be quality records are being maintained in a deleterious manner.

- b. Responsible managers unable to produce requested documents that will become part of the project QA files.
- c. Audited organizations unable to produce working files on documents currently in work.

Finding

None of the above indicators of system deficiency were found in the audit sample. The formal control system is in place and effective.

o CONTROL 6.1, IDENTIFICATION OF DOCUMENTS TO BE CONTROLLED

Purpose

To ensure that only correct data is used and to assure that documents used in site characterization that effect safety or waste isolation are accounted for.

Indicators of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed:

- a. Failure to identify or be aware of documents which are to be controlled.
- b. Finding evidence that a document identified as one to be controlled is not being controlled.
- c. Finding evidence that a recipient of a controlled document did not receive a document or a change to the document.

Finding

None of the above indicators of system deficiency were found in the audit sample. The formal control system is in place and effective.

o CONTROL 6.3, DOCUMENT REVIEW SYSTEM

Purpose

To assure that released documents are suitable for their subsequent use in site characterization activities.

Indicator of System Deficiency

Evidence that a document did not receive a review for adequacy, completeness and was not correct prior to approval and issuance.

Finding

No evidence of the above indicator of system deficiency was found in the audit sample; however, the formal control system implemented does not comply with ANSI/ASME NQA-1, 1983 and the BOARD (see Control 5.1). The system is ineffective in terms of credibility.

o CONTROL 6.4, APPROVAL AND ISSUE

Purpose

Provide clear evidence of the level of authority for the use of a document. The following indicator was evaluated.

Indicator of System Deficiency

Lack of evidence of a published approval list or other documented means of specifying approval authority.

Finding

No evidence of the above indicator of system deficiency were found in the audit sample. The formal control system is in place and is effective.

o CONTROL 6.5, DOCUMENT CHANGE CONTROL

Purpose

To assure that site characterization results are not compromised through the use of improper information, or through failure to provide for timely updates or revision. The following indicator was evaluated for credibility of the control.

Indicator of System Deficiency

Finding a controlled document which was revised without evidence of review and approval by the same organization that performed the original review and approval.

Finding

No examples of the above indicator of system failure were found in the audit sample. The formal control system is in place and is effective.

CONTROL 6.6, DISTRIBUTION CONTROLS

Purpose

To assure that only the correct, up to date documents are issued and available.

Indicators of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed:

- a. Finding source project documents or drawings used which are not current.
- b. Finding source or referenced project documents available for use by personnel which are out of date or uncontrolled.
- c. Lack of a distribution list (credibility).
- d. Evidence of document distribution inconsistent from one revision to the next.
- e. Ability to obtain a superseded document without its being identified as superseded.

Finding

None of the above indications of system deficiency were observed in the audit sample. The formal control system is in place and is effective.

o CONTROL 17.1, DESIGNATION OF DOCUMENTS OR DOCUMENT TYPES DESTINED TO BECOME RECORDS.

Purpose

To assure 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.

Indicator of System Deficiency

This system is deemed ineffective if one or more of the following indicators is observed:

- a. Failure of personnel to be aware of which documents are to become records.
- b. Failure to designate documents or document types as records.

Finding

Both of the indicators of system deficiency were observed in the audit sample. The formal control system has not yet been fully implemented (see Control 5.1), and the informal controls exercised by the audited activities are ineffective (Ref. QAF 8604-5).

o CONTROL 17.2, CONTROL/PROTECTION OF IN PROCESS DOCUMENTS PRIOR TO PACKAGE COMPLETION.

Purpose

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

Indicators of System Deficiency

- a. Evidence of lack of proper physical maintenance of records prior to submittal to BRMC.
- b. Lack of a records listing or log.
- c. Lack of evidence of a systematic method to maintain records.

Finding

None of the above indicators of system deficiency were found in the audit sample. The formal control system is in place and is effective.

As indicated in Control 5.3, the records were well maintained within the areas audited.

CONTROL 17.3, RECORD AUTHENTICATION/VALIDATION

Purpose

Ensure that documents incorporated into the formal records are authentic - i.e., that they truly record project activities and that they were generated by authorized persons or organizations. The following indicator was evaluated.

Indicator of System Deficiency

Inability to determine that a document is authentic.

Finding

The above indicator of system deficiency was not found in the audit sample. The formal control system is in place and is effective.