



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608

NOV 12 1996

L. D. Foust
Technical Project Officer
for Yucca Mountain
Site Characterization Project
TRW Environmental Safety Systems, Inc.
Bank of America Center, Suite P-110
101 Convention Center Drive
Las Vegas, NV 89109

**VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DR YM-96-D-089
RESULTING FROM OQA AUDIT YM-ARC-96-18 OF SANDIA NATIONAL
LABORATORIES**

The Office of Quality Assurance staff has verified the corrective action to Deficiency Report (DR) YM-96-D-089 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Stephen D. Harris at (702) 794-5522.

Richard E. Spence
Office of Quality Assurance

OQA:MRD-0298

Enclosure:
DR YM-96-D-089

cc w/encl:

T. A. Wood, DOE/HQ (RW-55) FORS
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
B. R. Justice, M&O, Las Vegas, NV
S. Y. Pickering, M&O/SNL, Albuquerque, NM, M/S 1395
Records Processing Center

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
S. D. Harris, OQA/QATSS, Las Vegas, NV
D. G. Sult, OQA/QATSS, Las Vegas, NV
D. G. Horton, DOE/OQA, Las Vegas, NV

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OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

ORIGINAL
Performance Report
THIS IS A RED STAMP
☒ Deficiency Report
NO. YM-96-D089
PAGE 1 OF 2
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

QAIP 6-3, Revision 03

2 Related Report No.

YM-ARC-96-18

3 Responsible Organization:

SNL

4 Discussed With:

Joe Schelling

5 Requirement/Measurement Criteria:

Section 5.1, Step 3, Note 2: states, "The review requester shall specify the criteria to be used to perform the review and shall assure that each reviewer is provided with those criteria (e.g., procedure checklists or review guidelines.) Example criteria are printed on the back side of the DRC form."

6 Description of Condition:

Contrary to the above requirement review criteria were not specified on DRC forms on 3 of 4 review packages audited:

WA-182, Revision 01

WA-205, Revision 02

QAIP 1-2, Revision 10 (Corrections made during audit)

Other blanks on the DRC forms were also not completed (e.g., Revision # of the document in review.)

7 Initiator

Stephen D. Harris

Date 8/1/96

9 Is condition an isolated occurrence?

☐ Yes

☒ No

☐ Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

All DRC forms need to be evaluated and corrected as necessary to indicate review criteria and document revision, as a minimum.

11 QA Review:

QAR Stephen D. Harris

Date 8/1/96

12 Response Due Date

20 working days from issuance

13 Affected Organization QA manager Issuance Approval: (QAR for PR)

Printed Name R.E. SPENCE

Signature

Robert B. Buntable

Date 8.7.96

22 Corrective Action Verified

QAR Stephen Harris

Date 11-4-96

23 Closure Approved by: (N/A for PR)

AOQAM

Date 11/7/96

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Continuation Page.

15 Extent of Condition: (Not required for PR)

See Continuation Page.

16 Root Cause Determination: (Not required for PR)

Required ☐ Yes ☒ No

17 Action to Preclude Recurrence: (Not required for PR)

Required ☐ Yes ☒ No

18 Corrective Action Completion Due Date:

October 30, 1996

19 Response by: *PR* R. RICHARDS OS F Ell

☒ Initial
☐ Amended

Date 9/7/96

Phone 855 898-0641

20 Response Accepted

QAR

N/A

Date

21 Response Accepted (N/A for PR):

AOQAM

N/A

Date

9/5/96 Brady & Spence

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

SEE AMENDED RESPONSE CONTINUATION PAGE.

15 Extent of Condition: (Not required for PR)

SEE AMENDED RESPONSE CONTINUATION PAGE.

16 Root Cause Determination: (Not required for PR)

Required ☐ Yes ☐ No

SEE AMENDED RESPONSE CONTINUATION PAGE.

17 Action to Preclude Recurrence: (Not required for PR)

Required ☐ Yes ☐ No

SEE AMENDED RESPONSE CONTINUATION PAGE.

18 Corrective Action Completion Due Date:

SEE A/R CONTINUATION PAGE

19 Response by:

☐ Initial
☒ Amended

SEE A/R CONTINUATION PAGE
Date _____ Phone _____

20 Response Accepted

QAR

Stephen Harris

Date

10-15-96

21 Response Accepted (N/A for PR):

AOQAM

James Playford Jr RES

Date

10/18/96

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BLOCK 14 - REMEDIAL ACTIONS:

For the QAIPs, there is no value to correct the Document Review and Comment forms as they are non-processed records and will never be submitted to the Project Records system. For the Work Agreements: The SNL QA Staff will inspect the approximately 120 active work agreement records packages and ensure that the criteria to be used for the review are specified or specify the default criteria on the reverse of the DRC form and ensure that the Work Agreement Revision number is on the DRC form or enter it. There does not appear to be sufficient impact to quality to submit revised records to the Records Processing Center in Las Vegas for the approximately 275 inactive, closed work agreement records packages.

Further, the DRC form will be modified with the next revision to QAIP 6-3 to state that, unless specified otherwise, the reviewer is to use the default criteria on the reverse of the form for the particular type of review (technical, management, or QA) being conducted.

Also, a QA Advisory will be issued to reinforce the concept that all blank spaces on a form must be accounted for.

BLOCK 15 - EXTENT OF CONDITION:

Because there are review criteria on the reverse of the DRC form and because the procedures requiring reviews all mention the criteria on the reverse, there are quite a few DRC forms without review criteria specified. And, since the Work Agreement is normally attached to the DRC form, there are quite a few with the revision number missing. However, since the number of DRC forms processed as QA records is finite and bounded and we are able to correct those records, there is no need to accomplish a root cause determination. Actions taken during the remedial action phase of the DR correction (modifying the form and issuing a QA advisory) should prevent recurrence of this deficiency so there is no need to specify additional actions to preclude recurrence.

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YM-96-D089, Amended Response (the information below supercedes the content of blocks 14 through 19 on page 2 of this DR)

Block 14, Remedial Action:

For the specific Work Agreements and QAIP cited, the completed Document Review and Comment (DRC) forms were treated, in accordance with the procedure in effect for their processing at the time, as "non-processed documents" (that is, they were not considered to be QA records). Therefore, since these documents are not in the Project Records System, generating corrections to them is not worthwhile, meaningful effort. Consequently, no remedial actions are appropriate.

Block 15, Extent of Condition:

The completed DRC forms for internal implementing documents, such as the cited QAIP and Work Agreement, have all been handled in the past as non-processed documents. Therefore, as above, there is no value in investigating and correcting those DRCs.

(Note: SNL QAIP 6-3, "Conducting and Documenting Reviews of Documents," is currently in the last stages of the revision process, incorporating the concept of "mandatory" and "discretionary" (non-mandatory) comments. With that revision, our approach to designating DRCs as records or not has changed; for the future, the DRCs which contain mandatory comments from reviews of internal implementing documents, as well as product documents, will be handled as QA records, making the actions specified in block 17, below, meaningful.)

Block 16, Root Cause Determination: Required ☒ No A root cause determination utilizing AP 16.4Q is not required because the cause of the discrepant condition is sufficiently clear, as detailed below.

The primary reasons that no entry was made, by the review requesters, in the "review criteria" space on the DRC form were:

- that the requester, knowing that general criteria were listed on the second page of the DRC form, and having no specific, different criteria to specify, thought that no statement concerning criteria needed to be placed in the designated space, or
- that the requester expected the reviewer to be more versed in criteria for a particular type of review than the requester.

Spaces were left blank on DRC forms due to the feeling on the part of the requester that the information was apparently clear from documents attached to the DRC, so

10/3/96 BRADY TO SPENCE

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need not be repeated on the DRC. Failure to enter "N/A" where appropriate arises from not applying knowledge gained in training about this subject, strongly supplemented by the fact that the entering "N/A" in blanks is, for most people, contrary to the expected and accepted practice in all other "life experience areas" involving completion of forms.

Block 17, Action to Preclude Recurrence: Required ☒ Yes, based on the information in block 16.

The DRC form cited in SNL QAIP 6-3 has been revised to include a statement in the "criteria space" to the effect that, if no entry is made in that space, the default criteria will be those on the second page of the form for the type of review indicated.

QA Advisories will be issued

- that reiterate the need and rationale for entering "N/A" in blanks on forms that serve a purpose under the OCRWM QA Program and
- that address the importance of considering and specifying criteria to be applied during document reviews.

Block 18, Corrective Action Completion Due Date:

October 31, 1996

Block 19, Response by:

☒ Amended Robert R. Richards



Date: Oct. 2, 1996 Phone: 505 848 0786

**SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)
QAIP 6-3**

CONDUCTING AND DOCUMENTING REVIEWS OF DOCUMENTS

Revision 04

Effective Date: _____

Author:

Thomas F. Ehrhorn
Thomas F. Ehrhorn

Date:

10/1/96

Concurrence:

R. R. Richards
QA Reviewer R. R. Richards

Date

10/14/96

Approval:

M. C. Brady
BNL CRWM Lab Lead M. C. Brady

Date:

10/31/96

**SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)
QAIP 5-1**

QUALITY ASSURANCE IMPLEMENTING PROCEDURES

Revision 06

Effective Date: _____

Author: Thomas F. Ehrhorn
Thomas F. Ehrhorn

Date: 10/16/96

Concurrence: R. P. Richards
QA Reviewer R. P. Richards

Date 10/16/96

Approval: Michael C. Brady
SNL CRWM Lab Lead M.C. Brady

Date: 10/30/96

Quality Assurance Advisory

November 1, 1996

WBS: 9.1.3.2


QA:

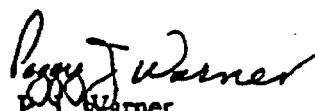
Those Pesky "N/As"

Once again, we need to provide a reminder about one of the details of the Office of Civilian Radioactive Waste Management QA Program. This time, it's those pesky N/As that we have to fill in on forms that become QA Records. The reminder is that, unless completion of a particular entry on a form is clearly optional (i.e., it says that on the form), then all spaces that would otherwise be blank must have "N/A" entered.

Why is this a concern? Well, the point is simply to ensure that documents that become QA records are generally unassailable from a completeness point-of-view. It has been learned in previous NRC licensing hearings that parties who wish to undermine the credibility of the applicant's technical case have attempted to do so by plays focusing on the applicant's QA program and records. One such effort, that has been successful in the past, has been to suggest that records with blanks containing no entry are apparently "incomplete" records, thereby being not representative of the actual technical work, or, even worse, representing falsified records from which critical information has been deleted.

We do not want the value of our technical work, nor the degree to which we have honestly implemented the QA program, to be undermined by such a tactic on the part of those who do not wish the Civilian Radioactive Waste Management Program to succeed. So, please check over forms that you generate to ensure that any blanks for which there is no appropriate information to be entered are marked "N/A" (actually lower-case "n/a" is fine, too). Likewise, as we develop and revise forms, we will attempt to designate information that is optional as such.


F. J. Schelling
CRWM QA Lead


P. J. Warner
Records Manager

Distribution (Please distribute within your department):

MS-1399 M.C. Brady, 6850

MS-1399 J. J. Danneels, 6853

MS-1326 H. A. Dockery, 6851

MS-1325 L. S. Costin, 6852

MS-1395 S. Y. Pickering, 6811

MS-1324 P. B. Davies, 6115

Copy to:

MS-1333 R. R. Richards, 6811

YMP:9.1.3.2:QAP:QA:QA Advisory

YMP RCP

Quality Assurance Advisory

November 1, 1996

WBS: 9.1.3.2

QA:

Non-Standard Criteria for Document Reviews

One of the procedures in our QA Program that is most frequently used is QAIP 6-3, "Conducting and Documenting Reviews of Documents." It is used for reviewing both internal implementing documents, such as Work Agreements, and "product" deliverable documents, such as SAND Reports. Any individual desiring any kind of review of a particular document can request and initiate that review by completing the top portion of the Document Review and Comment (DRC) form.

The purpose of this particular QA Advisory is to point out that review requesters have considerable flexibility in specifying what is reviewed and what criteria are used for the review.

The DRC form has recently been revised to make it clear that if no entry is made in the space for "Section of Document to be Reviewed and Review Criteria," then the entire document is to be reviewed using the criteria on the reverse of the form. However, this may not meet your needs as a review requester; you are free to request reviews for purposes other than the standard technical, QA, and management reviews. For example, you might want to get a review by Project Control to determine if a document agrees with the Project budget and schedule, or possibly you might want a review by the Budget/Procurement Specialist for consistency with SNL Purchasing policies. Similarly, you could focus technical reviewers on some aspect of the document that is not well-covered by the default technical review criteria, or, if the document is a revision of a previously issued document, limit the review to the new material.

The bottom line is, as a review requester, you can tailor the review you get to meet your needs, in addition to meeting the QA requirements for the documents. (Of course, this does not mean that required reviews of a document can be deleted, but you can customize or add to those minimum required reviews.)


F. J. Schelling

Lead for CRWM QA Lead

Distribution:

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MS-1333, R. R. Richards, 6812

MS-1333, QA Def. Doc. File

YMP:9.1.3.2:QAP:QA:QA Advisory

YMP RPC

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Verification of Corrective Action:

QAIP 6-3, revision 04, has been issued to clarify the use of the DRC form. The form now states that unless specified otherwise, the default criteria on the reverse of the form is to be used for the particular type of review. In addition, a QA Advisory has been issued to emphasize the accountability of blanks on forms.

Stephen D. Harris 11-4-96