



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

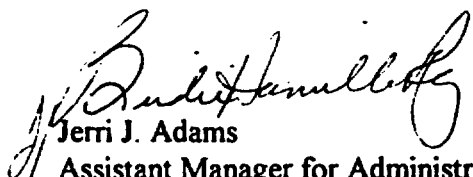
OCT 30 1996

D. G. Horton, Director
Office of Quality Assurance
U.S. Department of Energy
Office of Civilian Radioactive
Waste Management
P.O. Box 98608
Las Vegas, NV 89193-8608

RESPONSE TO DEFICIENCY REPORT (DR) YM-96-D-099 AND YM-96-D-102

Enclosed is the response to DRs YM-96-D-099 and YM-96-D-102 for your approval.

If you have any questions regarding the response, please contact either me at 794-1483, Sandra L. Moore at 295-5554, or Ruth M. Heidt at 794-5121.


Jerri J. Adams
Assistant Manager for Administration

AMA:JJA-0230

Enclosure:
DRs YM-96-D-099 and YM-96-D-102
Response

cc w/encl:

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Recip: NMSS/PAHL

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

8 ☐ Performance Report
☒ Deficiency Report
NO. YM-96-D-099
PAGE 1 OF 3
QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
Quality Assurance Requirements and Description (QARD), Rev. 5

2 Related Report No.
HQ-ARC-96-003

3 Responsible Organization:
Yucca Mountain Site Characterization Office (YMSCO)
-AMA

4 Discussed With:
Judith E. Zimmerman/Sandra L. Moore

5 Requirement/Measurement Criteria:
QARD, Section 5.0, Paragraph 5.2, states "Work shall be performed in accordance with controlled implementing documents."

QARD Section 6.0, Paragraph 6.2.5, states in part: "The distribution and use of documents, including changes and editorial corrections to documents shall include the following:

- A. Documents, either in hard copy or electronic media, used to perform work shall be distributed to, or made available to, and used at, the work location.
- B. Effective dates shall be established for approved implementing documents.
- C. The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work."

6 Description of Condition:

Contrary to the above requirements, the control of forms is such that a current revision of a form may not be available in the forms system for use.

Discussion:

Procedure Yucca Mountain Site Characterization Project Administrative Procedure YAP-5.20 Q, Revision 1, "Forms Administration," allowed the Technical Publications Management (TPM) organization the latitude to input into the electronically controlled forms system a new or revised form 20 working days after the effective date of the form. In discussions with the TPM it was ascertained that YAP-5.20Q was scheduled for deletion and was during the course of the audit. It was stated that Quality Assurance Procedure QAP 5.1 would be utilized to ensure that the forms system is updated. However, in review of QAP 5.1, it was found that no positive controls exist or are described as to how this is to be accomplished.

(Continued on Page 3)

7 Initiator

John S. Martin

Date 09/11/96

9 Is condition an isolated occurrence?

☐ Yes ☐ No ☒ Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)

- 1) Investigate the process to determine how only correct and current forms will be posted within the electronic database on the effective date.
- 2) It is recommended that a procedure similar to Yucca Mountain Site Characterization Project Line Procedure, YLP-5.2Q, Assistant Manager for Administration, "Maintenance of the OCRWM Program Procedures Database," be developed to ensure that only current forms are available for use.

11 QA Review

QAR

Date 9/15/96

12 Response Due Date

10/31/96

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

Printed Name Donald G. Horton

Signature

R.W. Clapper

Date 9/18/96

22 Corrective Actions Verified

QAR

Date

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

AQOAM

Date

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PR/DR NO. YM-98-D-099
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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

The Automated Forms System (AFS) administrator has agreed to work with Technical Publications Management to update the forms system when there is a rush procedure change or implementation. The form implementation will happen concurrently with the procedure effective date. This rush implementation would only be in such cases as CAR resolution or stop work situations.

15 Extent of Condition: (Not required for PR)

The current practice of concurrent release of procedures and forms on the same day, albeit a Monday, has precluded the instance of a quality affecting procedure becoming effective before the form is released on the form system.

16 Root Cause Determination: (Not required for PR)

Required ☒ Yes ☐ No

The decision to release form only on Mondays was a business practice. In response to this deficiency report, the AFS administrator, located in Vienna, Virginia, has agreed to replicate new forms on all servers for rush, quality affecting procedures. Generally, however, when procedures that are going through regular or systematic changes, have completed their review cycles and have been approved, the preparer, with the help of Technical Publications Management will continue to go through the same two week (minimum) preparation period. This period allows such actions as the determination of training requirements and the automation of forms to occur in an orderly fashion.

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

Required ☒ Yes ☐ No

The Automated Forms System (AFS) administrator has agreed to work with Technical Publications Management to update the forms system when there is a rush procedure change or implementation. The form implementation will happen concurrently with the procedure effective date. This rush implementation would only be in such cases as CAR resolution or stop work situations.

QCRWM QAP 5.1 Q, "Quality Assurance Program Procedures" will be amended with the following phrase added on to the end of Subsection 5.8.g) "on the effective date." With this change the Subsection will read, "Ensure that the Automated Forms System (AFS) is updated with new or revised forms and that cancelled forms are deleted *on the effective date.*" The clarification of this action will preclude recurrence.

10/31/96

☐ Initial
☐ Amended

Date

Phone

QAR

Date

AOQAM

Date

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WASHINGTON, D.C.

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PR/DR CONTINUATION PAGE

Description of Condition (continued from page 1).

In addition, in review of the Forms Control System, a note appears which indicates the user is responsible for ensuring that they are using the latest form. The electronic media Forms Control System provides controlled forms for use and was developed to provide access by project users. The current revision of forms should be available for use, as it is for procedures in the Program Procedures Database. It should not be left up to the user to ensure he has the latest form. It is the responsibility of the organization controlling input of the form into the system.

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WASHINGTON, D.C.

8 ☐ Performance Report
☒ Deficiency Report

NO. YM-96-D-102

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QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
Quality Assurance Requirements and Description (QARD), Rev. 5

2 Related Report No.
HQ-ARC-96-003

3 Responsible Organization:
Yucca Mountain Site Characterization Office (YMSCO)
- AMA

4 Discussed With:
Judith E. Zimmerman/Sandra L. Moore

5 Requirement/Measurement Criteria:

QARD, Section 5.0, Paragraph 5.2.4 Compliance with Implementing Documents states in part: "Individuals shall comply with implementing documents..."

6 Description of Condition:

Individuals cannot comply with Yucca Mountain Site Characterization Project Line Procedure (YLP) -4.1Q-YMSCO, "Procurement Actions." YLP-4.1Q-YMSCO stipulates the utilization of Administrative Procedure (AP) -6.17Q. AP-6.17Q was superseded by YAP-2.7Q, "Item Classification and Maintenance of the Q-List" on 3/1/95.

Discussion:

On March 1, 1996, Quality Assurance Procedure (QAP) 5.1, Revision 7, was issued addressing the requirement for impact review of documents that may be affected by a change to or cancellation of a procedure. Prior to this time no requirement existed for impact analysis.

7 Initiator *[Signature]*
John S. Martin Date 09/17/96

9 Is condition an isolated occurrence?
☐ Yes ☐ No ☒ Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)

- 1) Revise YLP-4.1Q to delete reference to the cancelled procedure and to add reference the correct one, as appropriate.
- 2) Investigate to determine extent of the condition and the impact of referencing a cancelled procedure, included should be an analysis as to whether or not the appropriate procedure was utilized during the time-frame.

11 QA Review
QAR *[Signature]* Date 9/18/96

12 Response Due Date
10/31/96

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

Printed Name Donald G. Horton

Signature *[Signature]*

Date 9/18/96

22 Corrective Actions Verified

QAR

Date

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

AQOAM

Date

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WASHINGTON, D.C.**

PR/DR NO. YM-96-D-102
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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

DAR 1960 was created in reference to YLP-4.1Q-YMSCO, "Procurement Actions," to delete the reference to AP-6.17Q, "Item Classification and Maintenance of the Q-List." This DAR was submitted to Technical Publications Management for processing on 10/15/96.

15 Extent of Condition: (Not required for PR)

Technical Publications Management initiated an analysis of all current OCRWM/YMP procedures to determine the extent to which any superseded or canceled procedure was referenced in any other procedure. Unfortunately, this problem seems to be widespread. The high percentage of procedures with this deficiency is largely due to two facts, discussed in the root cause determination Section, box 16, below.

16 Root Cause Determination: (Not required for PR)

Required ☒ Yes ☐ No

As discussed above, there seems to be two contributing factors to the cited deficiency. First, authors were not conducting a thorough analysis of how the change they sponsored in a procedure would impact other procedures; there was no mechanism to produce these results. The mechanism that produces these results is discussed below in box 17. The second contributing factor became evident as TPM technical writers took note of some of the impacts, but were told by preparers that there was no time planned to change procedures in the current fiscal year. Therefore, planning and priority also became an issue. The solution to this is presented in box 17 below as well.

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

Required ☒ Yes ☐ No

As a mechanism to ensure that an impact analysis is performed each time a procedure is changed, OCRWM QAP 5.1Q, "Quality Assurance Program Procedures" (Subsection 5.6- Document Interface Review) incorporates a requirement that the preparer reviews an RTN matrix printout listing procedures that are impacted by a change in the preparer's procedure. There is a similar step in YAP-5.1Q (Subsection 5.2.5.a). Both subsections list Technical Publications Management as a resource and facilitator in this process. This requirement will preclude recurrence.

While the priority of procedures maintenance has been an issue in past years, in fiscal year 1997 the YMSCO Project Manager has initiated an action (see attached documentation) for all AMs to review all of their procedures and change them as necessary. References and format are two of the issues that will be examined. It is recommended that if the reference section needs to have references changed and/or deleted, and no other procedure changes are required, that such reference changes be considered editorial. This initiative will continue on a yearly basis and will preclude future recurrence. The first step is to initiate DARs against those procedures containing potential reference changes. We anticipate that this will be complete on March 31, 1997. The second step is to ensure that the procedures are changed to reflect the correct procedures. The date of completion is scheduled to be

18 Corrective Action Completion Due Date:

12/31/96 and 09/11/97

19 Response by:

☐ Initial

☐ Amended

Date

Phone

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

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