

United States Government

Department of Energy

# Memorandum

QA: QA

DATE: JAN 09 2002

REPLY TO:

ATTN OF: RW-3 (James Blaylock/4-1420)

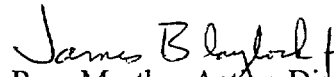
SUBJECT: VERIFICATION OF CORRECTIVE ACTIONS AND CLOSURE OF DEFICIENCY  
REPORT (DR) YMSCO-01-D-136

TO: YMSCO/DPM (D. G. Horton)

The Office of Quality Assurance staff has evaluated the corrective actions of DR YMSCO-01-D-136 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Christian M. Palay at (702) 794-1486.

OQA:JB-0490

  
Ram Murthy, Acting Director  
Office of Quality Assurance

Enclosure:  
DR YMSCO-01-D-136

*Nmsso7*  
*WM-11*

JAN 09 2002

cc w/encl:

N. K. Stablein, NRC, Rockville, MD  
Robert Latta, NRC, Las Vegas, NV  
S. W. Lynch, State of Nevada, Carson City, NV  
Engelbrecht von Tiesenhausen, Clark County, Las Vegas, NV  
D. L. Kirby, MTS, Las Vegas, NV  
E. P. Stoupe, BSC, Las Vegas, NV  
T. J. Wall, BSC, Las Vegas, NV  
W. J. Glasser, NQS, Las Vegas, NV  
K. A. Hodges, NQS, Las Vegas, NV  
D. G. Opielowski, NQS, Las Vegas, NV  
C. M. Palay, NQS, Las Vegas, NV  
J. R. Dyer, DOE/YMSCO, Las Vegas, NV  
C. E. Hampton, DOE/YMSCO, Las Vegas, NV  
D. G. Horton, DOE/YMSCO, Las Vegas, NV  
J. M. Replogle, DOE/YMSCO, Las Vegas, NV  
B. M. Terrell, DOE/YMSCO, Las Vegas, NV

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

8. ☒ DEFICIENCY REPORT  
☐ CORRECTIVE ACTION REPORT  
 NO. YMSCO-01-D-136  
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 QA: *YQA*

**DEFICIENCY/CORRECTIVE ACTION REPORT**

*049 9/18/01*

1. Controlling Document:

AP-5.1Q, Plan and Procedure Review, and Approval, Rev. 2/ICN 0

2. Related Report No.:

SA-SP-2001-001

3. Responsible Organization:

YMSCO  
BSC

4. Discussed With:

Deborah Kirby

5. Requirement:

AP-5.1Q, directs users to:

1. Sign and date...the first page of the requirements matrix (Paragraphs 5.6.1c) and 5.9.6b)
2. Run a 012 report from the RTN Web for a listing of QARD requirements implemented by the procedure. (Attachment 9)
3. Identify the Affected Organizations to which the procedure applies. (Attachment 9)

6. Description of Condition:

Contrary to the above requirements, a review of the requirement matrices for ten procedures revealed that all were unsatisfactory (see list below with specific deficiencies). Results are summarized as follows:

1. Signatures appeared on the last page instead of the first in three instances
2. A 014 report was used instead of a 012 report in four instances
3. Affected Organizations were not specified in eight instances

Requirement matrices were reviewed for ten procedures with the following results:

AP-6.1Q, Controlled Distribution, Rev. 6/ICN 0 (RTN 014 report; no Affected Organizations)  
 AP-15.2Q, Control of Nonconformances, Rev. 0/ICN 1 (RTN 014, no Affected Organizations)  
 AP-17.1Q, Record Source Responsibilities for Inclusionary Records, Rev. 2/ICN 0 (no Affected Organizations)  
 LP-4.1Q-OCRWM, Procurement Actions, Rev. 1/ICN 0 (signature on last page)  
 LP-17.1Q-BSC, Processing Inclusionary Records, Rev. 0/ICN 2 (no Affected Organizations)  
 AP-5.1Q, Plan and Procedure Preparation, Review, and Approval, Rev. 2/ICN 0 (signature on last page)  
 AP-7.6Q, Procurement of Items and Services, Rev. 1/ICN 0 (RTN 014 report; no Affected Organizations)  
 AP-7.7Q, Acceptance of Items and Services, Rev. 0/ICN 0 (signature on last page, RTN 014 report; no Affected Organizations)  
 AP-OM-006Q, Work Request/Work Order Process, Rev. 0/ICN 3 (no Affected Organizations)  
 AP-SI.1Q, Software Management, Rev. 3/ICN 1 (no Affected Organizations)

7. Initiator:

E. P. Stroupe

*E. P. Stroupe*

Date

*9/18/01*

9. Does a stop work condition exist? (Not required for a DR)

☐ Yes ☐ No

If Yes, Check One:

☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

*NONE.*

11. QA Review:

QAR

*Chris Palay*  
*Christian Palay*

Date

*09/27/01*

12. Response Due Date:

10 working days from issuance

13. DOQA Issuance Approval:

Printed Name

*09/21/01*  
*ROBERT DAVIS*  
*Ram Murthy*

Signature

*James Blaylock*

Date

*10/4/01*

22. Corrective Actions Verified

QAR

*Chris Palay*

Date

*01/04/02*

23. Closure Approved by:

DOQA

*James Blaylock*

Date

*1/9/02*

## TYPE RESPONSE:

- ☐ Initial  
☒ Complete  
☐ Amended

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DR/CAR NO. YMSCO-2001-D-136

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DGR 10/14/01

## DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

## 14a. Immediate Actions:

Document Control will modify internal instructions and/or checklists as follows:

For procedure approval packages submitted by the preparer in accordance with AP-5.1Q, Step 5.6.3a): 1) Include checks in the receipt inspection to verify that requirement matrices were signed and dated on the first page, a 012 Report was used for Q-requirements, and the applicability has been entered on the requirements matrix; 2) Return noncomplying packages to the preparer for correction; and 3) Notify BSC QA of each instance of a noncomplying requirements matrix, providing the affected procedure identifier.

Compliance Date: 10/19/01

## 14. Remedial Actions:

1. In all cases reviewed, the requirements matrix was signed and dated, either on the first page or the last page. Although the AP-5.1Q requirement for signing and dating a requirements matrix on the first page was not followed; AP-17.1Q does not specify where to sign and date a record. No impact on the authentication of these records occurred and no remediation of previously submitted requirements matrices is proposed.
2. Instances in which a 014 report was used instead of the 012 report: All of the information from the 012 Report is reflected in the 014 Report, even though the latter report contains additional detail. Although this condition is a noncompliance with AP-5.1Q, no impact to the requirements matrix occurred and no remediation of previously submitted requirements matrices is proposed.  
(See continuation page)

## 15. Extent of Condition:

Until the actions in Block 17 are complete, BSC QA will forward to OQA notifications received from Document Control regarding the following conditions:

1. Failure to sign and date requirement matrices on the first page
2. Failure to use a 012 Report for Q-requirements
3. Lack of an applicability entry on requirements matrices

## 16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

The cause is failure to implement actions specified by AP-5.1Q.

## 17. Action to Preclude Recurrence:

1. AP-5.1Q will be revised by 11/16/01 to: 1) Delete the requirement specifying the page where the signature and date must appear on the requirement matrix; and 2) Delete the requirement to identify the Applicability on the 012 Report.
2. Measures to ensure implementation of the revision to AP-5.1Q will be established as follows:
  - 1) QA will ensure during their review of Q-procedures that the specified report is used for Q-requirements
  - 2) Document Control will conduct inspections of requirement matrices as specified in Block 14a and will require correction and resubmittal of noncomplying matrices

## 18. Due Date: 11/16/01

- ☐ For submittal of complete response  
☒ For completion of corrective action

## 19. Response by:

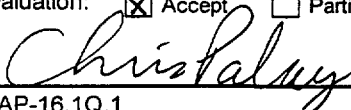


Date 10/11/01

Phone 4-1301

20. Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject

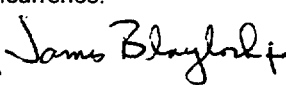
QAR



Date 10/17/01

## 21. Concurrence:

DOQA



Date 10/18/01

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WASHINGTON, D.C.

8. ☒ DR/CAR  
☐ Stop Work Order

NO. YMSCO-2001-D-136

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

Block 14 Remedial Actions (continued)

*DSO 10/16/01*

3. The lack of Applicability information on the 012 Report did not affect the requirements matrix. The correct information is available from the changed/revised procedure and is provided to data entry personnel separately when the detailed links are established and reported to Document Control. A QC process is implemented by Document Control personnel to verify the input information. No remediation of previously submitted requirements matrices is proposed.

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8. ☒ DR/CAR  
☐ Stop Work Order

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

Verification of Corrective Action for YMSCO-01-D-136

The initial/complete response outlined corrective actions requiring QAR verification in the following blocks:

14a. Immediate Actions

The immediate actions for this deficiency report were verified on 10/23/01. The immediate actions included the update to the Document Control Checklist governing the issuance of procedures. The updated checklist included the verification of the following requirements:

1. The 012 Requirements Traceability Network (RTN) Report for QARD requirements in procedures.
2. The signature and date on the first page of the RTN report.
3. The identification of the applicability entry on the RTN report.

14. Remedial Actions

No remedial actions were initiated for the conditions identified in block 6 for the following reasons:

1. All necessary RTN information were accurately captured albeit on the wrong RTN report.
2. The signature and date on the wrong page of the RTN report has no impact since this is for QA records authentication
3. The lack of applicability on the RTN 012 report has no impact since that information is already contained on the revised procedure and verified by Document Control.

15. Extent of Condition

The description of condition in block 6 of the deficiency report adequately captured the extent of condition. Additionally, BSC QA would have notified OQA if any further instance of the condition had occurred. No other similar instances of noncompliance with AP-5.1Q have been identified.

17. Actions To Preclude Recurrence

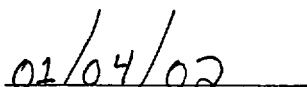
The primary action to preclude recurrence was the issuance of AP-5.1Q, Revision 3 ICN 0 (effective 01/07/01). The revision removed the overly prescriptive requirements that were considered to be administrative preferences. This included the deletion of the requirements:

1. Specify the signature and date on the first page of the RTN report.
2. Identify the applicability of the RTN report.

The secondary action to preclude occurrence will be to maintain the updated Document Control Checklist (see block 14a. Since the checklist and its implementation have already been verified, this is sufficient to preclude reoccurrence the wrong RTN report from being produced for QARD implementing procedures.

Based on the above evaluation, the QAR recommends closure of YMSCO-01-D-136.

  
QAR Signature

  
Date