



Department of Energy

Washington, DC 20585

QA: L

AUG 27 1997

R. E. Erickson, Director (EM-32)
Office of Eastern Operations
U. S. Department of Energy Headquarters
Trevion II Building
12800 Middlebrook Road
Germantown, MD 20874

REVIEW OF DRAFT RESPONSES TO DEFICIENCY REPORTS (DR) YM-97-D-062 THROUGH YM-97-D-064

The content of the draft response to DR YM-97-D-062 has been reviewed and determined to be acceptable. However, before this response can be formally accepted, the responding individual's signature and the date of the response must be entered in block 19 of the DR form. In addition to these signatures and dates required in block 19, the anticipated corrective action completion dates must also be included in the official responses to DRs YM-97-D-063 and YM-97-D-064. Please submit responses that include the aforementioned required information within ten working days of the date of this correspondence.

The following information is being provided in answer to your request for clarification of DRs YM-97-D 063 and YM-97-D-064:

DR YM-97-D-063 - As specified in the memorandum dated August 20, 1996, from James T. Conway to Distribution, the Quality Assurance Specialist that was appointed Audit Team Leader for Environmental Management internal audit 96-EA-IN-AU-01 was also assigned responsibility for implementation of Standard Practice Procedures 1.02, 4.01, 4.02 and 5.01 prior to performance of the audit.

DR YM-97-D-064 - The revision number for the document identified in "Description of Condition," Item 1, is Revision 16. The record file numbers for documents listed in Items 2 and 3 are 5724.30.02 and 5724.301.01, respectively, as identified in block 6 of the DR.

If you have any questions please contact either James Blaylock at (702) 794-1420 or Charles C. Warren at (702) 734-0858.

Handwritten signature: R.W. Cell
For Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-2103

Enclosure:
DRs YM-97-D-062 through
YM-97-D-064

Handwritten notes: 1/1, NH33, WM-11, 102.7

Handwritten note: leup; NMSS/pah.L



R. E. Erickson

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AUG 27 1997

cc w/encl:

R. A. Milner, DOE/HQ (RW-2) FORS
Ram Murthy, DOE/HQ (RW-3) FORS
James Conway, DOE/HQ (EM-37) TREV
S. E. Gomberg, DOE/HQ (RW-51) FORS
J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
G. D. Wood, OQA/QATSS, Washington, DC

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
C. C. Warren, OQA/QATSS, Las Vegas, NV
D. G. Sult, OQA/QATSS, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV

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

8 Performance Report
 Deficiency Report

NO. YM-97-D-062

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

EM Standard Practice Procedure (SPP) 4.16, Revision 4

2 Related Report No.

EM-ARC-97-18

3 Responsible Organization:

EM-32 and 37

4 Discussed With:

J. Conway

5 Requirement/Measurement Criteria:

- Section 4.b requires the Program Manager (PM), prior to initiation of a review, to prepare a memorandum to identify the scope of the review and review criteria. Then, based on the scope and review criteria, the PM select reviewers and transmits a copy of the memorandum initiating the review to reviewers, the Quality Assurance Program Manager (QAPM) and affected organizations.
- Section 4.c requires the PM to review documents to ensure program objectives are supported and to document comments on a Review Comment Record (RCR).

6 Description of Condition:

- For Issue 16 of the SPP manual, there was no memorandum on file from the PM to reviewers, the QAPM, or Affected Organizations designating the scope of the review and review criteria.
- There were no RCRs on file documenting PM review of procedures in Issue 16 of the SPP manual. One RCR is on file for each procedure revision in Issue 16. However, in the absence of the required memorandum, it is not known if this RCR is from a designated reviewer, or if additional reviewers from the same or other Affected Organizations were to be designated.

7 Initiator

Charles C. Warren

Charles C. Warren
Date 6-13-97

9 Is condition an isolated occurrence?

Yes No Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

- Evaluate impact of not designating reviewers and documenting management comments on the adequacy and extent of reviews for SPPs.
- Implement necessary corrective action based on the results of the above evaluation.
- Take action to assure future reviews are performed in accordance with procedural requirements.

11 QA Review:

QAR *Charles C. Warren*

Date 6-13-97

12 Response Due Date

20 working days from issuance

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

Printed Name Donald G. Horton

Signature

R. W. Horton

Date 6/25/97

22 Corrective Action Verified

QAR

Date

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

AQAM

Date

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PR OF NOYM-97-D-062

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Attachment No. 1.

15 Extent of Condition: (Not required for PR)

16 Root Cause Determination: (Not required for PR)

Required Yes No

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

Required Yes No

See Attachment No. 1

18 Corrective Action Completion Due Date:

19 Response by:

Initial

Amended

Date

Phone

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

Response to Deficiency Report No. YM-97-D-062

In complying with the EM-37 HLW QA Transition Plan, the HLW QAPM designated (ref. Memorandum dated September 17, 1996, subject "HLW QA SPPs") EM-32/EM-37 personnel to be responsible (i.e., Procedure Champions) for changing and implementing specific SPPs. Since the SPPs are QA documents, the HLW Program Manager (PM) for QA requested (ref. Memorandum dated December 30, 1996) the EM-32 Office Director to review thirteen SPPs which were revised to comply with Revision 5 of DOE/RW-0333P. This memorandum identified review criteria, referenced review guidelines and included Review Comment Record (RCR) forms for each draft SPP.

In concert with these two memoranda, the EM-32 Office Director assigned via a note the review action to EM-32 HLW staff whose comments were consolidated on one RCR form for each SPP. Each completed RCR form was signed by the QAS for EM-32 or the PM attesting to the fact that all comments were satisfactorily resolved.

Future reviews will be performed under SPP 4.04 "Technical and QA Documents" which defines responsibilities and actions required to prepare and review selected documents associated with HLW acceptance activities.

7/15/97 Conaway & Horton

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document
EM Standard Practice Procedure (SPP) 4.02, Revision 6

2 Related Report No.
Audit EM-ARC-97-18

3 Responsible Organization:
EM-37

4 Discussed With:
J. Conway

5 Requirement/Measurement Criteria:
SPP 4.02, Revision 6, Section 4.a. requires that the QAPM assign a certified lead auditor as Audit Team Leader and that the certified lead auditor and auditors be independent of any direct responsibility for performance of activities which they will audit.

6 Description of Condition:
In violation of the above procedural requirement, the Audit Team Leader for EM Internal Audit 96-EA-IN-AU-01 was designated by memorandum as being the QA Specialist responsible for implementing four of the SPPs evaluated during the internal audit.

7 Initiator
Charles C. Warren *Charles C. Warren* Date 6-13-97

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

10 Recommended Action: (Not required for PR)
• ~~During the next internal audit of EM, re-evaluate implementation of the four procedures in question for FY 1996 as well as FY 1997.~~
Rev 6/25/97
• Take action to assure assignment of Audit Team Leaders that are independent of direct responsibility for activities audited.

11 QA Review:
QAR *Charles C. Warren* Date 6-13-97

12 Response Due Date
20 working days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)
Printed Name Donald G. Horton Signature *D.G. Horton* Date 6/25/97

22 Corrective Action Verified
QAR _____ Date _____

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

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PR OR NO. YM-97-D-063

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Attachment No. 2

15 Extent of Condition: (Not required for PR)

See Attachment No. 2

16 Root Cause Determination: (Not required for PR)

Required Yes No

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

Required Yes No

See Attachment No. 2

18 Corrective Action Completion Due Date:

19 Response by:

Initial
 Amended Date Phone

20 Response Accepted

21 Response Accepted (N/A for PR):

QAR Date

AOQAM Date

7/15/97 Conway to Horton

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Response to Deficiency Report No. YM-97-D-063

The Audit Team Leader did not evaluate any activities during Audit No. 96-EA-IN-AU-01. The three auditors did not have direct responsibility for implementing any of the activities for the seven QA criteria that were evaluated during the audit. Since the auditors had sufficient authority and organizational freedom to make the audit process meaningful and effective, their evaluation (i.e., documented on audit checklists) of activities during the audit was not jeopardized.

SPP 4.02 "Audits will be revised to assure that the "independence requirements" for an audit team leader (ATL) satisfy Sections 18.2.5 and 18.2.6 of DOE/RW/0333P, and selection of ATLs for future internal EM-30 audits will be in compliance with these requirements.

In addition, please identify the four SPPs that EM-30 should "re-evaluate implementation of for FY 1966."

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8 Performance Report
 Deficiency Report
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
DOE/RW-0333P Quality Assurance Requirements and Description

2 Related Report No.
EM-ARC-97-18

3 Responsible Organization:
Office of Eastern Operations, EM-32/37

4 Discussed With:
Jim Conway, High-Level Waste QAPM

5 Requirement/Measurement Criteria:
A. The QARD, Element 5.0, Section 5.2.4, states in part " Individuals shall comply with implementing documents —."

1. SPP 3.01, Section 4.d, states in part that the Instructor " Signs the roster to attest to its accuracy."

2. SPP 3.01, Section 4. f.(a) requires that the training course package and training presentation package contain documentation of the instructors background.

3. SPP 3.01, Section 4.d.6.(8) requires that the instructor sign and send documentation showing successful completion of training to the HLW QAPM.

6 Description of Condition:
A. Contrary to the above requirements, the following instances of procedure noncompliance were identified during the audit.

1. Contrary to the above requirement, an attendance Sheet in record file 5724.30.02, SPP1.01-TR and one Attendance Sheet in record file 5724.301.01 do not contain the Instructors attestation signature.

2. Contrary to the requirement, record file 5724.30.02, SPP 1.01-TR did not contain the required instructor background documentation.

3. Contrary to the requirement, one training completion memorandum (for J. Conway) in record file 5724.301.01 did not have an authenticating signature of the instructor.

4. The System 28 training/personnel file for S. Ayers could not be located by EM-32/37 for review by the auditor.

7 Initiator
Gary Wood *[Signature]* Date 06/11/97

8 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes If PR

10 Recommended Actions: (Not required for PR)
1. Review the record files and ensure that the records include an authenticating signature and ensure that records are in or submitted to the Central Records Facility.
2. Complete actions for Blocks 14, 15, and 17.

11 QA Review:
QAR *C.C. Wan* Date 6-24-97

12 Response Due Date
20 working days from issuance

13 Director, OQA Issuance Approval: (QAR for PR)
Printed Name Donald G. Horton Signature *R.W. Clark* Date 6/27/97

22 Corrective Actions Verified
QAR Date

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

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Block 5.

4. SPP 3.02, Section 4.a.(5), states that the HLW QAPM "Maintains and provides access to the Personnel Certification, Qualification and Training records for each person in accordance with applicable portions of the DOE System 28 Records System."
5. SPP 3.01, Section 4.b.(1) states that the HLW QAPM "Ensure(s) that the following records are processed into the quality records system as nonpermanent records in accordance with SPP 7.01
- a. QA Training Plan
 - b. Completed RCR forms

Block 6.

5. Contrary to the above requirement, the Review and Comment Records (RCR) specified in the referenced requirement were not in the records center nor were they located prior to completion of the audit. The FY 1997 QA Training Plan is dated October 9, 1996.

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

See Attachment No. 3

15 Extent of Condition: (Not required for PR)

See Attachment No. 3

16 Root Cause Determination: (Not required for PR)

Required: Yes No

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

Required: Yes No

See Attachment No. 3

18 Corrective Action Completion Due Date:

19 Response by:

Date

Phone

20 Response Accepted

21 Response Accepted (N/A for PR)

QAR

Date

DOQA

Date

Response to Deficiency Report No. YM-97-D-064

With regards to the "Description of Condition," please clarify the following: Item 1-Revision No. for TR, Item 2-Record file No. and Revision No. for TR; and Item 3- Record file No. SPP 3.01 will be revised to delete superfluous requirements (e.g. those identified in Items 1 thru 3) which are not required by DOE/RW/0333P.

S. Ayers recently became involved with HLW acceptance activities, and his training and qualification package was being assembled during the audit. The appropriate records will be placed in the System 28 file.

Following the audit, the HLW QA Training Needs Matrix for FY 1997 (not "QA Training Plan") dated October 9, 1996 along with completed RCR forms were located in the files of the previous QAS for training. This QAS was dismissed from MACTEC in May 1997. These records have now been placed in the records center. All pertinent training records have been reviewed and found satisfactory.