

United States Government

Department of Energy

Memorandum

QA: QA

DATE: **MAY 15 2002**

REPLY TO


ATTN OF: RW-3 (R. B. Murthy/(702) 794-1460)

SUBJECT: VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY
REPORTS (DR) EM-01-D-090 AND EM-01-D-091 RESULTING FROM THE OFFICE
OF QUALITY ASSURANCE (OQA) AUDIT EM-ARC-01-09

TO: EM-5 (S. L. Johnson)

The OQA staff has evaluated the corrective action of DRs EM-01-D-090 and EM-01-D-091 and determined the results to be satisfactory. As a result, the DRs are considered closed.

If you have any questions, please contact me at (702) 794-1460 or Marilyn A. Kavchak at (702) 794-5423.



Ram B. Murthy, Acting Director
Office of Quality Assurance

OQA:JB-1153

Enclosures:

1. DR EM-01-D-090
2. DR EM-01-D-091

cc w/encls:

L. D. Vaughan, DOE/HQ (RW-5) FORS
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
T. J. Wall, BSC, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
M. A. Kavchak, NQS, Las Vegas, NV
D. G. Opielowski, 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

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WM-11

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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

ORIGINAL
THIS IS A RED STAMP
8. ☒ THIS IS A DEFICIENCY REPORT
☐ CORRECTIVE ACTION REPORT
NO. EM-01-D-090
PAGE 1 OF
QA: QA

DEFICIENCY/CORRECTIVE ACTION REPORT

1. Controlling Document:

Quality Assurance Requirements & Description (QARD), DOE/RW-0333P, Revision 10, High-Level Waste (HLW) Standard Practice Procedure (SPP) Glossary of Terms, Rev. 4

2. Related Report No.:

EM-ARC-01-09

3. Responsible Organization:

Office of Safety, Health and Security (EM-5)

4. Discussed With:

Larry Vaughan

5. Requirement:

QARD, Section 2.2.1 requires that organizations establish implementing documents that translate requirements into work processes. QARD, Section 16.2.6 requires that conditions adverse to quality be evaluated to identify adverse quality trends. Further, SPP criteria defined to determine Significant Conditions Adverse to Quality in the High-Level Waste Standard Practice Procedure (SPP) Glossary of Terms establishes "trends" as an element evaluated in determining if a condition is "significant".

6. Description of Condition:

Contrary to the requirement in QARD Section 2.2.1, no process is in place at the Office of Safety, Health and Security (EM-5) level to evaluate trends even though conditions adverse to quality are identified. Conditions identified there can not be fully evaluated for a significant condition adverse to quality as required by the SPPs. Instead, in the QARD Matrix prepared by EM-5 in Section 16.2.6A EM Headquarters is sighted as performing an oversight function and delegating trending to the field (i.e. sites) due to the lack of availability of trending data. Further, the passing down of this requirement to the sites dilutes the trending process for HLW when trend reports are segregated without a process in place for reviewing and integrating the trends.

7. Initiator:

Marilyn A. Kavchak

Marilyn A. Kavchak Date 6/20/01

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:

Develop a process for trending conditions adverse to quality such that "significant" conditions adverse to quality created by any trends are identified. Further, establish a method to review/evaluate trending data/reports from each site for HLW trends.

11. QA Review:

Marilyn A. Kavchak

QAR Marilyn A. Kavchak

Date 6/20/01

12. Response Due Date:

10 Working Days From Issuance

13. DOQA Issuance Approval

Printed Name Robert W. Clark

Signature

James Blaylock

Date 6/21/01

22. Corrective Actions Verified:

QAR

M. Kavchak

Date 4/30/02

23. Closure Approved by:

DOQA

[Signature]

Date 5/15/02

TYPE RESPONSE:

- ☐ Initial
☐ Complete
☒ Amended

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DR/CAR NO. EM-01-D-090

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DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Actions:

The HLW QA Program Manager reviewed the QARD requirements on Quality Trending, Sec. 16.2.6. The HLW QA Program Manager has tentatively scheduled a meeting with the EM HLW Program Managers on or before October 26, 2001 to review and discuss the feasibility of performing trends at Headquarters.

Compliance Date: October 26, 2001

14. Remedial Actions: Due to scheduling conflicts the meeting scheduled for September did not take place. Remedial actions will be determined after discussing and coordinating potential trending actions with the EM HLW Program Managers and a review of past deficiencies and observations. EM continues to support the position that trending of deficiencies identified at the EM HQ level adds no value to the waste acceptance activities at the sites. Plus, the HQ HLW QA Program does not generate sufficient data points to determine a trend of HQ identified deficiencies and observations. Therefore, this requirement is delegated to the HLW sites. The trending of deficiencies that impacts the quality of waste acceptance products are performed by each HLW site. The HLW sites perform trending activities of all deficiencies, including those identified by EM HQ QA Program. The HLW site trending activities are reviewed during the annual HLW QA audit. For the EM HLW QA Program to trend would add no value to the QA Program and would be redundant.

15. Extent of Condition: The EM HQ HLW QA Program identifies deficient conditions. However, trending of deficiencies is not performed. A review of deficiencies and observations issued by EM HQ HLW QA Program over the last two years was conducted. The review did not identify any adverse trends. The DR has no significant impact on the quality of work performed or the HLW acceptance activities.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.) There is no procedural requirement for EM HQ HLW QA Program to perform trending. This QARD requirement is delegated to the HLW sites. The EM HQ HLW QA Program has never conducted trending activities and is exempt from this requirement via RW's approval of the QARD Matrix for the reasons above (see Remedial Actions).

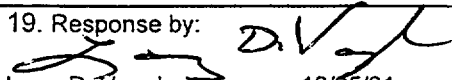
17. Action to Preclude Recurrence:

No action is required/needed at this time.

18. Due Date: October 26, 2001

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

19. Response by:

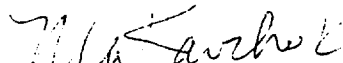

 Larry D. Vaughan
 HLW QAPM

10/05/01
 Date

(202) 586-2523
 Phone

20. Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject

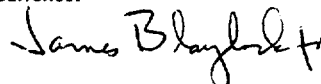
QAR



Date 10-31-01

21. Concurrence:

D00A



Date 11/1/01

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8. ☒ DR/CAR
☐ Stop Work Order

NO. EM-01-D-090

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

EVALUATION OF INITIAL/COMPLETE RESPONSE TO DEFICIENCY REPORT (DR) EM-01-D-090

Block 14: Remedial Actions

The response states (in Section 15) that deficiencies are, in fact, identified at Environmental Management High Level Waste Headquarters (EM HLW HQ). The auditor accepts that the limited number of DRs identified at EM HLW HQ to date may not be sufficient to establish a HQ trend. The response that the deficiencies in question are trended by the HLW sites is acceptable. However, EM needs to provide evidence of a process in place at EM HLW HQ to provide this information to the sites.

M. Kavchak

Marilyn A. Kavchak, QAR

11-01-01

Date

TYPE RESPONSE:

- ☐ Initial
☐ Complete
☒ Amended

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DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Actions:

The HLW QA Program Manager reviewed the QARD requirements on Quality Trending, Sec. 16.2.6. The HLW QA Program Manager has tentatively scheduled a meeting with the EM HLW Program Managers on or before October 26, 2001 to review and discuss the feasibility of performing trends at Headquarters.

Compliance Date: October 26, 2001

14. Remedial Actions: Due to scheduling conflicts the meeting scheduled for September did not take place. Remedial actions will be determined after discussing and coordinating potential trending actions with the EM HLW Program Managers and a review of past deficiencies and observations. EM continues to support the position that trending of deficiencies identified at the EM HQ level adds no value to the waste acceptance activities at the sites. Plus, the IIQ HLW QA Program does not generate sufficient data points to determine a trend of HQ identified deficiencies and observations. Therefore, this requirement is delegated to the HLW sites. The trending of deficiencies that impacts the quality of waste acceptance products are performed by each HLW site. The HLW sites perform trending activities of all deficiencies, including those identified by EM HQ QA Program. The HLW site trending activities are reviewed during the annual HLW QA audit. For the EM HLW QA Program to trend would add no value to the QA Program and would be redundant.

15. Extent of Condition: The EM HQ HLW QA Program identifies deficient conditions. However, trending of deficiencies is not performed. A review of deficiencies and observations issued by EM HQ HLW QA Program over the last two years was conducted. The review did not identify any adverse trends. The DR has no significant impact on the quality of work performed or the HLW acceptance activities.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.) There is no procedural requirement for EM HQ HLW QA Program to perform trending. This QARD requirement is delegated to the HLW sites. The EM HQ HLW QA Program has never conducted trending activities and is exempt from this requirement via RW's approval of the QARD Matrix for the reasons above (see Remedial Actions).

17. Action to Preclude Recurrence:

Pass history of instituting a trending process in Headquarters has shown that HQ does not generate sufficient data points to trend. However, the HLW QAPM will perform an annual review of all deficiencies and observations issued by the IIQ HLW QA Program to validate that there remains insufficient data to trend. SPP 5.01 will be revised and issued to reflect this process.

18. Due Date: December 6, 2001

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

19. Response by:

Larry D. Vaughan
 HLW QAPM

10/05/01
 Date

(202) 586-2523
 Phone

20. Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject

QAR

Makovichak

Date

11/30/01

21. Concurrence:

DODA

James Bragdon

Date

11/30/01

Exhibit AP-16.1Q.1

Rev. 12/20/1999

Response received in
 DQA 11/19/01
 Mak

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

Status of EM-01-D-090

Follow-up for Closure of Objective Evidence of Corrective Actions

Objective Evidence associated with corrective actions related to Deficiency Report EM-01-D-090 was reviewed during the recent internal audit of EM-5, Office of Safety, Health and Security (EM-ARC-02-01) December 11-14, 2001. As a result of the status, is it recommended that the DR remain open and that a revised response, corrective action date and request for extended processing be provided by the responsible individual. Below is a status of the corrective action as reviewed by the assigned Quality Assurance Representative:

Reviewed procedure revision that would require an evaluation of DCARs generated for HQ for trends. The revision was inadequate since it failed to define a trend and describe a process for handling the trend should one be discovered. There was no evidence available to confirm that deficiencies and observation issued by EM HQ HLW QA Program over the last two years had been evaluated for trends. This DR was not closed and requires a revised response including a new completion corrective action date and a request for extended processing.



Marilyn A. Kavchak 1/3/02



Director, Office of Quality Assurance

1/9/02

Date

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

Review of Revised Response to EM-01-D-089, 090, and 091

I have reviewed revised responses from L. Vaughn dated 1/25/02 to the subject Deficiency Reports (DRs) and provide the following recommendations:

DR EM-01-D-089 The revised response states that Memorandum of Agreements (MOAs) between EM-5 and the HLW sites will be cancelled, rather than updated, but fails to provide another method for describing the process that will be used to pass down QARD requirements and establish roles and responsibilities for implementing quality. **It is recommended that this response be rejected.**

DR EM-01-D-090 A revised response was submitted that agrees to define the term 'trend' and to fully develop the previously revised procedure to describe the trending process since the revised procedure failed to do this. A commitment to train personnel and provide documentation not previously available was also made. A new completion date of 3/1/02 was provided. **It is recommended that this response and the extended processing date of 3/1/02 be accepted.**

DR-EM-01-D-091 A new date of 3/1/02 to provide previously committed to corrective action was provided. **It is recommended that the new extended processing date of 3/1/02 be accepted.**

MaKavichak 1/30/02

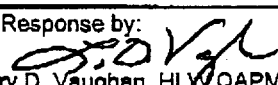
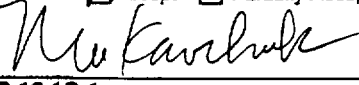
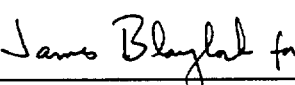
TYPE RESPONSE: <input type="checkbox"/> Initial <input type="checkbox"/> Complete <input checked="" type="checkbox"/> Amended		OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		DR/CAR NO. 090 PAGE 1 OF 2 QA: QA	
DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)					
14a. Immediate Actions: (See response submitted to RW dated October 5, 2001) Compliance Date:					
14. Remedial Actions: (See response submitted to RW dated October 5, 2001)					
15. Extent of Condition: (See response submitted to RW dated October 5, 2001)					
16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.) (See response submitted to RW dated October 5, 2001)					
17. Action to Preclude Recurrence: (See response submitted to RW dated October 5, 2001)					
18. Due Date: Mar. 1, 2002 <input type="checkbox"/> For submittal of complete response <input checked="" type="checkbox"/> For completion of corrective action			19. Response by:  Larry D. Vaughan, HLY QAPM Date 1/25/02 (202) 586-2523 Phone		
20. Evaluation: <input checked="" type="checkbox"/> Accept <input type="checkbox"/> Partially Accept <input type="checkbox"/> Reject QAR  Date 2/2/02			21. Concurrence: DDQA  Date 2/1/02		

Exhibit AP-16.1Q.1

Rev. 12/20/1999

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

On December 11-14, 2001, RW conducted audit No. EM-ARC-02-01, of the EM HQ HLW QA Program. The audit team evaluated corrective actions related to Deficiency Report No. EM-01-D-090. As a result of the evaluation, it was determined that corrective actions were incomplete and that a revised response, corrective action date and request for extended processing, be provided by the responsible individual.

Results of RW's evaluation:

Reviewed procedure revision that would require an evaluation of DCARS generated by HQ for trends. The revision was inadequate since it failed to define a trend and describe a process for handling the trend should one be discovered. There was no evidence available to confirm that deficiencies and observations issued by EM HQ HLW QA Program over the last two years had been evaluated for trends. This DR was not closed and requires a revised response including a new completion corrective action date and request for extended processing.

EM HQ HLW QA Program response:

1. A definition for the term "trend" will be generated and added to the SPP *Glossary of Terms and Acronyms*.

Completion date: March 1, 2002

2. A procedure will be developed to identify the trend process used by the EM HQ HLW QA Program. The procedure will be approve and issued, and HLW personnel trained to the procedure.

Completion date: March 1, 2002

3. Documentation will be available to show that deficiencies and observations issued by EM HQ HLW QA Program over the past two years were reviewed and evaluated for trends.

Completion date: March 1, 2002

February 28, 2002

AMENDED RESPONSE TO DR #90 TO REQUEST AN EXTENSION TO THE COMPLETION DATE FOR CORRECTIVE ACTIONS UNTIL APRIL 5, 2002.

The EM-5 High-Level Waste Quality assurance Program Manager requests an extension until April 5, 2002, to complete corrective actions to close DR #90. The extension is needed to allow for a more efficient and effective use of time and resources.

The response to DR #90 requires the development of a new procedure to address trending and changes to the SPP Glossary. Response to DR #91 also requires revisions to the SPP Glossary. The response to DR #55 and DR #89 requires revising SPP 4.04. Response to DR #56 requires a revision to SPP 3.02. The due date for responding to DR #89, DR #90, and DR #91 is 3/1/02. The due date for responding to DR #55 and DR #56 is 4/5/02.

It is requested that the due date for responding to DR #90 be extend to 4/5/02 to allow for a more efficient and effective review, approval, and training process by HLW personnel of changes to HLW SPPs at one time.

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☒ DR/CAR/QO
☐ SWO

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4/30/02
NO. EM-01-D-090PAGE OF
QA: QA**CONDITION ADVERSE TO QUALITY CONTINUATION PAGE**

Review of Committed Corrective Actions for EM-01-D-090 and Recommended Closure

Based on the objective evidence of committed corrective actions taken associated with Deficiency Report EM-01-D-090, it is recommended that the Deficiency Report be closed. The details of the review are provided below:

1. A review of deficiencies and observations issued by EM HQ HLW QA Program during the past two years was conducted as committed and no trends were identified - as a result the QAR agrees that there was no impact resulting from the lack of trending. The review is documented in a memo dated 1/28/02 and adequately addresses both the classification of deficiencies as Observations and the evaluation of deficiencies for potential trends.
2. Standard Practice Procedure (SPP) 5.03, "Trend Evaluation" was revised to adequately address evaluating deficiencies to identify trends. A training plan was also submitted as objective evidence of completion of this procedure revision and several others completed at the same time.
3. The Glossary of Terms and Acronyms which provided the committed to revision of definition of an 'Observation', a 'Trend,' and a 'Condition Adverse to Quality.'

Corrective actions are considered complete and it is recommended that EM-01-D-090 be closed.



Marilyn A. Kavchak
4/25/02

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8. ☒ **DEFICIENCY REPORT**

☐ **CORRECTIVE ACTION REPORT**

NO. EM-01-D-091

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DEFICIENCY/CORRECTIVE ACTION REPORT

1. Controlling Document:

Quality Assurance Requirement & Description (QARD), DOE/RW-0333P, Revision 10 and High Level Waste (HLW) Standard Practice Procedure (SPP) No. 5.01, Rev. 2, "Deviations and Corrective Actions/Tracking System"

2. Related Report No.:

EM-ARC-01-09

3. Responsible Organization:

Office of Safety, Health and Security (EM-5)

4. Discussed With:

Larry Vaughan

5. Requirement:

QARD, Section 16.2 requires that corrective actions be taken relative to Conditions Adverse to Quality (CAQ) as soon as practical. Further, the QARD Glossary defines a "condition adverse to quality" as "the state of noncompliance with quality assurance program requirements".

In line with the QARD requirements, HLW SPP No. 5.01, Section 3.0 requires that corrective action be taken in a timely manner and that CAQ be documented on Deviation and Corrective Action Reports (DCARs).

6. Description of Condition:

Contrary to the requirements to take corrective action as soon as practical and in a timely manner, commitments associated with Deficiency Report (DR) EM-00-D-101 scheduled for completion by March 1, 2001 have not been completed.

In addition, noncompliances with quality assurance program requirements were routinely identified in audits and surveillances as "observations", "potential deficiencies" or "problems" (i.e., OOV-RL-S-01) rather than DCARs required for such conditions. This condition is recurring because it was identified last year in the OCRWM audit, EM-ARC-00-09, but was considered isolated and corrected during the audit.

7. Initiator:

Marilyn A. Kavchak

Marilyn A. Kavchak Date 6/20/01

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:

Assure a position description is in place to correspond to the required experience and QA background necessary to perform HLW QA activities before hiring full time federal employee committed to in DR EM-00-D-101.

Since no process currently exist to trend deficient conditions, evaluate these conditions to determine if a trend exist and take immediate appropriate action.

11. QA Review:

QAR Marilyn A. Kavchak

Date 6/20/01

12. Response Due Date:

10 Working Days From Issuance

13. DQQA Issuance Approval:

Printed Name Robert W. Clark

Signature

James Blaylock

Date 6/24/01

22. Corrective Actions Verified:

QAR

M. Kavchak

Date 4/30/02

23. Closure Approved by:

DQQA

[Signature]

Date 5/15/02

TYPE RESPONSE:

- ☐ Initial
☐ Complete
☒ Amended

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DR/CAR NO. EM-01-D-091
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DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Actions: (1) EM senior management retracts its commitment to provide a full time federal personnel to support the HLW QA Program Manager for the following reasons:

- The EM HQ HLW QA Program has performed satisfactorily for the pass two years (since the changes in EM organizations) with the current level of support received from part-time federal personnel and contractors.
- The EM HQ HLW QA Program Manager (PM) no longer serves as the Chairperson of the DOE Quality Assurance Working Group, and thus more of his time/attention is available for HLW issues.
- Past EM HQ HLW Program Managers performed satisfactorily with less or equivalent support.
- As future HLW projects are funded, EM senior management will review this support issue at that time to ensure adequate QA support is available to the HLW QAPM.

(2) The EM HQ HLW Program has reviewed the definitions of the term "Condition Adverse to Quality" identified in the QARD and the EM HLW procedures. The definition in the HLW procedure is not word-for-word as stated in the QARD, but alternated to accommodate the specific needs and operations of the HLW QA Program. The term "Condition Adverse to Quality" has it's own definition within the term itself. It implies that there is a condition adverse to the quality of an item or service. This is true in some conditions, but not all. A state of noncompliance with quality assurance program requirements is not necessarily a condition adverse to the quality (or quality impacting) of an item or service.

EM HLW QA Program uses two definitions to describe deficient conditions – Observation and Deviation. A "Deviation" is defined as a condition adverse to quality that is a departure from specified requirements. An "Observation" is defined as a condition that, if uncorrected, could become a condition adverse to quality...Conditions that depart from specified program requirements, but have not passed milestones requiring the condition to be completed... The audit process used by EM allows the audit team members to use their technical judgement and expertise combined with the facts identified to determine if deficient conditions are classified as Deviations or Observations.

Compliance Date: None Required

14. Remedial Actions: (1) No remedial action is required on this issue (see above Immediate Actions response).

(2) A review of past deviations and observations identified by EM HQ HLW QA Program was performed. The review covered the pass two years performance period. The results were observations and deviations were correctly classified in accordance with the HLW SPPs.

15. Extent of Condition: (1) This issue is applicable to the HQ HLW QA Program activities and has no significant impact on the quality of work or the HLW acceptance activities.

(2) A review of "observations", "deviations", "potential deficiencies" and "problems" issued by the EM HQ HLW QA Program over the pass two years was conducted. The results identified two cases where deficiencies were classified as "potential deficiencies" or "problems." However, all "observations", "deviations", "potential deficiencies" and "problems identified had no significant impact on the quality of work performed or the HLW acceptance activities.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)
 None to be provided.

17. Action to Preclude Recurrence: (1) Each fiscal year, the HLW QA Program Manager assembles training requirements and establishes a QA Training Plan for EM HLW Personnel. This process ensures the HLW QA Program Manager that QA support personnel have the requisite experience in QA to support the HLW program. None required.

(2) Deviations and observations are tracked in the EM HLW Commitment Racking system to ensure closure in a timely manner. Observations are not tracked identically to deviations because they are not the same. However, responses to observations are provided to encourage best practices and future compliance with QA program requirements. EM HQ HLW QA Program does tracks all observations. No other actions are needed at his time.

18. Due Date: None Required

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

19. Response by:

Larry D. Vaughan
 HLW QAPM

10/05/00
 Date

(202) 586-2523
 Phone

20. Evaluation: ☐ Accept ☐ Partially Accept ☒ Reject

QAR *M. Kowchak* Date *10-31-01*

21. Concurrence:

DOQA

James Blaylock Jr

Date *11/1/01*

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8. ☒ DR/CAR
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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

EVALUATION OF INITIAL/COMPLETE RESPONSE TO DEFICIENCY REPORT (DR) EM-01-D-091

Block 14a: Immediate Actions

The response indicates that the current staffing levels are adequate since performance is considered by High Level Waste (HLW) to have been satisfactory. However, personnel support reviewed during the audit includes an individual who does not formally report to the HLW Quality Assurance (QA) Program Manager, creating a reporting situation that is in conflict with the independence required to conduct QA-related duties. Further, the use of augmented staff would be an indication that current staffing levels are inadequate. Unless current staff formally assigned to HLW QA is sufficient – without the use of augmented personnel, the original commitment seems inevitable.

Also, “departures from requirements”, the definition used by Environmental Management (EM) HLW QA Program to describe conditions adverse to quality or deviations, were found to have been identified as *observations*, during the audit, contrary to the response.

The definition of an observation being “a condition that, if uncorrected, could become a condition adverse to quality” is acceptable and used industry-wide. However, the expansion of this definition, “conditions that depart from specified program requirements, but have not passed milestones requiring the condition to be completed” is not acceptable and seems to have resulted in an inconsistent assignment of deficient conditions at EM HLW HQ based on objective evidence reviewed during the audit. The definition and use of conditions referred to as ‘problems’ or ‘potential deficiencies’, were not defined in the response by EM HLW, even though they were used.

The definition of an ‘observation’ and other terms used to define deviations needs further clarification and is insufficient to allow technical judgement and expertise to consistently identify “deviations and observations”. Procedural clarification and training to the definitions is required.

The submittal of an amended response addressing this issue is requested within 10 working days.



Marilyn A. Kavchak, QAR

11-01-01

Date

☐ Initial
☐ Complete
☒ Amended

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DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)

14a. Immediate Actions: (1) EM senior management retracts its commitment to provide a full time federal personnel to support the HLW QA Program Manager for the following reasons:

- The EM HQ HLW QA Program has performed satisfactorily for the past two years (since the EM organization) with the current level of support received from part-time federal personnel and contractors.
- The EM HQ HLW QA Program Manager (PM) no longer serves as the Chairperson of the DOE Quality Assurance Working Group, and thus more of his time/attention is available for HLW QA related activities.
- Past EM HQ HLW QA Program Managers performed satisfactorily with less or equivalent support.
- As future HLW projects are funded, EM senior management will review this support issue at that time to ensure adequate QA support is available to the HLW QAPM.

(2) The EM HQ HLW Program has reviewed the definition of the term "Condition Adverse to Quality" identified in the QARD and the EM HLW SPPs. The definition in the HLW procedure is not word-for-word as stated in the QARD, but alternated to accommodate the specific needs and operations of the HLW QA Program. The term "Condition Adverse to Quality" has its own definition within the term itself. It implies that there is a condition adverse to the quality of an item or service. This is true in some conditions, but not all. A state of noncompliance with quality assurance program requirements is not necessarily a condition adverse to the quality (or quality impacting) of an item or service.

EM HLW QA Program uses two definitions to describe deficient conditions – Observation and Deviation. A "Deviation" is defined as a condition adverse to quality that is a departure from specified requirements. An "Observation" is defined as a condition that, if uncorrected, could become a condition adverse to quality... Conditions that depart from specified program requirements, but have not passed milestones requiring the condition to be completed... The audit process used by EM allows the audit team members to use their technical judgement and expertise combined with the facts identified to determine if deficient conditions are classified as Deviations or Observations. In future audits, the ATL will stress the definition and use of these terms.

(continue on page 3)

Compliance Date: None Required

14. Remedial Actions: (1) No remedial action is required on this issue (see above Immediate Actions response).

(2) A review of past deviations and observations identified by EM HQ HLW QA Program was performed. The review covered the past two years performance period. The results reflected that deviations were incorrectly classified as observations.

15. Extent of Condition: (1) This issue is applicable to the HQ HLW QA Program activities and has no significant impact on the quality of work or the HLW acceptance activities.

(2) A review of "observations", "deviations", "potential deficiencies" and "problems" issued by the EM HQ HLW QA Program over the past two years was conducted. The results identified two cases where deficiencies were classified as "potential deficiencies" or "problems." However, all "observations", "deviations", "potential deficiencies" and "problems" identified had no significant impact on the quality of work performed or the HLW acceptance activities.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)
 None to be provided.

17. Action to Preclude Recurrence: (1) Each fiscal year, the HLW QA Program Manager assembles training requirements and establishes a QA Training Plan for EM HLW Personnel. This process ensures the HLW QA Program Manager that QA support personnel have the requisite experience in QA to support the HLW program. None required.

(2) Deviations and observations are tracked in the EM HLW Commitment Tracking system to ensure closure in a timely manner. Observations are not tracked identically to deviations because they are not the same. However, responses to observations are provided to encourage best practices and future compliance with QA program requirements. EM HQ HLW QA Program does track all observations from issuance to closure. No other actions are needed at this time. (cont. on page 3)

18. Due Date: (2) November 30, 2001

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

19. Response by:

Larry D. Vaughan
 HLW QAPM

10/05/01
 Date

(202) 586-2523
 Phone

20. Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject

QAR Makarchuk Date 11/30/01

21. Concurrence:

DOQA James Blaylock

Date 11/30/01

Exhibit AP-16.1Q.1

Rev. 12/20/1999

Response received
 in OQA 11/29/01
 Mak

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

14. a Immediate Actions: (2) The terms "potential deficiencies" and "problems" will no longer be used or referenced in future assessments activities. Therefore, there is no need to define the terms "potential deficiencies" and "problems."

17. Action to Preclude Recurrence:

(2) The definition of the terms "condition adverse to quality", "deviation" and "observation" will be reviewed revised, and issued, as necessary to reflect definitions listed in the QARD by December 6, 2001.

SPPs 4.02, 4.03, and 5.01 will be revised to allow for deficiencies that are identified as an isolated occurrence or does not adversely impact other activities to be corrected during the audit/prior to issuance of the audit report (CDA). Deficiencies that are CDA will be documented on a Deficiency Form and issued to the site for consideration in the site's trending process and HQ annual review of deficiencies and observations. SPPs 4.02, 4.03, and 5.01 will be reviewed, revised and issued by December 6, 2001 to reflect these changes. Training on the revised SPPs will be conducted on or before December 6, 2001.

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Status of EM-01-D-091

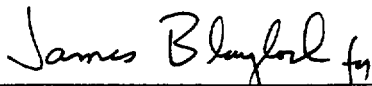
Follow-up for Closure of Objective Evidence of Corrective Actions

Objective Evidence associated with corrective actions related to Deficiency Report EM-01-D-090 was reviewed during the recent internal audit of EM-5, Office of Safety, Health and Security (EM-ARC-02-01) December 11-14, 2001. As a result of the status, it is recommended that the DR remain open and that a revised response, corrective action date and request for extended processing be provided by the responsible individual. Below is a status of the corrective action as reviewed by the assigned Quality Assurance Representative:

There was no evidence of a review of Past deficiencies and observations to determine that they were accurately classified. No change had been made to the Glossary to re-define conditions adverse to quality to correspond to the definition in the QARD as committed. This DR was not closed and requires a revised response including a new completion corrective action date and a request for extended processing.



Marilyn A. Kavchak 1/3/02



Director, Office of Quality Assurance

1/9/02

Date


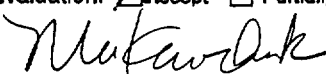
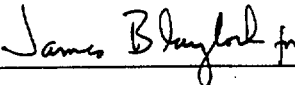
TYPE RESPONSE: <input type="checkbox"/> Initial <input type="checkbox"/> Complete <input checked="" type="checkbox"/> Amended	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	DR/CAR NO. 091 PAGE 1 OF 2 QA: QA
DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)		
14a. Immediate Actions: (See response submitted to RW dated October 5, 2001) Compliance Date:		
14. Remedial Actions: (See response submitted to RW dated October 5, 2001)		
15. Extent of Condition: (See response submitted to RW dated October 5, 2001)		
16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.) (See response submitted to RW dated October 5, 2001)		
17. Action to Preclude Recurrence: (See response submitted to RW dated October 5, 2001)		
18. Due Date: Mar. 1, 2002 <input type="checkbox"/> For submittal of complete response <input checked="" type="checkbox"/> For completion of corrective action	19. Response by:  Larry D. Vaughan, HLW QAPM Date 1/24/02 (202) 586-2523 Phone	
20. Evaluation: <input checked="" type="checkbox"/> Accept <input type="checkbox"/> Partially Accept <input type="checkbox"/> Reject QAR  Date 2/2/02	21. Concurrence: DOQA  Date 2/1/02	

Exhibit AP-16.1Q.1

Rev. 12/20/1999

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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

On December 11-14, 2001, RW conducted audit No. EM-ARC-02-01, of the EM HQ HLW QA Program. The audit team evaluated corrective actions related to Deficiency Report No. EM-01-D-091. As a result of the evaluation, it was determined that corrective actions were incomplete and that a revised response, corrective action date and request for extended processing, be provided by the responsible individual.

Results of RW's evaluation:

There was no evidence of a review of past deficiencies and observations to determine that they were accurately classified. No change had been made to the Glossary to re-define conditions adverse to quality to correspond to the definition in the QARD as committed. This DR was not closed and requires a revised response including a new completion corrective action date and a request for extended processing.

EM HQ HLW QA Program response:

1. Documentation will be available to show that deficiencies and observations issued by EM HQ HLW QA Program over the past two years were reviewed and evaluated to determine accurate classification.

Completion date: March 1, 2002

2. The terms "conditions adverse to quality" and "observation" will be revised correspond to the definition in the QARD.

Completion date: March 1, 2002

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Review of Revised Response to EM-01-D-089, 090, and 091

I have reviewed revised responses from L. Vaughn dated 1/25/02 to the subject Deficiency Reports (DRs) and provide the following recommendations:

DR EM-01-D-089 The revised response states that Memorandum of Agreements (MOAs) between EM-5 and the HLW sites will be cancelled, rather than updated, but fails to provide another method for describing the process that will be used to pass down QARD requirements and establish roles and responsibilities for implementing quality. **It is recommended that this response be rejected.**

DR EM-01-D-090 A revised response was submitted that agrees to define the term 'trend' and to fully develop the previously revised procedure to describe the trending process since the revised procedure failed to do this. A commitment to train personnel and provide documentation not previously available was made. A new completion date of 3/1/02 was provided. **It is recommended that this response and the extended processing date of 3/1/02 be accepted.**

DR-EM-01-D-091 A new date of 3/1/02 to provide previously committed to corrective action was provided. **It is recommended that the new extended processing date of 3/1/02 be accepted.**

MaKavichak 1/30/02

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☐ SWO

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

Review of Committed Corrective Actions associated with EM-01-D-091 and Recommended Closure

Based on the objective evidence of committed corrective actions taken associated with Deficiency report EM-01-D-091, it is recommended that the Deficiency Report be closed. The details of the review are provided below:

1. A review of the memo dated 1/28/02 from Larry Vaughan, HQ HLS QA Program Manager, provided sufficient objective evidence that a complete review was completed as committed of past deviations and observations identified by EM HQ HLW QA Program. Based on the review, although several cases were cited where conditions adverse to quality were cited as 'potential deficiencies' or 'problems,' the QAR agrees that there was no impact.
2. A revised 'GLOSSARY OF TERMS AND ACRONYMS' was presented as objective evidence of the change committed to that reflects the definitions listed in the QARD for conditions adverse to quality (CAQ).
3. Standard Practice Procedures 4.02, 4.03 and 5.01 were revised as committed and adequately corrected the process of identifying CAQ and to allow for deficiencies to be identified as isolated and corrected during the audit. A training plan was submitted that provided sufficient evidence of action taken to complete training to the new procedures.

Corrective actions are considered complete, and it is recommended that EM-01-D-091 be closed.



Marilyn A. Kavchak
4/25/02