Department of Energy
Washington, DC 20585

QA: QA

APR 09 2003

MEMORANDUM FOR: R. Dennis Brown (RW-3)

FROM: James Blaylock, Verification Lead
Office of Quality Assurance

SUBJECT: Verification of Corrective Action and Closure of Deficiency Reports (DR) OQA(O)-03-D-063, OQA(O)-03-D-066, and OQA(O)-03-D-071

The Office of Quality Assurance staff has evaluated the corrective actions of DRs OQA(O)-03-D-063, OQA(O)-03-D-066, and OQA(O)-03-D-071, 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) 794-1420.

OQA:JB-0978

Enclosures:
1. DR OQA(O)-03-D-063
2. DR OQA(O)-03-D-066
3. DR OQA(O)-03-D-071

cc w/encls:
N. K. Stablein, NRC, Rockville, MD
Robert Latta, NRC, Las Vegas, NV (2 cys)
S. W. Lynch, State of Nevada, Carson City, NV
L. W. Bradshaw, Nye County, Pahrump, NV
W. J. Glasser, NQS, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
W. J. Arthur, III, DOE/ORD (RW-2W), Las Vegas, NV
B. M. Terrell, DOE/ORD (RW-40W), Las Vegas, NV

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8 ☒ Deficiency Report ☐ Corrective Action Report

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document (Document ID and Revision or Date)
LP-2.2Q-OCRWM, Rev. 0, ICN 1

2 Related Report No
OQA-ARC-02-14

3. Responsible Organization
Office of Quality Assurance (OQA)

4 Discussed With
Denny Brown, Robert Hasson

5 Requirement
LP-2.2Q-OCRWM, *Maintenance of the QARD and ISMQAP*, section 5 2.2. states that the Responsible Individual (in this case it is the Director OQA) is required to determine the need for training on QARD revisions

6 Description of Condition
This step is not being implemented by the Director, OQA. The need for conducting QA training is determined by the Training Manager. The Training Manager reviews the change to the QARD and determines if a change is needed to the QARD Lesson Plan. The procedure, LP-2.2Q, was not kept current with the actual work process.

Has work been stopped? ☐ Yes ☒ No

7 Initiator
Wayne Booth — ROBERT BLYTH FOR W.B. — 1/9/03
Printed Name — Signature — Date

9 Does a stop work condition exist?
☐ Yes ☒ No ☐ N/A
If Yes, Check One ☐ A ☐ B ☐ C ☐ D

10 Recommended Actions
None

11. QAR Review
James Blaylock — James Blaylock — 1/16/03
Printed Name — Signature — Date

12 Response Due Date.
10 Working days after issuance.

13 QAM Issuance Approval
R Dennis Brown — James Blaylock for — 1/16/03
Printed Name — Signature — Date

14 Corrective Actions Verified/Closure
JAMES BLAYLOCK — James Blaylock — 3/25/03
QAR Printed Name — Signature — Date

15 QAM Closure Approval
DENNIS BROWN — James Blaylock for — 3/25/03
Printed Name — Signature — Date

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ENCLOSURE 1

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2 Check if Amended ☐
Check if also Initial Response ☒

3. Extended Processing

☒ No ☐ Yes (if yes, submit Extended Processing request)

1 DR/CAR NO OQA(O)-03-D-063

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE

4 Extent of Condition. (Amended response will be required if all Extent of Condition Investigations are not complete and documented herein)

This condition identified in Block 6 is limited to failure to implement a procedure step that was antiquated by the training methodology delineated in AP-2.1Q Rev.2, ICN1. The determination of training requirements is the responsibility of the individuals "Manager". This determination is documented in the individuals "Training Requirements Matrix". When the QARD is revised, a procedure Impact Evaluation is performed (this requirement is delineated in LP-2.2Q-OCRWM, Rev.1). Procedures impacted by a QARD revision are identified and revised. If the impacted procedure(s) is on individuals "Training Requirements Matrix" the requirements of AP-2.1Q prevail, as it would for any procedure revision regardless of the prime mover for the procedure revision.

5 Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)

There is no impact on systems structures or components important to safety or important to waste isolation, or any other work as a result of the condition identified in Block 6. Personnel training is governed by AP-2.1Q not LP-2.2Q-OCRWM.

6 Remedial Actions (Document all actions necessary to address the results of the Extent of Condition)

LP-2 2Q-OCRWM was revised 1/13/03. This revision deleted the requirement for the Director, OQA to make training determinations. The responsibility for specifying personnel training requirements rests with individual Managers as delineated in AP-2.1Q.

7. ☐ Root Cause (For a significant CAQ, attached results of formal root cause determination prepared in accordance with AP-16 4Q)
☐ Apparent Cause

N/A

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)

N/A

9 Due Date for Completion of Corrective Action:
N/A – Corrective Action was completed 1/13/03 when AP-2.2Q-OCRWM was revised.

10 Responsible Manager.
R. Dennis Brown — R. Dennis Brown — 3/17/03
Printed Name — Signature — Date

11 QAR Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject
☒ Re-evaluated for significance

James Blaylock — James Blaylock — 3/25/03
Printed Name — Signature — Date

12. QAM Concurrence

Dennis Brown — James Blaylock for — 3/25/03
Printed Name — Signature — Date

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☐ SWO

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

VERIFICATION OF CORRECTIVE ACTION FOR DEFICIENCY REPORT (DR) OQA(O)-03-D-063

The only action to be verified was the revision to LP-2.2Q-OCRWM, Maintenance of the QARD and ISMQAP, to remove the step that requires the Director, Office of Quality Assurance, to determine the need for training on QARD revisions. The need is already covered in AP-2.1Q.

As a result, I recommend that this DR be closed.

James Blaylock 3/25/03

James Blaylock, QAR Date

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6 ☒ Deficiency Report ☐ Corrective Action Report

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document. (Document ID and Revision or Date)	2 Related Report No
DOE/RW-0333P (QARD), Rev. 12	OQA-ARC-02-14

3 Responsible Organization	4 Discussed With
Office of Quality Assurance (OQA)	R Dennis Brown, Robert P. Hasson

5 Requirement

AP-6.28Q Document Review

QARD Requirements Matrix Criteria

6.1 Are appropriate QARD requirements linked to the document and are they adequately implemented?

6 Description of Condition

1.

QARD

7.2.1 Procurement Planning

Procurements shall be planned and documented to ensure a systematic approach to the procurement process Procurement planning shall:

C. Identify and document the sequence of actions and milestones needed to effectively complete the procurement

Detailed Requirements Matrix, rev (12) icn 0 print out dated 11/14/2002 shows OCRWM LP-4.1Q-OCRWM, 5.1.5b) as implementing this requirement.

OCRWM LP-4 1Q-OCRWM, 5.1.5b) does not address the sequence of actions and milestones needed to effectively complete the procurement

2.

Detailed Requirements Matrix, rev (12) icn 0 print out dated 11/14/2002 shows QARD Section 4 2 2B as being implemented by OCRWM LP-4.1Q-OCRWM sections 5.2.6, 5 2 7, 5.2.8 and 5.2.9.

In accordance with OCRWM LP-4.1Q-OCRWM sections 5.2.6 and 5 2 8 are performed by the CO (contracting Officer)

Interviews with project personnel indicate that sections 5.2.7 and 5 2 9 are performed by the procurement organization, not Technical Organization and OQA reviewers

Has work been stopped? ☐ Yes ☒ No

7. Initiator	9 Does a stop work condition exist?
Robert Blyth — Printed Name	☐ Yes ☒ No ☐ N/A
Signature	If Yes, Check One ☐ A ☐ B ☐ C ☐ D
1/9/03 — Date	

10. Recommended Actions

None

11. QAR Review	12 Response Due Date
James Blaylock — Printed Name	10 Working days after issuance
James Blaylock — Signature	
1/16/03 — Date	

13 QAM Issuance Approval

R. Dennis Brown — Printed Name

James Blaylock — Signature

1/16/03 — Date

14 Corrective Actions Verified/Closure	15 QAM Closure Approval
JAMES BLAYLOCK — QAR Printed Name	DENNIS BROWN — Printed Name
James Blaylock — Signature	James Blaylock — Signature
3/25/03 — Date	3/25/03 — Date

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ENCLOSURE 2

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2. Check if Amended ☐
Check if also Initial Response ☒

3. Extended Processing

☐ No ☐ Yes (if yes, submit Extended Processing request)

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE

4. Extent of Condition: (Amended response will be required if all Extent of Condition Investigations are not complete and documented herein)

N/A-see Condition Adverse to Quality Continuation Page.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)

N/A-see Condition Adverse to Quality Continuation Page.

6. Remedial Actions: (Document all actions necessary to address the results of the Extent of Condition)

N/A-see Condition Adverse to Quality Continuation Page.

7. ☐ Root Cause (For a significant CAQ, attached results of formal root cause determination prepared in accordance with AP-16.4Q)
☐ Apparent Cause

N/A-see Condition Adverse to Quality Continuation Page.

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)

N/A-see Condition Adverse to Quality Continuation Page.

9. Due Date for Completion of Corrective Action:

~~March 3, 2003~~ N/A

10. Responsible Manager:

Printed Name	Signature	Date
R. Dennis Brown	R Dennis Brown	3/17/03

11. QAR Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject
☐ Re-evaluated for significance

Printed Name	Signature	Date
James Blaylock	James Blaylock	3/25/03

12. QAM Concurrence:

Printed Name	Signature	Date
Dennis Brown	James Blaylock for	3/25/03

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

Response to Deficiency Report OQA(O)-03-D-066

This DR documents two conditions that are contrary to AP-6.28Q, *Document Review*, Revision 0 ICN 1, attachment 3 item 6.1. This item requires that the appropriate QARD requirements are linked to the document (being reviewed by AP-6.28Q) and they (the QARD requirements) are adequately implemented (within the document reviewed.)

Procedure LP-4.1Q-OCRWM, *Procurement Actions*, Revision 2, does implement QARD section 7.2.1 C via the entire procedure's section 5.0 by providing a documented sequence of actions for procurement. This sequence of actions provides the documentation associated with the necessary milestones to complete the procurement.

For clarification purposes, the Requirements Traceability Network (RTN) database that is cited in block 6 of this DR is considered non-Q data. The requirements matrices for OCRWM procedures are separate documents that have been prepared, reviewed and approved in accordance with AP-5.1Q, *Plans and Procedures Preparation, Review and Approval*, which are submitted to the Records Processing Center (RPC) as QA records. The RPC accession number for the requirements matrix of LP-4.1Q-OCRWM, revision 2, is MOL.20020425.0151. This matrix is a printed report from the non-Q RTN database, but it has been authenticated as a QA record as evident by the procedure preparer's dated signature as directed by AP-5.1Q.

The second condition of this DR could not be substantiated during the determination of the extent of condition. In fact, during the investigation for the extent of condition, there was objective evidence that the Technical Organization and the Office of Quality Assurance do conduct AP-6.28Q review of procurement documents For instance, the Q procurement for the Chemical Analysis For Alcove/Niche 3 Tracer Test Studies, UCCSN Task 35, there are AP-6.28Q review records from OPE (the Technical Organization) and from the Office of Quality Assurance. Given that there are no specific examples listed within the description of condition, no further investigation for the extent of condition is warranted

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

VERFICATION OF CORRECTIVE ACTION FOR DEFICIENCY REPORT (DR) OQA(O)-03-D-066

The citation in DR OQA(O)-03-D-066 was incorrect. The Detailed Requirements Matrix is not the record to determine the linkage. With the revision of a procedure, the records package with the implementation of AP-5.1Q, Plans and Procedures Preparation, Review and Approval, must include a requirements matrix. This requirements matrix for LP-4.1Q-OCRWM, Rev. 2, is included in records package MOL. 20020425.0151.

I recommend that this DR be closed.

James Blaylock 3/25/03

James Blaylock, QAR Date

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8 ☒ Deficiency Report
☐ Corrective Action Report

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document (Document ID and Revision or Date)	2 Related Report No
AP-16.1Q, Rev. 5	OQA-ARC-02-14

3 Responsible Organization	4 Discussed With
Office of Quality Assurance (OQA)	Denny Brown, Bob Hasson

5 Requirement.

AP-16 1Q, *Management of Conditions Adverse to Quality,* Section 3 12, provides the definition for a Quality Observation (QO) The definition, in part, states that the condition adverse to quality is isolated, and has no impact if not corrected Attachment 8 of AP-16.1Q states the requirements for processing a QO. The process requires, in part, a review of the condition adverse to quality (CAQ) by the Quality Assurance Representative, QAR, to ensure that it meets the definition of the QO.

6 Description of Condition

A QO was written (OQA(O)-02-O-058) to document a condition adverse to quality identified during a self-assessment. The self-assessment (OQA-2002-SA-02) identified where audit checklists were not signed nor dated by the Audit Team Leader (indicating that a review had been performed) on 14 audits over the past two years (The review by the Audit Team Leader is performed to ensure that the checklists are pertinent to the scope of work and that they are sufficiently adequate to evaluate the work.)

The QO evaluation by the QAR determined that "this procedure noncompliance revealed that the need for a signature is administrative only and that there is no impact on the acceptability or usability of the information contained within these checklists due to the missing signatures."

The QO was initiated and evaluated by the same individual

The CAQ should have been classified as a Deficiency Report.

Has work been stopped? ☐ Yes ☒ No

7. Initiator.	9 Does a stop work condition exist?
Wayne Booth (ROBERT BLYTH FOR W.B.) R L B 1/9/03	☐ Yes ☒ No ☐ N/A
Printed Name / Signature / Date	If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10 Recommended Actions

None

11. QAR Review	12 Response Due Date
James Blaylock James Blaylock 1/16/03	10 Working days after issuance
Printed Name / Signature / Date	

13 QAM Issuance Approval

R Dennis Brown — James Blaylock for — 1/16/03

Printed Name / Signature / Date

14 Corrective Actions Verified/Closure	15 QAM Closure Approval
JAMES BLAYLOCK James Blaylock 3/25/03	DENNIS BROWN James Blaylock for 3/25/03
QAR Printed Name / Signature / Date	Printed Name / Signature / Date

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ENCLOSURE 3

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2. Check if Amended ☐
Check if also Initial Response ☒

3. Extended Processing
☐ No ☐ Yes (if yes, submit Extended Processing request)

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1. DR/CAR NO.: OQA(O)-03-D-071
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE

4. Extent of Condition: (Amended response will be required if all Extent of Condition Investigations are not complete and documented herein)
N/A. See Condition Adverse to Quality continuation page.

5. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any)
N/A. See Condition Adverse to Quality continuation page.

6. Remedial Actions (Document all actions necessary to address the results of the Extent of Condition)
N/A. See Condition Adverse to Quality continuation page.

7. ☐ Root Cause (For a significant CAQ, attached results of formal root cause determination prepared in accordance with AP-16.4Q)
☒ Apparent Cause
N/A. See Condition Adverse to Quality continuation page.

8. Action to Preclude Recurrence: (Address those actions necessary to prevent the identified cause from recurring)
N/A. See Condition Adverse to Quality continuation page.

9. Due Date for Completion of Corrective Action:
~~2/18/2003~~ N/A RBB 3/17/03

10. Responsible Manager
RDennis Brown RDennis Brown 3/17/03
Printed Name Signature Date

11. QAR Evaluation: ☒ Accept ☐ Partially Accept ☐ Reject
☑ Re-evaluated for significance
James Blaylock James Blaylock 3/25/03
Printed Name Signature Date

12. QAM Concurrence:
Dennis Brown James Blaylock for 3/25/03
Printed Name Signature Date

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☐ SWO

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

This DR was issued as a result of OQA audit, OQA-ARC-02-14, during the review of QARD section 18,the processing of audit checklists. A CAQ was found involving OQA completed audit checklists not being signed by the OQA Audit Team Lead This CAQ had already been identified as a result of an OQA self-assessment. The CAQ was documented and closed on Quality Observation OQA(O)-02-O-058. It was determined during the audit of OQA that the CAQ documented in the Quality Observation (QO) should have been documented as a DR The difference between a DR and a QO is that an extent of condition investigation, an impact evaluation and recurrence control would have been documented in a DR response. However, as the below rationale illustrates, OQA did conduct these actions under the auspices of both the QO and the self-assessment report SA-OQA-2002-02.

The extent of the condition involving Audit Team Leads failing to sign completed audit checklists was confined to 14 audits over a period of three fiscal years of audits (FY 00, FY 01, FY 02). Therefore, the extent of the condition, documented on the QO, had already been determined during the course of the self-assessment.

The impact of not having the audit team lead not signing completed audit checklists is related to the cause of this condition adverse to quality. It was discovered during the self-assessment that the audit team leads actually did sign the checklists prior to conducting the audit, after the checklists were prepared by the audit team members in accordance with procedure. The discrepancy between the signed checklists and the records copy was that the team members fill out the checklists during the course of an audit and then retype them after the audit to improve legibility for the record system. The signed ATL copy does not become the official records copy of the checklists. The cause of this apparent non-compliance with the procedure is the ATL do not re-sign the completed checklists. However, the ATL does sign the checklist before the audit and thereby meet the intent of the procedure of approving the audit checklists. 3/25/03

The recurrence control was that the OQA/NQS ATLs were reminded that they should sign the checklists for a second time to provide objective evidence of their approval. This recurrence control was documented in the QO.

Given that all the above activities had occurred during the course of the self-assessment, OQA determined that a Quality Observation was the appropriate mechanism to document this condition adverse to quality ~~However, OQA will not continue the use of documenting CAQs using the QO process in the next revision to AP-16.1Q. This decision is independent of this DR, but relevant nonetheless to ensure that the CAQ cited in DR OQA(O)-02-D-058 does not occur again.~~ VB 3/25/03

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

VERIFICATION OF CORRECTIVE ACTION FOR DEFICIENCY REPORT (DR) OQA(O)-03-D-071

The basis of this DR was that the Audit Team Leader failed to sign the audit checklist (indicating that a review had been performed) on 14 audits over the past two years. This had been identified in a self-assessment (OQA-2002-SA-02) and documented as a Quality Observation (QO). The DR was written based on a requirement in AP-18.3Q, Rev. 0, with an effective date of 5/31/03. All of the audits identified in the self-assessment were performed prior to this date to AP-18.2Q, Rev. 8. Completion of the signature block was included in the instructions when filling out the form; there was no reference to why the signature was required. All audit checklists were either initialed and dated or signed and dated—not just the initial page. Hence, the audit team went beyond the procedural requirement and the initial determination that this was a QO is substantiated.

Based on the above, it is recommended that this DR be closed.

James Blaylock

James Blaylock, QAR

3/25/03

Date