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Department of Energy

Washington, DC 20585

QA: QA

APR 09 2003

	R. Dennis Brown (RW-3)
FROM:	James Blaylock, Verification Lead James Blaylock, Verification Lead James Blaylock
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



OFFICE OF CIVILIAN RADIOACTIVE U.S. DEPARTMENT O ORIGINAL WASHINGTON	FENERGY	δ ⊠ Deficiency Report ☐ Corrective Action Report No OQA(O)-03-D-063 Page 1 of 1 QA ⁻ QA
DEFICIENCY REPOR	T/CORRECTIVE ACTIC	N 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 IS 15 the Director OQA) is required to determine the nee		
 6 Description of Condition This step is not being implemented by the Director, C Manager. The Training Manager reviews the change Plan. The procedure, LP-2.2Q, was not kept current v Has work been stopped? ☐ Yes ⊠ No 	to the QARD and determines if	
Printed Name Signature [10 Recommended Actions None	Date If Yes, Check One	<u> </u>
11. QAR Review James Blaylock	12 Response Due Date.	
Printed Name Signature	10 Working di	ays after issuance.
13 QAM Issuance Approval R Dennis Brown	Jame Blaylorlyn	1/12/03
14 Corrective Actions Verified/Closure	Signature U 15 QAM Closure Appro	Date
James Blauford 3/2	5/03 DENNIS BROWN	James Bluebol in 3/25/03
	Date Printed Name	Signature Date Rev 3/25/02

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ENCLOSURE 1

Submittal Page (of)	1 DR/CAR NO OQA(O)- 03-D-063
2 Check if Amended	PAGE OF
Check if also Initial Response 🔀	QA-QA
3. Extended Processing	
No Yes (if yes, submit Extended Processing request)	
DEFICIENCY REPORT/CORRECTIVE AC	TION REPORT COMPLETE RESPONSE
4 Extent of Condition. (Amended response will be required if all Ex	tent of Condition Investigations are not complete and documented
herein) This condition identified in Block 6 is limited to failure to implement methodology delineated in AP-2.1Q Rev.2, ICN1. The determination "Manager". This determination is documented in the individuals " procedure Impact Evaluation is performed (this requirement is deline QARD revision are identified and revised. If the impacted procedur requirements of AP-2.1Q prevail, as it would for any procedure rev	nt a procedure step that was antiquated by the training on of training requirements is the responsibility of the individuals Training Requirements Matrix". When the QARD is revised, a neated in LP-2.2Q-OCRWM, Rev.1). Procedures impacted by a re(s) is on individuals "Training Requirements Matrix" the ision regardless of the prime mover for the procedure revision.
5 Impact: (Provide an impact statement relative to waste isolation	
There is no impact on systems structures or components important result of the condition identified in Block 6. Personnel training is g	to safety or important to waste isolation, or any other work as a governed by AP-2.1Q not LP-2.2Q-OCRWM.
6 Remedial Actions. (Document all actions necessary to address the result	s of the Extent of Condition)
LP-2 2Q-OCRWM was revised 1/13/03. This revision deleted the determinations. The responsibility for specifying personnel trainin 2.1Q.	requirement for the Director, OQA to make training g requirements rests with individual Managers as delineated in AP-
 7. Root Cause (For a significant CAQ, attached results of forma Apparent Cause N/A 	al root cause determination prepared in accordance with AP-16 4Q)
8. Action to Preclude Recurrence: (Address those actions necessa	ry to prevent the identified cause from recurring)
N/A	
	10. Responsible Manager D
9 Due Date for Completion of Corrective Action: N/A – Corrective Action was completed 1/13/03 when AP-2.2Q-	10 Responsible Manager. R. Dennis Brown ALOnnabury 3/17/03
OCRWM was revised.	Printed Name Signature Date
11 QAR Evaluation: 🛛 Accept 🗌 Partially Accept 🔲 Reject	12. QAM Concurrence
Re-evaluated for significance	
Printed Name Signature Date	Printed Name Signature Date
AP-16.1Q 8	Printed Name Signature Bate Rev. 03/25/2002

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	OFFICE OF N RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	DR/CAR/QO SWO No OQA(O)-03-D-063 Page 1 of QA QA
CONDITION A	DVERSE TO QUALITY CONTINUATION PA	
VERIFICATION OF CORRECTIV	VE ACTION FOR DEFICIENCY REPORT (D	R) OQA(O)-03-D-063
	revision to LP-2.2Q-OCRWM. <u>Maintenance of the service</u> of the Director, Office of Quality Assurance, to ed is already covered in AP-2.1Q.	
As a result, I recommend that this DR	be closed.	
James Blaylock, QAR	<u>3/25/03</u> Date	

OFFICE OF CIVILIAN RADIOACTIVE U.S. DEPARTMENT OF WASHINGTON,	FENERGY	No OQA(O)-03-D-066 Page 1 of 1
DEFICIENCY REPOR		
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 Office of Quality Assurance (OQA)	4 Discussed With R Dennis Brown, Robert 1	P. Hasson
5 Requirement AP-6.28Q Document Review		
QARD Requirements Matrix Criteria 6.1 Are appropriate QARD requirer	nents linked to the document :	and are they adequately implemented?
6 Description of Condition 1.		
process Procurement planning C. Identify and d complete the p	shall: locument the sequence of action procurement	estematic approach to the procurement
Detailed Requirements Matrix, rev (12) i 5.1.5b) as implementing this requirement		02 shows OCRWM LP-4.1Q-OCRWM,
OCRWM LP-4 1Q-OCRWM, 5.1.5b) do complete the procurement	es not address the sequence o	f actions and milestones needed to effectively
 Detailed Requirements Matrix, rev (12) icn 0 prin by OCRWM LP-4.1Q-OCRWM sections 5.2.6, 5 		QARD Section 4 2 2B as being implemented
In accordance with OCRWM LP-4.1Q-OCRWM	sections 5.2.6 and 5 2 8 are po	erformed by the CO (contracting Officer)
Interviews with project personnel indicate that sec Technical Organization and OQA reviewers	tions 5.2.7 and 5 2 9 are perfe	ormed by the procurement organization, not
Has work been stopped? 🗌 Yes 🔯 No		
7. Initiator Robert Blyth	9 Does a stop work co	
	03	
Printed Name Signature D 10. Recommended Actions	ate If Yes, Check One	
None		
11. QAR Review James Blavlock	12 Response Due Dat	e
Jom's Deargent 17	10 Working	days after issuance
13 QAM Issuance Approval R. Dennis Brown	James Blaubol +	1/12/03
Printed Name	Signature	Date
14 Corrective Actions Verified/Closure	15 QAM Closure Appl 5/03 DENHIS BROWD	
	ate Printed Name	Signature Date
Femplate AP161-1	, , , , , , , , , , , , , , , , ,	Rev 3/25/

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Submittal Page <u>1</u> of <u>2</u>			1. DR/CAR NO.: OQA(O)-03-D-066
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2. Check if Amended Check if also Initial Response 🔀	RADIOACTIVE WAS	4	QA [,] QA
	U.S. DEPARTME	NT OF ENERGY	
3. Extended Processing	WASHING	TON, D.C.	
No Yes (If yes, submit Extended Processing request)		· , ·	
DEFICIENCY RE	EPORT/CORRECTIVE A	CTION REPORT COM	MPLETE RESPONSE
4. Extent of Condition: (Amended	I response will be required if all Ex	tent of Condition Investigation	ons are not complete and documented
herein)	value Continuation Page		
N/A-see Condition Adverse to Qu	lanty Continuation Fage.		
5. Impact: (Provide an impact sta	tement relative to waste isolation	and safety, and impact to oth	ner work, if any)
N/A-see Condition Adverse to Qu			
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C. Demodel Actions (Decompositelle		a of the Extent of Condition)	
6. Remedial Actions: (Document all a N/A-see Condition Adverse to Qu		s of the Extent of Condition)	
N/A-see Condition Adverse to Qu	lanty Continuation I age.		
7. Root Cause (For a signification	ant CAO, attached results of forma	al root cause determination o	repared in accordance with AP-16.4Q)
Apparent Cause			
N/A-see Condition Adverse to Qu	uality Continuation Page.		
8. Action to Preclude Recurrence:	: (Address those actions necessa	ry to prevent the identified ca	ause from recurring)
N/A-see Condition Adverse to Qu	ality Continuation Page.		
	e e		
9. Due Date for Completion of Correct	tive Action:	10. Responsible Manager:	
-March 3, 2003- ~/17			Danna Blown 3/17/03
		Printed Name	Signature / D/ate
11. QAR Evaluation: 🔀 Accept		12. QAM Concurrence:	
1 2 1	ed for significance	72	R = R = R = 1
JAMES BLAYLOCK Jone		DENNIS BROWN	Simus Elaybork fr 3/25/0
Printed Name Signa		Printed Name	Signature J Date

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Submittal	Page	2	of	2

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

⊠ DR/CAR/QO □ SWO

NO OQA(O)-03-D-066 PAGE OF

QA QA

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

U.S. DEPARTMENT OF ENERGY	No OQA(O)-03-D-066
WASHINGTON, D.C.	Page <u>1</u> of QA Q/
CONDITION ADVERSE TO QUALITY CONTINUATION PA	AGE
VERFICATION OF CORRECTIVE ACTION FOR DEFICIENCY REPORT (D	R) OQA(O)-03-D-066
The citation in DR OQA(O)-03-D-066 was incorrect. The Detailed Requirements Mat determine the linkage. With the revision of a procedure, the records package with the is 5.1Q, <u>Plans and Procedures Preparation, Review and Approval</u> , must include a requirements matrix for LP-4.1Q-OCRWM, Rev. 2, is included in records package MC	implementation of AP- ments matrix. This
recommend that this DR be closed.	
James Blaylord 3/25/03	
James Blaylock, QAR Date	

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OFFICE OF CIVILIAN RADIOACTIVE WASTE M U.S. DEPARTMENT OF ENERGY	& Image: Deficiency Report ANAGEMENT Image: Deficiency Report Image: Deficiency Report Image: Deficiency Report
U.S. DEFARTMENT OF ENERGY U.S. DEFARTMENT OF ENERGY WASHINGTON, D.C	No OQA (O)-03-D-071
	Page 1 of 1
DEFICIENCY REPORT/CORREC	
1. Controlling Document (Document ID and Revision or Date) AP-16.1Q, Rev. 5	2 Related Report No OQA-ARC-02-14
3 Responsible Organization 4 Discussed Office of Quality Assurance (OQA) Denny Brow	Nith n. Bob Hasson
5 Requirement. AP-16 1Q, Management of Conditions Adverse to Quality, Section 3 12, p definition, in part, states that the condition adverse to quality is isolated, an 16.1Q states the requirements for processing a QO. The process requires, by the Quality Assurance Representative, QAR, to ensure that it meets the	id has no impact if not corrected Attachment 8 of AP- in part, a review of the condition adverse to quality (CAQ)
6 Description of Condition A QO was written (OQA(O)-02-O-058) to document a condition adverse t assessment (OQA-2002-SA-02) identified where audit checklists were not a review had been performed) on 14 audits over the past two years (The n that the checklists are pertinent to the scope of work and that they are suffi	signed nor dated by the Audit Team Leader (indicating that eview by the Audit Team Leader is performed to ensure ciently adequate to evaluate the work.)
The QO evaluation by the QAR determined that "this procedure noncomp only and that there is no impact on the acceptability or usability of the info 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. Referrence Figure S. 9 Doe	a stop work condition exist?
	s 🛛 No 🗋 N/A
	Check One [.] A B C D
10 Recommended Actions None	
11. QAR Review 12 Re	sponse Due Date
James Blaylock James Blaylor 1/11/03	10 Working days after issuance
Printed Name Signature U Date	
13 QAM Issuance Approval	0
R Dennis Brown James Cland Printed Name Signature	2 fr 1/12/03
	M Closure Approval
JAMES BLAYLOGIC James Blayfort 3/25/03 DENI	\mathcal{P} \mathcal

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Check if Amended □ OFFICE OF CIVILIAN PAE OF Check if also Initial Response ☑ No. DEPARTMENT OF ENERGY WASHINGTON, D.C. Listended Processing U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. INitial Processing To Conduct Report Concentration of the state of Condition Investigations are not complete and documented reini DEFICIENCY REPORT/CORRECTIVE ACTION REPORT COMPLETE RESPONSE Extended Processing Extended from state of Condition Investigations are not complete and documented reini /A. See Condition Adverse to Quality continuation page. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any) /A. See Condition Adverse to Quality continuation page. Impact: (Provide an impact statement relative to waste isolation and safety, and impact to other work, if any) /A. See Condition Adverse to Quality continuation page. Proof Cause (For a significant CAQ, attached results of formal root cause determination prepared in accordance with AP-16.40) @ Apparent Cause Asee Condition Adverse to Quality continuation page. Asee Condition Adverse to Quality continuation page. Dea Date for Correlation of Corrective Actor: 10 Restoreade Mangoer Mark #LB // 1/03 Mark #LB // 1/03 Date bot Correlation of Corrective Actor: 10 Restoreade Mangoer Mark #LB // 1/03 Mark #LB // 1/	Submittal Page 1 of 2						:
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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

DR/CAR/QO

NO. OQA(O)-03-D-071 PAGE OF

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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-signing 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.

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 $\sqrt{8} - 3/25/25$

CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. No OQA(O)-03-D-071 Page 1 of Page 1 of OQA(O)-03-D-071 Page 1 of Page 1 of OQA(O)-03-D-071 Page 1 of Page 1 of OQA(O)-03-D-071 Page 2 0 0QA(O)-03-D-071 Page 2 0 0QA(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 (QQ). The DR was written based on a requirement in AP-18.3Q, Rev. 0, with an effective date of 5/31/05, 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	Submittal Page 1 of 1	OFFICE OF	DR/CAR/QO
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