

Department of Energy

Washington, DC 20585

WBS 1.2.9.3 QA

DEC 19 1990

John W. Bartlett, Director, Civilian Radioactive Waste Management, HQ (RW-1) FORS

EVALUATION OF RESPONSES TO CORRECTIVE ACTION REQUESTS (CARS) HQ-91-008 AND HQ-91-010 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) AUDIT 90-1-01

The OQA staff has evaluated the responses to CARs HQ-91-008 and HQ-91-010. The responses have been determined to be satisfactory. Verification of completion of the corrective actions will be performed after the effective dates provided.

Any extension to the effective dates must be requested in writing with appropriate justification prior to those dates.

If you have any questions, please contact either Catherine E. Hampton at (702) 794-7973 or FTS 544-7973 or Stephen R. Dana of Science Applications International Corporation at (702) 794-7176 or FTS 544-7176.

Donald G. Horton, Director Office of Quality Assurance

OQA:CEH-1283

Enclosure:

HQ-91-008 and HQ-91-010

cc w/encl:

H. W. Washington, HQ (RW-3) FORS

K. R. Hooks, NRC, Washington, DC

S. W. Zimmerman, NWPO, Carson City, NV

N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

cc w/o encl:

J. W. Gilray, NRC, Las Vegas, NV

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FULL TEXT ASCII SCAN K HOOKS

102.7 WM-11 NH03



14CAR NO.:	HQ-91-008
DATE:	11/09/90
SHEET:	1 OF 2
	QA
WBS No.:	1.2.9.3

	CORRECTIVI	E ACTION REQUE	ST	
1 Controlling Document QAPD, Revision 3 and QAAP	-16.1, Revision 0		2 Related Report No. Audit No. 90-I-01	
3 Responsible Organization		4 Discussed With D. Horton/R. Laho	•	
10 Response Due 11/29/90	11 Responsibility for C	<u> </u>	12 Stop Work Order Y or N	
5 Requirement:			······································	
QAPD, Rev. 3, Section 1	Organization:			
Para. 1.1.1 responsibili	ties of Director, O	CRWM		
g. Maintain awareness	of quality assurance	e issues and problems	and effect resolution."	
Para. 1.1.2.1 responsibi	lities of Director,	OQA:		
"j. Establish and maint communication of th trends, and signifi	e status of the qua	lity assurance progra	ion system to facilitate effective m; status of resolution of issues,	
6 Adverse Condition:				
Based on the examples presented below, the CAR/DR/OBS tracking report and the monthly action due report have not been effective in conveying the status of open items to assure timeliness of responses, response evaluations, or verification and close-out.				
The 10/16/90 CAR/DR/OBS Tracking Data Dump was reviewed and the following conditions were noted for the 60 DRS/CARS listed.				
A. Untimely responses for 28 items. (Based on time from Response Due to Response Received) Responses were received from 2-109 days after the due date for 28 items, which included one CAR response for a significant deficiency that was received 43 days after the due date.				
(DRs 90-08, 09, 10, 07, 08, 11, 14, 15,	32, 33, 34, 11, 17, 17, 19; CAR 90-01.)	18, 20, 21, 23, 31,	36; DR 90-01, 02, 03, 04, 05, 06,	
7 Recommended Action(s): Identify the remedial actions to be taken to correct the deficiencies noted in Block 6. Identify the cause of the condition and the planned corrective action to prevent recurrence.				
8 Initiator Da	te: 9 Severity Leve	I - 13 Approved B	y: Date:	
Ardell Whiteside 10/19	^{1/90}	OQA Jan	- Blaylock to 11/9/90	
15 Verification of Corrective Action	on:			
16 Corrective Action Completed	and Accepted:	17 Closure Appro	ved By:	
OAR	Date	OOA		



CAR NO.: HQ-91-008
DATE: 11/09/90
SHEET: 2 OF 2

CORRECTIVE ACTION REQUEST (continuation sheet)

5 Requirements (continued)

QAAP-16.1, Revision 0, Para. 4.4 includes responsibilities for the Director, OQA, or designee to track the status of all CARs and DRs.

- 6 Adverse Condition (continued)
 - B. Untimely response evaluation actions for 44 items. (Based on time from Response Received to Accepted/Rejected)

NOTE: For the purpose of this deficiency, evaluations that occurred within 14 days of receipt of the response were considered acceptable.

Response evaluations ranged from 15-200 + days after receipt of response for 44 items, which included three CARs for significant deficiencies that noted 17, 19, and 23 days.

(DRs 89-01, -08 thru -13, -17; CARs 89-01, -02, and 90-01.)

C. Untimely verification/close-out actions for 23 items (Based on time from Corrective Action completion to close-out).

NOTE: For the purpose of this deficiency, close-outs that occurred within 30 days of completion of actions were considered acceptable.

Close-outs ranged from 31-337 days for 23 of 41 items.

(DRs 89-02, 03, 04, 06, 08 thru 11, 13, 15, 17, 24, 26 thru 29, 31 thru 34; 90-09, 10; CAR 89-01)

D. Only one item (DR-89-07) was voided. However, the DR was initiated in 3/89 and was not closed until 9/90. Therefore, the QA Evaluation of the cited problem was not timely.

CAR NO. HO-91-008			
DATE: 11-	-		
SHEET: 3	OF _	3	

CORRECTIVE ACTION REQUEST (continuation sheet)

CORRECTIVE ACTION RESPONSE:

Extent of Deficiency:

The cited deficiencies were isolated to the DR/CAR tracking system as noted in the audit report and this CAR.

B. **Root Cause:**

Single point responsibility within OQA for reviewing all DR/CAR related correspondence and for routine tracking and reporting of status had not been assigned and maintained.

C. Remedial Action:

A CAR coordinator has been assigned to track the status of CARs and DRs at both HO and YMP. The status of CARs and DRs will be tracked daily and status reports will be issued on a monthly basis. The first such report was completed November 9, 1990. Also, between October 1 and November 9, 1990, eight open DRs were closed.

Responsible individual: RW-3/Horton

Completion date: Completed 11/9/90

D. Corrective Action to Prevent Recurrence:

Procedure QAAP 16.1 was revised and reissued on October 3, 1990. The revision assigns the tracking of CARs to a CAR Coordinator, thereby centralizing responsibility for tracking and statusing CARs. By establishing a single point of contact for all correspondence and notifications regarding corrective action responses, corrective action completion and verification of corrective action, responsibility and accountability for the tracking and closing CARs has been greatly improved. Subsequent evaluations of the effectiveness of the system will take place through surveillances and audits. Initial classroom instruction on QAAP 16.1 will be completed by November 28, 1990.

Responsible individual: RW-3/Horton Completion date: Forecast 11/28/90

Response Approved:

Responsible Manager

Response Accepted:

Response Accepted:

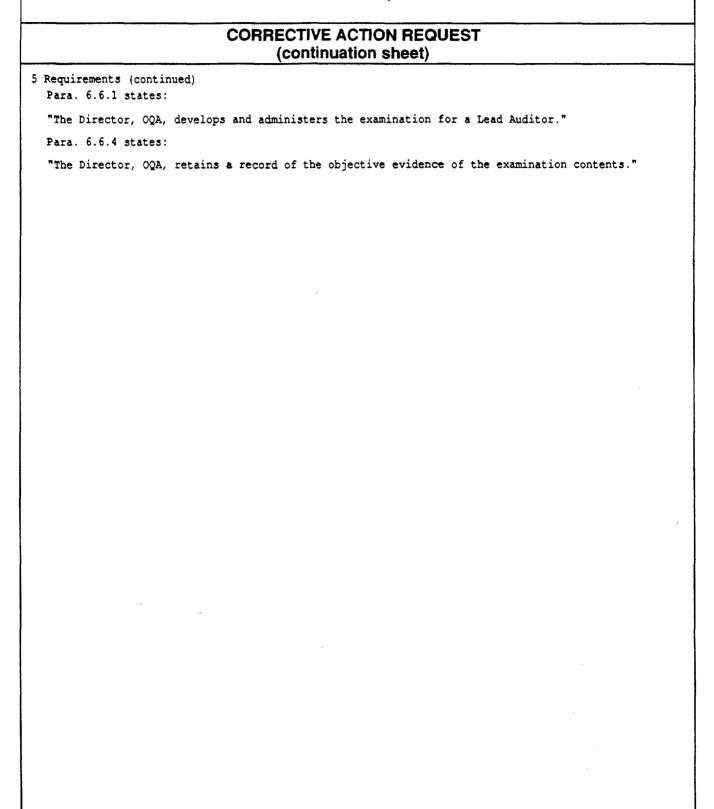


14CAR NO.:	RQ-91	-010	
DATE:			
SHEET: _	1	OF.	2
		QA	
WRS No :	1.2.9	3.3	

	WASII	ing ron, b.c.		WBS No.: 1.2.	9.3
CORRECTIVE ACTION REQUEST					
1 Controlling Document QAAP 18.1, Revision 0				ed Report No. No. 90-I-01	
3 Responsible Organization RW-3		4 Discussed With R. Clark/R. Lahoti	/D. Mil l	er	
10 Response Due 11/29/90	11 Responsibility for C D. Horton	orrective Action		Stop Work Order N	Y or N
Shequirement: QAAP 18.1, Rev. 0, Para. 6.3.3 states in part: "Based on annual evaluations, the Director, OQA, may extend the certificationThe Director, OQA, dated signature on Attachment I, indicates results of the evaluations are satisfactory and the certification is extended for a period of one year from the date of the evaluation." Para. 6.5.3 states: "A file for each Lead Auditor, auditor, and technical specialist is established and maintained by the Director, OQA, and contains copies of the individual's resume, documentation relating to or supporting the individual's qualifications, educational degree(s), training course certificates, training attendance records, audit participation records and applicable examination results." 6 Adverse Condition: Procedural requirements for Lead Auditors, auditors, and technical specialists are not being implemented accordingly. o Recertification for Lead Auditors are not being documented. o Files of Lead Auditor, auditor, and technical specialist do not contain all required documentation. o Objective evidence of the examination contents for Lead Auditors does not exist.					
7 Recommended Action(s): Identify the remedial act the cause of the condition	ions to be taken to on and the planned c	correct the deficien corrective action to p	cies not revent r	ed in Block 6. ecurrence.	Identify
8 Initiator Date Mario R. Diaz 10/19/90		- 13 Approved By	7 2 N	anloka 11	Date: /9 /9/2
15 Verification of Corrective Action 16 Corrective Action Completed a		17 Closure Approv	ed By:		



CAR NO.:	HQ-91-010
DATE:	11/09/90
SHEET: _	2 of 2



DATE: 11-26-90
SHEET: 4 OF

(continuation sheet)

CORRECTIVE ACTION RESPONSE

A. Extent of Deficiency:

Condition 1: To date, qualification records prepared in accordance with QAAP 18.1 have expired for only two of eight Lead Auditors. Both of these individuals had terminated involvement in the OCRWM program prior to the expiration of their qualifications, therefore recertification by the Director, OQA was not required. In addition, one individual had been certified as a Lead Auditor under OGR Procedure QIP 18.3, but certification had not been updated using the forms required by QAAP 18.1.

Condition 2: A total of seven individuals (four Lead Auditors, three auditors, and no technical specialists), who have been qualified in accordance with QAAP 18.1, remain actively involved with the OCRWM program. None of the files on these individuals included audit participation records for the current year.

<u>Condition 3</u>: Objective evidence of examination contents were not on file for three of the eight individuals who have been qualified as Lead Auditors.

B. Root Cause:

During the 1990 reorganization of the OCRWM project, responsibility for this task was never reassigned within OQA.

C. Remedial Action:

Condition 1: A Lead Auditor certification record was completed during the audit for the one individual whose OGR qualifications had not been updated.

<u>Condition 2</u>: Audit participation records have been prepared and placed in the files of each currently qualified individual.

Condition 3: Of three individuals whose files did not contain records of examination content, two are no longer involved with the OCRWM program and had never been assigned as Lead Auditor on an audit team, therefore those records will not be completed. Objective evidence of examination content will be obtained for the third individual and the file will be updated by December 7, 1990.

Responsible Individual: RW-3/Horton

Completion Date: Forecast December 7, 1990

CAR NO	HQ	-91-010
DATE:	11	-26-90
SHEET:	5	_of

CORRECTIVE ACTION REQUEST (continuation sheet)

D. Action to Prevent Recurrence:

Responsibility for maintenance of files on qualified audit personnel has been assigned to Janet Arpia. To assure that recertification is documented as required, these files now include a "tickle" system to identify when annual reviews are required.

Response Approved: Response Approved:	12/3/90
Responsible, Manager	Date
Response Accepted: Cather Thunk for	12-10-90
OQA	Date
Response Accepted: John Man J.	12-7-90
QAR	Date