

Department of Energy

Yucca Mountain Site Characterization Project Office P. O. Box 98608 Las Vegas, NV 89193-8608

WBS 1.2.9.3 QA

DEC 2 4 1991

Thomas E. Blejwas Technical Project Officer for Yucca Mountain Site Characterization Project Sandia National Laboratories P.O. Box 5800 Organization 6310 Albuquerque, NM 87185

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-91-079 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT YMP-91-07 OF SANDIA NATIONAL LABORATORIES

The YMQAD staff has verified the corrective action to CAR YM-91-079 and determined the results to be satisfactory. As a result, this CAR is considered closed.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or FTS 544-7945 or Richard L. Weeks at (702) 794-7853 or FTS 544-7853.

R.C. Sphere

Richard E. Spence, Director Yucca Mountain Quality Assurance Division

YMQAD: RBC-1426

Enclosure: CAR YM-91-079

cc w/encl: K. R. Hooks, NRC, Washington, DCC S. W. Zimmerman, NWPO, Carson City, NV R. R. Richards, SNL, 6319, Albuquerque, NM

cc w/o encl: J. H. Hines, OQD, AL J. W. Gilray, NRC, Las Vegas, NV N. J. Brogan, SAIC, Las Vegas, NV

360062 911224 WASTE PDR

ADD: Ken HODKS Ltr. Encl.

102:1-11 1/1 WM-11203



:	\smile		- 1	IS IS A RED S
	RADIOACTIVE U.S. DEPAR	E OF CIVILIAN WASTE MANAGEI TMENT OF ENER(INGTON, D.C.		14CAR NO.: <u>YM-91-079</u> DATE: <u>8/28/91</u> SHEET: <u>1</u> OF 2 QA WBS No.: <u>1.2.9.3</u>
	CORRECTIV	E ACTION REQUE	ST	
1 Controlling Document	 <u>.</u>		1	ed Report No.
QAP 16-1, Revision C, ICN	C3		Audit	: YMP-91-07
3 Responsible Organization Sandia National Lab		4 Discussed With R. Richards		
10 Response Due	11 Responsibility for C		12	Stop Work Order Y or N
20 days from issue	R. R. Richards		[
5 Requirement: QARD, Revision 4, Section 16, Paragraph 16.0 states, "The provisions of NQA-1 Basic Requirement 16 shall apply with the following amplifications." QAPP, Revision E, Paragraph 16.1 states, "A corrective action system is defined herein that ensures that conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical." QAP 18-1, Revision C, ICN 03, Sections 3.3 and 3.4 state the following: 3.3 Finding - A statement of fact regarding noncompliance with established policies, procedures, 6 Adverse Condition: Audit Finding and Observation Reports (AFORs) have been issued as "Observations" even though they identify a deficient condition and should be issued as a "Finding". Examples are as follows: NER-91-03 NER-91-04 AFORs identified in Oakridge Audit (ORNL-A91-1) Surveillance Reports were issued which identified conditions that were not in compliance with procedural requirements however, Deviation Reports were not issued but rather recommendations were made to document the violations. Examples are as follows: Surveillance Reports JVV 91-02, JVV 91-03, JVV 91-04 and CEF 91-01.				
7 Recommended Action(s): Identify the remedial ac Investigate the program similar deficient condit	process, activities	or documentation to (determine	the extent and depth of
8 Initiator Dat		- 13 Approved By	<i>r</i> : ,	Date:
M.R. Diaz 8/28/91 R.L. Beeks		malatha	DINCE	1000000 h. 8.78-91
15 Verification of Corrective Action	<u> </u>			
SEE ATTACHMENT TITLED "VERIFICATION"				
16 Corrective Action Completed	and Accepted:	17 Closure Approv	red By: ;	
OAR Lichard L. Ul	Date 12/19/	21 00A	<u>for</u>	Ince 1.2/.27/9/

.

1

• 3

1

ļ

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

CAR NO .:	YM-91-079
DATE:	8/28/91
	2 OF 8

CORRECTIVE ACTION REQUEST (continuation sheet)

5 Requirements (continued)

•

instructions, drawings, or other applicable requirements. (Findings require a documented response specifying corrective action and verification of its accomplishment.)

3.4 Observation - A statement of opinion regarding a potential quality problem, quality assurance program weakness or practice which could lead to a finding if not corrected. (Observations require a documented response specifying corrective action.)

QAIP 10-1, Revision 0, Section 3.4.2 states, "Any activity that is found to be in noncompliance with requirements will be documented on SNL NWRT Deviation Report (DR) in accordance with QAP 16-2."

7 Recommended Action(s) (continued)

required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

•		
	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	car no. YM-91-079 date: 10/17/91 eheet: 3 of 9
	CORRECTIVE ACTION REQUEST (continuation sheet)	
CORRECT	IVE ACTION RESPONSE:	
1. Cori	rective Action for Deficient Condition #1 (concerning	NER deficiencies)
Α.	Extent of Deficiency: Investigation has indicated the condition cited applies to both the New England Reservation Holometrix audit performed by SNL during FY91. Conce of this deficiency, it must be noted that audit result corrective action were documented on the AFOR and ide a Finding or Observation to satisfy corrective action the QAPP para. 16.1. Both Findings and Observations corrective action by the audited organization and for the same for both on conditions of any significance. will verify this statement.) Therefore, with respect action required of and implemented by the auditee, the difference between the two conditions.	arch audit and the erning the effect lts requiring entified either as n requirements of require llow-up by SNL is (SNL records t to corrective
Β.	<u>Root Cause</u> : The root cause of this deficiency (ident meeting the definition of "finding" as "observations" the part of the audit team to account for the follows audit documentation:	") was a desire on
- - -	 no quality-affecting work had been performed at a (Holometrix); quality-affecting work had only rea the other (NER), 	
	 the deficiencies identified in the audits were la of excessive SNL procedure requirements, rather a actions, 	
	 the knowledge that, from the audited organization SNL findings and observations require equivalent 	
	Regardless of those considerations, the subject defice have been identified as findings.	ciencies should
C.	<u>Remedial Action</u> : Appropriate corrective actions have for NER-91-03 and NER-91-04 (as well as the similar b deficiencies).	
D.	identify deficiencies discovered during audits as eig "observations" has been discussed with SNL QA audit p will be re-emphasized in writing. Responsible party: due 10/23/91.	ther "findings" or personnel. It R. R. Richards;
Str dts	L 10/18/91 RESPONSE AMENDED	ON 11-7-91

.

..

REY. 1090

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	7/91
CORRECTIVE ACTION REQUEST (continuation sheet)	
2. Corrective Action for Deficient Condition #2 (concerning audit ORNL-	-A91-1)
A. Extent of Deficiency: In this situation no deficiency actually exists. At the time of the audit, Oak Ridge National Laboratory (ORNL) was on an SNL-imposed "hold" requiring ORNL to obtain SNI approval prior to initiation of contract Task 3 (quality-affective work). The contract also contained a requirement for ORNL to perform a quality evaluation of prior work related to Task 3 prior to the approval called for in Task 1. The contract then required a compliance review to determine adequacy of the ORNL QA Program a correction of any deficiencies thereof to be completed prior to work under Task 3. The Executive Summary from the audit report, attached, clearly indicated the purpose of the audit as related contract requirements. Additionally, QAP 18-1, para. 4.1.1.5 cl states that audits can be conducted after award of a contract to determine the effectiveness of the implementation of a contract or program. It appeared prudent to perform an audit, in this case, evaluate a contractor after award and prior to release to perfor work. No quality-affecting work had been performed by ORNL at the other audit.	y L ing erform he SNL and any to learly o or QA , to rm
The conditions cited in our observations concerned differences by their QA implementing documents and contract requirements. They no cases of "violations" in which requirements had not been adhe to; in actual quality-affecting work.	re were
Considering the above, the documented situations were definitely	y:
 "potential quality problems, QA program weaknesses, or practices which <u>could lead</u> to a finding if not corrected" - is our definition of "observation." 	which
These observations were analogous to comments that would result from review of a QA program document; "Findings" are not utilized in such cases, and were not appropriate for the ORNL audit.	
ROOT CAUSE: N/A.	
REMEDIAL ACTION: N/A.	
ACTION TO PRECLUDE RECURRENCE: N/A.	
RESPONSE AMENDED ON 11-7-91	۱

.....

•

• .

CAR NO. YM-91-079 OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT 8HEET: 5 OF 8 U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. **CORRECTIVE ACTION REQUEST** (continuation sheet) 3 Corrective Action for Deficient Condition #3 (concerning surveillance documentation) Extent of Deficiency: A review of all 1991 surveillances was Α. performed and no further examples of the condition were identified. Similar conditions do not exist. Root Cause: As can be seen by evaluating the detailed information Β. under "Remedial Action," the situations documented as recommendations in the subject surveillance reports can be categorized as: 1. less-than-effective practices that deserved to be evaluated for improvement, even though they involved no procedure violation or other quality deficiency, individual deficiencies that were corrected and verified prior to 2. completion of the surveillance, or 3. uncorrected deficiencies that should have been documented as such. For the first category above, recommendations are an appropriate means of documenting the situation. Concerning the second category, it is accepted practice in the Project to not document such situations as deficiencies, since the immediate problem has been corrected. However, it is probably not always appropriate to categorize them as "recommendations," treating them instead as "deficiencies corrected during performance of the surveillance." For the last category above, the root cause is indeterminate, since the individual surveillor involved is no longer associated with SNL or the Yucca Mountain Site Characterization Project. C. <u>Remedial Actions</u>: The identified surveillances (JVV-91-02, 03, 04 and CEF-91-01) were reviewed to determine if the concerns/recommendations in the surveillances had any impact on quality. Each item was evaluated to determine if an unresolved quality issue existed. The evaluation disclosed the following:

Response amended on

REV. 10/90

11-7-9

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

CAR NO.	YM-91-079
DATE	10/17/91
SHEET:	6 OF 8

CORRECTIVE ACTION REQUEST (continuation sheet)

Surveillance Report No. CEF-91-01

This surveillance identified seven recommendations. The status of these recommendations, numbered as they are in the surveillance report, is as follows:

- 1. DR 91-32 was issued to document this condition (open).
- 2. Not quality related administrative error (typo).
- Not quality related administrative update; no requirement to do.
 PDMs 72-28, 29, and 30 now reference PCA 1.0.
- PDMs 75-13 and 76-08 were done to DOP 3.3, Rev. A, which did not require the listing of PCA numbers.
- 5. The training database was updated.
- 6. Training was completed.
- TOSPAC and NORIA-SP software has been certified. CA-DISSPLA software was addressed in DR-91-26 (closed 10/7/91).

With the exception of Recommendation No. 1 (which has now been documented on DR 91-32), all the recommendations had been addressed responsively prior to the issue of this CAR. No further actions are required.

Surveillance Report No. JVV-91-02

Three problem areas were discussed in the surveillance report. One had been documented and controlled by a Stop Work Order. Another concerned a nonmandatory Implementation Plan statement which conflicted with a procedural requirement; no procedural violation existed. The last involved unorthodox communication techniques used by YMPO to initiate SNL work. Additional documentation of these situations is not deemed necessary.

Surveillance Report No. JVV-91-03

One Deviation Report, two observations, and two recommendations were identified in the surveillance report. Both of the observations identified deficiencies that were corrected prior to completing the surveillance. It did not seem reasonable to issue DRs for these situations. Of the recommendations, one concerned training for handling SNL engineering drawings as QA records, however, the SNL work scope does not now include issuing engineering drawings. The second recommendation concerned what, at the time, was a <u>future</u> QARD requirement and could not then be treated as a deficiency.

RESPONSE AMENDED ON 11-7-9

CAR NO. YM-91-079 OFFICE OF CIVILIAN 10/17/91 DATE: RADIOACTIVE WASTE MANAGEMENT SHEET: 7 OF 8 U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. **CORRECTIVE ACTION REQUEST** (continuation sheet) Surveillance Report No. JVV-91-04 Two "concerns" were identified in this surveillance report. One was for working to an approved Experiment Procedure that had not been issued via Document Control. Differences between the procedure in use and a current, controlled version were found to be minor and did not affect the work in progress. Also, copies of the current, controlled version were obtained at the work site prior to completion of the surveillance. For these reasons, initiation of a Deficiency Report did not appear to be appropriate at the time, nor does it now. (Bv means of interacting with the surveillor on this topic the affected parties became sufficiently knowledgeable concerning use of controlled documents.) The second "concern" related to a situation that was not, at the time of the surveillance, a deficient condition. Its inclusion in the report was intended to serve as a reminder that documentation of the location of the work site should be completed prior to finishing the in-process work, in order to preclude the development of a deficient condition. (It has since been verified that the documentation of work-site location was properly completed.) D. Corrective Action to Prevent Recurrence: To address the causes and apparent causes of this situation, cited in "Root Cause," above, the following actions will be taken: written management direction will be provided to all SNL QA audit and surveillance personnel to the effect that: eficient conditions found during audits and surveillances that . are not immediately corrected shall be documented as such, not as "concerns" or "recommendations." Deficient conditions that are immediately corrected shall be reported in audit or surveillance reports straightforwardly as such. Responsible Party - R. R. Richards; due by 10/23/91. homas Response Approved: Thomas E. Blejwas, Actg//Mgr. Nuclear Waste Repository Technology Department 6310 RESPONSE AMENDED ON 11-7-91

	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	CAR NO. YM-91-079 DATE: SHEET: 8OF
	CORRECTIVE ACTION REQUEST (continuation sheet)	
Accept Response:	QAR	Date
Accept Response:	OQA	Date
	· · ·	

د

÷.,

,

•

Sandia National Laboratories

Albuquerque, New Mexico 87*85

date September 16, 1991

to: 6319 Staff

from: R. R. Richards, 6319

subject: Audit Reporting Process Improvements

As documented in a number of recent (and not-so-recent) audits and surveillances, we have had difficulties with timely issuance of audit reports and AFORs. Actions we have taken in response to those audits and surveillances will improve the situation. However, there are some other straightforward actions that will help that I would like implemented immediately. These are:

- Audit documentation of all types audit reports, AFORs, etc. will be typed here at SNL.
- Lead auditors and other audit personnel should set the goal of having audit reports issued within three weeks of performance of the audit.
- Problems or deficiencies discovered during audits that are attributable to SNL, rather than the auditee, will be documented on DRs, CARs, or memos, instead of AFORs.

Exceptions to the above practices may be appropriate on a case-by-case basis. However, implementation of these practices on a routine basis is now the standard.

RRR:6319:mjh

Copy to: 6310 T. E. Blejwas, Actg. 6319 R. R. Richards LIMITED-VALUE MATERIAL

 \checkmark

EXECUTIVE SUMMARY

The purpose of this audit was to perform a direct evaluation of the Oak Ridge National Laboratory (ORNL) QA Program to determine its adequacy and to identify any deficiencies or concerns requiring corrective action prior to initiating any technical work. This audit, supplementing Sandia National Laboratories (SNL's) prior review and approval activities on the ORNL QA Program Plan (QAPP), is intended to satisfy the QA compliance review requirements necessary for release of the mandatory hold point referenced in Contract 35-0023 Task 1.

The evaluation identified a number of observations (i.e., potential deficiencies) requiring corrective action by ORNL and by SNL. Several of the observations had been previously identified as "open items" requiring action. The ORNL QAPP as well as the SNL contract requires some changes, none of major significance. Agreement was reached on several changes needed in the ORNL QAPP to comply with Yucca Mountain Project (YMP) QA requirements.

The most serious problems impeding further ORNL work is the acceptance of prior work proposed by ORNL letter of June 30, 1990 and the need for an ORNL software QA plan and implementing procedures. These and other observations are documented in Audit Finding/Observation Reports (AFORs) in Appendix A for tracking purposes to ensure proper resolution.

۱	\sim
	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. AMENDED RESPONSE
	CORRECTIVE ACTION REQUEST (continuation sheet)
CORRECT	IVE ACTION RESPONSE:
1. Cor	rective Action for Deficient Condition #1 (concerning NER deficiencies)
Α.	Extent of Deficiency: Investigation has indicated that the deficient condition cited applies to both the New England Research audit and the Holometrix audit performed by SNL during FY91. Concerning the effect of this deficiency, it must be noted that audit results requiring corrective action were documented on the AFOR and identified either as a Finding or Observation to satisfy corrective action requirements of the QAPP para. 16.1. Both Findings and Observations require corrective action by the audited organization and follow-up by SNL is the same for both on conditions of any significance. (SNL records will verify this statement.) Therefore, with respect to corrective action required of and implemented by the auditee, there is no difference between the two conditions.
Β.	<u>Root Cause</u> : The root cause of this deficiency (identifying conditions meeting the definition of "finding" as "observations") was a desire on the part of the audit team to account for the following factors in the audit documentation:
	 no quality-affecting work had been performed at one contractor (Holometrix); quality-affecting work had only recently begun at the other (NER),
	 the deficiencies identified in the audits were largely the result of excessive SNL procedure requirements, rather than contractor actions,
	 the knowledge that, from the audited organization's point of view, SNL findings and observations require equivalent action.
	Regardless of those considerations, the subject deficiencies should have been identified as findings.
C.	<u>Remedial Action</u> : Although these deficient conditions that should have been documented as "findings" were identified as observations, in fact, the resolution, implementation of corrective and remedial actions, and follow-up was pursued for these deficiencies in the same manner as if they had been identified as "findings." The resolution, implementation of actions (by NER), and follow-up (by SNL) for AFOR-0-91-03 and AFOR-0-91-04 for NER (as well as for the equivalent deficiencies for Holometrix) is completed and these AFORs are closed. No additional actions of remedial nature by NER, Holometrix, or SNL is considered necessary.

At dtd 11/2/91 - Blegwin to Spenn

.

5

·	
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. AME	CAR NO. YM-91-079 DATE 11/7/91 BHEET: 4 OF 8 NDED RESPONSE
CORRECTIVE ACTION REQUEST (continuation sheet)	
D. <u>Corrective Action to Prevent Recurrence</u> : The need to identify deficiencies discovered during audits as eit "observations" has been discussed with SNL QA audit p will be re-emphasized in writing. Responsible party: due 10/23/91. (See attached memo, subject: "Guidance Deficient Conditions and Areas of Improvement.")	ther "findings" or personnel. It R. R. Richards;
2. Corrective Action for Deficient Condition #2 (concerning	audit ORNL-A91-1)
A. <u>Extent of Deficiency</u> : As represented in the report for ORNL-A91-1, the subject audit was performed to fulfil "post-award survey" or "readiness assessment" of Oak period during which their QA Program was being refine them being released to perform the technical work specontract. This particular timing, as described below the condition described in this CAR. This is the onl performed as such a "readiness assessment," so this is be an isolated situation.	I the need for a Ridge in the time ed but prior to ecified in the v, contributed to Ly audit recently
B. <u>Root Cause</u> : The root cause of these adverse condition documented as "observations" rather than "findings" in of the conditions themselves, as described below, and judgment in a less-then-conservative manner by the le	is the dual nature I the exercise of
Considered in different ways, the conditions cited in the audit report could fit either the definition of " "finding." On one hand, the conditions in the "obser differences between the ORNL QA-implementing document requirements. At this point, it was felt significant not been released to implement their QA controls in t	observation" or vation" concerned s and contract that ORNL had
Considering that, the documented situations were seen	to be:
• " <u>potential</u> quality problems,	
 QA program weaknesses, or practices which <u>could lead</u> (in future technical with if not corrected" - which fits the SNL definition "observation." 	· · ·
However, many of the conditions documented in Observa clearly cases in which ORNL had not adhered to contra in preparing their QAPP and implementing procedures. the "observation" included:	ict requirements
	REY. 104

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	CAR NO. YM-91-079 OATE: 11/7/91 EHEET: 5 OF 8 AMENDED RESPONSE
CORRECTIVE ACTION REQUEST (continuation sheet)	
 "statements of fact regarding noncompliance policies or other applicable requirements "findings." 	
Faced with the situation that these conditions of definition, the lead auditor considered the tota as he saw it, particularly the existence of the mandatory hold point, and elected to identify th "observations."	ality of the situation yet-to-be-released
C. <u>Remedial Action</u> : Responses were developed by boall the individual conditions cited in the subject of subsequent to that, all work under the subject of reasons related to funding and reassignment of reasons within YMP. Consequently, the observations closed. However, SNL to date has no evidence that actions were ever carried out and the deficient corrected. At last report, ORNL reported that of QAPP was still a future action. Therefore, SNL to "flag" ORNL with respect to the subject work requiring that the deficient conditions specifie observations be adequately resolved and correcte of any technical work. Additionally, approval of QAPP will be withdrawn until such corrections ar party: John Friend; due date: November 15, 199	ect audit report. contract was halted for responsibility for the s were administratively hat the ORNL resolution conditions actually correction of their will initiate action or similar work, ed in the subject audit ed prior to initiation of the existing ORNL re made. Responsible
D. <u>Action to Preclude Recurrence</u> : To address the r above, SNL will conduct a training and coaching currently qualified lead auditors wherein the si ORNL audit will be treated as a case study for t distinguishing between "findings" and "observati application of conservative judgment in indefini order to address a contributing cause, writing o are clear and unambiguous will also be covered d Responsible party: R. R. Richards; due date: D	session involving all tuation concerning the the purpose of ons" and the te situations. In of audit reports that luring training.
3. Corrective Action for Deficient Condition #3 (concer documentation)	ming surveillance
A. <u>Extent of Deficiency</u> : A review of all 1991 surv performed and no further examples of the conditi Similar conditions do not exist.	
۰ . .	

.

¥	
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. AMER	CAR NO YM-91-079 OATE 11/7/91 EHEET 6_0F 8 NDED RESPONSE
CORRECTIVE ACTION REQUEST (continuation sheet)	
B: <u>Root Cause</u> : As can be seen by evaluating the detaile under "Remedial Action," the situations documented as in the subject surveillance reports can be categorize	recommendations
 less-than-effective practices that deserved to be improvement, even though they involved no procedu other quality deficiency, 	
2. individual deficiencies that were corrected and ve completion of the surveillance, or	erified prior to
3. uncorrected deficiencies that should have been do	cumented as such.
For the first category above, recommendations are an of documenting the situation.	appropriate means
Concerning the second category, it is accepted practic to <u>not</u> document such situations as deficiencies, since problem has been corrected. However, it is probably appropriate to categorize them as "recommendations," instead as "deficiencies corrected during performance surveillance."	e the immediate not always treating them
For the last category above, the root cause is indeter the individual surveillor involved is no longer assoc the Yucca Mountain Site Characterization Project.	
C. <u>Remedial Actions</u> : The identified surveillances (JVV- CEF-91-01) were reviewed to determine if the concerns, in the surveillances had any impact on quality. Each evaluated to determine if an unresolved quality issue	/recommendations item was
The evaluation disclosed the following:	
Surveillance Report No. CEF-91-01	
This surveillance identified seven recommendations. These recommendations, numbered as they are in the surreport, is as follows:	
 DR 91-32 was issued to document this condition (op Not quality related - administrative error (typo) Not quality related - administrative update; no re 	•

•

.

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

	YM-91-079		
DATE	11/7/91	_	
BHEET:	7_0F_8		
_		-	

AMENDED RESPONSE

CORRECTIVE ACTION REQUEST (continuation sheet)

- 4. PDMs 72-28, 29, and 30 now reference PCA 1.0. PDMs 75-13 and 76-08 were done to DOP 3.3, Rev. A, which did not require the listing of PCA numbers.
- 5. The training database was updated.
- 6. Training was completed.
- TOSPAC and NORIA-SP software has been certified. CA-DISSPLA software was addressed in DR-91-26 (closed 10/7/91).

With the exception of Recommendation No. 1 (which has now been documented on DR 91-32), all the recommendations had been addressed responsively prior to the issue of this CAR. No further actions are required.

Surveillance Report No. JVV-91-02

Three problem areas were discussed in the surveillance report. One had been documented and controlled by a Stop Work Order. Another concerned a nonmandatory Implementation Plan statement which conflicted with a procedural requirement; no procedural violation existed. The last involved informal, poorly documented communication techniques used by YMPO to initiate SNL work. Additional documentation of these situations is not deemed necessary.

Surveillance Report No. JVV-91-03

One Deviation Report, two observations, and two recommendations were identified in the surveillance report. Both of the observations identified deficiencies that were corrected prior to completing the surveillance. It did not seem reasonable to issue DRs for these situations. Of the recommendations, one concerned training for handling SNL engineering drawings as QA records, however, the SNL work scope does not now include issuing engineering drawings. The second recommendation concerned what, at the time, was a <u>future</u> QARD requirement and could not then be treated as a deficiency.

Surveillance Report No. JVV-91-04

Two "concerns" were identified in this surveillance report. One was for working to an approved Experiment Procedure that had not been issued via Document Control. Differences between the procedure in use and a current, controlled version were found to be minor and did not affect the work in progress. Also, copies of the current, controlled version were obtained at the work site prior to completion of the

·	
	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. AMENDED RESPONSE
	CORRECTIVE ACTION REQUEST (continuation sheet)
	•surveillance. For these reasons, initiation of a Deficiency Report did not appear to be appropriate at the time, nor does it now. (By means of interacting with the surveillor on this topic the affected parties became sufficiently knowledgeable concerning use of controlled documents.)
	The second "concern" related to a situation that was not, at the time of the surveillance, a deficient condition. Its inclusion in the report was intended to serve as a reminder that documentation of the location of the work site should be completed prior to finishing the in-process work, in order to preclude the development of a deficient condition. (It has since been verified that the documentation of work-site location was properly completed.)
D.	<u>Corrective Action to Prevent Recurrence</u> : To address the causes and apparent causes of this situation, cited in "Root Cause," above, the following actions will be taken: written management direction will be provided to all SNL QA audit and surveillance personnel to the effect that:
	 Deficient conditions found during audits and surveillances that are not immediately corrected shall be documented as such, not as "concerns" or "recommendations."
•	Deficient conditions that are immediately corrected shall be reported in audit or surveillance reports straightforwardly as such.
	Responsible Party - R. R. Richards; due by 10/23/91. (See attached memo, subject: "Guidance on Reporting of Deficient Conditions and Areas of Improvement.")
	Response Approved: Thomas E. Blejwas, Accg. Mgr. Nuclear Waste Repository Technology Department 6310
	Response Accepted: Andre 11/12/91 Date Date
	Response Accepted: Jone Blonghak for pes <u>11/14/91</u> Date

•

۰.

Sandia National Laboratories

cate October 22, 1991

10 Distribution

from R. R. Richards, 6319

Albuquerque, New Mexico 87185

WBS: 12932 QA

subject. Guidance on Reporting of Deficient Conditions and Areas of Improvement

The recent Yucca Mountain QA Division audit identified some inconsistencies in the way deficient conditions and areas for improvement have been reported in our audits and surveillances. To help achieve greater consistency (and to accomplish some improvement ourselves), the following guidance on this topic is provided:

- Deficient conditions that are detected during audit or surveillance, and that are fully corrected by the responsible organization prior to the end of audit/surveillance performance, need not be documented via DR, CAR, AFOR, etc. They should be reported in the text of the audit/surveillance report, however. (Note: this specific guidance is very discretionary. If there are indications that the corrected deficient condition is a symptom of a deeper problem, an AFOR CAR, etc. may be initiated at the auditor's/surveillor's discretion.)
- Deficient conditions that are detected and <u>not</u> corrected during performance of an audit or surveillance shall be documented (via DR, AFOR, etc.) as such, <u>not</u> as "concerns" or "recommendations."
- Audit team members must exercise care to <u>properly</u> identify conditions cited in audit documentation as either "observations" or "findings." These terms are defined in Quality Assurance Procedure 18-1, "Quality Assurance Audits." In cases where an argument could be made that a particular condition might fit either definition, audit personnel should exercise their best judgment given their on-scene knowledge of the total situation.

If you have questions about this guidance, please contact me.

RRR:6319:mjh

Distribution: 6319 J. C. Friend 6319 D. R. Hawkinson 6319 T. G. Hersum 6319 J. A. Letz 6319 G. A. Smit 6319 J. V. Voigt Copy to: 6310 T. E. Blejwas, Actg. 6319 R. R. Richards 6319 B. A. Lewis 6310 94/12932/VER/1.0/YM-91-07/QA 6310 YMP CRF

VERIFICATION of YM-91-079

The following actions were required to be completed by SNL and verified by YMQAD prior to closure of this CAR:

* . /**•**

1) SNL Action: SNL QA Manager to provide written guidance to SNL QA audit personnel regarding the apropriate designation of a deficient condition as a "Finding" or "Observation".

YMQAD Verification: Refer to Memo dated 10/22/91, Richards to Distribution, "Guidance on Reporting of Deficient Conditions and Areas of Improvement". This satisfies corrective action committed to in Sections 1D and 3D of the Amended Response.

2) SNL Action: SNL to withdraw approval of ORNL QAPP until corrections to ORNL program are corrected.

YMQAD Verification: Refer to letter Richards to Klamerus, dated 11/13/91.

This letter instructs L. J. Klamerus not to initiate any technical work with ORNL until corrective actions required as a result of Audit ORNL-A91-1 have been completed and verified and revisions to the ORNL QAPP have been made and approved by SNL. This satisfies remedial action committed to in Section 2C of the Amended Response.

3) SNL Action: SNL QA Manager to complete classroom training of all qualified lead auditors for the purpose providing clarification as to when to issue a "Finding" or "Observation".

YMQAD Verification: It was verified on 12/9/91 that training was conducted by the QA Manager to clarify the issuance of a "Finding" or "Observation". Training Attendance Record, Titled, "Audit Reporting -Clarity and Conservatism" was examined. This training was conducted by R. R. Richards on 12/6/91 with the following individuals in attendance: James V. Voigt, David R. Hawkinson and Richard M. Baehr. These individuals represent all of the currently certified and active Lead Auditors working under the SNL YMP QA Program. This satisfies corrective action committed to in Section 2D of the Amended Response.

In addition to the three specific conditions discussed above, SNL provided a thorough discussion, as part of the Amended Response, of other remedial actions that were taken to correct this condition.

Verified by: Kuhm Lulut Date: 12/19/9/

YMP-063-R0 10/15/91 YUCCA MOUNTAIN SITE CHARACTERIZATIN PROJECT PROCEDURE COMPLIANCE DOCUMENTATION FORM	
I have read, and understood and complied with Document <u>GAAP</u> in accomplishing my responsibilities in this procedure.	<u>///</u> Rev <u>4</u> ICN# <u>///</u>
Signature Anihand Z. (Mules Name (Printed) 1	CHARD L. WEEKS
Title Q.A. ENGINEER	Date//2 / 9/
I have read, and understood and complied with Document \underline{QAP} by \underline{f} ICN# ICN# ICN#	
Signature Jame Blanfal Name (Printed)	AMES BIMLICE
Title <u>Cevenus</u>	Date _ <u>11 / / 4 / 9/</u>
I have read, and understood and complied with Document $\frac{PAP H_{a.I.}}{PA}$. Rev <u>4</u> ICN# <u>NA</u> in accomplishing my responsibilities in this procedure.	
Signature And a. (Multon Name (Printed)	RICHARD L. WEEKS
Title <u>Q.A. ENGINEER</u>	Date
I have read, and understood and complied with Document $QAAP16.1$, Rev 4 ICN# N/A in accomplishing my responsibilities in this procedure.	
Signature A.C. Appure Name (Printed) Ric Title Director (MQAD	hard E. Spence
Tille Director YMQAD	Date <u>/ 2/23 /9/</u>
I have read, and understood and complied with Document in accomplishing my responsibilities in this procedure.	, Rev ICN#
Signature Name (Printed)	
Title	Date
I have read, and understood and complied with Document in accomplishing my responsibilities in this procedure.	, Rev ICN#
Signature Name (Printed)	
Title	Date

.....