

Department of Energy

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

WBS 1.2.9.3 QA

MAR 12 1991

John H. Nelson
Technical Project Officer
for Yucca Mountain
Site Characterization Project
Science Applications International Corporation
The Valley Bank Center, Suite 407
101 Convention Center Drive
Las Vegas, NV 89109

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-91-016 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT 90-08 OF TECHNICAL AND MANAGEMENT SUPPORT SERVICES (T&MSS)

The YMQAD staff has verified the corrective action to CAR YM-91-016 and determined the results to be satisfactory. As a result, the CAR is considered closed.

If you have any questions, please contact either Catherine E. Hampton at (702) 794-7973 or FTS 544-7973, or Terry W. Noland at (702) 794-7212 or FTS 544-7212.

Donald G. Horton, Director

YMQAD: CEH-2579

Yucca Mountain Quality Assurance Division

Enclosure: CAR YM-91-016

cc w/encl:

K. R. Hooks, NRC, Washington,

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

W. V. Macnabb, SAIC, Las Vegas, NV, 517/T-04

K. W. Moore, SAIC, Las Vegas, NV, 517/T-28

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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YMP-5

14CAR NO.: TH-	91-016			
DATE: 11/	11/27/90			
	OF _2			
	QA			
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CORRECTIVE ACTION REQUEST							
1 Controlling Document			2 Related Report No.				
SP 1.37, Revision 1			Audit 90-08				
3 Responsible Organization		4 Discussed With	-				
SAIC		J. Harper					
10 Response Due 12/27/90	11 Responsibility for C J. Earper	orrective Action	12 Stop Work Orde	r YorN			
5 Requirement:							
SP 1.37, Paragraph 5.0, number 4, QA Manager, "Evaluate whether the finding constitutes a significant condition adverse to quality in accordance with criteria established below:							
a. A significant or ser	ious breakdown in an	y portion of the qua	lity assurance program	•			
6 Adverse Condition:							
QFR 90-001, Revision 0 as conditions which fulfill significant conditions.	nd Revision 1, QFR 9 the above cited def	0-013, 90-014, and 9 inition but were not	0-015 identified identified as				
note:				,			
QFR 90-001, Revision 0 at rate for training record		itten to identify an	average 39.1 failure				
Block 8 of the QFR stated, "Documentation deficiencies were noted in all surveilled departments. Files are incomplete and forms are inconsistently used." Response to QFR (Nelson 6/11/90) stated, "It can neither be satisfactorily demonstrated nor verified that T&MSS personnel are fully trained to perform quality affecting							
7 Recommended Action(s):							
			•				
8 Initiator Dat	e: Severity Level	- 13 Approved B	y:	Date:			
Catherine Hampton	1 2 2 3	" (~ 0 0 0				
Cothecter Janda 11/1	9/01	معد محمد	- Dlaylalfa	11/21/90			
15 Verification of Corrective Action		ion of 2/25/91 Am	ended Response Action	n S			
1. Verilied that QFR							
Rev. O on Ilistal.	SUB I	-	•				
Rev. 0 on illetal. Tulks. 2. SP 1.37, Rev. 3 beame effective 3/5/91. Section 5.1.4 of this procedure contains							
Critaria for avaluating deficiencies for "ciantina de actions							
Criteria for evaluating deficiencies for "Significant conditions							
adverse to quality". T. W. N.L.							
3/7/91							
16 Corrective Action Completed	and Accepted:	17 Closure Aporo	ved By:				
	•	L OOA Coh		1			
DAR T.W. Noll	Date 3/7/9	1 000 Carr	u mpa	X0-3/7/9/			

CAR NO.: YM-91-016

DATE: 11/27/90

SHEET: 2 OF 2

CORRECTIVE ACTION REQUEST (continuation sheet)

6 Adverse Condition (continued)
 activities."

QFR 90-013, 90-014, and 90-015 were written to document the deficiencies identified as a result of surveillance SR-90-006. The surveillance summary (dated 10/4/90) identified that the "overall program is insufficient to meet the requirements of the TAMSS QAPD."

CAR NO. YM-91-016

DATE: 12/27/90

SHEET: / OF 4/

CORRECTIVE ACTION REQUEST (continuation sheet)

CORRECTIVE ACTION FOR DEFICIENT CONDITION NO. 1

A. EXTENT OF DEFICIENCY:

The central issue with respect to this Corrective Action Request revolves around a difference of interpretation between the auditor and T&MSS management personnel on what constitutes a significant condition adverse to quality with respect to "a significant or serious breakdown in any portion of the quality assurance program. SP 1.37, Rev. 1, requires that significant conditions adverse to quality be documented on a Management Corrective Action Report (MCAR). In order to focus the concept of "significance" with respect to its intended meaning as used in SP 1.37, Section 1.0, PURPOSE, of the subject procedure is cited. It states: "This procedure describes the system to be used for identifying, documenting, and obtaining resolution of programmatic deficiencies, procedure violations and repetitive deficient conditions which are considered to be conditions adverse to quality. It also prescribes actions necessary to correct significant conditions which, if uncorrected, could have a serious effect on safety or operability of the Yucca Mountain Project. This is consistent with the definition of a significant condition adverse to quality which is contained in Para. 3.2.3 of the subject procedure. Although Para. 5.1.4 of SP 1.37 does contain specific criteria to be used when evaluating a deficiency for significance, these criteria are to be considered in terms of whether they represent a condition which may have a serious effect on safety or operability of the Yucca Mountain Project.

It should be noted that NQA-1, 1989, Section 16, "Corrective Action" states: "Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence." In terms of the T&MSS QA Program, SP 1.37 requires that all conditions adverse to quality be evaluated for cause and corrective action to preclude recurrence regardless of whether they are documented on a Quality Finding Report (QFR) or MCAR. Documentation of a deficiency as a MCAR would simply provide a stronger basis for evaluation of the problem for stop work considerations per SP 1.22. Specific data to support the T&MSS management decision to not classify QFRs 001, 013, 014, and 015 as MCARs is as follows:

QFR-001

The auditor concluded that this QFR should have been classified as a MCAR based upon the fact that on average of 39.1% of the training documentation reviewed was deficient and part of the management response indicated that "It can neither be satisfactorily demonstrated nor verified that T&MSS personnel are fully trained to perform quality affecting activities."

It should be noted that QFR-001 also identified that 93% of the Qualification Evaluation forms reviewed were found to be satisfactory. This form is

CAR NO. <u>YM-91-016</u>

DATE: 12/27/90

SHEET: 2 OF 4

CORRECTIVE ACTION REQUEST (continuation sheet)

Response to CAR YM-91-016 (Cont)

the most important of the training/qualification documents since it meets the minimum qualifications as stated in the job position description and has verified completion of the prescribed qualification requirements per Form TMSS/027/4. The management response concerning the satisfactory demonstration and verification that TEMSS are fully trained to perform quality affecting work was intended to convey that investigative action would be necessary to determine the scope of the problems identified. This is supported by a subsequent memo, Nelson to Harper (JHN:WKF:dn:M90-238) dated 9/4/90 which states that while implementing corrective action to QFR-002, three instances of individuals who performed quality affecting activities without proper training on the governing procedures were discovered. This small number illustrates that the majority of the TEMSS personnel performing quality affecting work were properly trained in the procedures governing their activities.

Another important aspect of QFR-001 which supports the original classification of the deficiency as a QFR in lieu of an MCAR is contained in the Discussion section of this QFR. It clearly recognizes that the TEMSS organization was going through a transition from working under the Project Office QA program to the TEMSS QA program and that training/qualification documentation did exist in many cases but on Project Office forms. QFR-001 was issued on 6/4/90 which was shortly after initial issue of the TEMSS QAPD. As such, it is not unreasonable to expect to encounter some "start-up" problems when transitioning to a new program with new implementing procedures.

Based on the above, it is the T&MSS position that the management decision to document the problems with training documentation as a QFR in lieu of a MCAR was appropriate.

QFRs 013, 014, and 015

These QFRs were issued as a result of Surveillance SR-90-006 and are summarized as follows:

QFR 90-013 - Failure to implement SP 2.4

QFR 90-014 - Identification and tagging of equipment requiring calibration.

QFR 90-015 - Failure to perform Performance Audit checks on a quarterly basis.

The auditor concluded that these QFRs should have been MCARs based on a statement in the surveillance report summary which reads: "...it can be

CAR NO. YM-91-016

DATE: 12/27/90

SHEET: 3 OF 4

CORRECTIVE ACTION REQUEST (continuation sheet)

Response to CAR YM-91-016 (Cont)

concluded that the overall program is insufficient to meet the requirements of the T&MSS QAPD. This, in the auditors view, represents a significant breakdown in a portion of the quality assurance program. We again have the "start-up" problem associated with implementing a new QA program. As such, the QA program is still evolving and has not yet reached maturity. This does not constitute a "breakdown."

The responses the the subject QFRs clearly mitigate the significance of these findings. The responses to QFRs 90-013 and 90-014 indicate that SP 2.4 was, in fact, being partially implemented and identified some procedural discontinuities between SP 2.4 and the work instructions being used by the environmental personnel as well as minor problems associated with resource allocation. Although the impact on quality is indeterminate until all investigative action has been performed, it is apparent that the deficiencies had no effect on safety or operability of the Yucca Mountain Project. The response to QFR-015 indicated that the identified deficiency had no adverse impact on quality. The fact that one quarterly performance audit had not been performed since the supplier of this service was not on the Qualified Suppliers List was determined to be a program start-up problem. The quarterly performance audits were resumed in October, 1990 and no further corrective action was deemed necessary. Again, this deficiency had no effect on safety or operability of the Yucca Mountain Project. The conclusion by the surveillance team during surveillance SR-90-006 that the overall program was insufficient to meet the requirements of the T&MSS QAPD was correct but was not intended to imply that there was a breakdown in the QA program since no such statement was made in the report and no MCARs were issued in this area. Again, it is the TEMSS position that the management decision to classify these deficiencies as QFRs was correct.

B. ROOT CAUSE:

The deficiency cited in CAR No. YM-91-016 did highlight the need to provide procedural clarification as to what constitutes a significant condition adverse to quality. This subject was discussed at the Project Quality Assurance Committee meeting which took place on November 30, 1990. The consensus among the Project participant and DOE QA managers was that in order for a deficient condition to be considered significant, there would have to be a direct affect on safety (worker or public) or on operability of the proposed repository. Additional clarification will be provided to SP 1.37 to reflect this consensus opinion and related the significance criteria to the limitations specified. This action will be completed by January 31, 1991.

CAR NO.	TH-	<u>91-(</u>)16
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CORRECTIVE ACTION REQUEST (continuation sheet)

Response to CAR YM-91-016 (Cont)

- C. REMEDIAL ACTION: None Needed - The justifications for the existing actions are adequate.
- D. CORRECTIVE ACTION TO PREVENT RECURRENCE: None

RESPONSE APPROVED: Kent & Johnson for JEHerper	12/27/90
Responsible Manager	Date /

AMENDED RESPONSE TO YMPO CORRECTIVE ACTION YM-91-016

This amended response supersedes the original response to YMPO CAR YM-91-016 in its entirety. The original response was transmitted to the Project Office via letter JBH:KBJ:ci:017, Nelson to Horton, dated 12/27/90.

QFR-001

Upon further consideration and based on a meeting which took place with Jim Harper, T&MSS QA Manager and Project Office QA staff on January 15, 1991, we are in agreement that QFR No. 90-001 should have been classified as a MCAR when it was issued. Accordingly, QFR No. 90-001 has been closed out and reissued as MCAR No. 91-001. Since an acceptable response to the original deficiencies identified in QFR No. 91-001 has been developed and corrective action is presently pending completion by February 15, 1991, no additional management action is deemed necessary with respect to MCAR No. 91-001, at the present time. However, MCAR No. 91-001 will be the document used to track, verify corrective action and close-out the original deficiencies documented on QFR No. 91-001.

QFRs 013, 014, and 015

These QFRs were issued as a result of surveillance SR-90-006 and are summarized as follows:

QFR 90-013 - Failure to implement procedure SP 2.4.

QFR 90-014 - Identification and tagging of equipment requiring calibration.

QFR 90-015 - Failure to perform Performance Audit checks on a quarterly basis.

The auditor concluded that these QFRs should have been MCARs based on a statement in the surveillance report summary which reads: "...it can be concluded that the overall program is insufficient to meet the requirements of the T&mSS QAPD." These deficiencies were considered to be representative of "start-up" problems associated with implementing a new QA program. As such, the QA program is still evolving and has not yet reached maturity. This does not constitute a "breakdown", therefore, issuance of an MCAR was not required.

The responses to the subject QFRs clearly mitigate the significance of these findings. The responses to QFRs 90-013 and 90-014 indicate that SP 2.4 was, in fact, being partially implemented and identified some procedural discontinuities between SP 2.4 and the work instructions being used by the environmental personnel as well as minor problems associated with resource allocation. Although the impact on quality is indeterminate until all investigative action has been performed, it is apparent that the deficiencies had no effect on safety or operability of the Yucca Mountain Project. The response to QFR-015 indicated that the identified deficiency had no adverse impact on quality. The fact that one quarterly performance audit had not been performed since the supplier of this service was not on the Qualified Suppliers List was determined to be a program start-up problem. The quarterly performance audits were resumed in October, 1990 and no further corrective action was deemed necessary. Again, this deficiency had no effect on safety or operability of the Yucca Mountain Project. The conclusion formed by the surveillance team during surveillance

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SR-90-006 that the overall program was insufficient to meet the requirements of the T&MSS QAPD was correct but was not intended to imply that there was a breakdown in the QA program since no such statement was made in the report and no MCARs were issued in this area. It is T&MSS's position that the management decision to classify these deficiencies as QFRs was correct.

It should be noted that NQA-1, 1989, Section 16, "Corrective Action" states: "Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence." In terms of the T&MSS QA Program, SP 1.37 requires that all conditions adverse to quality be evaluated for cause and corrective action to preclude recurrence regardless of whether they are documented on a Quality Finding Report (QFR) or a MCAR.

However, the deficiency cited in CAR No. YM-91-016 did highlight the need to provide procedural clarification as to what constitutes a significant condition adverse to quality. To summarize, the following actions either have been, or will be taken:

Remedial Action

QFR No. 90-001 was closed out based upon the issuance of MCAR No. 91-001. This action was completed on January 18, 1991.

Corrective Action to Preclude Recurrence

The root cause of this deficiency is that SP 1.37 can presently be interpreted to limit significant conditions adverse to quality to those deficiencies that have a serious effect on safety or operability of the Yucca Mountain Project. As such, this limitation is inappropriate for this phase of the Project. SP 1.37 will be revised to remove the limitation and clarify the criteria for determining whether a deficiency represents a "significant" condition adverse to quality. This action will be completed by 2/28/91.

Response Accepted Qual Thank Date 02-25-91

QAR

Response Accepted Other Lugta for Date 2-25-91

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RESPONSIBLE ORGANIZATION	DATE	
PROJECT MANAGEMENT	1/17/91	OFR NoRev MCAR No91-001 Rev 0_

Based upon Yucca Mountain Project Office Corrective Action Request YM-91-016 which was issued as a result of external audit No. 90-08 of TEMSS activities, and as agreed upon during a meeting with Project Office QA staff on January 15, 1991, QFR 90-001, Rev. 1 has been reclassified as MCAR 91-001, Rev. 0. Since an acceptable response to QFR 90-001, Rev. 1 has been developed and QFR 90-001, Rev. 1 is pending completion of corrective action, no additional response to MCAR 91-001 is presently required. Blocks 7, 8, 14, 15, 16, 17, 18, 19, 20, 21, and 26 are as documented on QFR 90-001, Rev. 1 (see attachment):



JEN: EEC: js: M90-11442 WBS \$1.2.9 QA

T&MSS QA

INTEROFFICE MEMO

NOV 0 8 1990

DATE:

November 7, 1990

TO:

J. B. Harper, Manager, 517/T-38

TEMSS Quality Assurance

FROM:

J. H. Nelson, 517/T-04

Project Manager

SUBJECT: Response to Quality Finding Report (QFR) 90-001, Revision /2 /

4port 11/9/90

Enclosed please find our response to the subject QFR. If you have any questions regarding this response, please call Henry Caldwell of my staff at extension 4-7740.

Enclosure: As stated

cc w/encl:

H. H. Caldwell, T-29

D. K. Chandler, T-29

K. O. Gilkerson, T-22

K. A. Hodges, T-22

RESPONSE TO QFR 90-001, REVISION 1 NOVEMBER 6,1990

- 14. IMPACT ON IN-PROCESS OR COMPLETED WORK
 At this time, the impact on in-process or completed work is indeterminant
 for the three recurring deficiencies cited.
- 15. ROOT CAUSE OF THE ADVERSE CONDITION
 Failure to fully implement the committed to corrective actions outlined in Revision 0 of the OFR
- 16. REMEDIAL CORRECTIVE ACTION

 The following are our proposed remedial corrective actions for the three recurring deficiencies cited:
 - A. Issue a revised SP 1.31 which addresses the clarified use of forms, procedure revisions, approval of lesson plans, and time limits on training.
 - B. Hold a formal indoctrination meeting for <u>all</u> TEMSS managers and training coordinators on Revision 2 of the procedure and require reading by all affected TEMSS personnel.
 - C. Perform a review of all T&MSS Participant training files and resolve all deficiencies identified. Those deficiencies that cannot or are not corrected within the course of this review will be documented on a QFR/MCAR.

EXPECTED COMPLETION DATE: 12/30/90

17. CORRECTIVE ACTION TO PREVENT RECURRENCE

We concur that the recurring deficiencies cited are indicitive of a broader root cause. As such we propose to establish and operate a system to monitor and update the training requirements for all TAMSS personnel. This system would be established at the APM/Department level and would be modeled after the one outlined in OP 1.13, Revision O(currently in production).

EXPECTED COMPLETION DATE:

Establishment of a tracking/monitoring system 12/30/90

Review and update of training files for T&MSS personnel; on-going



JHN:HHC:js:M90-11904 WBS \$1.2.9

OA

INTEROFFICE MEMO

T&MSS QA

DEC 26 1990

DATE:

December 20, 1990

TO:

J. B. Harper, Manager

TEMSS Quality Assurance, T-38

FROM:

J. H. Nelson

Project Manager, T-04 1

SUBJECT: Request For Extension - Corrective Actions QFR 90-001, Revision 1.

and QFR 90-009, Revision 1

This is to request an extension to the time limits outlined in the corrective actions statements of the referenced QFRs.

A number of reasons serve as the basis for this request. Primary among these is the need to make further revisions to Standard Practice Procedure SP 1.31, Revision 2, based on operating experience. Input provided from using organizations indicated that an amplification of the qualification and proficiency review processes and clarification of forms usage is warranted.

By copy of this memo, it is requested that an extension be granted for the corrective actions stipulated in QFR 90-001 and QFR 90-009 until February 15, 1991.

cc:

D. K. Chandler, T-29

H. H. Caldwell, T-29

R. O. Gilkerson, T-22

K. A. Hodges, T-22

A. L. Temple, T-38

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	90-001, Rev	. 0	J. Nel	son	1/17/	91
REQUIREMENT SEE CONTINUATION PAGE						
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SIGNIFICANT CONDITION ADVERSE TO	QUALITY					
16 STOP WORK ORDER REQUIRED	☐ YES	© NO		SWO NO		
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COMMENT						
24 CLOSURE		8				
QA STAFF DATE		. QA MANAG	ER		DATE -	
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ORIGINAL

THESE TOTAL AND MANAGEMENT SUFFORT SERVICES WBS: 1.2.9.3 PCG 1 of 1 QA DEFICIENCY REPORTING SYSTEM QA: X						
QUALITY FINDING/MANAGEMENT CORRECTIVE ACTION REPORT						
1 RESPONSIBLE ORGANIZATIO	NC	2 DATE	3		·	
Project Management		10/24/90			_ MCAR No	Rev
4 IDENTIFIED DURING	5 PERSO	ONS CONTACTED		⁶ MANAGER	NOTIFIE	ED/DATE
SR-90-1	See at	tached Rev.	0	J. Nelson	10/24/9)0
7 REQUIREMENT See attached QFR 90-						
8 FINDING/CONDITION ADVER				444 Bar /		
Incomplete committee 90-001, Rev. 0 for o	original	l finding.	to QFK 9U-	001, Rev. U). See attach	ed QFR
9 SIGNIFICANT CONDITION AD	VERSE TO	O QUALITY				
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17 CORRECTIVE ACTION TO P	REVENT I	RECURRENCE				
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18 RESPONSE PREPARED BY			19 MANAG	EMENT APPRO		11/30/30
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20 RESPONSE EVALUATION ACCEPT	ECT		21 QA SŢA	FF KAST	boffee DATE	11/9/98
COMMENT			OA MAI	NAGER #	DATE.	4/9/90
22 VERIFICATION OF CORRECT ACCEPT REJE	ECT		23 QA STA	VF XA	Lockya DATE	1/18/91
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24 CLOSURE			25	1		
OA STAFF K. A. Holy	L DA	TE 1/18/91	_ QA MA	NAGER /	DATE	1-18-91
TRENDING CODE: 2-3 Note: This QFR is closed based upon 155uance of MCAR No. 91-001.						