



Department of Energy
 Yucca Mountain Site Characterization
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WBS 1.2.9.3
 QA

MAR 04 1991

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 Technical Project Officer
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 Site Characterization Project
 Science Applications International Corporation
 The Valley Bank Center, Suite 407
 101 Convention Center Drive
 Las Vegas, NV 89109

EVALUATION OF RESPONSE TO 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 evaluated the response to CAR YM-91-016. The response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to the date. Please send a copy of extension requests to Nita J. Brogan, Science Applications International Corporation, Las Vegas, Nevada.

If you have any questions, please contact Catherine E. Hampton at 794-7973.

Catherine E. Hampton
 Donald G. Horton, Director
 Yucca Mountain Quality Assurance Division

YMQAD:CEH-2426

Enclosure:
 YM-91-016

cc w/encl:
 K. R. Hooks, NRC, Washington, DC
 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-28
 S. W. Zimmerman, NWPO, Carson City, NV

cc w/o encl:
 J. W. Gilray, NRC, Las Vegas, NV

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 WM-11 PDR

FULL TEXT ASCII SCAN

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WASHINGTON, D.C.**

14 CAR NO.: YM-91-016
DATE: 11/27/90
SHEET: 1 OF 2
QA
WBS No.: N/A

CORRECTIVE ACTION REQUEST

1 Controlling Document SP 1.37, Revision 1		2 Related Report No. Audit 90-08	
3 Responsible Organization SAIC		4 Discussed With J. Harper	
10 Response Due 12/27/90	11 Responsibility for Corrective Action J. Harper	12 Stop Work Order Y or N N	

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 serious breakdown in any portion of the quality assurance program.

6 Adverse Condition:
QFR 90-001, Revision 0 and Revision 1, QFR 90-013, 90-014, and 90-015 identified conditions which fulfill the above cited definition but were not identified as significant conditions.
NOTE:
QFR 90-001, Revision 0 and Revision 1 was written to identify an average 39.1 failure rate for training records.
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 Catherine Hampton <i>Catherine Hampton</i>	Date: <u>11/17/90</u>	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <i>James Blaylock</i>	Date: <u>11/21/90</u>
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15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted: QAR _____ Date _____	17 Closure Approved By: OQA _____
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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 TEMSS QAPD."

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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

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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 T&MSS 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 T&MSS 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 T&MSS organization was going through a transition from working under the Project Office QA program to the T&MSS 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 T&MSS 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

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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 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 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 T&MSS 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.

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C. **REMEDIAL ACTION:**

None Needed - The justifications for the existing actions are adequate.

D. **CORRECTIVE ACTION TO PREVENT RECURRENCE:**

None

RESPONSE APPROVED:

Kent B Johnson for JB Harper
Responsible Manager

12/27/90
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 *Richard A. Janak* Date 02-25-91
QAR

Response Accepted *Catherine L. Hempter* Date 2-25-91
OQA