



Department of Energy

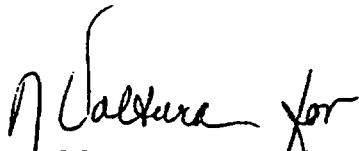
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QA

Carl P. Gertz, Project Manager, YMP, NV
ATTN: Roxanne Edwards

RESPONSE TO CORRECTIVE ACTION REPORT (CAR) 89-001

Enclosed is the response to CAR 89-001. If you have any questions regarding the enclosed, please contact Catherine E. Hampton of my staff at 794-7973.


Donald G. Horton, Director
Quality Assurance Division
Yucca Mountain Project Office

YMP:CEH-1470

Enclosure:
CAR 89-001

cc w/encl:

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PDR WASTE
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ADD: J Kennedy

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CORRECTIVE ACTION REQUEST (CAR)

Part I

CAR No: 89-001

Condition:

See Enclosure 1

Initiated By: Catherine Hampton Date: 12-14-89

Reviewed By: N. Valdura Date: 12/14/89

Approved By: Catherine Hampton Date: 12/15/89

Part II

Response Assigned To: C. Hampton Response Required By: 1/8/90

Corrective Action:

See attached

Prepared By: C. Hampton Date: 1/5/90
Catherine Hampton 1/5/90

Part III

Approvals:

Branch Chief: _____ Date: _____ PQM: _____ Date: _____

Verification:

Verified By: _____ Date: _____

ENCLOSURE

A sample of 60 Severity Level 1 & 2 Standard Deficiency Reports (SDRs) that have been issued on the Project were reviewed to determine compliance to Yucca Mountain Project Office (Project Office) Quality Management Procedure QMP-16-03, Revision 0 or 1, as applicable. The following SDRs were reviewed:

001	003	006	007	018	019	055	070	071	073	089	119	120
121	122	123	124	125	127	128	170	171	172	179	224	225
227	228	230	232	233	235	237	238	241	243	250	252	253
256	258	262	286	296	298	341	353	357	367	368	370	371
372	375	376	377	378	379	408	426					

NOTE: Of the SDRs reviewed, numbers 001 through 298 were issued when QMP 16-03, Revision 0 was in effect and numbers 341 through 426 were issued when Revision 1 was in effect. The effective date for QMP-16-03, Revision 1 was June 5, 1989.

From this sample, 22 instances of noncompliance with QMP-16-03 were identified as detailed below.

1. When stating requirements, SDR 055 did not note the document violated with revision and paragraph number as required by QMP-16-03, Revision 0.
2. SDRs 019, 235 and 368 did not quote or paraphrase the requirement violated (i.e. the deficiency identified in Block 9 was not a violation of the stated requirement) as required by QMP-16-03, Revision 0 and 1.
3. SDRs 055, 121, 123, 256, 286, 367, 370, 371, 372, 375, 376, 377, 378 and 379 were reviewed and approved for issuance without all of the required boxes in block 10 of these SDRs being checked to designate recommended actions based on the severity level of each SDR. This designation of action is required by QMP-16-03, Revisions 0 and 1. As a result of not designating the proper recommended actions in Block 10 (i.e. Remedial/Investigative/Corrective), some of the actions required by the procedure to correct the identified deficiencies were not adequately addressed or were not addressed whatsoever in the responses to these SDRs. It should be noted that SDRs 121, 286 and 378 appear to have addressed necessary action in their responses although it was not required by Block 10. However, SDRs 055, 123 and 256 do not appear to address all procedurally required action although the responses to these SDRs have been accepted and the SDRs have been closed. SDRs 367, 370, 371, 372, 375, 376 and 377 also did not adequately address required action in their responses, however, they were not accepted and amended responses have been requested.
4. The documented responses to SDRs 006, 073, 224 and 353 were reviewed and accepted although one or more of the actions checked in Block 10 (remedial/investigative/corrective) were not addressed by the responses as required by QMP-16-03, Revisions 0 and 1. Although all of these SDRs except #353 have been closed, there is no indication that all of the actions required by Block 10 of these SDRs have been completed.

The results of the above sample indicate pervasive areas of noncompliance in implementation of the Standard Deficiency Reporting System that may have negatively impacted the quality of programs, procedures or work activities and caused the following significant conditions adverse to quality to be identified:

1. Project Office Supervisory and Management personnel have approved SDRs for issuance and approved acceptance of SDR responses when a number of these SDRs did not comply with the requirements of Project Office Management Procedure QMP-16-03 in the areas of documenting deficiencies, designating recommended actions and evaluating responses.
2. Project Office Supervisory and Management personnel have reviewed and approved the closure of a number of SDRs that do not indicate in their responses that all of the appropriate actions necessary to investigate, correct and prevent recurrence of identified deficiencies have been completed. These appropriate actions are designated in Block 10 of each SDR based on severity level and the scope of deficiencies.

These significant conditions should be fully investigated for all severity level 1 and 2 SDRs in order to identify each instance of noncompliance, determine its impact on quality, and provide for the identification of appropriate corrective action.

Response to CAR 89-001

In response to the deficiencies cited in CAR 89-001, Project Office QA will perform the following remedial, investigative and corrective actions to prevent recurrence.

Project Office QA will conduct a review of all Level 1 and 2 Standard Deficiency Reports (SDRs). The review will include an examination of all SDRs to ensure the following:

- o Block 8 of SDRs correctly quoted or paraphrased the requirement violated.
- o Block 10 of SDRs were marked to designate recommended actions based upon the severity level. If SDRs did not correctly designate actions, responses were evaluated to determine if procedurally required actions were addressed by the resposdee.
- o Required actions designated in Block 10 were addressed in response prior to acceptance.

Upon completion of the review, all noncompliances will be evaluated for impact on quality. Corrective actions will be taken based upon assessment of impact. Actions necessary to rectify impact on quality will be incorporated into this CAR. Closure of this CAR will be contingent upon correction of all quality-impacting noncompliances identified.

Cause of this condition is a lack of management attention to ineffective training for QMP 16-03 Revision 0 and 1. In addition, the QA organization has failed to identify and correct weaknesses within the Standard Deficiency Reporting System QMP 16-03 Revision 1.

Based upon noncompliances identified within the investigation stage, Project Office QA will compile recommended procedural changes. QMP 16-03 Revision 1 will be revised to provide an effective corrective action system.

As a method to prevent recurrence, all Project Office personnel will be required to attend training on the revised Standard Deficiency Reporting System. This training will provide procedural requirements in addition to guidance on the documentation of SDRs and methods for effective evaluation.

Effective Date

SDR Investigation and Impact Assessment	2/28/90
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Corrective Action on Quality-Impact Noncompliances Procedure Revision Training	5/31/90
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