



CHANGE NOTICE

CN No.: 16.0-3-1

Effective Date: 12/5/91

Affected Document: 033-YMP-QP 16.0, "Corrective Action"

J. Blink

Prepared by:

N/A

Approved by: (Technical Area Leader)

Date

Roger S. Monks 12/4/91
Approved by: (YMP QA Manager) Date

W. L. L. Lame 12/4/91
Approved by: (YMP Leader) Date

Training Required: Yes ☒ No ☐Major Changes ☒Minor Changes ☐

Reason for Change:

Consolidate QA Action Item List and QA Status Report. Disseminate information pertaining to significant conditions adverse to quality and lessons learned.

1. Replace page 4 of 8 and 7 of 8 (See attached)

Section 16.0.5.6, new title.

Section 16.0.5.6.1, new first paragraph.

New Section added, 16.0.5.6.2 "TASK LEADERS AND OTHER MANAGERS"

2. Exhibit B has been deleted from this procedure.

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

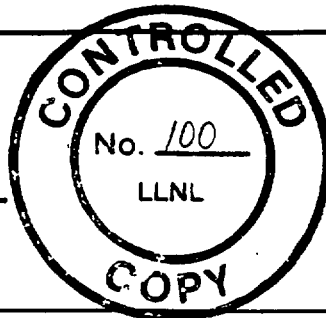
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YUCCA MOUNTAIN PROJECT



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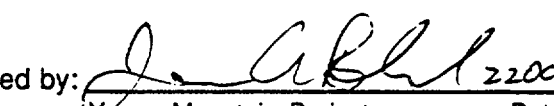
Subject:

CORRECTIVE ACTION

Training Required: Yes ☒ No ☐

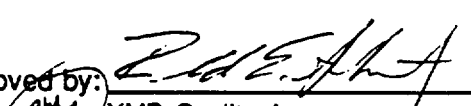
Comment:

Approved by:


 Yucca Mountain Project
 Leader

Date

Approved by:


 YMP Quality Assurance
 Manager

Date

COMPLETE REWRITE

16.0.1 PURPOSE

This procedure describes the method for documenting, reporting, monitoring, implementing and verifying corrective action for conditions adverse to quality that are not related to items.

16.0.2 SCOPE

This procedure applies to all LLNL-YMP activities.

16.0.3 DEFINITIONS

See Tab C, "Terms and Definitions", for definitions that particularly apply to this procedure.

Corrective Action
 Condition Adverse to Quality
 Significant Condition Adverse to Quality

The conditions that can produce a CAR are summarized in Exhibit C.

16.0.4 RESPONSIBILITIES

The Task Leader of the affected activity is responsible for implementing corrective action, including, where necessary, corrective action to prevent recurrence.

The YMP Leader is responsible for reviewing and approving corrective actions accomplished in accordance with this procedure.

The Quality Assurance Organization is responsible for initiating Corrective Action Requests (CARs) and monitoring the implementation of corrective action. The QA Organization is also responsible for verifying the adequacy and effectiveness of the corrective action.

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16.0.5 PROCEDURE

16.0.5.1 Initiation and Distribution of Corrective Action Reports

QA ORGANIZATION: 16.0.5.1.1 Initiates a CAR, Exhibit A, when a condition adverse to quality is identified. CARs may result from any of the following:

- a. An adverse trend identified as a result of trend analysis.
- b. An Adverse Finding not related to an item. Adverse Findings may result from Audits or Surveillances.
- c. Repeated nonconformances of engineered items or M&TE. See Procedure 033-YMP-QP 15.0, "Nonconforming Items". The condition of repeated nonconformances is the trigger for the CAR.
- d. Other adverse conditions reported to the QA Manager.

16.0.5.1.2 Assigns a sequential number (starting with CAR-LLNL-001), and completes items 1 through 9 of the CAR.

QA MANAGER

16.0.5.1.3 Completes items 10 through 14. Items 10, 11, and 12 are coordinated with the YMP Leader prior to issuing the CAR. If the QA Manager approves the CAR, the QAM signs item 14 and documents in item 13 whether the identified adverse condition is "Significant to Quality" or "Not Significant".

If the QA Manager disapproves the recommended action, the disapproval and basis for that decision are documented and attached as a continuation of the CAR. The CAR is returned to the originator who will review the recommended action and, if appropriate, resubmit the CAR to the QAM.

16.0.5.1.4 Distributes copies of the CAR to the Project Leader, Associate Project Leader, Assistant Project Leaders and to the cognizant Technical Area Leader and Task Leader.

16.0.5.2 Tracking of CARs

QA ORGANIZATION: Enters the CAR on the QA Action Item List, Exhibit B, and opens a file for collection of documents related to the CAR.

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16.0.5.3 Completion of Corrective Action

COGNIZANT TASK LEADER or ASSIGNED INDIVIDUAL: 16.0.5.3.1 Completes items 15 through 17 of the CAR indicating proposed corrective action and a recommended date of completion.

For adverse conditions assessed to be "Significant to Quality" in Item 13, the completion of the following documentation is required:

- Extent of the deficiency
- Root Cause
- Remedial Action
- Corrective Action to Prevent Recurrence

These items may be documented in Item 15 of the form or on an attachment.

Adverse conditions assessed as "Not Significant" require the completion of the following documentation:

- Remedial Action
- Corrective Action to Prevent Recurrence

These items may be documented in Item 15 of the form or on an attachment.

YMP LEADER: 16.0.5.3.2 Reviews the proposed corrective action. If acceptable, approval can be documented by entering "approved" in item 18. If not acceptable, the YMP Leader enters the modified corrective action and completion date in item 18. The YMP Leader then signs and dates in item 19.

QA MANAGER 16.0.5.3.3 Indicates concurrence with the proposed corrective action and completion date by signing in item 20. If the corrective action and completion date are unacceptable, the QAM and YMP Leader resolve the disagreement.

16.0.5.4 Verification

QA ORGANIZATION: 16.0.5.4.1 Verifies completion and adequacy of the specified corrective action. If acceptable, items 21 and 22 of the CAR are completed.

QA MANAGER 16.0.5.4.2 Indicates closure of the CAR by signing item 23. A copy of the completed CAR is sent to the Project Leader, Associate Project Leader, Assistant Project Leaders, the cognizant Technical Area Leader and Task Leader and to the Director, QA Division - YMP.

16.0.5.5 Changes to In-Progress CARs

COGNIZANT TASK LEADER OR OTHER INDIVIDUAL: 16.0.5.5.1 Documents proposed changes to CARs (such as changes in corrective action or completion date) by sending a memorandum to the YMP Leader/QA Manager for approval.

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YMP LEADER AND QAM: 16.0.5.5.2 Review proposed changes. Approval is documented by their signatures on the memorandum requesting the change or on attachment.

16.0.5.6 QA Action Item List

QA ORGANIZATION: 16.0.5.6.1 The status of open CARs is monitored until satisfactory resolution through the use of a "QA Action Item List" which lists the status of CARs, NCRs, YMPO CARs, and delinquent receipt acknowledgements. The QA Action Item List also notifies affected managers of significant conditions adverse to quality and lessons learned.

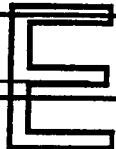
This list is issued to the Project Leader, Associate Project Leader, Assistant Project Leaders and all Technical Area Leaders and Task Leaders.

TASK LEADERS AND OTHER MANAGERS 16.0.5.6.2 Consider the applicability of significant conditions adverse to quality and lessons learned to their areas of responsibility.

16.0.6 RETAINED DOCUMENTATION

QA ORGANIZATION: Forwards completed CARs and supporting documentation, and weekly Action Item Lists, as QA Records to the Local Records Center in accordance with 033-YMP-QP17.0.

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CORRECTIVE ACTION REPORT			1. CAR No. : CAR-LLNL-	
2. Controlling Document:		3. Related Report No.:		
4. Responsible Organization:		5. Discussed with:		
6. Requirement:				
				
7. Adverse Condition:				
				
8. Recommended Action(s):				
				
9. Initiator:				
Signature Date				
10. Response Due:		11. Responsibility for Corrective Action:		12. Stop Work Order: Y or N
13. Severity: Significant to Quality ☐ Not Significant ☐		14. Approved By: _____ Date: _____ OA Manager: _____		
15. Proposed Corrective Action:				
				
16. Proposed Date To Complete Corrective Action:			17. Signature of Responsible Individual: _____ Date: _____	

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EXHIBIT A
CORRECTIVE ACTION REPORT

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CORRECTIVE ACTION REPORT (Continued)				
18. Approval or Modification of the Proposed Corrective Action and Completion Date:				
L P				
19. YMP Leader:		20. QA Manager:		
_____ Signature		_____ Signature		
_____ Date		_____ Date		
21. Verification of Corrective Action:				
M A S				
22. Corrective Action Completed and Accepted:		23. Closure Approved By:		
QA Org.: _____ Date: _____		QA Mgr.: _____ Date: _____		

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EXHIBIT A
CORRECTIVE ACTION REPORT (Cont.)

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**EXHIBIT B HAS BEEN
DELETED FROM THIS PROCEDURE**

