



**Department of Energy**  
Office of Civilian Radioactive Waste Management  
Yucca Mountain Site Characterization Office  
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APR 04 1995

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VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-95-023 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YM-ARP-95-02 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR (SCPB: N/A)

The YMQAD staff has verified the corrective action to CAR YM-95-023 and determined the results to be satisfactory. As a result, the CAR is considered closed.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Kenneth O. Gilkerson at 794-7738.

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2742

Enclosure:  
CAR YM-95-023

cc w/encl:  
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**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

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**CORRECTIVE ACTION REQUEST**

1 Controlling Document OCRWM QARD DOE/RW-0333P, Revision 1		2 Related Report No. YM-ARP-95-02	
3 Responsible Organization M&O		4 Discussed With R. Ruth/R. Justice/D. Franks	
5 Requirement: DOE/RW-0333P, Revision 1, QARD Section 5.2.2D requires the implementing documents include: "Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished."  M&O Procedure QAP-5-1, Revision 3, Attachment IV, Paragraph 5 requires that the author of procedures "...include or reference quantitative or qualitative criteria such that the person performing the QAP steps or reviewing and approving the results of the QAP can determine that activities controlled by the QAP have been satisfactorily accomplished."			
6 Adverse Condition: Contrary to the above requirements, qualitative and quantitative criteria have not been established in all M&O procedures. Specifically procedures QAP-3-8, Specifications, and QAP-3-10, Drawings, do not require that qualitative and quantitative acceptance criteria be established for the activities governed by these procedures. Nor is the criteria effectively established in QAP 16.1.7 (see related CAR YM-95-024 for details) <i>and 1-7-95</i>  Although the criteria in QARD Section 5.0 is not driven by QAPs 3-8 and 3-10 to be included in specifications and drawings, the YMQAD QAP 6.2 reviews of design products being released by the M&O assure that the appropriate criteria have been met. There should be no impact at this time on the past drawings and specifications released for construction.			
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
13 Response Due Date: 20 Working Days From Issuance			
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination			
12 Recommended Actions: 1) Revise QAPs 3-8 and 3-10 as necessary to meet QARD Section 5.0 requirements. 2) Review other procedures for same or similar conditions. 3) Review to determine that QAPs 5.1 and 5.2 appropriately require that the QARD Section 5.0 requirements are adequately imposed on the activities governed by the procedures.			
7 Initiator Kenneth O. Gilkerson <i>Kenneth O. Gilkerson 2-1-95</i>		14 Issuance Approved by QADD <i>[Signature]</i> Date <u>2-3-95</u>	
15 Response Accepted QAR <i>[Signature]</i> Date <u>3-9-95</u>		16 Response Accepted QADD <i>[Signature]</i> Date <u>3-15-95</u>	
17 Amended Response Accepted QAR <i>[Signature]</i> Date <u>3/6</u>		18 Amended Response Accepted QADD <i>[Signature]</i> Date <u>3/6</u>	
19 Corrective Actions Verified QAR <i>[Signature]</i> Date <u>3/31/95</u>		20 Closure Approved by QADD <i>[Signature]</i> Date <u>4-4-95</u>	

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

1. Corrective Action Response for CAR# YM-95-023

DISCUSSION

The condition identified addresses the establishment of qualitative and quantitative criteria in M&O procedures. The M&O procedure which addresses the development of procedures (QAP-5-1) require the author to "include or reference appropriate qualitative or quantitative criteria such that the person performing the QAP steps or reviewing and the results of the QAP can determine that the activities controlled by the QAP have been satisfactorily accomplished". Additionally, Review Criteria Q-5 (QAP-5-1, Attachment V) states "Does the procedure contain appropriate quantitative and qualitative acceptance criteria for determining that prescribed processes have been satisfactorily accomplished?" This review criteria is applied to every procedure review. QAP-5-2 (Preparation of M&O Implementing Line Procedures) references QAP-5-1 for compliance with format and review criteria.

The next level of addressing quantitative and qualitative acceptance criteria is in those developed documents that establish requirements which must be verified to ensure proper compliance with the document. These documents are the products of approved procedures and take the form of specifications or drawings. All other work is performed by procedures which have to meet the requirements identified in the paragraph above.

The M&O procedures which address specifications and drawings are QAP-3-8 and QAP-3-10, respectively. These procedures were developed under QAP-5-1 and as such we applied the above referenced criteria to their development. The products produced under QAP-3-8 and QAP-3-10 also are required to specify the appropriate acceptance criteria. These products are subjected to review and Review Question #11(QAP-3-8) and #6 (QAP-3-10) asks "Are the acceptance criteria incorporated in the specification/drawing sufficiently detailed and specific to allow verification that design requirements have been satisfactorily accomplished?" Although this wording does not specifically say "quantitative or qualitative criteria" the result is the same. One cannot verify accomplishment of requirements unless they are specified in sufficient detail to facilitate documented compliance.

A. Remedial Action:

Initiate Procedure Action Requests per QAP-5-1 to have procedures QAP-3-8 and QAP-3-10 specifically address "quantitative and qualitative acceptance criteria" in the next scheduled revision.

3/7/95 LV.QA.BRJ.03/95-085

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B. Extent of Deficiency:

All M&O procedures have been reviewed by M&O Quality Assurance to determine if (1) they are in compliance with the M&O procedures for their development (the revision in effect at the time of their development), (2) they generate documents which contain requirements which have to be verified for compliance, and (3) if so, do similar conditions as identified in the CAR exist? QAP-3-8 and QAP-3-10 were the only procedures identified which need to be modified to explicitly say that "quantitative and qualitative acceptance criteria" was being addressed in the products produced by those respective procedures (reference the Discussion above). QAP-16-1 was being revised (Revision 2, effective 2/27/95) at the time of the audit and now addresses the concern of the auditor by including the necessary criteria. The M&O considers that the remaining procedures contain the necessary criteria for proper implementation.

C. Root Cause Determination:

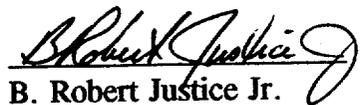
Not Required

D. Corrective Action to Preclude Recurrence:

Since past products have been determined acceptable and the addition of the terms "qualitative and quantitative" does not alter the intent or application of the wording which is already in the M&O procedures, no additional actions are necessary beyond those described in the remedial action.

2. The Procedure Action Requests for QAP-3-8 and QAP-3-10 will processed through QA approval by March 24, 1995. The individual assigned responsibility for this action is Robert Justice.

3.

  
B. Robert Justice Jr.

3/7/95  
Date

**CAR YM-95-23**  
**Corrective Action Verification**

Verification of the Corrective Action commitments to CAR YM -95-023 were performed by K. O. Gilkerson (YMQAD) on 3-27 through 3-30, 1995. The following actions were taken:

1. QAP-16-1 Revision 2 was reviewed to assure that appropriate quantitative and qualitative criteria was incorporated into the procedure. This action was verified as satisfactory.
2. Procedure Action Requests (PAR) generated for QAPs 3-8 and 3-10 dated 3/13/95 were reviewed. These requests identified that changes to the procedures to address the CAR conditions would be completed on the next scheduled revision to the procedure which was anticipated to be 5/31/95. They were requested by Robert Justice on 3/9/95 and approved by George Carruth and Ron Ruth. Although the procedures have not yet been revised, the PARs have initiated the formal change process and the CAR will be closed based on this action. The accepted CAR response commitment was to process these PARs by 3/24/95. This has been done.

NOTE: A followup surveillance to the M&O Procedure Change Process may be performed to determine its effectiveness of getting procedures changed based on PARs being processed.

3. Additionally procedures QAP-3-9, QAP-6-1 and NLP-2-0 (current revisions) were independently selected and reviewed for appropriate qualitative and quantitative criteria (QARD Section 5) and found to be acceptable. Based on this, it is believed that the extent of deficiency investigation was satisfactory.
4. It is recommended that CAR YM-95-023 be closed.

  
3/31/95