



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608

SEP 28 1995

L. Dale Foust
Technical Project Officer
for Yucca Mountain Site
Characterization Project
TRW Environmental Safety Systems, Inc.
101 Convention Center Drive, Suite P-110
Las Vegas, NV 89109

EVALUATION OF AMENDED RESPONSE TO DEFICIENCY REPORT (DR)
YMQAD-95-D-004 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION'S (YMQAD) AUDIT YM-ARP-95-16 OF THE CIVILIAN RADIOACTIVE
WASTE MANAGEMENT SYSTEM MANAGEMENT AND OPERATING CONTRACTOR
(SCP: N/A)

The YMQAD staff has evaluated the amended response to DR
YMQAD-95-D-004. The amended 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 that date.

If you have any questions, please contact either Robert B.
Constable at 794-7945 or John R. Matras at 794-7197.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4708

Enclosure:
DR YMQAD-95-D-004

~~cc w/encl:~~

J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. A. Wood, HQ (RW-14) FORS
R. L. Strickler, M&O, Vienna, VA
Richard Jiu, M&O, Las Vegas, NV
R. P. Ruth, M&O, Las Vegas, NV

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

8 Performance Report
 Deficiency Report
NO. YM-QAD-95-D-004
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
QARD and QAP 2-0, "Control of Activities." 2 Related Report No.
YM-ARP-95-16

3 Responsible Organization:
CRWMS M&O 4 Discussed With:
Hugh Benton, Tom Doering

- 5 Requirement/Measurement Criteria:
1. QARD Para. 2.2.3.F "...quality assurance controls (grading) shall be applied to the degree commensurate with the 1) function or end use of the item, 2) consequence of failure..."
 2. QARD Para. 3.1 "This section provides requirements to ensure that designs (from conceptual through final) are defined, controlled, and verified."
 3. QAP-2-0 Para. 5.2.A.2 "If the activity must proceed prior to the item being evaluated in accordance with QAP-2-3, assume the item will be subject to QARD requirements."

6 Description of Condition:

1. None of the design analysis that will be resulting from waste package Advanced Conceptual Design activities will be subject to QARD requirements based on CRWMS M&O QAP-2-0 Evaluation forms. The rationale for this determination is contained on QAP-2-0 Evaluation forms and does not reflect consideration of the requirements of QARD Paras. 2.2.3.F and 3.1. The same Evaluation forms are being used for the next phase of Waste Package design activities, Preliminary Design.
2. Shielding analyses have been completed for the waste package transporter. The QAP-2-0 Evaluation form (BB0000000-01717-2200-00026) indicates the analyses are not subject to QARD controls because, in part, the transporter is not on the Q-List or otherwise subject to the QARD. A QAP-2-3 Evaluation has not yet been completed for the transporter.

7 Initiator *John R Matras for* Date *8/2/95* 9 QA Review *John R Matras*
Marc J. Meyer QAR *John R Matras* Date *8/2/95*

10 Response Due Date 20 Working Days From Issuance 11 QA Issuance Approval
QAR (PRI)/AOQAM (DR) *PR Powell for* Date *8.2.95*

12 Remedial Actions:

13 Remedial Action Response By: *SEE ATTACHED PAGES* Date *8/31/95* 14 Remedial Action Due Date
SEE ATTACHED PAGES Date

15 Remedial Action Response Acceptance *PR Powell for* Date *8/31/95* 16 PR Verification/Closure
QAR *SEE ATTACHED PAGES* Date

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DEFICIENCY REPORT

17 Recommended Actions:
Update evaluation forms as appropriate.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

<p>21 Response by: <i>ps</i> <i>8/31/95</i> See Attached Pages Date</p>	<p>22 Corrective Action Completion Due Date: <i>ps</i> <i>8/31/95</i> See Attached Pages Date</p>
<p>23 Response Accepted <i>ps</i> <i>8/31/95</i> QAR See Attached Pages Date</p>	<p>24 Response Accepted <i>PRC</i> <i>9/15/95</i> AOQAM SEE ATTACHED PAGES Date</p>
<p>25 Amended Response Accepted QAR Date</p>	<p>26 Amended Response Accepted AOQAM Date</p>
<p>27 Corrective Actions Verified QAR Date</p>	<p>28 Closure Approved by: AOQAM Date</p>

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
QARD and QAP 2-0, "Control of Activities."

2 Related Report No.
YM-ARP-95-16

3 Responsible Organization:
CRWMS M&O

4 Discussed With:
Hugh Benton, Tom Doering

5 Requirement/Measurement Criteria:

1. QARD Para. 2.2.3.F "...quality assurance controls (grading) shall be applied to the degree commensurate with the 1) function or end use of the item, 2) consequence of failure..."
2. QARD Para. 3.1 "This section provides requirements to ensure that designs (from conceptual through final) are defined, controlled, and verified."
3. QAP-2-0 Para. 5.2.A.2 "If the activity must proceed prior to the item being evaluated in accordance with QAP-2-3, assume the item will be subject to QARD requirements."

6 Description of Condition:

1. None of the design analysis that will be resulting from waste package Advanced Conceptual Design activities will be subject to QARD requirements based on CRWMS M&O QAP-2-0 Evaluation forms. The rationale for this determination is contained on QAP-2-0 Evaluation forms and does not reflect consideration of the requirements of QARD Paras. 2.2.3.F and 3.1. The same Evaluation forms are being used for the next phase of Waste Package design activities, Preliminary Design.
2. Shielding analyses have been completed for the waste package transporter. The QAP-2-0 Evaluation form (BB000000-01717-2200-00026) indicates the analyses are not subject to QARD controls because, in part, the transporter is not on the Q-List or otherwise subject to the QARD. A QAP-2-3 Evaluation has not yet been completed for the transporter.

7 Initiator

Marc J. Meyer

John R Matras Jr
Date 8/2/95

9 QA Review

QAR

John R Matras
Date 8/2/95

10 Response Due Date

20 Working Days From Issuance

11 QA Issuance Approval

QAR (PR)/AOQAM (DR)

[Signature]
Date 8.2.95

12 Remedial Actions:

SEE RESPONSE ON P.3 OF 3

13 Remedial Action Response By:

Date 8/30/95

14 Remedial Action Due Date

OCTOBER 6, 1995

Date

15 Remedial Action Response Acceptance

QAR

John R Matras
Date 8/31/95

16 PR Verification/Closure

QAR

N/A

Date

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DEFICIENCY REPORT

17 Recommended Actions:
Update evaluation forms as appropriate.

18 Investigative Actions:
SEE RESPONSE ON P. 3 OF 3

19 Root Cause Determination:
SEE RESPONSE ON P. 3 OF 3

20 Action to Preclude Recurrence:
SEE RESPONSE ON P. 3 OF 3

21 Response by: <i>[Signature]</i> Date <i>8/30/95</i>	22 Corrective Action Completion Due Date: <i>OCTOBER 6, 1995</i>
23 Response Accepted: QAR <i>John R Matras</i> Date <i>8/31/95</i>	24 Response Accepted: AOQAM <i>[Signature]</i> Date <i>9-5-95</i>
25 Amended Response Accepted: QAR <i>John R Matras</i> Date <i>9/26/95</i>	26 Amended Response Accepted: AOQAM <i>[Signature]</i> Date <i>9/28/95</i>
27 Corrective Actions Verified: QAR _____ Date _____	28 Closure Approved by: AOQAM _____ Date _____

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PR/DR CONTINUATION PAGE

Continuation of Block 12 (Remedial Actions):

1. All Waste Package Development Department QAP-2-0 evaluations will be reviewed and revised as necessary, to insure that QARD control of activities related to MGDS Q-List items is applied properly.
2. Waste Package Development Department activities which include scoping analyses will be reevaluated to determine QARD applicability.

Continuation of Block 18 (Investigative Actions):

1. All Waste Package Development Department QAP-2-0 evaluations have been reviewed and revised as necessary to insure proper QARD control of activities related to MGDS Q-List items.
2. Waste Package Development Department activities which include scoping analyses have been reevaluated to determine QARD applicability.
3. A review of QAP-2-0, Control of Activities, REV 02, reveals that further clarification of what constitutes being "related" to an item on the WAST/MGDS Q-List would be helpful to the user of QAP-2-0. The scope of QAP-2-0 shall meet QARD requirements addressing scoping analyses. A Procedure Action Request for QAP-2-0 will be submitted which will expand on these recommendations.
4. The shielding analysis in question will be evaluated to determine whether its validity is impacted by the revised QAP-2-0 evaluation.

Continuation of Block 19 (Root Cause Determination):

No root cause determination based on investigative actions.

Continuation of Block 20 (Action to Preclude Recurrence):

1. All applicable QAP-2-0 evaluations have been revised to reflect that activities which include scoping analyses will be subject to QARD control. This action will preclude the recurrence of this deficiency.

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WASHINGTON, D.C.

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QA: L

PR/DR CONTINUATION PAGE

Continuation of Block 12 (Remedial Actions):

1. All Waste Package Development Department QAP-2-0 evaluations will be reviewed and revised as necessary, to insure that QARD control of activities related to MGDS Q-List items is applied properly.

2. Waste Package Development Department activities which include scoping analyses will be reevaluated to determine QARD applicability.

Continuation of Block 18 (Investigative Actions):

1. All Waste Package Development Department QAP-2-0 evaluations have been reviewed and revised as necessary to insure proper QARD control of activities related to MGDS Q-List items.

2. Waste Package Development Department activities which include scoping analyses have been reevaluated to determine QARD applicability.

3. A review of QAP-2-0, Control of Activities, REV 02, reveals that further clarification of what constitutes being "related" to an item on the WAST/MGDS Q-List would be helpful to the user of QAP-2-0. The scope of QAP-2-0 shall meet QARD requirements addressing scoping analyses. A Procedure Action Request for QAP-2-0 will be submitted which will expand on these recommendations.

4. The shielding analyses in question have not been signed off to indicate completion and have been stopped indefinitely due to budget constraints. As a result of this, no direct or indirect design input will result from the shielding analyses.

Continuation of Block 19 (Root Cause Determination):

No root cause determination based on investigative actions.

Continuation of Block 20 (Action to Preclude Recurrence):

1. All applicable QAP-2-0 evaluations have been revised to reflect that activities which include scoping analyses will be subject to QARD control. This action will preclude the recurrence of this deficiency.

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I. Description of Activity (by task, as necessary)

Activity Title (See Description block below)	Document Identifier (including Revision No.) BB0000000-01717-2200-00026 REV 01	Date 8/21/95
<p>Description:</p> <p>Activity Title: Perform Criticality, Thermal, Structural, and Shielding Scoping Analyses SCPB: N/A</p> <p>This activity covers the work required to conduct criticality, thermal, structural, and shielding scoping analyses for the purpose of investigating variations from baseline configurations or other similar purposes. Results of the analyses will be used to assess the feasibility of alternative configurations, and to respond to internal and external requests for information.</p> <p>This activity is related to items on the MGDS Q-List, however, the products produced by this activity will not be used as qualified input into products subject to QARD requirements (i.e., QA specifications, QA drawings, QA analysis, etc.) without being identified as unverified in accordance with the M&O QA program.</p> <p>A scoping analysis may involve developing analytical capability or testing an analytic approach. Unqualified software (or software for which verification and validation activities have not been completed) may be used for these activities.</p> <p>Result of QA Assessment: Subject to QARD Controls; Applicable as identified in Block III</p>		

Activity Evaluation (Continued)

Document Identifier (including Revision No.)
BB0000000-01717-2200-00026 REV 01

II. Evaluation of Activity

- | | | |
|--|-------------------------------------|--------------------------|
| <p>1. Is the activity related to an item listed on the WAST/MGDS Q-list or an item otherwise assumed to be subject to QARD requirements (e.g., design, procurement, construction, fabrication, production, handling, packaging, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, decontamination, dismantling, decommissioning, permanent closure)?</p> | Yes | No |
| | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Rationale:

The activity is related to an item on the MGDS Q-List and is subject to the QARD requirements listed on page 3. The activity is not subject to Design Control procedures because the activity will not be used to provide input to items on the Q-List or an item otherwise subject to QARD requirements. Internal and external requests for preliminary and scoping information produce data/results that will not be considered qualified. Results of this activity may not be used as qualified inputs, and when used, must be identified as unqualified data/results per applicable procedure.

- | | | |
|--|--------------------------|-------------------------------------|
| <p>2. Is the activity related to site characterization sample collection or analysis of data used to support performance confirmation or performance assessment?</p> | | |
| | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

Rationale:

This activity is not related to site characterization sample collection or analysis of data used to support performance confirmation or performance assessment.

- | | | |
|---|--------------------------|-------------------------------------|
| <p>3. Can the activity adversely impact the waste isolation function of the natural or engineered barriers or impact site characterization results (for MGDS only)?</p> | | |
| | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

Rationale:

This activity cannot adversely impact the waste isolation function of the natural or engineered barriers or impact site characterization results.

- | | | |
|---|-------------------------------------|--------------------------|
| <p>4. Is the activity (or does the activity include) QARD-required support (e.g. training, procedure development, document control, records management, QA functions, etc.) of other activities subject to QARD requirements?</p> | | |
| | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Rationale:

This activity may include QARD-required support of other activities subject to QARD requirements, such as document control and records management.

If the answer to any of the above questions is "yes," the activity is subject to QARD requirements

Activity Evaluation
(Continued)

Document Identifier (including Revision No.)
BB0000000-01717-2200-00026 REV 01

III. Application of Controls (Selection of Procedures for work subject to QARD requirements per Section II)

QARD Section		Applicable Procedures (Revision No. Not Required)
1	Organization	QAP-1-0*, 1-1*
2	QA Program	QAP-2-0*, 2-1*, 2-2*
3	Design Control	
4	Procurement Document Control	
5	Implementing Documents	
6	Document Control	
7	Control of Purchased Items and Services	
8	Identification and Control of Items	
9	Control of Special Processes	
10	Inspection	
11	Test Control	
12	Control of Measuring and Test Equipment	
13	Handling, Storage, and Shipping	
14	Inspection, Test, and Operating Status	
15	Nonconformances	
16	Corrective Action	0.02 8-21-95 AP-16.1Q, 16.2Q QAP-16-1*, 16-2*
17	QA Records	QAP-17-1*
18	Audits	
Supp I	Software	
Supp II	Sample Control	
Supp III	Scientific Investigation	
Supp IV	Field Surveying	

IV. New or revised procedures required for conduct of this activity? Yes No
(If "yes," refer to QAP-5-1 or QAP-5-2 as applicable)

Responsible Manager Hugh A. Benton <i>Hugh A. Benton</i>	Date 8/23/95	Approved by <i>[Signature]</i>	Date 8/30/95
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I. Description of Activity (by task, as necessary)

Activity Title (See Description block below)	Document Identifier (including Revision No.) BB0000000-01717-2200-00031 REV 01	Date 8/21/95
<p>Description:</p> <p>Activity Title: Perform Probabilistic Waste Package Concept Scoping Analyses SCPB: N/A</p> <p>This activity entails performing scoping statistical analysis of potential failure mechanisms of components of waste package designs and the consequences of their failure. The activity also includes containment failure scoping analyses of waste package concepts.</p> <p>The products produced by this activity will not be used as qualified input into products subject to QARD requirements (i.e., QA specifications, QA drawings, QA analysis, etc.) without being identified as unverified in accordance with the M&O QA program.</p> <p>A scoping analysis may involve developing analytical capability or testing an analytic approach. Unqualified software (or software for which verification and validation activities have not been completed) may be used for these activities.</p> <p>Result of QA Assessment: Subject to QARD Controls; Applicable as identified in Block III</p>		

**Activity Evaluation
(Continued)**

Document Identifier (including Revision No.)
BB0000000-01717-2200-00031 REV 01

II. Evaluation of Activity

- | | | |
|--|-------------------------------------|--------------------------|
| <p>1. Is the activity related to an item listed on the WAST/MGDS Q-list or an item otherwise assumed to be subject to QARD requirements (e.g., design, procurement, construction, fabrication, production, handling, packaging, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, decontamination, dismantling, decommissioning, permanent closure)?</p> | <p>Yes</p> | <p>No</p> |
| | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Rationale:

The activity is related to an item on the MGDS Q-List and is subject to the QARD requirements listed on page 3. The activity is not subject to Design Control procedures because the activity will not be used to provide input to items on the Q-List or an item otherwise subject to QARD requirements. Internal and external requests for preliminary and scoping information produce data/results that will not be considered qualified. Results of this activity may not be used as qualified inputs, and when used, must be identified as unqualified data/results per applicable procedure.

- | | | |
|--|---------------------------------|--|
| <p>2. Is the activity related to site characterization sample collection or analysis of data used to support performance confirmation or performance assessment?</p> | <p><input type="checkbox"/></p> | <p><input checked="" type="checkbox"/></p> |
|--|---------------------------------|--|

Rationale:

This activity is not related to site characterization sample collection or analysis of data used to support performance confirmation or performance assessment. The scoping risk analysis is for informational purposes only.

- | | | |
|---|---------------------------------|--|
| <p>3. Can the activity adversely impact the waste isolation function of the natural or engineered barriers or impact site characterization results (for MGDS only)?</p> | <p><input type="checkbox"/></p> | <p><input checked="" type="checkbox"/></p> |
|---|---------------------------------|--|

Rationale:

This activity cannot adversely impact the waste isolation function of the natural or engineered barriers or impact site characterization results. The scoping risk analysis is for informational purposes only.

- | | | |
|---|--|---------------------------------|
| <p>4. Is the activity (or does the activity include) QARD-required support (e.g. training, procedure development, document control, records management, QA functions, etc.) of other activities subject to QARD requirements?</p> | <p><input checked="" type="checkbox"/></p> | <p><input type="checkbox"/></p> |
|---|--|---------------------------------|

Rationale:

This activity may include QARD-required support of other activities subject to QARD requirements, such as records management

If the answer to any of the above questions is "yes," the activity is subject to QARD requirements

Activity Evaluation (Continued)

Document Identifier (including Revision No.)
BB0000000-01717-2200-00031 REV 01

III. Application of Controls (Selection of Procedures for work subject to QARD requirements per Section II)

QARD Section		Applicable Procedures <small>(Revision No. Not Required)</small>
1	Organization	QAP-1-0*, 1-1*
2	QA Program	QAP-2-0*, 2-1*, 2-2*
3	Design Control	
4	Procurement Document Control	
5	Implementing Documents	
6	Document Control	
7	Control of Purchased Items and Services	
8	Identification and Control of Items	
9	Control of Special Processes	
10	Inspection	
11	Test Control	
12	Control of Measuring and Test Equipment	
13	Handling, Storage, and Shipping	
14	Inspection, Test, and Operating Status	
15	Nonconformances	
16	Corrective Action	A.O.D. B-21-95 AP-16.1Q, 16.2Q QAP-16-1*, 16-2*
17	QA Records	QAP-17-1*
18	Audits	
Supp I	Software	
Supp II	Sample Control	
Supp III	Scientific Investigation	
Supp IV	Field Surveying	

IV. New or revised procedures required for conduct of this activity? Yes No
(If "yes," refer to QAP-5-1 or QAP-5-2 as applicable)

Responsible Manager Hugh A. Benton	Date 8/23/95	Approved by 	Date 8/30/95
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