



Department of Energy

Washington, DC 20585

NOV 9 1993

Mr. Joseph J. Holonich, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Holonich:

By letter dated October 20, 1993 (Shelor to Holonich), the U.S. Department of Energy (DOE) provided your office with a copy of Corrective Action Request (CAR) No. YM-93-041. The CAR was provided in response to a request by the U.S. Nuclear Regulatory Commission at the July 20, 1993, Quality Assurance meeting and is relative to the DOE study plan review process.

Inadvertently, the copy of the CAR provided to all recipients of the DOE October 20, 1993, letter may be missing pages 2 and 5. Enclosed is a corrected copy which contains pages 1 through 5 to correct this error. DOE regrets any inconvenience in this regard.

If you have any questions, please call Sharon Skuchko of my office at (202) 586-4590.

Sincerely,

Dwight E. Shelor
Associate Director for
Systems and Compliance
Office of Civilian Radioactive
Waste Management

Enclosure:
Corrected copy of DOE
CAR No. YM-93-041

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

8 CAR NO.: YM-93-041
 DATE: 03/26/93
 SHEET: 1 OF 25
 QA 8/3/93

CORRECTIVE ACTION REQUEST

1 Controlling Document QOE/RW-0214, QARD, Revision 4	2 Related Report No. RTN
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3 Responsible Organization YMPO/YMQAD	4 Discussed With C. Hampton/R. Rogers
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5 Requirement:
 QARD, DOE/RW-0214, Revision 4, Section 6.3 states, "The quality assurance organization shall review, and where applicable, concur with controlled documents that contain or implement quality assurance requirements."

6 Adverse Condition:
 Contrary to the above QARD Requirement, the following revisions of AP-1.100, "Preparation, Review, Approval, and Revision of Site Characterization Plan Study Plan," did not require QA review of Study Plans:

- * Revision 2 (effective 10/9/90)
- * Revision 3 (effective 3/26/91)
- * Revision 4 (effective 7/5/91)
- * Revision 5 (effective 4/15/91)

9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 20 Working Days from Issuance
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12 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

13 Recommended Actions:
 Establish a listing of all study plans processed through AP-1.100 from 10/9/90 to present. Investigate Participant QA Program to determine if study plans processed during this period were reviewed under Participant QA programs. Generate CARs identifying Participant QA program that have not addressed QA review of study plans. Instruct participants to provide documentation of QA reviews on study plans generated from 10/9/90 to present.

7 Initiator <u>John A. Gray</u> Date <u>3/26/93</u>	14 Issuance Approved by: QADD <u>[Signature]</u> Date <u>3/30/93</u>
15 Response Accepted QAR <u>C.C. Wam</u> Date <u>5-6-93</u>	16 Response Accepted QADD <u>[Signature]</u> for Date <u>05-17-93</u>
17 Amended Response Accepted QAR <u>C.C. Wam</u> Date <u>5-18-93</u>	18 Amended Response Accepted QADD <u>[Signature]</u> Date <u>5/26/93</u>
19 Corrective Actions Verified QAR <u>C.C. Wam</u> Date <u>6-30-93</u>	20 Closure Approved by: QADD <u>[Signature]</u> for Date <u>07-21-93</u>

OFFICE OF CIVILIAN
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DATE: 4/14/93
PAGE: 2 OF 5
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

1. Corrective Action Response for CAR YM-93-041:

Remedial Action

A. The following requirements have been added to AP-1.10Q, Revision 6:

- 1) The organization responsible for the draft study plan shall complete a QA review of the plan prior to submitting to YMPO;
- 2) disputed mandatory QA review comments shall be resolved prior to approval of a draft study plan;
- 3) The Director, YMQAD shall perform a QA review of study plans;
- 4) QA review criteria is identified; and
- 5) the Director, YMQAD approval signature/date entry has been added to the MSCP Study Plan Approval form.

B. In addition to the above listed requirements, CAR(s) will be written, as required, on participating organizations that processed study plans through AP-1.10 Q, from 10/9/90 to present, without conducting QA reviews.

2. John Gray (4-7633) of YMQAD, is assigned responsibility for response actions. Anticipated completion dates are:

A. For "A" above (approval and issuance), 4-30-93

B. For "B" above, 5-7-93.

3. Response approved:

Catherine [Signature]

Date:

4/15/93

Std dtd 4/23/93 - YMQAD: CEH-3913

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

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DATE: 5-13-93
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CORRECTIVE ACTION REQUEST (Continuation Page)

1. Amended Corrective Action Response for CAR YM-93-041

Remedial Action (part B amended)

- B. In addition to the above listed requirements being added to the procedure, all approved study plans will be checked for YMPO QA review/approval signatures. Those not signed will be submitted to the Director, YMQAD for formal review.

NOTE: Study plans presently in the review cycle will be directed to YMQAD for QA review.

2. John A. Gray (4-7633) of YMQAD is assigned responsibility for response actions. The amended anticipated completion date for Part B above (including review of in process study plans) is:

- B. YMQAD QA review of 16 study plans (previously approved) and 18 study plans in the review cycle is estimated to be completed by July 16, 1993. These study plans are:

* Previously Approved;

8.3.1.2.2.1 ✓	8.3.1.2.2.2 ✓	8.3.1.2.3.3 ✓
8.3.1.4.2.1 ✓	8.3.1.4.2.2 ✓	8.3.1.5.1.2 ✓
8.3.1.5.1.3 ✓	8.3.1.5.2.1 ✓	8.3.1.5.2.2 ✓
8.3.1.8.1.1 ✓	8.3.1.8.5.1 ✓	8.3.1.14.2 ✓
8.3.1.15.1.8 ✓	8.3.1.17.4.2 ✓	8.3.1.17.4.3 ✓
8.3.4.2.4.3 ✓		

* Currently in Review Cycle;

8.3.1.2.2.4 ✓	8.3.1.2.2.6 ✓	8.3.1.2.2.7 ✓
8.3.1.2.2.8 ✓	8.3.1.2.2.9 ✓	8.3.1.3.1.1 ✓
8.3.1.3.4.1/3 ✓	8.3.1.3.5.1/2 ✓	8.3.1.3.6.1 ✓
8.3.1.8.1.2 ✓	8.3.1.8.5.2 ✓	8.3.1.12.2.1 ✓
8.3.1.15.1.1 ✓	8.3.1.15.1.2 ✓	8.3.1.15.1.4 ✓
8.3.1.15.1.5 ✓	8.3.1.15.2.2 ✓	8.3.1.17.3.5 ✓

3. Amended Response Approved:

Catherine Hampton

Date: 5/13/93

VERIFICATION OF CORRECTIVE ACTION FOR CAR YM-93-041

Completion of corrective action specified in the accepted responses to this CAR was verified as follows:

1. Review of YMP Procedure AP-1.10Q, Revision 6 to assure inclusion of the five requirements listed in section 1.A of the CAR response.
2. Review of YMP Study Plan Review Checklists (Form YMP-017-R2) for the 34 Study Plans listed in part 2.B of the amended response to the CAR. All of these checklists were signed and dated by YMQAD personnel.

Based on the results of this verification, it is recommended that CAR YM-93-041 be closed.

Charles C. Warren
Charles C. Warren
QAR

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

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 QA

GAR SUMMARY SHEET

	<u>Date</u>	<u>Letter Reference</u>
<u>Issuance Letter/Memo</u>	<u>3/30/93</u>	<u>YMQAD:RBC-3441</u>
<u>Response Extension Request</u>	<u>N/A</u>	<u>N/A</u>
Acceptance	<u>↓</u>	<u>↓</u>
<u>Response Received</u>	<u>4/23/93</u>	<u>YMQAD:CEH-3913</u>
Acceptance	<u>5/12/93</u>	<u>YMQAD:RBC-4173</u>
<u>Request Amended Response</u>	<u>N/A</u>	<u>N/A</u>
Response	<u>5/18/93</u>	<u>YMQAD:CEH-4234</u>
Acceptance	<u>5/27/93</u>	<u>YMQAD:RBC-4348</u>
<u>Request Amended Response</u>	<u>N/A</u>	<u>N/A</u>
Response	<u>↓</u>	<u>↓</u>
Acceptance	<u>↓</u>	<u>↓</u>
<u>C/A Extension Request</u>	<u>^{nh 4/23/93} 6/18/93</u>	<u>N/A</u>
Acceptance	<u>^{nh} 6/18/93 7/26/93</u>	<u>^{nh} YMQAD:RBC-4680 7/26/93</u>
<u>C/A Extension Request</u>	<u>N/A</u>	<u>N/A</u>
Acceptance	<u>↓</u>	<u>↓</u>
<u>Unsatisfactory Verification</u>	<u>↓</u>	<u>↓</u>
Response	<u>↓</u>	<u>↓</u>
Acceptance	<u>↓</u>	<u>↓</u>
<u>Closure Letter</u>	<u>7/2/93</u>	<u>YMQAD:RBC-4882</u>

Other _____

