



Department of Energy

Washington, DC 20585

NOV 18 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:

This letter further responds to the U.S. Nuclear Regulatory Commission (NRC) letter dated February 17, 1993 (Holonich to Roberts) which enclosed NRC Observation Audit Report No. 93-04 of the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Audit No. HQ-93-02 of the DOE Office of Environmental Restoration and Waste Management Vitrification Projects Division (EM-343) Quality Assurance (QA) program.

The NRC report identified a weakness in Section 5.9.2 concerning "the list for those items and activities to which the EM-343 QA program applies."

By DOE letter dated March 29, 1993 (Shelor to Holonich), DOE reported that the weakness identified in the NRC report was documented by the DOE audit team as an adverse condition on Corrective Action Request (CAR) No. HQ-93-011 (refer to Enclosure 1). As requested, EM-343 provided a response to CAR HQ-93-011 to address remedial and investigative actions, root cause determination, and corrective action to prevent recurrence (refer to Enclosure 2).

As requested by the NRC Observation Audit Report No. 93-04 of OCRWM Audit HQ-93-02, this letter notifies NRC that the response to CAR HQ-93-011 has been evaluated by the OCRWM Office of Quality Assurance and determined to be acceptable. A copy of this CAR (Enclosure 1), the corrective action response and amended response (Enclosures 2 and 4), and associated correspondence (Enclosures 3 and 5) are enclosed for your information.

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If you have any questions or require additional information, please contact either Robert W. Clark at (202) 586-1238 or 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

Enclosures:

1. Copy of CAR HQ-93-011 and DOE Issuance Letter dated February 16, 1993;
2. Copy of EM-343 Response to CAR HQ-93-011 dated May 25, 1993;
3. Copy of OCRWM (Office of Quality Assurance) Evaluation of EM-343 Response to CAR HQ-93-011 dated October 4, 1993;
4. Copy of EM-343 Amended Response to CAR HQ-93-011; and
5. Copy of OCRWM (Office of Quality Assurance) Evaluation of EM-343 Amended Response to CAR HQ-93-011.

cc w/Enclosures:

R. Nelson, YMPO
T. J. Hickey, Nevada Legislative Committee
R. Loux, State of Nevada
S. Zimmerman, State of Nevada
D. Bechtel, Las Vegas, NV
L. Fiorenzi, Eureka County, NV
R. Williams, Lander County, NV
P. Niedzielski-Eichner, Nye County, NV
W. Offutt, Nye County, NV
L. Bradshaw, Nye County, NV
C. Schank, Churchill County, NV
F. Mariani, White Pine County, NV
V. Poe, Mineral County, NV
J. Pitts, Lincoln County, NV
J. Hayes, Esmeralda County, NV
B. Mettam, Inyo County, CA
K. Hooks, NRC

memorandum

FEB 16 1993

DATE: RW-3.1
REPLY TO:
ATTN OF:SUBJECT: ISSUANCE OF CORRECTIVE ACTION REQUESTS (CARS) HQ-93-009 THROUGH
-012

TO: Acting Director, Vitrification Projects Division, EM-343

Attached are copies of CARS HQ-93-009 through -012 which document deficiencies identified during OCRWM Audit HQ-93-02 of the Office of Environmental Restoration and Waste Management (EM) Vitrification Projects Division (EM-343). You are requested to provide responses to these CARS to the Office of Quality Assurance by the response due date entered in Block 11 of the CAR forms.

The responses must be signed by the responsible manager and include a concise statement of the corrective actions to be taken, the names of the responsible individuals, and the scheduled completion dates. A CAR continuation sheet and preferred response format are provided.

If you have any questions, please contact me at (202) 586-1238.



Robert W. Clark, Director
Headquarters Quality
Assurance Division

AttachmentsCC:
T. Johnson, RW-3.1
W. Booth, WESTON
J. George, CER
M. Meyer, CER
J. Conway, EM-343

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

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DATE: 1/20/93
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QA

CORRECTIVE ACTION REQUEST (Continuation Page)

⁹ Requirements: (Continued)

DOE/EM/WO/02, Rev.1

Paragraph 2.1.4 states: "Considering all elements of a quality assurance program, EM-343 selectively applies a portion of the quality assurance controls to its own management and overview activities and issues implementation requirements to the field offices."

SW4-1.8, Rev 6

Part 3, Attachment 1, requires that a detailed listing be developed.

¹³ Recommended Actions: (Continued)

2. The EM-343 Program Manager should approve the list prior to performing activities qualifying the waste acceptance process.
3. EM-343 and DWPD should include the listed items and activities in their planning and performance of audits and surveillances.
4. Describe the methodology developed to identify those items and activities to which the quality assurance program applies and to selectively apply the quality assurance program requirements and controls shall be described in the DWPF Waste Form Compliance Plan."

memorandum

DATE: MAY 25 1993

REPLY TO
ATTN OF: EM-343

SUBJECT: Response to the Office of Civilian Radioactive Waste Management Quality Assurance Audit Report HQ-93-02

TO: Director, Headquarters Quality Assurance Division, RW-3.1

Attached are responses to Corrective Action Requests HQ-93-009 through HQ-93-012 resulting from Office of Civilian Radioactive Waste Management Audit HQ-93-02. These responses incorporate your comments on the draft responses that were provided to you previously.

If you have any questions, please contact me at (301) 903-7188, or Jim Conway at (301) 903-7450.


Ralph Erickson, Director
Vitrification Projects Division
Office of Waste Management Projects
Environmental Restoration
and Waste Management

Attachments

cc:
J. Conway, EM-343
T. McIntosh, EM-343
K. Picha, EM-343
K. Grisham, EM-343
J. Hennessey, EM-361

RECEIVED CER CORPORATION PROJECT OFFICE JUN 16 1993
ROUTE:
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OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO.	-O-93-011
DATE:	12/93
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CORRECTIVE ACTION REQUEST (Continuation Page)

1. Corrective Action Response for CAR HQ-93-011

A. Remedial Action

The methodology developed to identify those items and activities to which the QAP applies is being reincorporated into the WCP. This will supplement the existing reference to the QAPD.

DOE RW-0214, Rev 4, Appendix B, requires that Waste Form Producers identify items and activities which are included in the Waste Acceptance Process. A list of items and activities is contained in the WSRC QAPD as required by DOE RW-0214. This list has been accepted by DWPD SR field office and EM-343. The DWPD SR field office has received a detailed listing of items and activities from WSRC and is reviewing the document for acceptance. The document (WSRC, OPS-DTL-930015), dated February 1, 1993, being reviewed is titled "Items/Activities Important to the Waste Acceptance Process." The document will also be reviewed for acceptance by EM-343.

B. Investigative Action

Part 6, Item 100 "Quality Assurance" of the Revision 1 to the WCP, states that "The DWPF program to comply with the QARD, RW-0214, is described in the (WSRC) QAPD." The WSRC QAPD, SW4-1.8, is listed as reference #2 in the WCP. This referencing, which replaced the methodology discussion in Rev. 0 of the WCP, was intended to preclude the addition of information into the WCP that was contained in another program document.

Part 3, Attachment 1 of the QAPD SW4-1.8, Rev. 6, "Items and Activities to which the HLW Form Production Quality Assurance Program Applies," contains a table that identifies those items and activities that are to be controlled by the QAP. This attachment states that "A detailed listing of the items, procedures, and activities which support these processes is being developed..." An initial detailed listing of items and activities important to the WAP was developed and sent to the DWPD, SR field office on June 26, 1992. Since the June 26 letter was not formally reviewed by DWPD, it was not transmitted to EM-343 for review and acceptance. The June 26 letter did state that "A complete report documenting the entire program would be available by February 1, 1993."

The complete report, dated February 1, 1993, was provided by WSRC to DWPD. The report did contain the "detailed listing" of items and activities that support the processes described in the attachment of the QAPD (SW4-1.8). Because the evaluation of items and activities is a continuous process and is subject to change as a result of the waste qualification tests, it will not become a part of the QAPD.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.

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CORRECTIVE ACTION REQUEST (Continuation Page)

B. Investigative Action (Continued)

The method for controlling the items and activities of this detailed listing is described in the Part 6, Item 100 "Quality Assurance" of the WCP, Rev 1. The WCP states that the listing of controlled items and activities is maintained by the DWPF's Waste Acceptance Group. This process is subject to the evaluation and assessment process of DWPD and EM-343.

DWPF not having a final, approved detailed listing of the items and activities important to the waste acceptance process did not adversely affect the DWPF QA Program. This is due to the fact that an accepted detailed list is not necessary until prior to the waste qualification runs, currently scheduled for October 1993. The data collected during the Cold Chemical Runs will not become an input to the WCP or WQR. Data collected during the Waste Qualification Runs will be incorporated in the WCP or WQR.

C. Root Cause Determination

The methodology for identifying items and activities to which the quality assurance program applies was described in Revision 0 of the WCP; however, it was removed and replaced with a reference or pointer to the QAPD as discussed in the investigative action section 1B, above.

The detailed listing of items and activities was in the early stage of review (draft) and acceptance by DWPD, therefore, it could not be considered an accepted document within the context of the audit.

D. Corrective Action to Preclude Recurrence

Because of the RW-0214 requirement to describe the methodology developed to identify those items and activities to which the QAP applies, the methodology will be reincorporated into the next revision of the WCP. The methodology developed to identify those items and activities to which the QAP applies will continue to be an item for review by the TRG. The TRG will assure that the methodology is included in the WCP as required by RW-0214.

During a recent audit of the WVPO (93EA-WV-AU-001), an initial items and activities listing was reviewed and discussed. HWVP has also developed a preliminary list. Control of the detailed items and activities listings for DWPF will be verified through the E&A process. Through a coordinated effort by EM-343, the detailed listing of items and activities will be more consistent for all of EM-343 sites. Because of the importance of these listings to the waste acceptance process they will be reviewed and accepted by the respective Field Offices and EM-343. Accepted detailed listings of items and activities will not be included in the QAPD, but will be controlled by the respective sites through procedures or other accepted methods.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.

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DATE: 2093
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QA

CORRECTIVE ACTION REQUEST (Continuation Page)

2. Estimated Completion Dates

The methodology developed to identify those items and activities to which the QAP applies will be incorporated in the next revision of the DWPF WCP. The draft of the revision is presently being reviewed by the TRG, and is scheduled for reissue by DWPF by August, 1993.

Control of the detailed items and activities listings will be verified through the E&A process. This will begin with the scheduled audit of DWPD in May of 1993. The detailed listing of items and activities for DWPF will be reviewed and accepted by EM-343 prior to the Waste Qualification Runs, currently scheduled to begin October 1993.

Responsible Individual(s):

Ken Picha, Acting DWPF Program Manager, is responsible for the corrective action relating to the incorporation of the methodology in the WCP.

Chet Miller, TRG Chairman, is the individual responsible for the corrective action relating to incorporating the methodology into the WCP.

James Conway, QA Program Manager, is responsible for ensuring that the items and activities listing are reviewed and accepted by EM-343.

3. Response Approved:



Date: 5/26/93

Ralph Erickson, Director
Vitrification Projects Division

memorandum

OCT 4 - 1993

DATE: RW-3.1

REPLY TO: Evaluation of Responses to Corrective Action Requests (CARs) HQ-93-009
ATTN OF: through HQ-93-012

SUBJECT: Director, Vitrification Project Division, Office of Waste Management
Projects Environmental Restoration and Waste Management, EM-343

TO: The Headquarters Quality Assurance Division (HQAD) has evaluated the responses (dated May 25, 1993) to CARs HQ-93-009 through HQ-93-012 resulting from OCRWM Audit HQ-93-02. Copies of these evaluations are attached. Three of the four CARs require revised responses: CARs HQ-93-009, 010, and 011. The response to CAR HQ-93-012 has been determined to be acceptable.

Please provide your amended corrective action responses to this office by October 20, 1993. If you have any questions, please contact me at (202) 586-1238 or Marlin Horseman at (703) 841-0043.



Robert W. Clark, Director
Headquarters Quality Assurance
Division

Attachments:
Evaluation of CARs HQ-93-009, 010, 011

CC:
C. Weber, RW-3.1
T. Johnson, RW-3.1
M. Horseman, QATSS
K. Ransom, QATSS
J. Conway, EM-343
K. Picha, EM-343

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EVALUATION OF RESPONSE TO CAR HQ-93-011

EM-343 response to CAR HQ-93-011 is partially acceptable.. This CAR was written to identify the need to address three aspects of the application of the EM-343 QA Program for the Waste Acceptance Process:

1. The lack of a formal and approved list of items and activities that are to be completed in accordance with EM-343 QA program requirements. The EM response addresses this issue and is acceptable for Savannah River, however, the West Valley Demonstration Project should be subject to the same controls as Savannah River.
2. The lack of defined methodology for the selective application of QA requirements and controls. The EM response does not describe the "selective application of the quality assurance program requirements and controls."
3. An evaluation of completed activities to ensure the proper implementation of the QA program. Based upon the approved list and methodology for the selective application of QA requirements, previous activities need to be evaluated to ensure that all QA program requirements have been fulfilled. The response should address this evaluation.

memorandum

CC Juc
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BLC

DATE: October 13, 1993

REPLY TO:
ATTN OF: EM-343

SUBJECT: Response to the Office of Civilian Radioactive Waste Management Quality Assurance Audit Report HQ-93-02

TO: R. W. Clark, RW-3

Attached are amended corrective action responses to Corrective Action Request Nos. HQ-93-009 through HQ-93-011 resulting from the Office of Civilian Radioactive Waste Management Audit No. HQ-93-02. These amended responses supplement the original response (ref. R. Erickson to R. Clark memorandum dated May 25, 1993, on the above subject) and are based on your memorandum of October 4, 1993. The individual(s) initially assigned responsibility for corrective action remains the same.

If you have any questions, please contact Jim Conway at 903-7450.


Ralph E. Erickson, Director
Vitrification Projects Division
Office of Waste Management Projects
Environmental Restoration
and Waste Management

Attachments

- cc:
- J. Conway, EM-343
- T. McIntosh, EM-343
- K. Picha, EM-343
- K. Grisham, EM-343
- J. Hennessey, EM-361
- R. Hartstern, MACTEC
- R. Toro, BDM/SAIC

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Amended responses are as follows:

HQ-93-009

RW's overall disposition is "partially acceptable." EM-343's corrective action response is augmented as follows relative to RW's comments:

Since the RW audit, the Technical Review Group procedure (SPP 4.15) has been revised to state that "To achieve thorough TRG consensus evaluations and maximum synergy, all members are responsible for reviewing all sections of WCPs and WQRs with particular emphasis on sections related to their respective area of expertise and without concern for overlap of review comments."

EM-343 will also conduct an audit/surveillance with a technical specialist of the objective evidence (records) from the last TRG review of the DWPF WCP to verify that, in accordance with the SPP, 1) a discipline oriented review was conducted of the entire document, 2) the individual TRG members reviewed and commented on WCP contents which specifically pertained to their respective areas of expertise, and 3) the technical content of the WCP was thereby adequately covered. This audit/surveillance will be completed by November 19, 1993.

HQ-93-010

RW's overall disposition is "partially acceptable." EM-343's corrective action response is augmented as follows relative to RW's respective dispositioning comments:

1. "Deficiencies identified during audits which are identified as observations rather than DCARs." (Ref. A4, B1, C1, and D1)

Since the RW audit, EM-343 has revised it's procedure (SPP 5.01) for documenting deviations and corrective actions to add decision criteria, clear definitions, and examples of observations and conditions adverse to quality requiring DCARs. These expanded criteria, definitions and examples are entirely consistent with RW 0333P requirements and audit documentation practices. Also, since the RW audit, EM-343 audits at Savannah River and West Valley have verified that there were no negative impacts on technical activities related to previous EM-343 audit documentation, and that the baseline transition of the Savannah River WCP from the RW WAPS to the RW WA-SRD/EM-WAPS was completed with no loss of technical control or negative impact on completed work pertaining to waste qualification or acceptance.

2. "Conflicts between completed checklists and reported audit results." (Ref. A7, B2, C2 and D2)

The apparent conflict between the audit checklist summary and the audit report regarding whether or not the CPES software is "High Impact" is an isolated occurrence. No other internal or external audits or surveillances of EM-343 audit records have identified such an inconsistency. However, the EM-343 followup surveillance of this audit will specifically compare additional audit checklists and reports for

consistency. This surveillance will be accomplished by December 15, 1993. In addition, a technical specialist will be assigned to clearly verify the proper classification of the CPES software and also document any technical impact should it prove not to have been properly classified. This verification will be accomplished by November 26, 1993.

3. "Inadequate technical evaluation (not including technical specialist activities in the audit scope)." (Ref. C3)

Since the RW audit, EM-343 has significantly increased the participation of technical specialists in its audits and surveillances. Four technical specialists with expertise in separate applicable disciplines participated in the May 1993 audit at Savannah River, and EM-343 plans to continue this high level of participation by such specialists. Also, since the RW audit, EM-343 procedures have been revised to more clearly address the audit training and participation responsibilities of technical specialists.

HQ-93-011

RW's overall disposition is "partially acceptable." EM-343's corrective action response is augmented as follows relative to RW's respective dispositioning comments:

1. The EM-343 Division Director will issue a memorandum by November 1, 1993, to the major vitrification operations offices stressing the importance of these items and activities lists. Since the RW audit, EM-343 audits at Savannah River and West Valley have included evaluations of their lists, and future audits at Savannah River and West Valley, will continue to do so.
2. Since the RW Audit, the DWPF WCP has been updated to provide a description of the methodology for selective application of QA program requirements and controls and to add applicable references to current DWPF implementing plans and procedures.
3. The EM audits discussed in 1, above, included evaluations of previous activities to verify that QA requirements had been fulfilled based on current methodologies for selective QA program applications and the associated lists. The development of these lists continues to be a dynamic process paralleling respective projects' technology developments, construction schedules, and accomplishments. Significant QA milestones will be accomplished during the evaluations of the lists and activities required for waste acceptance prior to each project's Waste Qualification Tests.

memorandum

DATE: OCT 28 1993

REPLY TO: RW-3.1
ATTN OF:

SUBJECT: Evaluation of Amended Responses to Corrective Action Requests
(CARs) HQ-93-009 through HQ-93-011

TO: Director, Vitrification Project Division, Office of Waste
Management Projects Environmental Restoration and Waste
Management, EM-343

The Headquarters Quality Assurance Division (HQAD) has evaluated the amended responses (dated October 13, 1993) to CARs HQ-93-009 through HQ-93-011 resulting from OCRWM Audit HQ-93-02. The amended responses have been determined to be acceptable. The verification of completion of corrective action will be performed after the due dates provided in your responses.

If you have any questions, please contact me at (202) 586-1238 or Marlin Horseman at (703) 841-0043.



Robert W. Clark, Director
Headquarters Quality Assurance
Division

CC:
C. Weber, RW-3.1
T. Johnson, RW-3.1
M. Horseman, QATSS
K. Ransom, QATSS
J. Conway, EM-343
K. Picha, EM-343