

memorandum

QA

DATE: May 2, 1994
REPLY TO:
ATTN OF: RW-3.1
SUBJECT: Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Surveillance HQ-SR-94-03 of EM Implementation and Effectiveness of Remedial Actions
TO: Ralph Erickson, Director, Vitrification Projects Division (EM-343)

Attached please find the subject report issued as a result of a recent surveillance conducted by the Headquarters Quality Assurance Division (HQAD) at your facility in Germantown, MD. HQAD would like to express our appreciation for the cooperation received during the conduct of the activities.

There were no Corrective Action Requests (CARs) issued. However, three recommendations are presented by the surveillance team for consideration by EM-343 management.

R.W. Horton
For Donald G. Horton, Director
Office of Quality Assurance

Attachment: Surveillance Report HQ-SR-94-03

cc:

D. Dreyfus, RW-1
T. Johnson, RW-3.1
D. Spence, RW-3.2
R. Milner, RW-40
S. Zimmerman, Carson City, NV
R. Loux, Carson City, NV
C. Schank, Churchill Co., NV
J. Bingham, Clark Co., NV
D. Betchel, Clark Co., NV
J. Hayes, Esmeralda Co., NV
L. Fiorenzi, Eureka Co., NV
B. Mettam, Inyo Co.
R. Michener, Inyo Co.
G. Derby, Lander Co.
J. Pitts, Lincoln Co.
M. Baughman, Lincoln Co.
V. Poe, Mineral Co.
L. Bradshaw, Nye Co.
P. Niedzielski-Eichner, Nye Co.
F. Mariani, White Pine Co.
W. Belke, NRC
J. Conway, EM-343
K. Grisham, EM-343
M. Horseman, QATSS-HQ

*Add: Ken Hooks 4/11
NH03 4/11
102.7
WM-11*

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PDR WASTE
WM-11 PDR

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

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Surveillance No. HQ-SR-94-03

QUALITY ASSURANCE SURVEILLANCE RECORD

SURVEILLANCE DATA

¹ ORGANIZATION/LOCATION: EM-343, Germantown, MD	² SUBJECT: Implementation and Effectiveness of Remedial Actions	³ DATE: 3/14-16/94
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⁴SURVEILLANCE OBJECTIVE:
To verify that Remedial Actions continue to be effective for identified deficient areas of QA Program.

⁵ SURVEILLANCE SCOPE: Surveillance evaluation to include: Remedial actions to deficient areas corrected during verification activities and other appropriate actions to address OCRWM recommendations, identified by audit HQ-93-02; surveillance HQ-SR-93-01; and observations 94EA-VP-S-05/20, 94EA-WV-AU-01, 94EA-AN-S-01.	⁶ SURVEILLANCE TEAM: Team Leader: <u>Tom Swift</u> Additional Team Members: <u>Fred Bearham</u> <u>Conrad Coulombe</u>
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⁷ PREPARED BY: <u>Thomas R. Swift</u> <u>3/7/94</u> Surveillance Team Leader Date	⁸ CONCURRENCE: <u>R.W. Culp</u> <u>3/9/94</u> QA Division Director Date
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SURVEILLANCE RESULTS

⁹BASIS OF EVALUATION / DESCRIPTION OF OBSERVATIONS:
 Previous OCRWM audits, surveillances and Observations reports and DOE/EM Standard Practice Procedures (SPPs)
 See attached pages 2 through 5.

¹⁰ SURVEILLANCE CONCLUSIONS:
 See page 6.

¹¹ COMPLETED BY: <u>Thomas R. Swift</u> <u>4/12/94</u> Surveillance Team Leader Date	¹² APPROVED BY: <u>R.W. Culp</u> <u>5/2/94</u> QA Division Director Date
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9 BASIS OF EVALUATION/DESCRIPTION OF OBSERVATIONS:

Surveillance HQ-SR-94-03 was conducted using checklists designed to evaluate:

- the effectiveness of the remedial actions taken to address deficiencies identified and corrected during previous audits and surveillances; and
- actions taken regarding recommendations made by OCRWM during audits, surveillances, and observations conducted during the last two years (March 1992 to present).

PERSONNEL CONTACTED

The personnel contacted during the course of the surveillance are listed in Attachment 1.

SURVEILLANCE RESULTS

The following is a summary by QA program element of the activities evaluated.

QA Program Element 1, Organization

One recommendation from audit report HQ-93-02 suggested adding a footnote to an Organization Chart to clarify that the reporting relationship between the DWPF and EM-343 is for Waste Acceptance Process activities only. This recommendation was implemented by including this statement in the "Purpose and Scope" section of SPP-1.02.

See Recommendation 2 in Section 10 relating to updating QA responsibilities and adding a missing line to an organization chart. The Quality Assurance Program Manager (QAPM) stated that major organizational and schedular changes are in process and that delays are anticipated at some sites.

EM-343 implementation of the previous OCRWM audit recommendation was determined to be adequate.

QA Program Element 2, QA Program

Audit Report HQ-93-02 identified three QA program element 2 recommendations for EM-343 consideration. The surveillance team verified that the FY-1993 Program Execution Guidance (PEG) Document was properly issued and RW-3 is on distribution for the EM-343 Quarterly Vitrification Project Division QA Programs and Status Report.

9 BASIS EVALUATION/DESCRIPTION OF OBSERVATIONS (Continuation)

The FY-1993 Management Assessment was conducted October 26-November 10, 1993. The final report was issued March 11, 1993 and included proper documentation and reference to DOE/RW-0333P and SPP 8.02. The surveillance team did not review resolution of the Management Assessment recommendations because the report had only recently been received by EM-343.

FY-1994 PEG Sections 1 and 2 (QA requirements) have been issued by the EM-343 Director to ensure that requirements are transmitted to all affected groups pending the issuance of the final PEG. The team reviewed three Memorandum of Agreements (MOA) that define HLW QA activities. These have been reviewed by EM-343 and should be reviewed by other responsible DOE Organizations (See Recommendation 2a).

The Quality Assurance Specialist, for DWPF, HWVP, and WVDP have issued their QA reports on a timely basis, thereby correcting a concern noted during the HQ-93-02 audit which the QAPM had previously documented.

A problem concerning the receipt of information required by the PEG, was stated by EM-343 in their QA reports. In a memo written during the surveillance to Savannah River, the EM-343 QAPM documented previous discussions and meetings in which Savannah River agreed to provide the information to EM-343. (See Recommendation 3).

An OCRWM observation report of EM surveillance 94 EA-VP-S-20 recommended conducting interviews with the TRG members and holding entrance and exit meetings. The EM QAPM agreed that future verification activities, such as those identified in Recommendation 1, would include interviews with the TRG. The EM QAPM would not commit to the recommended entrance and exit surveillance meetings. The EM QAPM, however, did agree to stress the importance of communication to ensure that proper personnel are available and aware of surveillance activities.

EM-343 implementation of three OCRWM recommendations from the previous audit and observation reports was determined to be adequate.

QA Program Element 5, Implementing Documents

The previous OCRWM audit identified a recommendation to improve the TRG process by adding a QA representative on the TRG. Several actions taken by EM-343 indicate a conscious effort to improve the TRG process. The following enhancements were noted by the surveillance team during discussions with the TRG Program Manager and contractor representatives involved in the TRG process. A QA representative was added to the Group and additional RW representation was requested.

9 BASIS EVALUATION/DESCRIPTION OF OBSERVATIONS (Continuation)

Another improvement included the appointment of a statistician specialist, reporting directly to the Vitrification Program Managers, to attend the TRG meetings. The Vitrification Program Managers also have attended TRG meetings. However, this is not a commitment since they do not always attend meetings. Currently the location of the TRG Secretary and TRG records are at the Germantown facility.

To broaden their knowledge, the TRG has met with their Canadian counterparts and plan to schedule more of these meetings.

It is recognized that elements of the TRG process have been subject to audits and surveillances by EM-343 and OCRWM, but the complete process has not been audited. See Recommendation 1 suggesting that EM-343 conduct a performance based audit of the entire TRG process. This audit would provide the opportunity to further evaluate these enhancements.

EM-343 implementation of the OCRWM recommendation from the previous audit was determined to be adequate.

QA Program Element 6, Document Control

A recommendation stated in Audit HQ-93-02 identified minor enhancements to the document distribution lists. Apparently, these were due, in part, to duplicate responsibilities/assignments that would be resolved when a specific contractor and a Quality Assurance Specialist became responsible for document distribution. These measures have produced the desired effect as determined during the review of distribution lists and interviews with document holders.

EM-343 implementation of the OCRWM recommendation from the previous audit report was determined to be adequate.

QA Program Element 16, Corrective Action

The OCRWM Observation Report for EM-343 audit 93EA-SR-AU-01 identified a concern about instances in which deviations were documented as Observations rather than DCARs. There was also a concern that the EM quality procedures did not address the use of Observations to document deviations. A review of SPP 5.01 "Deviations and Corrective Actions" revealed that the revision has now added a definition of "Observation" and defined criteria that will be used to clarify when a deviation may be documented as an Observation. Personnel have been trained to this procedure. A review of recent Observations indicated that the criteria for defining Observations is being applied

9 BASIS EVALUATION/DESCRIPTION OF OBSERVATIONS (Continuation)

effectively. Also, Observations are tracked in the Evaluation and Assessment Commitment Tracking and Reporting System in the same manner as DCARs. EM-343 has established an internal policy that it will respond to all Observations assigned to EM-343 activities.

EM-343 implementation of OCRWM recommendations from a previous observation report was determined to be adequate.

QA Program Element 17, QA Records

Surveillance HQ-SR-93-01 recommended that the records be filed in a logical sequence and each page be numbered. During audit HQ-93-02, missing records for several ORR team members were corrected. SPP 7.01 "Preparation, Transfer, and Receipt of Quality Records" Rev. 5 dated 8/6/93 has incorporated a Quality Record Package Contents Sheet to identify each page in the records package. After reviewing records packages for personnel, audits, TRG Work Plans, and surveillances, the team determined that the records packages were complete and well organized as required by the SPPs.

The Records Management QA Specialists, the TRG Secretary and the TRG QA Representative are working together to define the TRG records to be transmitted to the Central Records Facility. Volume 12 of the DWPF Waste Qualification Report was in the process of being prepared for transmittal to the CRF, and was reviewed for completeness, legibility, annotation, indexing and logical sequence. No adverse conditions were noted and the examination determined that Records Management Activities are performed in accordance with established controls.

EM-343 implementation of OCRWM recommendations from a previous surveillance report was determined to be adequate. Also, records packages in the area of the previous audit remedial action are effectively processed in accordance with the SPPs.

QA Program Element 18, Audits

Audit HQ-93-02 identified two recommendations for improvement of the Evaluation Schedule. The first concerned the need to consistently review field office monthly progress status reports to help develop priorities for the Evaluation Schedule. The second recommendation was to identify on the Evaluation Schedule which verifications had been completed, postponed, or cancelled. SPP 4.01 "Planning and Scheduling of Evaluation Activities", Rev. 3 dated 8/6/94 added requirement that updates of the quarterly and annual schedules include updated information from field project offices if relevant. A review of the Evaluation Activities (EA) Schedules (Quarterly and 15-month) activities

9 BASIS EVALUATION/DESCRIPTION OF OBSERVATIONS (Continuation)

indicated that adequate information from Operations Offices is received and used during the development and revision of the EA schedules. Changes to the schedule are now being noted in the STATUS column of the quarterly schedules. These include delays, reschedules, and cancellations. The annual schedule is updated to reflect completed evaluations, changes, delays, and reschedules. Information on Operations Offices evaluation activities has improved and is factored into the EM-343 EA schedules. (See Recommendation 3).

The enhancements implemented by EM-343 were determined to adequately address the two previous OCRWM audit recommendations.

LIST OF ATTACHMENTS

Attachment 1: List of personnel contacted

Attachment 2: List of Objective Evidence Reviewed

10 SURVEILLANCE CONCLUSIONS:

The OCRWM surveillance team determined that remedial actions taken to correct one previously identified deficiency continues to be effective and actions, when taken, regarding recommendations provided by OCRWM were appropriate and effective. No Corrective Action Requests (CARs) were issued. The surveillance team offered three recommendations for consideration by EM-343 management.

ITEMS CORRECTED DURING THE SURVEILLANCE

None.

RECOMMENDATIONS

The following recommendations are presented by the surveillance team for consideration by EM-343 management:

1. EM-343 should schedule a performance based audit of the Technical Review Group (TRG) Process.
2. EM-343 should review the organizational structure and assigned responsibilities to ensure:
 - a. That Memorandum of Agreements (MOA) are reviewed by all appropriate organizations annually as stated in the MOA.
 - b. That the missing organizational reporting line for Savannah River Operations Office (SR) in SPP 1.02, Attachment A is corrected.
 - c. That correct QA responsibilities for Richland and Idaho are identified in SPP 1.02.
3. EM-343 should follow-up on the QAPM letter written in reply to a surveillance team member question (March 16, 1994) to C. Terrell, Savannah River (HLWPD) to ensure:
 - a. Proper submittal of monthly reports.
 - b. Timely submittals of Evaluation and Assessment and Trend Reports.
 - c. Submittal of revised responses to deficiencies and observations.

ATTACHMENT 1

Personnel Contacted During The Surveillance

<u>Name</u>	<u>Organization</u>	<u>Title</u>
Fred Bearham	QATSS (CER)	Surveillance Team
Jim Conway	DOE/EM-343	QA Program Manager
Conrad Coulombe	QATSS (CER)	Surveillance Team
Kriss Grisham	DOE/EM-343	QA Specialist
Robert Hartstern	MACTEC	QA Project Manager
C. Pete Hunter	MACTEC	QA Specialist
Robert Jakubic	BDM	Senior Principal Engineer
Lynn Ledingham	MACTECH	QA Specialist
John LeVea	BDM/SAIC	QA Specialist
Dick Lowder	MACTECH	QA Specialist
Bill McClanahan	BDM/SAIC	QA Specialist
Lew Sirianni	SAIC	QA Specialist
Jack Spraul	NRC/NMSS	Observer
Dennis Strother	MACTEC	QA Specialist
Tom Swift	QATSS (CER)	Surveillance Team Leader
Bob Toro	BDM/SAIC	QA Specialist
Lou Wade	MACTECH	QA Specialist

ATTACHMENT 2

List of Objective Evidence Reviewed During the Surveillance

<u>Document Title</u>	<u>Date/Revision</u>
Standard Practice Procedure (SPP) Index	12/07/93
SPP 1.02 Organization	Rev. 0
EM Organization for Waste Acceptance Process Activities of High-Level Waste Form Producers	08/06/93
Memorandum of Agreement (MOA) for Coordination of QA Waste Acceptance Process Activity	10/30/91
Cover Memo for MOA dated 10/30/91 to RW-1 from Assistant Secretary EM (former Dir. EM)	10/15/91
MOA between Dir. EM-343 and Dir EM-361 for QA Program using EM-343 Organization	11/10/92
Cover Memo of MOA to Donald G. Horton/Dir. OQA of EM-361 using EM-343 QA Program	12/21/92
Delegation of Execution Responsibility for HLW QA Program to EM-343 by J.E. Lytle	02/11/92
SPP 4.12 QA Input PEG	Rev. 3
QA Requirements for the FY 1993 PEG	12/21/92
1993 Program Execution Guidance Document	03/03/93
QA Requirements for the FY 1994 PEG	09/28/93
Review of MOAs by R.F. Hartstern	03/15/94
SPP 8.03 QA Program Progress Reports	Rev. 3
HWVP QA Progress and 3rd Qtr. FY 1993 Status Report	07/21/93

ATTACHMENT 2

List of Objective Evidence Reviewed During the Surveillance (Continued)

<u>Document Title</u>	<u>Date/Revision</u>
HWVP QA Progress and 4th Qtr. FY 1993 Status Report	10/11/93
HWVP QA Progress and 1st Qtr. FY 1994 Status Report	01/24/94
QA Quarterly Report April-June 1993, DWPF	07/22/93
QA Quarterly Report Fourth Period 1993, DWPF	10/21/93
DWPF 1st Qtr. FY 1994 QA Progress and Status	01/12/94
WVDP QA Status Report for Third Quarter 1993	07/20/93
WVDP QA Status Report for Fourth Quarter FY 1993	10/13/93
WVDP QA Status Report 1st Qtr. FY 1994	01/10/94
EM-343, Vitrification Project Division (VPD) 1st Qtr. FY 1993 QA Program Progress and Status Report	02/16/93
EM-343, VPD, 2nd Qtr. FY 1993 QA Progress and Status Report	05/14/93
EM-343, VPD, 3rd Qtr. FY 1993, QA Program and Status Report	08/03/93
EM-343, VPD, 4th Qtr. FY 1993, QA Program and Status Report	11/8/93
EM-343, VPD, 1st Qtr. FY 1994 QA Program and Status Report	01/31/94
Quality Assurance, potential problems identified by VPD, EM-343, of HLWPD	03/16/94

ATTACHMENT 2

List of Objective Evidence Reviewed During the Surveillance (Continued)

<u>Document Title</u>	<u>Date/Revision</u>
SPP 8.02 Annual Assessment of QA	Rev. 3
EM-343 Management Assessment Report	03/11/94
Annual Assessment of the Quality Assurance Program	08/06/93
Surveillance 94EA-VP-S-06 Annual Assessment of QA Program	01/10/94
SPP 3.01 Training Assessment	Rev. 3
VPD, EM-343 Training Needs	12/30/93
Training Needs Assessment	08/06/93
SPP 3.02 Preparation and Conduct Training	Rev. 3
Root Cause Analysis Training	03/07/94
SPP 4.16 Document Reviews	Rev. 1
Distribution List for EM WAPS	09/13/93
SPP 6.05 Controlled Documents	Rev. 3
Distribution List of EM SPPs	02/24/94
EM 30 QAPD	07/02/93
EM WAPS	02/19/93
SPP 4.08 Conduct of Peer Reviews	Rev. 3
EM WAPS Revised Pages	04/13/93
Controlled Copy Nos. 22 and 24 of EM WAPS	Rev. 0

ATTACHMENT 2

List of Objective Evidence Reviewed During the Surveillance (Continued)

<u>Document Title</u>	<u>Date/Revision</u>
Waste Qualification Report, Volume 12	10/18/93
Work Plan and Statements of Independence	05/18/93
Final Report and Program Manager Review	09/93
DWPF WCP	03/93
SPP 4.15 Technical Reviews	Rev. 2
Waste Form Specifications	04/93
Waste Acceptance	04/93
Final Report and Program Manager Review	06/29/93
SPP 7.01 Preparation, Receipt of Quality Records	Rev. 5
Transition Plan for Records from PDC to BDM	06/02/92
SPP 7.02 Quality Record Management	Rev. 3
SPP 4.02 Conduct of Audits	Rev. 4
SPP 4.04 Conduct of Surveillance	Rev. 3
Surveillance Report EM-343	12/13/93
Surveillance Report	12/13/93
Trip Report by Jakubic for TRG Meeting at Dallas 2/23-25/93	2/25/93
Trip Report by Jakubic for TRG Meeting at Denver 3/30-31/93	04/06/93

ATTACHMENT 2

List of Objective Evidence Reviewed During the Surveillance (Continued)

<u>Document Title</u>	<u>Date/Revision</u>
Letter Erickson to Horton 5/19/93 re: responses to recommendations of HQ-93-02 plus attachments	05/19/93
SPP 4.01 Planning Evaluation Activities	Rev. 3
Planning & Scheduling of Evaluation Activities	08/06/93
EM-343 Evaluation Schedule - 15 month	01/05/94
EM-343 Evaluation Schedule - 1st Qtr. FY 1994	01/05/94
EM-343 Evaluation Schedule - 2nd Qtr. FY 1994	01/05/94
DWPF Quarterly Report - 3rd Qtr. FY 1993	07/22/93
DWPF Quarterly Report - 4th Qtr. FY 1993	10/21/93
DWPF Quarterly Report - 1st Qtr. FY 1994	01/12/94
WVDP Quarterly Report - 1st Qtr. FY 1994	01/04/94
WVDP Quarterly Report - 4th Qtr. FY 1993	10/13/93
HWVP Quarterly Report - 1st Qtr. FY 1994	01/24/94
WVPO Weekly Progress Report (3) Preparation, Transfer and Receipt of Quality Records	08/06/93
Quality Records Management	08/06/93
Qualification, Certification and Training Packages for: C. Hunter, S. Crawford, J. Hennessey, R. Lowder and D. Miller	N/A
TRG Work Plan - Review of DWPF WCP - Record Package	05/18/93

ATTACHMENT 2

List of Objective Evidence Reviewed During the Surveillance (Continued)

<u>Document Title</u>	<u>Date/Revision</u>
TRG Work Plan - Review of DWPF - WQR Vol. 12	07/27/93
SPP 5.01 Deviations and Corrective Action	Rev. 3
Deviations and Corrective Actions	08/06/93
SPP 5.07 Tracking and Reporting	Rev. 2
EM-343 Audit of West Valley Demonstration Project Record Package	02/26/93
EM-343 Audit of West Valley Demonstration Project Record Package	11/05/93
EM-343 Audit of Argonne National Lab - Record Package	03/31/93