

United States Government

Department of Energy

memorandum

DATE: JUL -1 1992

REPLY TO
ATTN OF: EM-343


SUBJECT: Quality Assurance Audit of Vitrification Projects Division

TO: Distribution

On July 20-24, 1992, an independent audit team will conduct a quality assurance (QA) audit (No. 92EA-VP-AU-01) of the Vitrification Projects Division (EM-343). This audit will assess the overall adequacy, implementation, and effectiveness of the EM-343 QA Program for the waste acceptance activities related to high-level waste form production.

The attached Audit Scope and Planning Document describes the scope of the audit, activities to be audited, audit team members, applicable requirements, and the proposed audit schedule. Please notify appropriate management personnel of the proposed audit schedule so they may participate in the audit as appropriate and attend the pre and postaudit meetings. In addition, the audit team will need facilities to conduct the pre and postaudit meetings, to review the documentation, and to meet with audit participants. Please provide work space for audit team members and make provisions for access to personnel and facilities during the scheduled audit dates.

If you have any questions or need additional information, please contact Jim Conway at 301-903-7450.


Kenneth A. Chacey, Director
③ Vitrification Projects Division
② Office of Waste Management Projects
① Environmental Restoration
and Waste Management

Attachment

9208100096 920701
PDR WASTE
WM-11 PDR

ADD: Bill Belke
1 1

Att. Encl.

102.7
WM-11
NH03

Distribution:

J. Conway, EM-343
R. Erickson, EM-343
T. Gutmann, EM-343
J. Hennessey, EM-343
T. McIntosh, EM-343
M. Rawlings, EM-343
L. Stevens, EM-331
L. Vaughan, EM-20
D. Horton, RW-3
R. Lowder, MACTEC
R. Stockman, BDM
W. McClanahan, SAIC
J. Smith, PDC/GTN

Audit Scope & Planning Document

Audit No. 92EA-VP-AU-001
Scheduled Dates 7/20-7/24/92

I. Organization Being Audited EM Vittrification Projects Division (EM-343)

II. Audit Scope and Activities to be Audited The audit will: (1) evaluate the overall adequacy of, compliance to, and effectiveness of implementation of the EM-343 High-Level Waste (HLW) QA program; (2) focus on the activities of the EM-343 organization (the Field Offices will not be evaluated); (3) only evaluate those QA criteria that are applicable to the EM-343 organization (i.e., the audit will address sections 1, 2, 3, 4, 5, 6, 7, 15, 16, 17, and 18 of the EM-343 QAPD). Technical adequacy of the EM-343 QA Program will not be evaluated.

III. Requirements, including previous Evaluation Activities Of Same Or Similar Areas For Follow-up

1. OCRWM QARD, RW-0214, Revision 4, and ICN 4.1.
2. OCRWM 5/8/92 draft Quality Assurance and Requirements Description (to be used as "look-ahead" guidance).
3. EM-343 QAPD, DOE/EM/WO/02, Revision 1.
4. EM-343 SPPs for Quality Assurance (revisions of applicable SPPs in effect at the time work being audited was performed).
5. OCRWM Audit Report of EM-343, Audit No. HQ-91-003

IV. Team Members

T. Colandrea, Audit Team Leader
G Braun, Auditor
C McFarland, Auditor
W Morrison, Auditor
P. Stuart, Auditor

V. Organizations To Be Notified

DOE/RW
EM-20
EM-30
EM-343
Support Contractors

VI. Controlling Documents And Revisions

Includes the program-related controlling documents identified in III. 1. (RW-0214), III. 3. (EM-343 QAPD), and, III. 4. (EM-343 SPPs for QA), above.

Prepared by:

T. K. Colandrea
Audit Team Leader

Date:

6/8/92

Approved by:

James T. Conway
Quality Assurance Program Manager

Date:

6/19/92

PRELIMINARY AUDIT SCHEDULE

<u>Activity</u>	<u>Date</u>	<u>Time</u>
Preaudit Meeting	07/20/92	8:00 a.m. - 9:00 a.m.
Conduct Audit	07/20/92	9:00 a.m. - 5:00 p.m.
Conduct Audit	07/21/92	8:00 a.m. - 5:00 p.m.
Conduct Audit	07/22/92	8:00 a.m. - 5:00 p.m.
Conduct Audit	07/23/92	8:00 a.m. - 5:00 p.m.
Prepare Audit Summary	07/24/92	8:00 a.m. - 12:00 p.m.
Postaudit Meeting	07/24/92	1:00 p.m. - 2:00 p.m.

memorandum

DATE: JUL 15 1992

REPLY TO
ATTN OF: EM-343

SUBJECT: Quality Assurance Program Audit No. 92EA-VP-AU-001 of EM-343

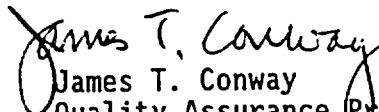
TO: Distribution

You are requested to attend a pre-audit conference for the subject audit. The conference will be held on July 20, 1992, at 8:00 a.m. in the fourth floor conference room of the Trevion I building.

Items that will be covered include the following:

- Introduction of audit team members
- Introduction of EM-343 and contractor support personnel
- Audit Scope
- Audit team agenda
- Audit logistics including channels of communication and facilities available for use.

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


James T. Conway
Quality Assurance Program Manager
Vitrification Projects Division
Office of Waste Management
Environmental Restoration
and Waste Management

Distribution:

K. Chacey, EM-343
R. Erickson, EM-343
T. Gutmann, EM-343
J. Hennessey, EM-343
T. McIntosh, EM-343
M. Rawlings, EM-343
O. Truskett, EM-343

J. LeVea, BDM/SAIC
W. McClanahan, BDM/SAIC
L. Siranni, BDM/SAIC
R. Stockman, BDM/SAIC
R. Toro, BDM/SAIC
S. Crawford, BDM/SAIC
B. Eastham, BDM/SAIC

C. Betts, PDC
C. Payton, PDC
J. Smith, PDC
D. Strother, PDC

R. Lowder, MACTEC
L. Wade, MACTEC

EM-343 DAILY AUDIT TEAM AGENDA

AUDIT NO. 92EA-VP-AU-001

Rev. 1

Page 1 of 4

		MONDAY 7/20/92	TUESDAY 7/21/92	WEDNESDAY 7/22/92	THURSDAY 7/23/92	FRIDAY 7/24/92
<u>AUDIT</u> <u>SUB-TEAM A</u> W. E. Morrison		Commence Audit <u>Contact & Phone #</u> K. A. Chacey, Div. Dir. (903-7186)	Criterion #2 <u>Contact & Phone #</u> J. T. Conway, QAPM	Criterion #2 <u>Contact & Phone #</u> T. W. McIntosh	Criterion #2 <u>Contact & Phone #</u> O. Truskett	• FOLLOW-UP
* C. R. McFarland to Assist	Note: • Pre Audit Conference • Tour of Facilities (Optional)	Note: QAPD Section 2 SPP 3.01, 3 02, & 3.05 * Also May Want to Contact: T. W. McIntosh T. S. Gutmann J. E. Hennessey	Note: SPP 5.03 Also May Want to Contact: J. T. Conway O. Truskett	Note: SPP 8.03 Also May Want to Contact: T. W. McIntosh T. S. Gutmann J. E. Hennessey K. A. Chacey		
	Criterion #1 <u>Contact & Phone #</u> K. A. Chacey, Div. Dir.	<u>Contact & Phone #</u> T. W. McIntosh	<u>Contact & Phone #</u> O. Truskett	<u>Contact & Phone #</u> O. Truskett		
** P. S. Stewart to Assist	Note: QAPD Section 1 May Also Want to Contact: J. T. Conway, QAPM (903-7450) T. W. McIntosh, WVDP/PM (903-7189) T. S. Gutmann, DWPF/PM (903-7187) J. E. Hennessey, HWVP/PM (903-7191)	Note: SPP 4.01 ** Also May Want to Contact: T. W. McIntosh T. S. Gutmann J. E. Hennessey O. Truskett Tech/PM (903-7194)	Note: SPP 8.02 Also May Want to Contact: K. A. Chacey Also Assist G. S. Braun with SPP 2.03	Note: SPP 10.03 Also May Want to Contact: T. W. McIntosh T. S. Gutmann J. E. Hennessey K. A. Chacey		
	• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>		• <u>SUMMARIZE RESULTS</u> • <u>POST AUDIT</u> <u>CONFERENCE</u> • <u>DRAFT AUDIT REPORT</u>

EM-343 DAILY AUDIT TEAM AGENDA

AUDIT NO. 92EA-VP-AU-001

Rev. 1

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		MONDAY 7/20/92	TUESDAY 7/21/92	WEDNESDAY 7/22/92	THURSDAY 7/23/92	FRIDAY 7/24/92
<u>AUDIT</u> <u>SUB-TEAM B</u> G. S. Braun		Commence Audit <u>Contact & Phone #</u> K. A. Chacey, Div. Dir. (903-7186) Note: • Pre Audit Conference • Tour of Facilities (Optional)	Criterion #6 <u>Contact & Phone #</u> J. E. Hennessey Note: QAPD Section 6	Criterion #5 <u>Contact & Phone #</u> J. E. Hennessey Note: QAPD Section 5 SPP 2.01 ** Also May Want to Contact: T. W. McIntosh	Criterion #3 <u>Contact & Phone #</u> O. Truskett Note: SPP 4.14 ** Also May Want to Contact: Jeff Allison (903-7193)	• FOLLOW-UP
* C. R. McFarland to Assist ** W. E. Morrison to Assist		Criterion #3 <u>Contact & Phone #</u> O. Truskett, Tech/PM (903-7194) Note: QAPD Section 3 SPP 4.08	Criterion #6 <u>Contact & Phone #</u> T. W. McIntosh Note: SPP 6.05 *	Criterion #5 <u>Contact & Phone #</u> T. W. McIntosh Note: SPP 2.03 **	Criterion #3 <u>Contact & Phone #</u> O. Truskett Note: SPP 4.15 T. W. McIntosh, WVDP/PM (903-7189) T. S. Gutmann, DWPF/PM (903-7187) J. E. Hennessey, HWVP/PM (903-7191)	• SUMMARIZE RESULTS • POST AUDIT CONFERENCE • DRAFT AUDIT REPORT
		• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>	

EM-343 DAILY AUDIT TEAM AGENDA

AUDIT NO. 92EA-VP-AU-001

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	MONDAY 7/20/92	TUESDAY 7/21/92	WEDNESDAY 7/22/92	THURSDAY 7/23/92	FRIDAY 7/24/92
<u>AUDIT</u> <u>SUB-TEAM C</u> P. S. Stuart	Commence Audit <u>Contact & Phone #</u> K. A. Chacey, Div. Dir. (903-7186) Note: • Pre Audit Conference • Tour of Facilities (Optional)	Criterion #7 <u>Contact & Phone #</u> T. W. McIntosh Note: QAPD Section 7	Criterion #18 <u>Contact & Phone #</u> T. S. Gutmann Note: QAP-EM-1-2.1	Criterion #18 <u>Contact & Phone #</u> T. S. Gutmann Note: SPP 4.02	• FOLLOW-UP
	Criterion #4 <u>Contact & Phone #</u> J. E. Hennessey, HWVP/PM (903-7191) Note: QAPD Section 4 SPP 4.12 Also May Want to Contact: T. W. McIntosh, WVDP/PM (903-7189) T. S. Gutmann, DWPF/PM (903-7187) O. Truskett, Tech/PM (903-7194)	Criterion #18 <u>Contact & Phone #</u> J. E. Hennessey Note: QAPD Section 18 Also Assist W. E. Morrison with SPP 4.01	<u>Contact & Phone #</u> J. E. Hennessey Note: SPP 3.03 & 3.04	<u>Contact & Phone #</u> T. S. Gutmann Note: SPP 4.04 & 4.13	• <u>SUMMARIZE RESULTS</u> • <u>POST AUDIT</u> <u>CONFERENCE</u> • <u>DRAFT AUDIT REPORT</u>
	• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>	• <u>DAILY SUMMARY</u>	

EM-343 DAILY AUDIT TEAM AGENDA

AUDIT NO. 92EA-VP-AU-001

Rev. 1

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AUDIT SUB-TEAM D C. R. McFarland	MONDAY 7/20/92	TUESDAY 7/21/92	WEDNESDAY 7/22/92	THURSDAY 7/23/92	FRIDAY 7/24/92
	<p>Commence Audit</p> <p><u>Contact & Phone #</u></p> <p>K. A. Chacey, Div. Dir. (903-7186)</p> <p>Note:</p> <ul style="list-style-type: none"> • Pre Audit Conference • Tour of Facilities (Optional) <p>Criterion #15</p> <p><u>Contact & Phone #</u></p> <p>K. A. Chacey</p> <p>Note:</p> <p>QAPD Section 15</p> <p>• <u>DAILY SUMMARY</u></p>	<p>Criterion #15</p> <p><u>Contact & Phone #</u></p> <p>J. E. Hennessey</p> <p>Note:</p> <p>SPP 5.01 Also May Want to Contact: J. T. Conway T. S. Gutmann J. E. Hennessey T. W. McIntosh Also Assist W. E. Morrison with SPP 3.05</p> <p>Criterion #15</p> <p><u>Contact & Phone #</u></p> <p>J. E. Hennessey</p> <p>Note:</p> <p>QAPD Section 16 Also May Want to Contact: K. A. Chacey (903-7186) T. W. McIntosh, WVDP/PM (903-7189) T. S. Gutmann, DWPF/PM (903-7187)</p> <p>• <u>DAILY SUMMARY</u></p>	<p>Criterion #16</p> <p><u>Contact & Phone #</u></p> <p>K. A. Chacey</p> <p>Note:</p> <p>SPP 5.07</p> <p>Criterion #16</p> <p><u>Contact & Phone #</u></p> <p>J. E. Hennessey</p> <p>Note:</p> <p>SPP 10.01</p> <p>• <u>DAILY SUMMARY</u></p>	<p>Criterion #17</p> <p><u>Contact & Phone #</u></p> <p>K. A. Chacey</p> <p>Note:</p> <p>SPP 7.01 Also May Want to Contact: T. W. McIntosh T. S. Gutmann O. Truskett</p> <p>Criterion #17</p> <p><u>Contact & Phone #</u></p> <p>K. A. Chacey</p> <p>Note:</p> <p>SPP 7.02 Also Assist G. S. Braun with SPP 6.05</p> <p>• <u>DAILY SUMMARY</u></p>	<p>• FOLLOW-UP</p> <p>• <u>SUMMARIZE RESULTS</u></p> <p>• <u>POST AUDIT CONFERENCE</u></p> <p>• <u>DRAFT AUDIT REPORT</u></p>

AUDIT PLANNING/PREPARATION GUIDELINES

1. Identify Audit Scope and Objectives:

Sufficient thought should be given early in the audit planning process to address the relevant technical objectives and schedule for the activities to be audited. Further consideration must be given to complete quality assurance programmatic coverage via the audit process, on an annual basis as a minimum, and the planning process for each audit must include adequate attention to previously identified problems and adverse trend results.

2. Select the Audit Team Members:

- a. Observe independence requirements
- b. Select members based upon specialized expertise as related to the type and scope of the audit
- c. Collect evidence of auditor(s) qualifications and lead auditor certification (as appropriate) for the file

3. Establish and issue an audit plan that describes:

- Audit scope and objectives
- Who will be audited and by whom (organizational identities)
- Location of audit activities including schedule of daily activities and affected organizations
- Audit dates and times for pre-audit conference and post-audit conference
- Identify audit team leader and auditors, observers, and technical specialists, as applicable
- Identify required reference documents and facilities needed in addition to escort staff requirements (as appropriate)

4. Collect audit reference data for background to support development of the audit checklist

5. Identify and make advance request to ensure auditee has necessary documents, files, and reference materials on hand to support audit planning and conduct

6. Prepare audit team members and make assignments

7. Develop a schedule for audit planning to identify need dates for major steps in the audit planning process to include but not limited to the above, including:

- Identify audit scope and objectives

AUDIT PLANNING/PREPARATION GUIDELINES
(Continued)

- Draft audit notification letter (attach Audit Plan and request facilities and reference documents be made available for the audit term's use)
- Draft audit plan
- Establish audit team (commensurate with audit scope and complexity)
- Issue audit notice and plan
- Draft audit plan
- Collect/verify audit team member qualifications
- Develop audit daily schedule identifying organizational contacts, phone numbers and include special notes and technical areas, systems, documents, equipment, etc., to be audited
- Develop audit checklist
- Approve audit checklist
- Assemble audit notebooks
- Conduct audit team briefing and document same

AUDIT TEAM BRIEFING GUIDELINES

Prepare for Audit

1. Review audit scope, location, dates, and audit plan
2. Review and discuss type of audit; compliance/effectiveness/technical, etc.
3. Describe roles of:
 - Audit Team Leader - Manages audit process
 - Auditor - Investigates/records results
 - Technical Specialist - Advises/audits/records results
 - Observer - Does not ask audit questions of organization being audited
4. Verify audit team member qualifications
5. Review audit team member assignments/sub-team arrangements
6. Review daily audit schedule and audit strategy
7. Review pre-audit and post-audit functions
8. Discuss previous audit findings and/or areas of specific concern for follow-up
9. Review auditor checklist areas of responsibility. Auditors are to:
 - Ask questions that cause auditee to describe how things are being done; avoid yes/no questions
 - Record on checklist: a description of what was looked at (documents, systems, equipment), record numbers where possible including results, (whether positive or negative), and any DCAR nos. generated
 - Record names of persons contacted and their organizational relationship
 - Get copies of problem documents for future reference
 - Follow-up previous audits, reviews, surveillances, results for evidence of corrective action completion
 - Use blank checklist forms to write in new questions as appropriate during the audit
 - Prepare daily audit summaries to support the audit team leader's daily briefing to management of the audited organization
10. Identify that auditee will be requested to describe the present scope of work and percent completion or current status
 - Identify audit logistics - access, escorts, transportation, admin support, etc.

AUDIT TEAM BRIEFING GUIDELINES
(Continued)

11. Discuss audit mechanics

- Audit Team caucus
- Audit Team consensus for development of daily audit summaries to be presented to management of the organization being audited
- Plans for audit summary preparations prior to post-audit conference
- Development of the audit report (whom, how, when)

12. Discuss special concerns or questions from audit team personnel

13. All sign attendance sheet

14. Adjourn meeting

PRE-AUDIT CONFERENCE GUIDELINES

1. Introductory remarks by auditing and audited organization's management
2. Introductions - all members present (introduce audit team members)
3. Route Attendance Sheet
4. Distribute audit plan - discuss audit dates, times, post-audit conference, audit scope and type
5. Have auditee brief audit team on present contract activities and general scope and status of work relative to the audit
6. Request identification of organizations to be contacted during the audit in accordance with the daily audit schedule and knowledgeable contacts for audit team interface and escorts
7. Request appropriate number of copies of reference and quality assurance documents be available in audit team caucus room
8. Inform auditee that audit team will be available on a daily basis to summarize results of that days activities. Audit team will caucus each day prior to the briefing
9. Request short familiarization tour of facilities prior to start of audit activities
10. Open for questions and answers
11. Close Pre-audit Conference
12. Collect Attendance Sheet(s)
13. Caucus with audit team prior to start
14. Review audit team agenda with designated contacts prior to start of audit to confirm whom to interview and where they are located

POST-AUDIT CONFERENCE GUIDELINES

1. Route Attendance Sheet
2. Thank management for staff cooperation during the audit, if appropriate
3. Give a brief, overall summary - general observation of audit results (positive and negative)
4. Describe how findings are categorized: deviations, observations, and comments
5. Ask that auditee comments be held until after results are presented
6. Present positive points
7. Read findings of deviations, observations, and comments
8. Identify results of follow-up activities to previous audit(s), evaluations, etc., if applicable
9. Open the meeting for brief comments and discussion regarding results
10. Indicate when the audit report will be issued
11. Indicate when the audit report response is due and to whom and where the response is to be addressed. Indicate that the response is to identify:
 - Root cause of identified deficiencies
 - Corrective action(s) proposed to correct the identified deficiencies and any similar conditions
 - Corrective action(s) proposed or taken to prevent recurrence
 - Date(s) when the proposed action(s) were completed or a schedule for completion of all proposed corrective actions
12. If no questions - collect Attendance Sheet(s)
13. Thank participants - close meeting

memorandum

DATE OCT 25 1991

REPLY TO
ATTN OF RW-3

SUBJECT Report of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit HQ-91-003 on the Vittrification Projects Branch (EM-343)

TO Chief, Vittrification Projects Branch
Office of Waste Operations, EM-343

Reference: Memorandum from EM-30 to Donald G. Horton dated October 4, 1991, "Stop Work on the Vittrification Projects Technical Review Groups"

Attached is the report for QA Audit HQ-91-003. The audit was conducted by the OCRWM Headquarters QA Division at EM-343 facilities in Germantown, MD on August 26-30, 1991.

During the course of this audit, the audit team generated nine Corrective Action Requests (CARs) documenting deficient conditions and eight observations of areas where EM-343 might improve their QA program.

Because of the collective severity of the deficiencies found during the audit, EM-30 took the initiative to stop work by the Vittrification Projects Technical Review Groups on October 4, 1991, (see referenced memorandum). RW-3 believes that the actions to be completed prior to lifting the stop work, as given in the referenced memorandum, need to be supplemented to support OCRWM needs. It is requested that EM-343 provide a more detailed list of prerequisite actions necessary to resume work. This list should take into consideration approved responses to open OCRWM CARs, as appropriate, previously issued to EM-343. It is also requested that EM-343 transmit to this office, for the record, documented evidence that this "stop work" is being controlled under the EM QA program (DCAR, etc.). Also, during the period of the stop work, OCRWM OQA representatives shall:

- o participate in all verification activities (e.g., audits, surveillances and assessments) performed by EM-343, and
- o prior to lifting the stop work, verify completion of all agreed to prerequisite actions.

Responses to the CARs (which were transmitted via separate letter) are due by the date indicated in block ten of the CARs. A response to this audit report is not necessary. The subject audit is considered completed as of the date of this letter; however, any open CARs will continue to be tracked until they have been closed to the satisfaction of the audit team leader and the Director, OQA.

If you have any questions, please contact Bob Clark or myself at (202) 586-8858.



Donald G. Horton, Director
Office of Quality Assurance
Office of Civilian Radioactive
Waste Management

Attachments

cc:

S. Cowan, EM-30
M. Frei, EM-34
J. Hennessey, EM-343
K. Chacey, EM-343
F. Peters, RW-2
C. Gertz, RW-20
J. Roberts, RW-30
R. Milner, RW-40
D. Spence, YMSPCO
S. W. Zimmerman, NWPO, Carson City, NV
K. Whipple, Lincoln County, NV
M. Baughman, Lincoln County, NV
J. Bingham, Clark County, NV
D. Bechtel, Clark County, NV
Englebrecht von Tiesenhasuen, Clark County, Las Vegas, NV
P. Seidler, SAIC
R. Campbell, Inyo County, CA
R. Michener, Inyo County, CA
G. Derby, Lander County, NV
C. Schank, Churchill County, NV
C. Jackson, Mineral County, NV
F. Sperry, White Pine County, NV
L. Vaughan, Esmeralda County, NV
K. Hooks, NRC, Washington, D.C.
J. Conway, NRC, Washington, D.C.
J. Buckley, NRC, Washington, D.C.
R. J. Brackett, TESS, HQ (RW-3) FORS

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT REPORT
OF
EM-343, VITRIFICATION PROJECTS BRANCH
AUDIT NO. HQ-91-003
AUGUST 26 THROUGH AUGUST 30, 1991

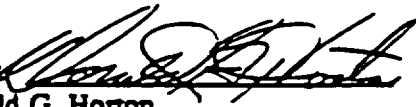
Prepared by:


Norman C. Frank
Audit Team Leader
CER Corporation

Date:

10/22/91

Approved by:


Donald G. Horton
Director
Office of Quality Assurance

Date:

10/25/91

EXECUTIVE SUMMARY

The audit team concluded that, in general, the quality assurance program for the Vittrification Projects Branch, EM-343, was not being fully implemented and for this reason was determined to be "not effective." Two of the 11 criteria audited were found to be effective. Two criteria were found to be indeterminate because insufficient work had been done to allow an evaluation. Seven criteria were found to be "not effective" for the work done. Nine Corrective Action Requests resulted from this audit. In addition, eight observations are presented to the auditee for consideration.

As a result of discussions among RW-3, EM-30 and EM-343 management, EM-30 has taken limited stop work action. Because of the general lack of compliance with the quality assurance program, the infrastructure needed to support the technical review activities is not adequate. Work on the technical review activities has been stopped until specified actions to ensure compliance with the quality assurance program and establish the infrastructure needed to support the technical activities have been taken. EM-343 has agreed to keep OCRWM apprised of the status of completion of prerequisite actions to resume work in this area.

1.0 Introduction

The Office of Civilian Radioactive Waste Management (OCRWM) performed a quality assurance audit (number HQ-91-003) of the Vitrification Projects Branch (EM-343) of the Waste Operations Division of the Office of Environmental Restoration and Waste Management. The audit was conducted by an audit team from the Headquarters Quality Assurance Division (HQAD) of the Office of Quality Assurance (OQA). The audit was performed in accordance with Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program," and the associated audit plan [reference letter from RW-3 to Associate Director, EM-30, dated July 29, 1991, "Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit HQ-91-003 of the Vitrification Projects Branch (EM-343)"].

2.0 Audit Scope

The audit evaluated compliance to and the effectiveness of the EM-343 QA program as described in the Environmental Restoration and Waste Management (EM) Quality Assurance Program Description (QAPD), DOE/EM/WO/01 and DOE/EM/WO/02 and their associated Standard Practice Procedures (SPPs).

The adequacy of the QAPD was evaluated separately and was not included as a component of this audit (Reference DOE letter from RW-3 to Chief, Vitrification Projects Branch, EM-343, dated April 8, 1991, "Review of EM QAPD, Revision 0"). The adequacy of the SPPs (revision 0) was not reviewed in detail because of the already identified weaknesses in the EM QAPD.

No previous audits of EM-343 had been performed by OCRWM. Although three surveillances had been performed by OCRWM within the past two months, only one surveillance report had been issued and EM-343 had not had time to respond to the report. The results of these surveillances (HQ-SR-91-011, HQ-SR-91-016, and HQ-SR-91-014) were taken into account when auditing the following SPPs:

- SPP 3.04, "Documentation of Surveillance and Review Personnel Qualifications" - qualifications of review personnel only
- SPP 4.05, "Administration of Technical Reviews"
- SPP 4.06, "Conduct of Technical Reviews"
- SPP 4.11, "Review of Waste Acceptance Process Technical Documents"
- SPP 4.12, "Review of Program Execution Guidance Documents"
- SPP 7.01, "Preparation, Transfer, and Receipt of Quality Records"
- SPP 7.02, "Quality Records Management"

The following procedure was not included in the audit because it was determined that it had been adequately covered during surveillance HQ-SR-91-014:

- SPP 3.03, "Certification of Quality Assurance Audit Personnel"

The programmatic elements audited are identified below:

OA PROGRAM ELEMENTS

- 1 - Organization
- 2 - Quality Assurance Program
- 3 - Design Control (including software and scientific investigation)
- 4 - Procurement Document Control
- 5 - Instructions, Procedures, and Drawings
- 6 - Document Control
- 7 - Control of Purchased Items and Services
- 15 - Control of Nonconforming Items
- 16 - Corrective Action
- 17 - Quality Assurance Reports
- 18 - Audits

The following programmatic elements were not reviewed during the audit because they are not included within the scope of the EM quality assurance program and no work had been done in these areas:

- 8 - Identification and Control of Items
- 9 - Control of Processes
- 10 - Inspection
- 11 - Test Control
- 12 - Control of Measuring and Test Equipment
- 13 - Handling, Storage, and Shipping
- 14 - Inspection, Test, and Operating Status

The audit of implementation and statements of effectiveness were based on the issued revisions of the QAPD and SPPs at the time of the audit.

The audit of technical areas was limited to a review of:

- 1. Qualifications of technical personnel
- 2. Understanding of procedural requirements as they pertain to the development and qualification of waste forms.

3.0 Audit Team and Observers

The following is a list of audit team members and observers.

Audit Manager Robert W. Clark
Audit Team Leader Norman C. Frank

DOE, Washington, D.C.
CER Corp., Arlington, VA

Auditors	R. Dennis Brown Robert G. Thomas Craig G. Walenga Clyde D. Morell Thomas E. Rodgers Louis Wade	CER Corp., Arlington, VA CER Corp., Arlington, VA CER Corp., Arlington, VA CER Corp., Arlington, VA CER Corp., Arlington, VA WESTON, Washington, DC
Observers	John T. Buckley USNRC James T. Conway Frank E. Nash	USNRC Duke Eng/TESS

4.0 Summary of Audit Results

4.1 Program Effectiveness

The audit team concluded that, in general the quality assurance program for EM-343 was not being fully implemented and for this reason was determined to be "not effective." Two of the 11 criteria audited were found to be effective. Two criteria were found to be indeterminate because insufficient work had been done to allow an evaluation. Seven criteria were found to be "not effective" for the work done. Nine Corrective Action Requests resulted from this audit. In addition, eight observations are presented to the auditee for consideration.

4.2 Stop Work Action

As a result of discussions among RW-3, EM-30 and EM-343 management, EM-30 has taken limited stop work action. Because of the general lack of compliance with the quality assurance program, the infrastructure needed to support the technical review activities is not adequate. Work on the technical review activities has been stopped until specified actions to ensure compliance with the quality assurance program and establish the infrastructure needed to support the technical review activities have been taken. EM-343 has agreed to keep OCRWM apprised of the status of completion of prerequisite actions to resume work in this area.

4.3 Programmatic Audit Activities

Details of programmatic audit activities are provided in Attachment 1. A list of objective evidence reviewed during the audit is provided in Attachment 2.

4.4 Technical Activities

The qualifications of review personnel were evaluated during the audit. EM personnel's understanding of procedural requirements as they pertain to the development and qualification of waste forms was also evaluated during the audit. The results are included in this report.

4.5 Summary of Deficiencies

The audit team identified numerous deficiencies during the audit. These were consolidated into nine CARs. A synopsis of the CARs and observations is presented in Section 6.0. Information copies of the draft CARs are included in Attachment 3.

Of the nine CARs written, three represented significant failures of the EM personnel to understand and implement the quality assurance program, one represented insufficient definition of the quality assurance program, and five represented deficiencies in the implemented portion of the quality assurance program.

5.0 Audit Meetings and Personnel Contacted

The preaudit conference was held at EM-343 offices in the Trevion II building in Germantown, MD on August 26, 1991. A daily debriefing and coordination meeting was held with EM-343 management and staff. The postaudit conference was held in the Trevion I building in Germantown, MD on August 30, 1991. A list of personnel involved in the audit is included in Attachment 4.

6.0 Synopsis of Corrective Action Requests Issued and Observations Noted

6.1 Corrective Action Requests (CARs)

HQ-91-035 Personnel demonstrated a general lack of compliance with the issued Standard Practice Procedures.

HQ-91-036 The training program was inadequate and ineffective.

HQ-91-037 No management assessments or internal QA program audits of EM-343 had been completed.

HQ-91-038 The QARG-1 (SPP) did not: a) comply with the applicable SPPs or its own charter, nor b) adequately review the draft revision 1 or draft revision 0 SPPs.

- HQ-91-039 EM-343 has not established and implemented a systematic method for defining the work that is subject to the EM-343 QA program requirements. SPP 2.05, "Selective Application of Quality Assurance Activities," was not issued at the time of the audit. No method existed for the selective application of QA activities to EM-343 work.
- HQ-91-040 ✓ The EM-343 Branch Chief had not designated a person to fill the HLW Quality Assurance Program Manager position.
- HQ-91-041 ✓ Deficiencies identified in Surveillance Report 91EA-VP-S-003, dated 6/14/91, were not documented on deviation reports. In addition, no action had been taken to correct the identified deficiencies. The deficiencies had been included in the Quality Improvement Log rather than being documented on deviation reports. The surveillance report had not been "accepted" by EM-343.
- HQ-91-042 ✓ The administrative support contract for BDM does not require BDM to perform work in accordance with the SPPs or the EM-343 QAPD.
- HQ-91-043 EM-343 has not reviewed and accepted the West Valley or Richland Office implementing procedures.

6.2 Observations/Recommendations

1. Several of the existing SPPs are concerned with topics of an administrative/program management nature that, although needed, do not have to be included within the scope of the quality assurance program, yet are shown in the EM QAPD requirements matrix as being necessary to satisfy DOE/RW-0214 (QARD). These procedures are fairly prescriptive, and any flexibility in their implementation is forfeited by maintaining them as procedures that affect quality. Because they are auditable, implementation and compliance problems are inevitable. EM-343 should consider removing the following procedures from the EM QAPD requirements matrix:
 - ✓ SPP 6.01 "Official HLW Office Files"
 - ✓ SPP 6.02 "Preparation of Correspondence"
 - ✓ SPP 6.03 "Incoming Mail"
 - ✓ SPP 6.04 "Commitment Control"
 - ✓ SPP 9.01 "Preparation and Maintenance of the Program Schedules"
 - ✓ SPP 9.02 "HLW Monthly Progress Reporting"
 - ✓ SPP 9.03 "Preparation and Maintenance of the Work Breakdown Structures (WBS)"

2. The procedures for corrective action, including the Deviation and Corrective Action Report (DCAR), quality improvements, and trending systems should be evaluated for unnecessary overlap of system function and definition of applicability. Consolidation of procedures with significant overlap is recommended.
3. Deficiencies identified during audits of the Savannah River Operations Office are not being promptly corrected. The response to DCARs issued as a result of a February 1991 audit was only recently received. Several DCARs from the June 1990 audit remain open. The audit team recognizes that considerable effort by EM has been made to obtain responses from Savannah River, but the audit team also recognizes that the responsibility rests with EM-343 for timeliness and for adequacy of responses.
4. The audit team was informed that the EM-343 working files are to contain a complete set of the working documents. However, the audit team identified numerous instances where complete working files were not present. Examples are:
 - personnel qualification and certification records for the WVDP technical review groups
 - complete working files for such areas as complete DCARs and completed audit checklists
 - training and qualification records for some audit team members.

The audit team recognizes that EM is now in the process of completing the working files.

5. The qualifications of two technical specialists used on audit 91EA-WV-AU-001 were reviewed. While their overall qualifications were excellent, a concern exists that the two technical specialists were not qualified for the areas of review that they were assigned. One technical specialist was assigned to sections 1, 2, 16, and 18 of the West Valley QAPD while the other technical specialist was assigned to sections 3, 5, 6, 10, 17, and 19. Since the audit report was deficient in addressing exactly what was audited, and the completed checklists of these two technical specialists were not available to the audit team, this concern could not be resolved. EM-343 should ensure that the qualifications of future technical specialists match the expertise needed to review areas assigned. It is further recommended that technical specialists be used to review the adequacy of work products and work performed.
6. The PEGD provides requirements to be met by the Operations Offices' QAPDs. The guide sheets (review plans) for the EM-343 reviews of Operations Office QAPDs do not list the PEGD as one of the base documents to be used during the review.

7. A trend analysis of DCARs has not been performed. There are approximately 40 DCARs that could be analyzed for trends. The audit team recognizes that a new system to track and analyze DCARs is now being developed.
8. There is no objective evidence that the Richland Operations Office has been sending quarterly "QA and Safety Status Reports" to EM-30 as required by the PEGD.

7.0 Required Actions

Responses to the CARs were requested in a separate memorandum that formally transmitted the CARs to EM-30. Responses will be evaluated and followup action will be performed in accordance with QAAP 16.1, "Corrective Action."

Responses to the recommendations are not required, but appropriate management attention and action should be taken.

8.0 List of Attachments

- Attachment 1: Audit Details
- Attachment 2: List of Objective Evidence Reviewed During the Audit
- Attachment 3: Information Copy of Draft CARs
- Attachment 4: Personnel Involved in the Audit

ATTACHMENT 1

Audit Details

The following is a summary of programmatic activity covered during the audit. A list of objective evidence reviewed during this audit and the full document identification number, revision status, and title for Standard Practice Procedures (SPPs) referenced below are given in Attachment 2.

1.0 Organization

The evaluation of Criterion 1 was based on personnel interviews and a review of the current organizational structure. The areas evaluated included:

- Organizational Responsibilities and Authority
- External and Internal Interfaces
- Differing Staff Opinions and Allegations (SPP 10.03)
- Control of Unsatisfactory Conditions (Stop Work Orders) (SPP 5.03)

The organization as depicted in the QAPD does not accurately describe lines of responsibilities and authority for the implementation of Standard Practice Procedures nor does it accurately describe the interfaces with other organizations, for example, EM-1, EM-20, EM-30, RW, WAC, MSC. This concern had been previously addressed in the formal comment review of the DOE/EM/WO/02 (QAPD) Rev.0.

The SPPs use titles for the "performer" that have not been defined within the EM-343 organization. Examples include: SPP Coordinator, Manager (Project or EM-343?) Approver, and Organizational Director (there is no "Director" in EM-343). As a consequence, personnel interviewed were unsure who was to perform the specified actions.

Deficiencies identified were included in Corrective Action Request HQ-91-035 and HQ-91-040.

An evaluation of SPP 10.03, "Differing Staff Opinions and Allegations," concluded that personnel are aware of the procedure and have been indoctrinated, however, to date no differing opinions or allegations have been identified.

An evaluation of SPP 5.03, "Control of Unsatisfactory Conditions (Stop Work Order)," concluded that to date, stop work authority had not been exercised. In addition, the evaluation revealed that no indoctrination or training had been presented to EM-343 personnel on SPP 5.03.

Based on the facts that organizational interfaces are not clearly defined and performers identified in SPPs have not been defined, Criterion 1 is found to be not effective in its implementation.

2.0 Quality Assurance Program

The evaluation of Criterion 2 was based on personnel interviews and review of objective evidence. The evaluation included:

- QA Program Documentation
- Indoctrination and Training of Personnel
- Qualification and Certification of Personnel
- Surveillance and Assessments
- Review and Reporting of QA Program Status

The evaluation identified the following deficiencies that were included in Corrective Action Requests resulting from the audit.

1. Indoctrination and training (CAR HQ-91-036)

- There were provisions for ensuring that people performing quality-affecting activities are indoctrinated/trained prior to performing the activity.
- Of the 43 SPPs issued to implement the QA Program, only 16 have been identified as requiring indoctrination/training.
- Lesson plans were not approved by the QA Specialist or the manager (Branch Chief) as required by procedure.
- Personnel were not indoctrinated/trained on procedures for which they have responsibility to implement.

2. No annual assessments have been performed to date (CAR HQ-91-037).

3. Deviations identified in EM-343 Surveillance Report 91EA-VP-S-003 were not documented on deviation reports (CAR HQ-91-041).
4. The audit team evaluated the qualifications of the reviewers. Deficiencies were identified and included in CAR HQ-91-036. The evaluation of audit and surveillance personnel qualifications had been previously addressed in Surveillance Report HQ-SR-91-014 and resulted in the issuance of CAR HQ-91-034. However, the reviewers qualifications were not evaluated during the surveillance.

The following SPPs could not be audited due to insufficient activities occurring to demonstrate implementation:

- SPP 8.01, "Coordination of Reviews and Evaluation by Outside Organizations"
- SPP 9.01, "Preparation and Maintenance of the Program Schedules"
- SPP 9.02, "HLW Monthly Progress Reporting"
- SPP 9.03, "Preparation and Maintenance of the Work Breakdown Structure"
- SPP 10.01, "Identification and Analysis - Trends"

Based on the numerous instances of procedural noncompliance identified during the audit, Criterion 2 has been found to be not effective in its implementation.

3.0 Design Control

The implementation of SPPs related to design control were reviewed as follows:

SPP 4.05, "Administration of Technical Reviews", Rev. 0; and
SPP 4.06, "Conduct of Technical Reviews", Rev. 0

The audit team conducted interviews with the WVDP Program Manager and the Tech. Rev. Manager regarding the implementation of the SPPs.

The audit team reviewed the statement of work for both the WVDP Waste Form Compliance Plan (WCP) #1 and the WVDP Waste Form Qualification Report (WQR) #3. In addition, the Technical Review Group charter was reviewed for the WVDP WCP#1. The Review Log for the TRG Waste Acceptance Activities and the WVDP WQR TRG Log Sheet were also reviewed. The TRG Review and Comment Records were reviewed. In all cases, it appeared that the implementation of the two TRGs had been conducted in accordance with the controlling SPPs. The audit team considered that adequate review criteria existed between the statement of work and the TRG charter to support a meaningful review.

It was not possible to verify the qualifications and experience of the TRG review team due to the fact that those records were currently retained by the TRG Executive Secretary at Argonne National Laboratory. EM-343 personnel could not locate duplicate copies of these records in the working files for the subject TRGs.

Based on discussions held with the Assistant Program Manager for WVDP, it was determined that the EM-343 level of activity regarding facilities, software, and scientific investigation was in its beginning stages and did not yet warrant review. Consequently, the effectiveness of the implementation of Criterion 3 is not determinate.

4.0 Procurement Document Control

EM-343 has two types of procurement documents. The Program Execution Guidance Document (PEGD) is used to transmit EM-343 technical and QA requirements to West Valley, Hanford, and Savannah River Operations Offices. It was already identified in an

earlier surveillance that EM-343 was not reviewing the PEGD in accordance with Standard Practice Procedure (SPP) 4.12. The PEGD (FY1991) was found to be inadequate because the requirements of DOE/RW-0214 were not included in the PEGD.

The other procurement vehicle is a contract. EM-343 has a direct support services contract with BDM Corporation. The BDM/SAIC support team was under the direct supervision of EM-343 personnel. The audit team could not verify that support team personnel were contractually required to work to the QAPD or the SPPs. CAR HQ-91-042 was written for this deficiency.

The only other activity reviewed under this criterion was the work performed by PDC personnel. It was determined that PDC personnel are receiving contractual direction from the Richland Operations Office and technical direction from EM-343.

Based on the above, procurement document control was found to be not effective in its implementation.

5.0 Instructions, Procedures, and Drawings

The audit team reviewed the working files of seven revision 0 SPPs. The files were available at the PDC-Germantown offices. Each working file was neatly maintained and contained a copy of the original DWTM-HLW version of the respective SPP, an instruction file index for the working file, an approved-original section, an instruction coordination log section, a memo to file, a reviewer comment and disposition section, and a reference material section. For each of the seven working files, the instruction file index sheet was not completed, there was no approved original SPP in the working file, the coordination log had not been completed, and the reviewer comment and disposition forms were in various stages of completeness with no one form fully completed. These working files are to be maintained by the SPP Coordinator, who was identified as PDC. Numerous violations of SPP 2.01 requirements were noted in reviewing the incomplete working files. These procedural noncompliance problems have been addressed in CAR HQ-91-035.

The audit team was informed that though the SPPs were issued in February 1990 the entire process of procedural development and review was done prior to the approval of SPP 2.01, which accounts for the incompleteness of the working files. It appeared to the audit team that the completeness of the revision 0 SPP working files was a low priority to the SPP Coordinator as draft revision 1 SPPs have already been written and reviewed.

Criteria for the review of the SPPs were not found though an after-the-fact informal review of the SPPs against the DOE/RW-0214, QARD, Rev. 2, Requirements Matrix was performed.

The audit team did not find evidence in the working files that any EM-343 staff member was involved in the formal review process for the revision 0 and draft revision 1 SPPs audited.

A check for the establishment of any quality records packages showed that only the issued SPPs have been set up as quality records while the remaining quality records required by SPP 2.01 have not been created due to the incompleteness of the working files.

The audit team evaluated the preparation of the 47 draft SPPs of which most were modifications to the revision 0 SPPs. SPP 2.01 revision 0 was used to determine compliance. The same SPPs selected for the revision 0 review were selected for the revision 1 review along with SPP 2.05. The working files of these SPPs were presented to the audit team. The working files were similar in nature in that they contained something called a "document traveller" which replaced the SPP coordination log that had been used previously for revision 0 SPP working files. In general, the document traveller contained or could contain the information required by SPP 2.01 for each SPP. The document traveller identified the author of the SPP or SPP revision and had the signatures or initials of the reviewers. It was noted that for four SPPs of the eight evaluated, the author of the SPP was also listed as a reviewer.

The audit team did not find evidence that any EM-343 staff member was involved in the formal review process of the draft SPPs reviewed.

No reviewer comments or resolutions of the comments were present in the working files. Though SPP 2.01 revision 0 requires the maintenance of reviewer comments and comment resolutions, the SPP Coordinator stated that reviewer comments were no longer being kept although some [an unknown quantity] completed forms may still be available in Oak Ridge. After a review of the draft SPP 2.01 revision 1, the auditors noted that the SPP Coordinator was not complying with the existing SPP 2.01 revision 0 but was basically implementing the unapproved process described in draft SPP 2.01 revision 1.

While discussing the adequacy of these reviews, the PDC SPP Coordinator and support personnel informed the audit team that SPPs were also reviewed by a QARG and the documentation of their review comments and comment resolutions would show a thorough review. The audit team attempted to establish if the QARG review represented a quality assurance program review or was actually a management function that was performed outside of the quality assurance program because the EM-343 QAPD and the SPPs did not address this review group. The EM-343 Branch Chief informed the audit team that the QARG review of the SPP was done to meet the review requirements of the SPPs. The audit team was first told that the QARG review was not performed to comply with any SPP but was done in accordance with a charter. Later, SPPs 4.05 and 4.06 were identified as the applicable SPPs for the QARG. The charter and review documentation were provided to the audit team. It was noted that two members of the QARG-1 (SPP) were not members of the core group listed in the charter.

The adequacy of the QARG-1 (SPP) review was assessed based on the documentation provided in a March 5, 1991 letter from M.H. Campbell to W.J. Kehew that contained the agenda for the QARG-1 (SPP) meeting, review criteria, and the SPP review assignments. The results are included in CAR HQ-91-038.

To evaluate the adequacy of the QARG-1 (SPP) review, the audit team reviewed the draft SPP 2.01 revision 1 and draft SPP 2.05, revision 0 that had been reviewed by the QARG-1 (SPP) for compliance with DOE/RW-0214, QARD. The results are included in CAR HQ-91-038.

Based on the numerous instances of procedural noncompliance and inadequate reviews identified during the audit, Criterion 5 has been found to be not effective in its implementation.

6.0 Document Control

The audit team attempted to verify that the requirements contained within the EM QAPD for Document Control were adequately reflected within the SPPs to ensure adequate implementation. Several instances were identified in which QAPD requirements were not contained within the SPPs, thus jeopardizing their implementation. No objective evidence could be found that the following QAPD requirements had been satisfied:

The QA Program Manager and the QA Specialists have reviewed the document control system and have confirmed its readiness to function prior to implementation (Para. 6.1.1).

Controlled documents have been reviewed for adequacy by the QA Program Manager (Para. 6.1.3).

The Branch Chief has established an appropriate review schedule for the accepted controlled document (Para. 6.1.3).

The QA Program Manager participates in and monitors the execution of the document control system (Para. 6.1.5).

These results are not included in a CAR but are expected to be addressed in the next revision to the SPPs. The SPPs will be revised to also address changes to the QAPD necessitated by upgrading to meet Revision 4 of the QARD and to address deficiencies identified in the HQ review of the EM QAPD.

SPP 2.03, "Quality Assurance Program Description Preparation, Maintenance, and Control", Rev. 0

The audit team interviewed the PDC Program Manager and a BDM QA Support person regarding the implementation of SPP 2.03.

The audit team reviewed the working file for the preparation of the EM QAPD DOE/EM/WO/02, Rev. 0 which is currently in effect. The development of the QAPD appeared to comply with the requirements contained within the SPP. The establishment of formal review and acceptance criteria was not as formalized as it could have been. The Quality Assurance Review Group (QARG) used the review matrix for the NRC Standard

Review Plan and the 0214 Document for their review criteria. The EM-343 internal reviewers used an internal letter from the Branch Chief which basically stated to review the document relative to their areas of responsibility. Although the criteria provided could have been more specific, they are considered to have met the intent of the SPP. An opportunity exists for management to establish more definitive review and acceptance requirements for the upcoming Rev. 1 to the EM QAPD.

The audit team reviewed the Review and Comment Records as well as the annotated drafts. In all cases, comments appeared to have been adequately resolved. Mandatory comments were initiated by each reviewer indicating acceptance of the resolution.

The audit team reviewed the control and distribution of the EM QAPD. A distribution list, approved by the PDC Program Manager, was in effect. The list had been most recently revised on 8/26/91 to reflect two recent additions. The Document Transmittal/Receipt forms were randomly compared against the Distribution List to verify accuracy. No problems were noted. Two sets of EM-343 QAPDs were randomly pulled and verified to be accurately reflected on the Distribution List and the Transmittal/Receipt Forms.

SPP 2.04, "Control of the Standard Practice Procedures Manual", Rev. 0

The audit team interviewed the PDC Program Manager and a BDM QA Support person regarding the implementation and requirements of SPP 2.04.

PDC is responsible to EM-343 to perform document control responsibilities on their behalf. A PDC Oak Ridge person has been designated as the SPP Coordinator. She maintains the SPP Distribution List, which is approved by the PDC Program Manager. The latest Distribution List was issued 8/26/91 to reflect several current additions. The list appeared to be accurate and was in compliance with the requirements of the SPP. The audit team randomly sampled several individuals to verify distribution was as stated. No revisions have been made to any of the SPPs to date.

The Transmittal/Receipt Memorandums were reviewed to verify acknowledgement. In all but one case, which was still within the allowable 10 day time frame, the forms had been returned and were available for review.

The audit team verified that PDC Oak Ridge SPP Coordinator had received training on SPP 2.04.

SPP 2.05, "Selective Application of QA Activities", Rev. 0

This SPP existed in a draft form but had not yet been issued. As a result, no mechanism was in existence to support the implementation of the QAPD requirement [Paragraph 2.7.1.(1)] for the selective application of QA controls. This is included in CAR HQ-91-039.

SPP 6.01, "Official HLW Office Files", Rev. 0

The audit team interviewed the EM-343 Branch Chief Secretary and a BDM QA Support person relative to the implementation and requirements of SPP 2.01. Both individuals demonstrated adequate knowledge of the procedure.

EM-343 Branch Chief has designated in writing his secretary as File Administrator. File numbers have been assigned to the HLW Office Files in accordance with DOE Order 1324.3 and Attachment A of the SPP. Alterations, additions, and deletions are tracked and reflected in periodic revisions to the file index. It was verified that the File Administrator had received training on SPP 6.01.

SPP 6.02, "Preparation of Correspondence", Rev. 0

The audit team interviewed the EM-343 Branch Chief Secretary regarding the implementation and associated requirements of SPP 6.02. The Secretary was adequately familiar with the SPP requirements.

EM-343 outgoing correspondence is prepared within the guidelines of DOE Order 1325.1A and SPP 6.02, Attachment A. The following three letters were reviewed for compliance to the guidelines:

- EM-343 to the Secretary dated 8/16/91
- EM-343 to Murial Scarborough, PR-23, dated 8/16/91
- EM-343 to Corinne Macaluso, RW-331, dated 7/30/91

The above correspondence was found to comply with procedural requirements.

SPP 6.03, "Incoming Mail", Rev. 0

The implementation of SPP 6.03 was not verified because: 1) this SPP is scheduled for cancellation in the next revision, and 2) the process described is not necessary to be contained within the scope of the QA Program.

SPP 6.04, "Commitment Control", Rev. 0

The audit team interviewed the EM-343 Branch Chief Secretary relative to the implementation of SPP 6.04. She was adequately familiar with the requirements of the SPP.

Several instances of procedural noncompliance were identified. These deficiencies are supporting elements for CAR HQ-91-035, which addresses the issue of procedural noncompliance.

The audit team verified that the Secretary had received training on SPP 6.04.

The audit team noted that SPP 6.01, SPP 6.02, SPP 6.03, and SPP 6.04, although necessary from an administrative standpoint, are not required to be included within the scope of the QA program.

SPP 6.05, "Controlled Documents", Rev. 0

The audit team interviewed PDC Program Manager and a BDM QA Support person regarding the implementation of SPP 6.05.

PDC, in the role of a direct support contractor to EM-343, performs the document control functions.

Controlled Document Master Lists have been developed and are maintained by PDC for each individual assignee. A sample of these lists was selected for the three EM-343 Program Managers and verified to be accurate regarding the controlled documents they actually had in their possession.

The audit team verified that the BDM SPP Coordinator and a BDM QA Support person had received training on SPP 6.05.

Although minor instances of noncompliance were noted with several administrative SPPs, controlled documents were found to be current and no obsolete/superseded procedures were found. Criterion 6 is considered to be effectively implemented.

7.0 Control of Purchased Items and Services

EM-343 oversees the quality affecting activities at the Operations Offices by reviewing their QAPDs and implementing procedures and by conducting QA audits and surveillance. The audit team evaluated activities in the QAPD and relevant implementing procedures. The log of review activities was current but did indicate several unreviewed documents. The auditors observed that EM-343 was using the QARG to perform the QAPD review required by SPP 4.10. However, these reviews were not performed in accordance with SPP 4.10. The Operations Office QAPDs did not include the requirements of the EM-343 QARD. The review plans did adequately address DOE Order 5700.6B, ASME NQA-1, and DOE/RW-0214. In addition, there was no evidence of DOE Project Managers approving review plans and review team compositions for Hanford and West Valley.

The auditors also reviewed the EM-343 review of Savannah River's QA implementing procedures. The review appears to have been adequate.

Based on the ineffective audit program (see Section 18.0) and the QAPD review irregularities, it can be concluded that Criterion 7 was not effective in its implementation.

15.0 Control of Nonconforming Items

EM-343 uses audits and surveillance to identify nonconforming items and conditions. They use a Deviation and Corrective Action Report (DCAR) form to document these nonconformances. PDC has recently developed a database for EM-343 to track the status of all DCARs and other nonconformances. The database is scheduled to be completed and ready for formal use on September 15, 1991.

The audit team reviewed files for eleven DCARs issued in the last two years. Most of the files were incomplete as the original records were being stored at PDC in Oak Ridge. However, based on records available for review, enough evidence existed to conclude that EM-343 was properly implementing the DCAR system. Criterion 15 is considered to be effectively implemented.

16.0 Corrective Action

EM-343 uses the DCAR form to document the corrective action activities required for nonconformances that are significantly adverse to quality. For the eleven DCARs reviewed the audit, there was not sufficient records to adequately review and evaluate the criterion. The lack of documentation in the working files made Criterion 16 not determinate.

17.0 Quality Assurance Records

Surveillance Report HQ-SR-91-016 covered the quality records system. Corrective Action Request HQ-91-033 issued as a result of this surveillance stated, "A Vitrification Projects Branch quality records system has not been established and implemented, and objective evidence does not exist that an effective quality records system has been implemented for or by any contractor that is required to comply with procedures SPP 7.01 and SPP 7.02."

Based on this surveillance, Criterion 17 was found to be not effective in its implementation.

18.0 Audits

SPP 4.02, "Administration of Quality Assurance Audits", Rev. 0, and SPP 4.03, "Conduct of Quality Assurance Audits", Rev. 0

The audit team assessed the implementation of SPPs 4.02 and 4.03. The third and fourth quarter 1991 evaluation plans were reviewed to verify the scheduling of audits. Audits were scheduled.

The audit team requested the working files for any conducted internal audits and was informed that EM-343 has not performed any internal audits. A CAR HQ-91-037 was written to address this condition.

Only three internal audits have been completed; two audits of Savannah River (SR) and one audit of West Valley (WV). The audit team chose to review the latest SR audit working file and the only West Valley audit working file. The certifications and qualifications of the lead auditors and auditors were not addressed as this area had been reviewed in surveillance HQ-SR-91-003.

Both audit working files contained an audit notification letter, audit plans, copies of the checklists that were to be used, and the audit report. The SPPs do not require the keeping of completed checklists as quality records.

Without the completed checklists as part of a quality records package, both audit reports were reviewed to assess the quality of the audit by evaluating the way the audit was conducted, the evidence reviewed, the assigned reviewers, and the overall conclusions made by the team. Both audit reports lack details as to what was reviewed, the depth and details of the areas reviewed, identification of the auditors to the areas reviewed, and the results of each of the areas audited. What was present was a description of only the negative findings and negative observations and effectiveness statements along with the usual information about the scope, attendees, and preaudit and postaudit conferences. This is contrary to SPP 4.03 Attachment B. This deficiency is included in CAR HQ-91-035.

The completed checklists were requested for the West Valley audit that was completed in June 1991. Only four completed checklists could be found in the working files. The four completed checklists were reviewed for completeness and content. The four checklists reflected various levels of completeness from very good to poor with the checklist of one previously qualified lead auditor being evaluated as poor because the documented information, in most cases, failed to identify who was interviewed and the details as to what was reviewed. The checklist also identified weaknesses that were not found to have been addressed in either the audit checklist or the audit report.

A review of the qualifications of two technical specialists was conducted. The two technical specialists had excellent technical qualifications; however, based on the audit plan and the audit report, it appeared that the technical specialists were either unneeded or were used in areas where they were not qualified or experienced to review. Completed checklists for these two technical specialists were not available for review and the audit report, as previously noted, was deficient in providing any details to support or dismiss this concern. An observation was written to address this concern.

No quality records had been created for the audits that have been performed.

SPP 4.13, "Participation in Evaluation Activities Led by External Organization", Rev. 0

The audit team interviewed an EM-343 QA Specialist and a PDC QA Specialist relative to the implementation of SPP 4.13 and the associated requirements.

EM-343 has participated in only one audit led by an external organization under the SPP 4.13 procedure. The EM-343 QA Specialist was originally scheduled to be the participant. However, just prior to the audit performance, a BDM person was substituted to act as EM-343's representative on the audit. ANL Audit # QA-91-07 was conducted 5/29-31/91. EM-343 took credit for this activity through the participation of the BDM person under Audit # 91-EA-AN-AU-001 of the Chemical Technology Division.

Both the EM-343 QA Specialist and the BDM person had received training on SPP 4.13, which was included in training modules 1, 2, & 3.

The audit team was unable to evaluate the BDM person's qualifications and experience in order to assess adequacy relative to the audit performed. These records were retained at PDC's Oak Ridge Office where he is normally assigned. However, based on interview, he appeared to be adequately experienced and qualified to participate on the audit.

An Audit Summary Report was not completed as required by SPP 4.13 requirements. However, the BDM person did file a Trip Report dated 5/31/91, which provided his assessment of the audit. This report is considered to adequately meet the intent of the Audit Summary Report since it contains the same type of information.

An External Evaluation Participation Record , Parts 1 & 2, had been completed and was contained in the audit working file. A quality records package for Audit # 91-EA-AN-AU-001 had not been prepared at the time of this audit.

Internal audits have not been performed, the audit reports do not contain the information required by the procedure and are insufficient to stand alone, and corrective action from Savannah River has not been received in what the audit team considers a timely manner. Based on this Criterion 18 is found to be not effective in its implementation.

ATTACHMENT 2

List of Objective Evidence Reviewed During the Audit

EM Quality Assurance Program Descriptions (QAPDs)

DOE/EM/WO/01, QAPD for High-Level Waste Processing

DOE/EM/WO/02, QAPD for High-Level Waste Form Development and Qualification

Standard Practice Procedures

- SPP 1.01, "Index of High-Level Waste Standard Practice Procedures for Quality Assurance", Revision 0
- SPP 2.01, "Standard Practice Procedures", Revision 0 and draft Revision 1
- SPP 2.03, "Quality Assurance Program Description Preparation Maintenance, and Control", Revision 0
- SPP 2.04, "Control of the Standard Practice Procedures Manual", Revision 0
- SPP 2.05, "Selective Application of QA Activities Manual", Draft Revision 0
- SPP 3.01, "Preparation and Maintenance of Plans for Personnel Training, Indoctrination, and Orientation", Revision 0
- SPP 3.02, "Preparation and Conduct of Personnel Training, Indoctrination, and Orientation", Revision 0
- SPP 3.03, "Certification of Quality Assurance Audit Personnel", Revision 0
- SPP 3.04, "Documentation of Surveillance and Review Personnel Qualifications", Revision 0
- SPP 3.05, "Administration of Personnel Certification and Qualification Records", Revision 0
- SPP 4.01, "Planning and Scheduling of Evaluation Activities", Revision 0
- SPP 4.02, "Administration of Quality Assurance Audits", Revision 0
- SPP 4.03, "Conduct of Quality Assurance Audits", Revision 0
- SPP 4.04, "Administration and Conduct of Surveillance", Revision 0
- SPP 4.05, "Administration of Technical Reviews", Revision 0
- SPP 4.08, "Administration of Peer Reviews", Revision 0
- SPP 4.09, "Conduct of Peer Reviews", Revision 0
- SPP 4.10, "Review of Operations Offices Quality Assurance Program Descriptions and Procedures", Revision 0
- SPP 4.11, "Review of Waste Acceptance Process Technical Documents", Revision 0
- SPP 4.12, "Review of Program Execution Guidance Documents", Revision 0
- SPP 4.13, "Participation in Evaluation Activities Lead by External Organizations", Revision 0
- SPP 5.01, "Deviation Reporting and Disposition", Revision 0
- SPP 5.02, "Management Action Request", Revision 0
- SPP 5.03, "Control of Unsatisfactory Conditions (Stop Work Order)", Revision 0
- SPP 5.04, "Disposition of Deviations Identified By Outside Organizations", Revision 0
- SPP 5.05, "Review of Unusual Occurrences", Revision 0

- SPP 5.06, "Control and Disposition of Deviations and Recommendations for Improvement by Outside Organizations", Revision 0
- SPP 6.01, "Official HLW Office Files", Revision 0
- SPP 6.02, "Preparation of Correspondence", Revision 0
- SPP 6.03, "Incoming Mail", Revision 0
- SPP 6.04, "Commitment Control", Revision 0
- SPP 6.05, "Controlled Documents", Revision 0
- SPP 7.01, "Preparation, Transfer, and Receipt of Quality Records", Revision 0
- SPP 7.02, "Quality Records Management", Revision 0
- SPP 8.01, "Coordination of Reviews and Evaluations by Outside Organizations", Revision 0
- SPP 8.02, "Quality Assurance Program Evaluation and Assessment of Adequacy and Effectiveness", Revision 0
- SPP 8.03, "Review and Reporting of Quality Assurance Program Progress and Status", Revision 0
- SPP 9.01, "Preparation and Maintenance of the Program Schedules", Revision 0
- SPP 9.02, "HLW Monthly Progress Reporting", Revision 0
- SPP 9.03, "Preparation and Maintenance of the Work Breakdown Structures (WBS)", Revision 0
- SPP 10.01, "Identification and Analysis of Adverse Quality Trends and Problems", Revision 0
- SPP 10.02, "Planning and Conduct of Quality Improvement", Revision 0
- SPP 10.03, "Differing Staff Opinions and Allegations", Revision 0

Working Files For:

- SPP 4.01, Revision 1, (Draft)
- SPP 4.02, Revision 1, (Draft)
- SPP 4.03, Revision 1, (Draft)
- SPP 7.01, Revision 1, (Draft)
- SPP 7.02, Revision 1, (Draft)
- SPP 2.01, Revision 1, (Draft)
- SPP 2.05, Revision 0, (Draft)
- SPP 4.05, Revision 1, (Draft)
- SPP 4.06, Revision 1, (Draft)
- SPP 4.01, Revision 0
- SPP 4.02, Revision 0
- SPP 4.03, Revision 0
- SPP 7.01, Revision 0
- SPP 7.02, Revision 0
- SPP 2.01, Revision 0
- Audit 91EA-SR-AU-001
- Audit 91EA-WV-AU-001

Organizational Charts

- Waste Acceptance Participants Organizational Chart Fig. 1.2.11(see QAPD).
- DOE EM Headquarters Organizational Chart - Fig. 1.0.1(see QAPD)
- DOE Waste Operations Organizational Chart - Fig. 1.0.2(see QAPD)
- Participants in High-Level Waste Processing Organizational Charts - Fig. 2.2.1-2

QA Planning

- FY 90-92 Long Range Plan and Schedule
- FY 89 4th Quarter Evaluation Plan and Schedule
- FY 90 1st Quarter Evaluation Plan and Schedule
- FY 91 2nd Quarter Evaluation Plan and Schedule
- FY 91 3rd Quarter Evaluation Plan and Schedule
- FY 91 4th Quarter Evaluation Plan and Schedule

Management Reports

- Management Assessment of EM-343 by PTSO (Draft) dated March 5, 1991

Monthly QA Program Status Reports

- EM-HLW, SR-HLWD and WSRC, dated May 14, 1991
- EM-343 HLW, dated June 25, 1991
- SR-HLWD, EM-HLW and WSRC, dated July 30, 1991

QA Program Reviews

- Letter dated July 30, 1991 from K. Chacey directing the implementation of SPPs effective October 31, 1990.
- Letter dated May 07, 1991 from K. Chacey acceptance of the HLW Form Producers Quality Assurance Program Interface Arrangements.
- Letter dated February 13, 1991 from W.J. Kehew addressing the review of the West Valley Demonstration Project QA Program.
- Letter dated July 30, 1991 from K. Chacey delegating authority to T. McIntosh, V. Trice and T. Gutmann.
- Letter dated April 8, 1991 from D. Horton transmitting formal comments on DOE/EM/WO/02 (QAPD)
- Letter dated October 23, 1990 from S. Cowan, conditionally accepting the SR/HLWD and WSRC Quality Assurance Program Descriptions.

Training

- Training Attendance Rosters
- Lesson Plans 03.901024.01 and HLW-9002
- Orientation to the QA Audit, dated 5/24-25/90
- QAMT Orientation to the SPPs, dated 10/16-18/90
- EM-343 QA Orientation, dated 10/29/90
- QA Orientation, dated 10/15/90
- QAMT Orientation to the SPPs, dated 12/12/90
- Needs Assessment Worksheets for K. Chacey, T. Gutmann, T. McIntosh, V. Trice and J. Hennessey
- Training Course Critique for QAMT Orientation to SPPs (Lesson HLW 9002) dated 10/18/90
- TI&O Status report for supporting contractor personnel, dated April 26, 1991.
- TI&O Status of EM-343 and Supporting Contractor Personnel (BDM/GER-RES 16027-91 to KA Chacey dated June 26, 1991)
- Description of SPP Training Modules #1, 2 & 3.
- QARG reviewer training records
 - QARG reviewer S. Marra (qualification records)
 - QARG reviewer D. Ryder
 - QARG reviewer R. Stockman
 - QARG reviewer M. Campbell
 - QARG reviewer B. Kehew
 - QARG reviewer J. Hummel
 - QARG reviewer J. Smith
 - Lesson plan for course #HLW 9101
 - Lesson plan for course #QARG 9001

Procurement Documents

- Fiscal Year 1991 Program Execution Guidance Document (PEGD).
- BDM/SAIC contractor support contract.

Control of Purchased Materials and Services

- EM-343 review documentation for the Hanford/Richland site Quality Assurance Program Description.
- EM-343 review documentation for the West Valley QAPD.
- EM-343 review documentation for the Savannah River site implementing procedures.

Technical Review Group Documentation

- Statement of Work for the TRG Evaluation of the WVDP Waste Form Compliance Plan, Rev. 0, dated 5/22/90

- Statement of Work for the TRG Evaluation of the WVDP Waste Qualification Report, Rev. 1, dated 5/11/90
- TRG Charter for the WVDP Waste Form Compliance Plan, Rev. 0, dated 5/22/90
- Review Log for the TRG Waste Acceptance Activities
- West Valley/WQR TRG Log Sheet

Nonconforming Items/Corrective Action

DCAR Nos. 91EA-SR-AU-001-003
91EA-SR-AU-001-005
91EA-SR-AU-001-009
QA90-EM-30-01-01
QA90-EM-30-01-06
90EA-SR-S-003-01
90EA-SR-S-003-02
91EA-SR-S-001-01
91EA-SR-S-001-02
91EA-WV-AU-001-03
91EA-WV-AU-001-05

Management Action Request #MAR-001, 5/9/91

Surveillances Reports

- 90EA-SR-S-002
- 90EA-SR-S-003
- 91EA-VP-S-003
- 91EA-SR-S-004
- 91EA-VP-S-006

Audit-Related Documents

- Audit 91EA-WV-AU-001 checklists for Lefman, Crawford, Stockman, and Ryder.
- Qualification Records for J. Flaherty, SAIC and M.H. Campbell, WHC

Audit Reports

Audit Report #90-15-03-1006 (external)
Audit Report #91-15-03-1012 (external)

Audit Report #91EA-AN-AU-001 (internal, BDM participated only)
Audit Report #91EA-WV-AU-001 (internal)
Audit Report #91EA-SR-AU-001 (internal)

Record Files

EM-343 Quality Records File located at the EM-343 offices

Correspondence

- M.H. Campbell to Mr. W.J. Kehew, March 5, 1991 Subject: QARG-1 SPP Review
- EM-343 Memorandum to Corinne Macaluso, RW-331, dated 6/30/91
- EM-343 Memorandum to the Secretary dated 8/16/91
- EM-343 Memorandum to Murial Scarborough, PR-23, dated 8/16/91
- Assignment Letter - BDM/GER-KJM-11480-91 dated August 23, 1991

Miscellaneous

Commitment Summary Log dated 8/27/91
WGWA Charter dated July 18, 1990
Position description for a Quality Assurance Specialist - not dated (Position Announcement)
QARG Charter
Quarterly QA Status Report for Hanford site
Quarterly QA Status Report for Savannah River site
Quality Improvement Log
Commitment Tracking & Reporting Log

United States Government

Department of Energy

memorandum

DATE: OCT 28 1991

REPLY TO
ATTN OF RW-3

SUBJECT: Office of Civilian Radioactive Waste Management (OCRWM)
Quality Assurance (QA) Surveillance HQ-SR-91-011 on the
Vitrification Projects Branch (EM-343)

TO
Chief, Vitrification Project Branch
Office of Waste Operations, EM-343

Attached is the report of Surveillance OCRWM HQ-SR-91-011
conducted of EM-343's activities at Germantown, Md. on
July 17 and 19, 1991.

This surveillance was conducted to verify the process being
used to review technical and programmatic documents. The
surveillance focused on SPP 4.11, Review of Waste Acceptance
Process Technical Documents and SPP 4.12, Review of Program
Execution Guidance Documents.

Three deficiencies were identified and addressed in
Corrective Action Reports (CARs) number HQ-SR-91-026, 028 and
030 which will be issued separately. Copies are attached to
the report for your information.

Observations included in this report do not require a written
response; however, will be investigated further during
subsequent OCRWM verification activities.

If you have any questions, please contact Bob Clark of this
office at (202) 586-8858.

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

Attachments

cc:

J. Bartlett, RW-1
J. Arpia, RW-3.1
J. Lytle, EM-30
F. Bearham, CER
M. Meyer, CER

U.S. Department of Energy
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

QUALITY ASSURANCE SURVEILLANCE REPORT
OFFICE OF QUALITY ASSURANCE

Surveillance Number:
HQ-SR-91-011

Dates of Surveillance:
July 17 and 19, 1991

Surveilled Organizations:
Office of Environmental Restoration and
Waste Management, Vitrification Projects
Branch (EM-343)

Surveillance Team:
Fred Bearham, Lead (CER)
Marc Meyer, QA & Technical (CER)

Location of Surveillance:

U.S. Department of Energy, 12800 Middlebrook Road, Germantown, MD 20874

Scope of Surveillance:

This surveillance was limited to EM-343 activities associated with the acceptance of high-level nuclear waste that will be produced at DOE's Hanford, Savannah River and West Valley Project Offices. It focused on the adequacy of technical reviews (EM-343 Procedure SPP 4.11) and reviews of EM-343 documents providing programmatic direction to sub-tier organizations (EM-343 Procedure SPP 4.12). Refer to Attachment I for personnel contacted and Attachment II for requirements and related documents that formed a basis for surveillance checklist questions.

CONTENTS

<u>Section</u>	<u>Title</u>
1.0	Executive Summary
2.0	Corrective Action Requests (CARs)
3.0	Observations
4.0	Detailed Discussion
5.0	List of Attachments

F. Bearham 8/22/91
Surveillance Team Leader Date

R. W. Czap 10/28/91
for Director, Office of Quality Assurance Date

1.0 EXECUTIVE SUMMARY

1.1 BACKGROUND

The surveillance team evaluated the adequacy of technical reviews of waste acceptance process documents and programmatic requirements being imposed by EM-343 (Vitrification Projects Branch) on sub-tier organizations. The objective was to verify:

- a) That technical reviews were identifying errors and omissions in technical documents prior to their issuance for use. Surveillance checklist questions were based on EM-343 Procedures SPP 4.11, *Review of Waste Acceptance Process Technical Documents*; SPP 3.04, *Documentation of Surveillance and Review Personnel Qualifications*; SPP 4.01, *Planning and Scheduling of Evaluation Activities*; and SPP 7.01, *Preparation, Transfer, and Receipt of Quality Records*. It also contained a few questions based on DOE/EM/WO/02, *Quality Assurance Program Description for High-Level Waste Form Development and Qualification*, and NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*.

During the surveillance, the surveillance team learned two other technical review procedures were being implemented in lieu of SPP 4.11. Accordingly, the surveillance team redirected its efforts to focus on requirements in SPP 4.05, *Administration of Technical Reviews*, SPP 4.06, *Conduct of Technical Reviews*; and DOE/RW-0214, *Quality Assurance Requirements Document*.

- b) That reviews of Program Execution Guidance Documents (PEGDs) were being reviewed in accordance with the requirements of Procedure SPP 4.12, *Review of Program Execution Guidance Documents*. Surveillance checklists were based on SPP 4.12 and DOE/EM/WO/02.

1.2 FINDINGS

The surveillance team identified five (5) deficiencies during the surveillance. These deficiencies were documented in CARs (Corrective Action Requests) HQ-91-026 through 030. In addition, the surveillance team identified four (4) apparent weaknesses in the QA Program that warrant management consideration. These as addressed in Section 3.0, *Observations*.

The deficiencies pertained to indoctrination of personnel (HQ-91-026), technical oversight responsibilities (HQ-91-027), traceability of review records to documents reviewed (HQ-91-028), working to unapproved documents (HQ-91-029) and non-compliance with established procedures (HQ-91-030).

The four (4) apparent weaknesses in the QA Program that warrant management attention in order to prevent future deficiencies are identified as observations in Section 3.0 of this report. They concern records; audits and surveillances; technical review procedures; data in WQRs; and waste form canisters.

The surveillance team was unable to verify the adequacy of technical reviews due to a lack of documentation at DOE's Germantown offices. At the surveillance team's request, documentation of two reviews was expressed mailed from Argonne National Laboratories to Germantown. The documentation was incomplete. This fact alone, however, was cause for concern and the subject of both a deficiency (CAR HQ-91-033) and observation regarding the availability of objective evidence during audits and surveillances.

2.0 CORRECTIVE ACTION REQUESTS

2.1 INTRODUCTION

H-57 & H-29 are not incorporated in report - why?

Copies of CARs HQ-91-026, 028 and 030 are included in Attachment VI of this report. A summary of each is contained below with reference to other Subsections that provide additional details pertaining to the deficiencies.

2.2 CAR HQ-91-026

NQA-1 requires that personnel receive indoctrination on key Program documents, quality assurance principles, and job responsibilities as they relate to particular functions. This requirement did not appear in the EM-343 QAPD or implementing procedures. To varying degrees, EM-343 project managers were unfamiliar with key technical documents, NQA-1 requirements, and responsibilities associated with approving project office documents. For additional details, see Attachment VI.

2.3 CAR HQ-91-028

EM-343 procedures require that review comments be recorded on a RCR Form and the status of reviews be tracked in a Review Log. Review comments and Review Log entries were not traceable to documents reviewed. For additional details, see Attachment VI.

2.4 CAR HQ-91-030

SPP 4.12 requires that the review of PEGDs be performed, evaluated, documented and distributed in a controlled sequence by assigned personnel. The only available evidence of a review was a "buck" slip and margin notes. No evidence of evaluation or distribution of comments was available and no personnel were assigned as QA Specialists or Evaluators. For additional details, see Attachment VI.

3.0 OBSERVATIONS

3.1 INTRODUCTION

The following observations are not deficiencies and, other than brief mention in Subsection 1.2, are not discussed elsewhere in this report. Each observation represents a programmatic weakness warranting further consideration by management.

3.2 RECORDS SYSTEM

The surveillance team is concerned that EM-343's reliance on off-site contractors to conduct technical reviews, perform audits and surveillances of these reviews, and store records off-site will make it unreasonably difficult to verify the adequacy of such reviews, audits and surveillances. Because Germantown personnel have not been participating in these activities, interviews must be conducted by telephone or at various locations across the United States. However, since records are at Argonne National Laboratory (ANL), to conduct such interviews, copies of records must first be made available to both the interviewees and interviewers. Alternately, all interested parties must meet at ANL's records facility. This surveillance team did not verify the adequacy of the QA records system but notes this concern as it may affect capability to get records into the system.

Based on an interview with the EM-343 Branch Chief, EM-343 Project Managers, consistent with the EM-343 QAPD Policy Statement, are responsible for achieving, maintaining and ensuring technical quality. The surveillance team found that the Savannah River and West Valley Project Managers did not have enough objective evidence to know whether or ensure that quality is being achieved and maintained. Project managers did not have copies of key documents associated with Technical Review Group (TRG) reviews of Waste Form Compliance Plans and Qualification Reports. Missing documents included documents reviewed, review comments, responses to comments and qualifications of reviewers. Records of TRG reviews are maintained by Argonne National Laboratory at its Argonne, IL., facilities. It is recommended that the EM-343 project managers obtain and maintain copies of key technical documents, related documentation of technical reviews, etc.

3.3 SURVEILLANCES AND AUDITS

The surveillance team is concerned about the adequacy of audits and surveillances of technical reviews performed by EM-343. The surveillance team reviewed the results of Audit 90EA-AU-001 at ANL during January 17-19, 1990 and Surveillance 90EA-SR-S-002/003 at ANL during September 24-27, 1990. Specific concerns are as follows:

See
comment
next page!

- Go be addressed in SPP 3.02 & 3.03 Revis 12/5/91 Rev 11/11*
- a) Traceability Records of Audit 90EA-AU-001 did not identify what was audited. For example, there was no way of determining whether the audit team audited technical reviews of the WCP, WQR Package No. 1, both reviews, or some other reviews. This information may exist in backup documentation but it was not available for review by the surveillance team.
 - b) Technical Specialists Though both Audit 90EA-AU-001 and Surveillance 90EA-SR-S-002/003 were of technical reviews, technical specialists did not participate in either of the activities. Identified findings pertained to procedural matters rather than the adequacy of the technical reviews. There was no assurance that the verification team had the necessary qualifications to determined effectiveness (e.g. whether review procedures are adequate and meaningful technical reviews are being conducted).

3.4 TECHNICAL REVIEW PROCEDURES

SPP 4.05 & 4.06 Cancelled & are now in 4.15 Rev 0 4.11 has been cancelled

The surveillance team is concerned that EM-343's two principal technical review procedures may be inadequate. These two procedures are SPP 4.06, Conduct of Technical Reviews, and 4.11, Review of Waste Acceptance Process Technical Documents. SPP 4.06 is supported by a closely related procedure, SPP 4.05, Administration of Technical Reviews.

SPP 4.11 is being used to review project office SARs (Safety Analysis Reports). These reviews fall outside the scope of the OCRWM Program and do not need to meet QARD requirements. SPP 4.06 is being used to review WCPs and WQRs. These reviews fall within the scope of the OCRWM Program and must meet QARD requirements.

Specific concerns are as follows:

- a) Applicability Though Page F-16 of the EM QAPD shows that both SPP 4.06 and SPP 4.11 are used to satisfy requirements in the OCRWM QARD for technical reviews, only SPP 4.06 is being used. The surveillance team found no guidance in either procedure that would indicate when one should be used versus the other. The Branch Chief did indicate that he plans to consolidate both into one procedure.
- b) Background Information NQA-1 Supplement 6S-1, Subsection 3.1, requires that reviewers "have access to pertinent background data or information upon which to base their approval". Because the surveillance team did not interview reviewers or examine the documents they reviewed, they were unable to verify that the reviewers had access to background information. Though source documents cited in WCPs and WQRs were not available at EM-343's Germantown offices, they may have been available to off-site reviewers used by EM-343. This should be verified during future audits and surveillances. Also, SPPs should be revised to make use of such information as a stated versus unstated requirement.

This statement is abstracted & used in the wrong context. This reference is for Major Document changes!

SPP 15 Rev 0 addresses the fact that the work plan shall address the QA requirements.

SOWs reference back to the contract & SPP's, which are silent on the QA requirements.

- c) Review Criteria SPP 4.06 does not say what reviewers should be looking for when they review technical documents other than "applicability, correctness, adequacy and completeness". This is already required by NQA-1 and does not explain how this requirement will be satisfied by reviewers. SPP 4.06 does not require that reviewers or the review coordinator identify specific review criteria prior to initiating a review. This review criteria should include verification that source documents be reviewed to verify that they are applicable and information from the documents is correctly translated into the document being reviewed. It does not require that reviewers verify that sources of input have been identified including the status of the input.

- d) Review Teams Page 8 of SPP 4.05 lists the composition of a group of five core members on review teams, called the TRG (Technical Review Group) core group. A note at the bottom of the page says, "The [TRG] Chairman has the authority to change the above list [of core group members] as needed to provide the necessary technical expertise." However page 3 says, the "Review Coordinator approves appointment of TRG core group membership."

To date, the TRG Chairman has been an off-site contractor and the Review Coordinator a EM-343 project manager. The review of the Savannah River WCP had a core group of four versus five members. Their expertise was in waste form technology, repository engineering, HLW process controls, and statistics. SPP 4.05 requires expertise in waste form technology, repository engineering, HLW process controls, mechanical design, and metallurgy. It is not clear why expertise in statistics (versus mechanical design and metallurgy) was necessary, who authorized this change, and whether they had such authority. This needs to be investigated further during forthcoming audits or surveillances.

3.5 DATA IN WASTE FORM QUALIFICATION REPORTS (WQRs)

Work is moving forward at Savannah River and West Valley based on unapproved Waste Form Compliance Plans. Additionally, preparation of the Waste Form Compliance Plans themselves were initiated based on unapproved QA programs. Finally, none of the following WQR Packages, issued for EM-343 review, have been approved by EM-343:

Project	WOR Package	EM-343 Review Status
Savannah River	1	Review completed 12/18/89
"	2	Review completed 10/26/89
"	3	Review in progress
"	4	Review completed 12/21/90
West Valley	1	Review completed 08/20/90
"	2	Review in progress
"	3	Review in progress
"	4	Review completed 08/20/90

For the most part, the above WQR Packages were developed while working to an unapproved QA Program and unapproved Waste Form Compliance Plan. Thus, WQRs contain unqualified data. Nothing in the WQRs indicate this and there are no plans for qualifying this data prior to or during production of high-level waste. During discussions with the EM-343 Branch Chief, the surveillance team was told this is an unscheduled activity because,

WOKK Plan -
ATTACH D - SPP 4.15
Item 7 identifies
QA criteria
Experts are performing
reviews!!!

Deleted in
SPP 4.15

4.15
Does not
specify type
of expertise
req'd!
4.2.1
HART will state
fraction of 3.5

at present, there is no budget for qualifying unqualified data. Specific recommendations are as follows:

- a) Rules should be established for determining what constitutes qualified versus unqualified data. Procedures need to say how unqualified data is to be identified and tracked until requalified. Procedures and the EM-343 QAPD should state, at what point in the waste acceptance process, unqualified data must be qualified. Waste forms cannot be qualified using unqualified data.
- b) Technical Reviews Procedures should require that reviewers verify that unqualified data is at least "best available" data, that unqualified data is not used when qualified data is available, and that technical documents do not identify unqualified data as qualified data.
- c) Approvals If and when EM-343 approves the above WQRs, approval letters should state whether the approval is conditional or unconditional, what must be done to obtain unconditional approval, and what restrictions are in force until such approval is obtained.

3.6 WASTE FORM CANISTERS

Waste form canisters were designed, qualification tests completed, and manufacturing started prior to approval of Savannah River's QA Program and WCP. Manufacturing is temporarily on hold pending resolution of findings resulting from a EM-343 audit. Once procurement documents are revised and material traceability is established, manufacturing will resume. The surveillance team recommends that manufacturing not resume until:

- a) Approvals Savannah River addresses Items 1 and 2 in EM-343's conditional acceptance of the Savannah River QAPDs (see Attachment III). The Savannah River WCP should have received at least EM-343 approval prior to restarting manufacturing.
- b) Readiness Review EM-343 should conduct a readiness review prior to allowing the resumption of canister manufacturing.
- c) Unqualified Data If canister drawings, specifications, and qualification test reports contain unqualified data, a plan should be developed for replacing this data with qualified data. High-level waste should not be placed in canisters prior to updating or replacing all canister documents that contain unqualified data.

Peer Review
Per business
documented
in 01

Can't start
Did they start
at all?

4.0 SURVEILLANCE DETAILS

The morning of Wednesday, July 17, began with an entrance meeting with the EM-343 Branch Chief and his staff. During the meeting the Branch Chief provided the surveillance team with an overview of his organization and the status of Program activities. A list of meeting attendees is contained in Attachment IV.

After the meeting, Marc Meyer spent the balance of the morning discussing the status of technical activities at Savannah River with EM-343's Savannah River Project Manager. During this interview, it was determined that SPP 4.06, rather than SPP 4.11, was being used to conduct technical reviews. Fred Bearham spent the rest of the morning interviewing the West Valley Project Manager.

During the afternoon, Marc Meyer reviewed records of technical reviews of the Savannah River WCP, Glass Product Control Program Description, and WQR Package Nos. 1, 2, 3 and 4. Since the records were incomplete, Marc Meyer asked that a complete set of records on WQR Package No. 3 be expressed mailed from Argonne National Laboratory to EM-343's Germantown offices. Fred Bearham spent the afternoon discussing the implementation of SPP 4.12 with EM-343's West Valley Project Manager and the Acting QA Manager.

The morning of Friday, July 19, began with a presentation by the Branch Chief on a variety of technical topics associated with the waste acceptance process. After the presentation, Marc Meyer met with the Savannah River Project Manager to follow up on unanswered questions from the Wednesday's interview. Fred Bearham spent the rest of the morning interviewing the Savannah River Project Manager and the Hanford Project Manager.

Marc Meyer began the afternoon interviewing EM's West Valley Project Manager. Discussions pertained to the status of technical reviews and approvals, procedures used to conduct reviews, and NQA-1 requirements for identifying and controlling technical input. The balance of the afternoon was spent reviewing records obtained from Argonne National Laboratory. The records included records of technical reviews of Savannah River WQR Package Nos. 3 and 4, Audit No. 90EA-AU-001, and Surveillance No. 90EA-SR-S-002/003. The records were incomplete in that they did not contain copies of documents reviewed, individual review comments, and forms identified on pages 9, 11, and 14 of SPP 4.05. During the afternoon, Fred Bearham met with the Branch Chief to discuss findings related to SPP 4.12 and the proposed QA organization within EM 343. He also interviewed BDM's QA Specialist. The surveillance team spent an hour or so with the Branch Chief late on Friday to discuss identified problems and recommend corrective actions.

On Friday August 2nd, the surveillance team met with the EM-343 Branch Chief to discuss surveillance findings. A list of attendees is contained in Attachment V.

LIST OF ATTACHMENTS

- ATTACHMENT I - List of Personnel Contacted
- ATTACHMENT II - Requirements Documents
- ATTACHMENT III - Memorandum
- ATTACHMENT IV - Attendance Record
- ATTACHMENT V - Attendance Record
- ATTACHMENT VI - Corrective Action Reports

***ATTACHMENT I
LIST OF PERSONNEL CONTACTED***

The surveillance team interviewed the following EM-343 personnel during the course of Surveillance SR-HQ-91-011:

Ken Chacey

Tom Gutmann

Ted McIntosh

Virgil Trice

Jack Hennessey

Dick Stockman

**ATTACHMENT II
REQUIREMENTS DOCUMENTS**

The surveillance team used the following requirements documents in preparing for and conducting Surveillance HQ-SR-91-011:

DOE/RW-0214, QARD (Quality Assurance Requirements Document), Revision 4

NQA-1, Quality Assurance Program Requirements for Nuclear Facilities, September 15, 1989

DOE/RW-0260, WAPS (Waste Acceptance Preliminary Specifications for the Defense Waste Processing Facility High-Level Waste Form), Revision 1

DOE/RW-0261, WAPS (Waste Acceptance Preliminary Specifications for the West Valley Demonstration Project High-Level Waste Form), Revision 1

DOE/EM/VO/02, QAPD (Quality Assurance Program Description for High-Level Waste Form Development and Qualification, Revision 0

SPP 3.01, Preparation and Maintenance of Plans for Personnel Training, Indoctrination, and Orientation.

SPP 3.02, Preparation and Conduct of Personnel Training, Indoctrination, and Orientation.

SPP 3.04, Documentation of Surveillance and Review Personnel Qualifications, Revision 0

SPP 4.01, Planning and Scheduling of Evaluation Activities, Revision 0

SPP 4.05, Administration of Technical Reviews, Revision 0

SPP 4.06, Conduct of Technical Reviews, Revision 0

SPP 4.11, Review of Waste Acceptance Process Technical Documents, Revision 0

SPP 4.12, Review of Program Execution Guidance Documents, Revision 0.

SPP 7.01, Preparation, Transfer, and Receipt of Quality Records, Revision 0

ATTACHMENT III
MEMORANDUMDOE F-1218
(8-89)

United States Government

EM file 478
Department of Energy

memorandum

DATE: OCT 23 1990

REPLY TO
ATTN OF: EH-343

SUBJECT: Conditional Acceptance of Quality Assurance Program Descriptions

TO: A. Lee Watkins, Director
High-Level Waste Division
Savannah River Operations Office

In response to your August 30, 1990, subject memorandum, the Quality Assurance Review Group (QARG) has completed its review of the Savannah River Operations Office/High-Level Waste Division (SR/HLWD) and Westinghouse Savannah River Company (WSRC) Quality Assurance Program Descriptions (QAPDs). These QAPDs are accepted for use on Defense Waste Processing Facility work, contingent on their implementation satisfying Department of Energy requirements. Further, these QAPDs are accepted subject to the following conditions:

1. Acceptance of the SR/HLWD QAPD, DOE-SR-2006-2, Revision 2 is conditional, pending incorporation of proposed changes that are responsive to: 1) DOE/Office of Civilian and Radioactive Waste's (RW) earlier comments against the SR-HLWD QAPD based upon the DOE/RW-0214, Revision 1 quality assurance requirements; and 2) informal QARG-1 comments based upon DOE/RW-0214, Revision 2 quality assurance requirements. Further, it is understood that the proposed changes will be incorporated in the next revision of the QAPD, i.e., DOE-SR-2006-2, Revision 3. Please provide your schedule for this revision.
2. Acceptance of the WSRC QAPD, SW 4-1.8, Part 2, Revision 5 is conditional, pending incorporation of proposed changes that are responsive to: 1) DOE/RW's earlier comments against the WSRC QAPD based upon the DOE/RW-0214, Revision 1 quality assurance requirements; and 2) informal QARG-1 comments based upon DOE/RW-0214, Rev. 2 quality assurance requirements. Further, it is understood that the proposed changes will be incorporated in the next revision of the QAPD, i.e., SW 4-1.8, Part 2, Revision 6. Please provide your schedule for this revision.

The QARG will now commence its review of the quality assurance procedures that implement the requirements of QAPD DOE-SR-2006-2. If the requirements of RW-0214 are not presently incorporated into these procedures, please provide your plan and schedule for accomplishing this incorporation.

If you have any questions, please contact me or Tom S. Gutmann at
FTS (301) 427-1605.



Stephen P. Cowan
Deputy Director
Office of Waste Operations
Environmental Restoration
and Waste Management

cc: K. A. Chacey, EM-343
T. S. Gutmann, EM-343
W. J. Kehew, CH
M. H. Campbell, WHC-PTSO
R. S. Scott, EM-20

ATTACHMENT IV ATTENDANCE RECORD

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

 SHEET 1 OF 1
WBS NO

ATTENDANCE RECORD

☐ AUDIT
☒ SURVEILLANCE
☐ TRAINING/INDOCTRINATION

 SUBJECT
 SPD 2-11 & 2-12

☐ TEAM BRIEFING
☒ PRE-CONFERENCE
☐ POST-CONFERENCE

AUDIT OR SURVEILLANCE LEADER/INSTRUCTOR(S)

J. Beaman
 Signature
 Signature

 DATE 7/17/91
 CLASS LENGTH N/A

BRIEF SUMMARY OF MATERIAL COVERED

INTRODUCTION OF PERSONNEL. SCHEDULE
 SCOPE OF SURVEILLANCE. OUTLINE OF EM 303
 ACTIVITIES & RESPONSIBILITIES BY CER C-ACCU

NAME OF ATTENDEE PRINTED	SIGNATURE	ORGANIZATION/ COMPANY	POSITION/TITLE	PHONE NUMBER
REED BEACHAM	<u>J. Beaman</u>	CER	QA Specialist	(703) 276-2304
Mike Meyer	<u>Mike Meyer</u>	CER	Production Officer	(703) 276-5300
T. Hennessey	<u>T. Hennessey</u>	DCE-EM-343	QA Specialist	353-7101
Tom Gutman	<u>Tom Gutman</u>	DCE/EM-343	Foreign NSE	(201) 353-7101
Ted McIntosh	<u>Ted McIntosh</u>	DCE-EM-343	WVDP Program Manager	353-7101 353-7109
Ha Nguyen	<u>Ha Nguyen</u>	DCE-EM-343	Vibration Engineer	(201) 353-7175
Cleone Truskett	<u>Cleone Truskett</u>	DCE-EM-343	Field Service Manager	353-7104
LARRY VAUGHAN	<u>Larry Vaughan</u>	DCE-EM-20	QA ADVISOR	580-2523
DICK STECKMAN	<u>Dick Steckman</u>	BDM (EM-343)	QA SPECIALIST	(201) 353-1250
John Rice	<u>John Rice</u>	DCE-EM-20	Program Manager	353-7102
Henry F. Miller	<u>Henry F. Miller</u>	DCE/EM-343	Medical Consultant	301-313-7922
KEN CHACON	<u>Ken Chacon</u>	DCE/EM-343	QA Specialist	353-7101

ATTACHMENT V
ATTENDANCE RECORD

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

SHEET _____ OF _____
WBS NO _____

ATTENDANCE RECORD

☒ ²³ sh/14
☒ AUDIT

☒ SURVEILLANCE

☐ TRAINING/INDOCTRINATION

SUBJECT

☐ TEAM BRIEFING

☐ PRE-CONFERENCE

☐ POST-CONFERENCE

AUDIT OR SURVEILLANCE LEADER/INSTRUCTOR(S)

J. Beaman

Signature

DATE 8/21/91

Signature

CLASS LENGTH N/A

BRIEF SUMMARY OF MATERIAL COVERED

Review of survey observations & recommendations
Review of CARs

NAME OF ATTENDEE
PRINTED

SIGNATURE

ORGANIZATION/
COMPANY

POSITION/TITLE

PHONE NUMBER

FRED BEAMAN

J. Beaman

CER

QA Specialist

276-9300

Ken CHASEY

K. Chasey

DOE - EM-343

DOE - EM-343

353-7166

Marc Meyer

M. Meyer

CER

Program Manager

(703)
276-9300

United States Government

Department of Energy

memorandum

QA
6.07

DATE OCT 10 1991
REPLY TO
ATTN OF. RW-3

SUBJECT. Office of Civilian Radioactive Waste Management (OCRWM)
Quality Assurance (QA) Surveillance of EM-343

TO Ken Chacey, Chief
Vitrification Projects Branch, EM-343

Attached is a report on Surveillance HQ-SR-91-014 of the Vitrification Projects Branch (EM-343) in Germantown, Md. on August 20, 21, and 22, 1991.

The surveillance was of EM-343's certification/qualification of audit and surveillance personnel. It was based on verifying compliance with requirements in SPP 3.03, Certification of Audit Personnel and SPP 3.04, Documentation of Surveillance and Review Personnel Qualifications. The surveillance did not cover the qualifications of reviewers as identified in SPP 3.04. This area will be covered during Audit HQ-91-003. One adverse condition was identified and documented Corrective Action Report HQ-91-034 which was issued separately.

If you have any questions, please contact Bob Clark on 586-1238.


Donald G. Horton, Director
Office of Quality Assurance

Attachments

cc: S. Cowan, EM-30
J. Arpia, RW-3.1
C. Morrell, CER
D. Hendrix, CER

U.S. Department of Energy
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

QUALITY ASSURANCE SURVEILLANCE REPORT
OFFICE OF QUALITY ASSURANCE

Surveillance Number:
HQ-SR-91-014

Dates of Surveillance:
August 20 - 22, 1991

Organization Surveilled:
Office of Environmental Restoration and Waste Management, Vitrification Projects Branch (EM-343)

Surveillance Locations :

- 1) U.S. Department of Energy, 12800 Middlebrook Road, Germantown, MD 20874
- 2) Performance Development Corporation, 19500A Amaranth, Germantown, MD 20874

Scope of Surveillance:

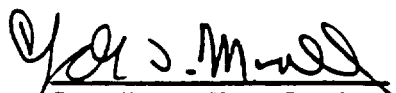
The scope of this surveillance was to evaluate compliance with and the effectiveness of EM-343 procedures SPP 3.03, *Certification of Audit Personnel*, and SPP 3.04, *Documentation of Surveillance and Review Personnel Qualifications*.

Surveillance Team:

Clyde Morell, Lead (CER)
Don Hendrix, (CER)

Personnel Contacted:

Ken Chacey, EM-343
John E. Hennessey, EM-343
Henry F. Walter, EM-343
Ted McIntosh, EM-343
Clark J. Payton, PDC
James L. Smith, PDC
R. E. Stockman, BDM


Surveillance Team Leader 9/1/91
Date


Director, Office of Quality Assurance 10/10/91
Date

1.0 EXECUTIVE SUMMARY

The surveillance team assessed the implementation of EM-343 procedures SPP 3.03, *Certification of Audit Personnel*, and SPP 3.04, *Documentation of Surveillance and Review Personnel Qualifications*. The surveillance team used a combination of interviews of EM-343 management and direct-support contractors (PDC and BDM/SAIC) and reviews of the personnel qualification and certification files in performing the surveillance. The surveillance did not include verifying qualification of review personnel due to the limited time schedule. This will be investigated during the EM-343 audit planned for August 26-30, 1991.

The surveillance team found that SPP 3.03 and SPP 3.04 are not being adequately implemented for the qualification/certification of audit and surveillance personnel. Corrective Action Request (CAR) HQ-91-034 was initiated to address this condition adverse to quality.

2.0 PERFORMANCE

2.1 General

The surveillance team used SPP 3.03, *Certification of Audit Personnel*, and SPP 3.04, *Documentation of Surveillance and Review Personnel Qualifications*, to prepare checklists to evaluate implementation of the audit and surveillance personnel qualification process at EM-343.

A pre-surveillance briefing was held the morning of August 20, 1991 to inform EM-343 Vitrification Projects Branch Chief, Program Managers, and direct-support contractors of the scope and purpose of the surveillance. See Attachment I of this report for the entrance briefing attendance record.

A post-surveillance briefing was held the afternoon of August 22, 1991 with the EM-343 Vitrification Projects Branch Chief to present findings identified during the surveillance and to answer any questions. See Attachment II of this report for the exit briefing attendance record.

2.2 Surveillance Performance

The surveillance team interviewed the EM-343 Vitrification Projects Branch Chief and two of the three Program Managers to determine how audit and surveillance personnel had been qualified for their respective projects. The surveillance team also interviewed a EM-343 direct-support contractor who is maintaining and controlling qualification/certification records for EM-343 at its Germantown, Maryland and Oak Ridge, Tennessee offices.

3.0 FINDINGS

3.1 Corrective Action Request (CAR)

EM-343 provided the surveillance team a listing of three completed audits and a listing of thirteen individuals who were either Auditors or Lead Auditors. The surveillance team used the completed audit reports and the listing to determine who participated in the audits and determine if qualification/certification documentation met the requirements of SPP 3.03. None of the files contained all of the documentation needed to meet the requirements of SPP 3.03.

The surveillance team was also provided a listing of seven qualified surveillance personnel. Of the surveillance qualification files reviewed, four did not contain documentation needed to meet the requirements of SPP 3.04.

Based on interviews and review of 13 files, the surveillance team determined that EM-343 is not effectively implementing SPP 3.03 and SPP 3.04. This finding was documented in draft CAR HQ-91-034. A copy is included as Attachment III of this report.

3.2 Other Concerns

The following concerns were outside the scope of this particular surveillance, they were not pursued further:

The surveillance team was concerned that Vitrification Projects Program Managers did not have an overall understanding of SPP 3.03 and SPP 3.04. Specific examples are:

- a. Program Managers were unsure who was responsible for activities assigned to the "Quality Assurance Specialist", "Coordinator of Personnel Certification", "Audits Coordinator", "Surveillance Coordinator", and "Certifying Official" in SPPs 3.03 and 3.04. However, in general, they indicated that either Jack Hennessey, Bud Kehew, or PDC personnel were performing these activities. The surveillance team was unable to find any documentation delegating these tasks to these or any other individuals.
- b. The surveillance team interviewed PDC personnel to determine if they were aware of responsibilities within SPP 3.03 and SPP 3.04 for "Quality Assurance Specialist", "Coordinator of Personnel Certification", "Audits Coordinator", "Surveillance Coordinator", and "Certifying Official". PDC personnel interviewed were aware of the responsibilities assigned in SPP 3.03 and SPP 3.04 and had delegated PDC personnel to perform these tasks. However, the PDC personnel interviewed were not aware that they were responsible for performing these tasks for EM-343, outside DOE organizations, or other support contractors.

These concerns will be investigated on subsequent OCRWM audits and surveillances.

4.0 ATTACHMENTS

Attachment I - Entrance Briefing Attendance Record

Attachment II - Exit Briefing Attendance Record

Attachment III - Draft Corrective Action Request HQ-91-034.

ATTACHMENT I

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

SHEET 1 OF 1
WBS NO. _____

ATTENDANCE RECORD

[] AUDIT
[X] SURVEILLANCE
[] TRAINING/INDOCTRINATION

SUBJECT *EM-343 Implementation*
of SPP 3.03, 20 and
SPP 3.04, 20

[] TEAM BRIEFING
[X] PRE-CONFERENCE
[] POST-CONFERENCE

AUDIT OR SURVEILLANCE LEADER/INSTRUCTOR(S)

[Signature]
[Signature]
Signature
Signature

DATE 8/29/91
CLASS LENGTH _____

BRIEF SUMMARY OF MATERIAL COVERED _____

NAME OF ATTENDEE PRINTED	SIGNATURE	ORGANIZATION/ COMPANY	POSITION/TITLE	PHONE NUMBER
John E. Hennessey	<i>[Signature]</i>	EM 347	Phys. Sci.	353-7191
JAMES L. SAORIN	<i>[Signature]</i>	POC	STAFF ADVISOR	601-9082 (615)
CLARK J. PAYTON	<i>[Signature]</i>	POC	STAFF ADVISOR	462-9004
Henry F. Welter	<i>[Signature]</i>	EM-343	Physical Scientist	353-7192
R.E. STOCKMAN	<i>[Signature]</i>	BDM	STAFF SUPPORT	(301) 601-1280
T.W. McIntosh	<i>[Signature]</i>	EM-343	WVDP Program Manager	301-353- 3589
H.P. Nguyen	<i>[Signature]</i>	EM-343	DWPF Support Engineer	(301) 353-7195
K.A. Chang	<i>[Signature]</i>	EM-343	Phys. Chief	301-353-7195
G. Truskett	<i>[Signature]</i>	EM-343	Tech Review Mgr.	301-353-7194

ATTACHMENT II

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

SHEET 1 OF 1
WBS NO. _____

ATTENDANCE RECORD

☐ AUDIT
☒ SURVEILLANCE
☐ TRAINING/INDOCTRINATION

SUBJECT *EM 343 Implementation*
of SPP 3.03,20 and
SPP 3.04,20

☐ TEAM BRIEFING
☐ PRE-CONFERENCE
☒ POST-CONFERENCE

AUDIT OR SURVEILLANCE LEADER/INSTRUCTOR(S)

Eide J. Meyer

Signature
Donald C. [unclear]

Signature
K. Chacey

Signature

DATE 8-22-91

CLASS LENGTH _____

BRIEF SUMMARY OF MATERIAL COVERED _____

_____NAME OF ATTENDEE
PRINTED

SIGNATURE

ORGANIZATION/
COMPANY

POSITION/TITLE

PHONE NUMBER

*KEN CHACEY**K. Chacey**EM-343**Chief, Vir DR**353-7186*

ATTACHMENT III

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

¹⁴ CAR NO. HQ-91-034
DATE: 8/26/91
SHEET: 1 OF QA
WBS NO.: 6.07

CORRECTIVE ACTION REQUEST

¹ Controlling Document
SPP 3.03, and SPP 3.04

² Related Report No.
HQ-SR-91-014

³ Responsible Organization
EM-343

⁴ Discussed With
Ken Chacey

¹⁰ Response Due

¹¹ Responsibility for Corrective Action

¹² Stop Work Order Y or N

⁵ Requirement:

1. SPP 3.03 Para. 4.0 states: "Auditors are certified in accordance with this instruction prior to being assigned responsibility for performing quality assurance audits."
"When auditors or lead auditors from outside organizations are utilized these personnel are certified/recertified in accordance with this SPP or the assigned Quality Assurance Specialist (QAS) determines and confirms on writing that individuals have valid certifications under a system that has been accepted or is determined to be acceptable in accordance with the same or equivalent requirements. In either case the QAS maintains supporting documentation."

(continued on following page)

⁶ Adverse Condition:

A Vitrification Projects Branch program for the qualification/certification of audit, surveillance and review personnel has not been effectively implemented. This finding is based on the following objective evidence:

1. EM-343 completed audits QA90-EM-30-01 (June 90), 91EA-SR-AU-001 (Feb. 91) and 91EA-WV-AU-001 these audits were performed by personnel from external organizations. Of the 11 external Auditors and Lead Auditors who participated in these three audits, only one qualification/certification file contained documentation evaluating and accepting the external organization's auditor certification program as being equivalent to the requirements of SPP 3.03, Para 4.0 (See Page 3 of this CAR).

(continued on following page)

⁷ Recommended Action(s):

Correct deficiencies as identified in this CAR and re-evaluate training requirements for personnel responsible for implementing procedures SPP 3.03 and SPP 3.04.

⁸ Initiator

Date:

⁹ Severity Level -

1 ☐ 2 ☐ 3 ☐

¹³ Approved by

Date:

Clyde Morell

8/26/91

OQA _____

¹⁵ Verification of Corrective Action:

¹⁶ Corrective Action Completed and Accepted:

OQA _____

Date _____

¹⁷ Closure Approved By:

OQA _____

DRAFT

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

CAR NO. HO 91-034
DATE: 8/26/91
SHEET: 2 OF

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

*** Requirement: (continued)**

2. SPP 3.03, Para. 5.a.4, b.1, and c.4 state in part: (Certifying Official) "Evaluates the candidates and certifies or rejects the candidates using the criteria and guidance provided below:"
 - "(b) Documents the results of the evaluation on a Certification of Qualification Form (Attachment C) for each candidate and thereafter signs and dates each form."
 - "(c) Signs the Certification Certificate (Attachment D) for each candidate."

(Coordinator of Personnel Certification) "Reviews completed certification documentation for adequacy and completeness including the verification of credit allocation of professional requirements and prepares a Notification of Certification Memorandum (Attachment E)."

(Certifying Official) "Reviews the original certification documentation and additional supporting documentation accumulated during the annual period and updates the certification form for annual evaluation or returns the form with a written explanation for not certifying".
3. SPP 3.04 Para. 4.0 states: "The qualifications of personnel are documented in accordance with this instruction prior to being assigned responsibility for performing quality assurance surveillances in accordance with SPP 4.04. The assigned Quality Assurance Specialist (QAS) documents the qualifications of organizational candidates meeting the minimum requirements. When the organization uses external personnel to perform surveillances, these personnel are certified/recertified in accordance with this instruction. Otherwise the QAS determines and confirms in writing that the program under which their qualifications were documented determined to be acceptable in accordance with the same or equivalent requirements. In either case the QAS maintains supporting documentation."

*** Adverse Condition: (continued)**

2. The surveillance team reviewed 13 external personnel qualification/certification files and found the following deficiencies (See Page 3 of this CAR):
 - a) Three files did not have a "Certification of Qualification Form".
 - b) One file contained an undated "Certification of Qualification Form".
 - c) 10 files did not have a "Certification Certificate".
 - d) 10 files did not have a "Notification of Certificate Memoranda".
 - e) One file did not have documented evidence of an annual review (last reviewed 3/22/90).
 - f) One file contained date gaps in audit requalification history.
 - g) One file was missing the audit participation history documentation.
 - h) Five files did not have any documented evidence of initial annual evaluation.
3. The qualification files of seven surveillance personnel were reviewed. None of the external personnel qualification records reviewed contained documentation evaluating and accepting the external organization's surveillance qualification program as being equivalent to the requirement of SPP 3.04, Para 4.0 (See Page 4 of this CAR).

REQUIRED AUDITOR / LEAD AUDITOR DOCUMENTATION

Candidate For Auditor/Lead Auditor	Organization	Candidate Position	Letter of Equivalent Qualification Certification Program (Ref. Para. 4.0)	Certification of Qualification Form (Ref. Attach. "C")	Certification Certificate (Ref. Attach. "D")	Notification of Certification Memo. (Ref. Attach. "E")	Annual Evaluation (Ref. Item "G" Attach A, Page 6 of 6 Exhibit 2, Para. 4. (b))	Comments on File
*W.J. Kehew	DOE-CH	Lead Auditor	No	Yes	No	No	Yes - 3/22/90	Evaluation out of Date
*C.J. Payton	PDC	Lead Auditor	No	Yes	No	Yes	Yes - 12/13/90	Date Gap in Audit Requalification History
*R.E. Stockman	BDM	Lead Auditor	No	1/31/91 - Yes	BDM - Yes	No	N/A	Documentation of Audits History Missing
D.T. Bourgette	PDC	Lead Auditor	No	Yes	No	Yes	Yes - 12/13/90	
*I.J. Lefman	SAIC	Lead Auditor	No	2/1/91 - Yes	SAIC - Yes	No	N/A	
*S.L. Crawford	SAIC	Lead Auditor	No	1/21/91 - Yes	SAIC - Yes	No	N/A	
*P.E. Deeds	WVNS	Lead Auditor	No	Yes	No	No	No	
*J.P. Hummel	WVNS	Lead Auditor	No	No	No	No	No	No Records Found (No File)
*D.B. Ryder	PNL	Auditor	No	No Qual. Date on Form	No	No	No	Resume, and Reading Assignment
*F.C. Hood	PNL	Lead Auditor	No	No	No	No	No	Resume Only in File
*E.H. Webb	DOE-SR, QMAD	Lead Auditor	No	10/13/89 - Yes	No	No	Yes - 10/25/90	
D.J. Hornstra	PDC	Lead Auditor	No	No	No	No	No	Letter dated 1-22-91, and Resume
*J.L. Smith	PDC	Lead Auditor	3/8/91 - Yes	3/8/91 - Yes	No	Yes	N/A	

* Participated in Audits

CORRECTIVE ACTION REQUEST
(continuation sheet)

CAR NO. HO-91-004
DATE: 8/26/91
SHEET: 3 OF

REQUIRED DOCUMENTATION for SURVEILLOR

Candidate For Surveillor	Organization	Date Certified	Letter of Equivalent Qualification Certification Program Ref. Para. 4.0	Surveillance and Review Qualification Form Ref. Attachment "B"	Notification of Certification Memorandum Ref. Attachment "C"	Requalification Schedule Ref. Attachment "D"	Annual Review Ref. Attachment "A" Para 4.(a)
W.J. Kehew	DOE-CH	5/14/91	No	Yes	Yes	Yes	N/A
C.J. Payton	PDC	1/22/90	No	Yes	Yes	Yes	Yes - 1/15/91
R.E. Stockman	BDM	5/14/91	No	Yes	Yes	Yes	N/A
P.L. Slattery	EM-30	5/14/91	No	Yes	Yes	Yes	N/A
R.D Walton Jr.	EM-343	5/14/91	N/A	Yes	Yes	Yes	N/A
J.E. Hennessey	EM-343	5/14/91	N/A	Yes	Yes	Yes	N/A
C.F. Pegg	PDC	1/22/90	No	Yes	Yes	Yes	Yes - 1/15/91

CORRECTIVE ACTION REQUEST
(continuation sheet)

CAR NO. HO-91-004
DATE: 8/28/91
SHEET 4 OF

memorandum

DATE: AUG 23 1991

WBS 6.07
QA

REPLY TO: RW-3
ATTN OF:

SUBJECT: OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) SURVEILLANCE HQ-SR-91-016 OF EM-343

TO: Deputy Director, Office of Waste Operations, EM-30

Attached is the report of Surveillance, HQ-SR-91-016 conducted at EM's Vitrification Project Branch at Germantown, Maryland, August 6-8, 1991.

This surveillance was conducted to verify the process being used to implement EM-343's quality records system. The surveillance focussed on SPP 7.01, Preparation, Transfer, and Receipt of Quality Records and SPP 7.02, Quality Records Management.

One adverse condition was identified and addressed in Corrective Action Report (CAR) HQ-SR-91-033 which will be issued separately.

The identified observations do not require a written response; however, they will be investigated further during Audit HQ-91-003.

If you should have any questions, please contact Bob Clark at 586-1238.



Donald G. Horton, Director
Office of Quality Assurance
Office of Civilian Radioactive
Waste Management

Attachments

CC:
J. Bartlett, RW-1
K. Chacey, EM-343
J. Arpia, RW-3.1
C. Walenga, CER

**U.S. Department of Energy
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM**

**QUALITY ASSURANCE SURVEILLANCE REPORT
OFFICE OF QUALITY ASSURANCE**

Surveillance Number:
HQ-SR-91-016

Dates of Surveillance:
August 6 - 8, 1991

Organization Surveilled:
Office of Environmental Restoration and Waste Management, Vitrification Projects Branch (EM-343)

Surveillance Locations :

- 1) U.S. Department of Energy, 12800 Middlebrook Road, Germantown, MD 20874
- 2) BDM/SAIC, 12850 Middlebrook Road, Germantown, MD 20874
- 3) Performance Development Services Corporation (PDC), 19500A Amaranth, Germantown, MD 20874

Scope of Surveillance:

The scope of this surveillance was to verify the implementation of EM-343 quality records management procedures SPP 7.01, *Preparation, Transfer and Receipt of Quality Records*, and SPP 7.02, *Quality Records Management*.

Surveillance Team:

Craig Walenga, Lead (CER)
Cheryl Nye (CER)

Personnel Contacted:

Ken Chacey, EM-343
Krystal Carter, EM-343
Thomas Gutmann, EM-343
Virgil Trice, EM-343
Ted McIntosh, EM-343
Olenna Truskett, EM-343
Ha Nguyen, EM-343
Abdullah Dasti, BDM/SAIC
John Knightly, PDC
Stephen Rodock, PDC


Surveillance Team Leader

8/22/91
Date


Director, Office of Quality Assurance

8/23/91
Date

1.0 EXECUTIVE SUMMARY

The surveillance team assessed the implementation of two quality assurance program procedures that represented EM-343's quality records management system controls. These procedures were SPP 7.01, *Preparation, Transfer, and Receipt of Quality Records* and 7.02, *Quality Records Management*. The records management systems of EM-343 and two direct-support contractors, BDM-SAIC and PDC, were reviewed to determine the effectiveness of the procedures. The surveillance team used a combination of interviews and reviews of the quality records files in performing the surveillance.

The surveillance team found that the quality records management system procedures are being inadequately implemented to the degree that EM-343 does not have a functioning quality records management system. Corrective Action Request (CAR) HQ-91-033 was initiated to address this significant condition adverse to quality.

2.0 PERFORMANCE AND RESULTS

2.1 General

The surveillance team prepared checklists to evaluate implementation of SPP 7.01 and SPP 7.02 based on requirements found in the procedures. SPP 7.01 outlines the activities required for the preparation, transfer, and receipt of quality records and SPP 7.02 describes the additional activities required for managing, storing, and dispositioning of not only quality records, but all HLW records. See Attachment I for a complete list of requirements documents and procedures reviewed in preparing the checklist questions.

A pre-surveillance briefing was held the morning of August 6, 1991. See Attachment II for the Attendance Record of the briefing. The surveillance team then reviewed files and interviewed personnel involved in quality records management activities at EM-343 and two direct support contractors, BDM/SAIC and PDC, whose offices are located near EM-343's offices in Germantown. A summary of the surveillance results follows.

2.2 EM-343

- 2.2.1 The surveillance team interviewed EM-343 project managers about their involvement with the quality records system and their familiarity with SPPs 7.01 and 7.02. The team interviewed an EM-343 secretary and examined the contents of a cabinet identified as the quality records file to determine what quality records are being maintained at EM-343. A listing of the file contents representing approximately the first eighty percent of the file is found in Attachment III. The Quality Records Index (QRI), Revision 1 was also reviewed and compared to folders in the quality records file.

2.2.2 During the interviews, it was found that none of the project managers had implemented SPP 7.01 or 7.02. A "quality records file" was established at EM-343 but the contents of the files do not reflect the results of systematic quality records management activities as described by the SPPs. There was no clear understanding on the part of the project managers as to how the quality records management system operated on a broad scale. Specific examples of these conditions are as follows:

- a. The project managers were unsure of who performed activities assigned to the "quality records coordinator" and the "quality assurance specialist" in SPPs 7.01 and 7.02. One project manager named a BDM staff member as this quality assurance specialist. In general, the project managers felt contractors currently provided the quality assurance specialist support required by the SPPs. During the pre-surveillance briefing, a proposed organization chart was shown that included a quality assurance specialist supporting each of EM-343's three project managers.
- b. EM-343 records are being stored in various locations by various individuals and organizations throughout the country. Project managers could not identify the location of their dual records. Storage locations are determined by whoever is performing the task. For example, records for audits lead by PDC are being kept by PDC. Various technical review groups maintain records at different locations depending on who is the assigned secretary. The following storage locations were identified during interviews:

DOE (with BDM/SAIC providing dual storage), Germantown
PDC, Oak Ridge and Germantown
PTSO, Richland, Washington
Argonne National Lab, Illinois
- c. Project managers exhibited a lack of understanding as to what a quality record is (see SPP 7.01, Section 4) and who creates a quality record. One project manager said that a controlled set of SPPs was a quality record. When reviewing the Quality Record Index, one project manager accepted responsibility for various categories of records listed, but could not provide examples of project records that fell into these categories.
- d. The Quality Record Index, Revision 1 was prepared and approved according to SPP 7.01 Section 5.a. However, inspection of files revealed that the index did not coincide with file folders in the cabinet. For example, files for categories 5720.31.401 through 5720.31.408, as listed on the index, were not present in the cabinet. In several cases the file folders reflected additional subcategories not specified on the index.

- e. The project managers stated that the EM-343 quality records file contained quality records. The surveillance team determined that the files did not contain quality records as described in SPP 7.01, Section 4. Furthermore, documents in the files had not been processed in accordance with SPP 7.01 and the applicable work implementing SPPs. The quality records file did contain documents that could be part of potential quality record packages as listed on the Quality Records Index, but the files also included documents that have no potential quality record value. For example, the file category 5720.31.411.01 identified on the Quality Records Index for Technical Review Documentation generated by SPP 4.11 contained only a list of the WCP and WQR document titles. (See Attachment III for additional examples.)
- f. None of the documents in the file were accompanied by Quality Record Verification Sheets (QRVS) required by the SPP for preparation and transmittal of quality records (SPP 7.01, Section 5.b.8 and Section 5.c.5). In addition, there was no evidence of a Quality Records Inventory List and Receipt having been completed (SPP 7.01, Section 5.c.1). The Inventory List and Receipt along with the QRVS is required for inspection and verification that the documents received for the quality record files are complete and acceptable (SPP 7.01 Section 5.c.4).
- g. No Quality Records Log was found in the file and what should be found in the files could not be established. The Quality Records Log must be completed upon receipt of a quality record (SPP 7.02, Section 5.d.5) and is the mechanism by which the total inventory of quality records in storage is identified and controlled.
- h. The secretary had the key to the quality records file and kept it locked. The secretary stated that only project managers were authorized or could authorize access to the files. There was no written authorized access list for the EM-343 quality records file (SPP 7.02, Section 5.d.8).

2.3 BDM/SAIC

- 2.3.1 The surveillance team interviewed the BDM/SAIC staff member who provided support in the quality records area as the quality assurance specialist and quality records coordinator. The team examined BDM/SAIC files identified as secondary dual storage for EM-343's quality records file.
- 2.3.2 The following was found at BDM/SAIC:
 - a. There was no formal control of the EM-343 dual storage location. The staff member indicated that there was no established method for transfer and receipt of quality records between the two storage files. The Quality Records Log illustrated in SPP 7.02, Attachment B includes a section for recording information about the transfer of quality records to dual storage, but again, no inventory or log was found (SPP 7.01, Section 5.c.4 and SPP 7.02, Section 5.d.5).

- b. The quality records file in the BDM/SAIC office was kept locked and the staff member had the key. No controlled access list was available (SPP 7.02, Section 5.d.8).
- c. The quality records file contained folders identical to the EM-343 quality records file, but when asked to produce certain documents, six of the ten file folders retrieved did not contain the same information that was found in the EM-343 file. For example, file folders for numbers 5720.31.411.01 through 5720.31.411.04 were empty. Upon indicating these deficiencies, the staff member was able to retrieve copies of the requested documents elsewhere in the BDM/SAIC offices.
- d. Files did not contain any BDM/SAIC records on training. The staff member stated that training records are kept by BDM/SAIC but they have not yet been entered into the EM-343 files. Also, the staff member stated that dual storage existed for the training records because one set of training records was kept in the "official" BDM/SAIC file and another by a secretary. The staff member stated that BDM/SAIC is required to comply with the SPPs.
- e. The staff member stated that he has not implemented SPP 7.01 because BDM/SAIC has not yet been given responsibility for generating quality records. However, the surveillance team noted that BDM/SAIC staff has conducted EM-343 QA Program orientation classes that should have resulted in quality records required by SPP 3.02, *Preparation and Conduct of Training, Indoctrination, and Orientation*.

2.4 PDC

- 2.4.1 The surveillance team interviewed the PDC Quality Records Administrator and examined the contents of the quality records files at PDC-Germantown office. These quality record files were represented to the surveillance team as secondary dual storage for quality records files maintained at the PDC Oak Ridge office. The team was informed that this file contained the only completed quality records maintained by EM-343.

The team also reviewed a PDC Memorandum dated 7/9/91 from John Knightly to Paul Evans re: Transmittal of Quality Records Documents to Washington Office. Attachments were identified as: 1) a Quality Records Index, 2) Quality Records as listed on the index, and 3) a list of individuals authorized access to the quality record file. A Quality Records Inventory List and Receipt from J.C. Standifer to Quality Records Coordinator dated 7/9/91 was also included as an attachment.

2.4.2 The following results were found:

- a. PDC-Germantown office files, identified as containing quality records, did not contain total quality records packages as required by the appropriate SPP and described in SPP 7.01. PDC did not follow the SPPs when processing records.
- b. The Quality Record Index attached to a memo by PDC's Mr. Knightly memo was not the same as the Quality Record Index identified in SPP 7.01 that had been prepared by EM-343. The PDC Index was actually used to identify individual documents in the file. PDC did not use the Quality Records Log format illustrated in SPP 7.02, Attachment B, and its Index did not contain all the information required by the SPP.
- c. PDC-Germantown office quality records were not assigned a subject file number and were not filed according to the EM-established indexing system.
- d. Quality record number 46, which had been sent by the PDC-Oak Ridge office to the PDC-Germantown office, was missing all even-numbered pages. The Quality Records Inventory List and Receipt had been signed off on 7/9/91, indicating receipt of the documents. A notation on the QRVS indicated that PDC-Germantown office had identified the problem and that PDC-Oak Ridge was correcting the problem. However, a month later, the incomplete document had not yet been replaced.
- e. The files did not contain a completed QRVS for each quality record as required by SPP 7.01. One QRVS had been completed for all 43 SPPs. QRVSs completed in Oak Ridge did not contain all information requested on the form, such as author and total number of pages. Also, the QRVS had been used improperly to make a notation about a deficiency found in the dual storage copy (see Paragraph 2.4.2.d).
- f. The Records Administrator indicated that the Germantown office file contained all records that were in the primary file at the PDC-Oak Ridge office. The team could not verify that the PDC-Germantown office had all the records contained in the primary files due to the informal nature of the controls for the two storage systems.
- g. The Manager, Organization Development and Training at the PDC-Oak Ridge office provided a memo that stated there were no training records available for the PDC staff because they had received no formal training on the quality records SPPs. A document attached to the memo indicated that one file administrator had attended an internal PDC training session on project file management.
- h. The quality records file was being used to store documents other than quality records. This condition was corrected during the surveillance.

- i. The Records Administrator could not provide a statement or identify in the procedure criteria for accepting quality records packages.
- j. Quality records packages collected by PDC for the development of the SPPs did not constitute the total quality records packages. SPP 2.01 requires that the following be prepared as quality records for each SPP: 1) the implementing SPP, 2) the SPP Coordination Log, 3) the SPP Index, and 4) Review/Comment forms for each reviewer of the SPP. However, only copies of SPPs were in the files. The Records Administrator indicated that other records that should be in the records packages were kept at the PDC-Oak Ridge offices.
- k. The Records Administrator indicated that though there were specific procedural requirements, it was acceptable to conduct work to potential changes to procedures. When the Records Administrator was told about the incorrect filing of quality records, he indicated that it was not necessary to correct the file.

3.0 FINDINGS

3.1 Corrective Action Request (CAR)

Based on the information gathered during this surveillance the surveillance team finds that EM-343 is not effectively or adequately implementing SPP 7.01 and SPP 7.02 and, as such, the basic assertion in QAPD Section 17 that EM-343 has established a "a quality assurance records system for collecting, storing, and maintaining Vitrification Projects Branch-prepared records" cannot be verified. EM-343 does not have a functioning quality records management system. This finding is documented in draft CAR (Corrective Action Request) HQ-SR-91-033. A copy of the draft CAR is included in Attachment IV of this report. The conditions adverse to quality that support this finding in the draft CAR were as follows:

- a. The surveillance team did not find one procedurally correct total quality records package being maintained by or for EM-343. Individual documents are being maintained, but no quality records representing a total package as defined by the SPPs was found. An example of this condition is described in detail in Section 2.4.2.j of this report.
- b. The personnel interviewed did not understand the basic concepts of a quality records management system prescribed by the procedures, including what a quality record is. Personnel who are performing quality records management activities have not been trained on the implementing procedures and others had received only orientation training. One contractor employee exhibited a disregard for the need to adhere to approved procedures.

- c. The existing quality records files provide evidence that implementation of the procedures is ineffective throughout the records process. Specific deficiencies were identified in:
- identification of quality records (incomplete packages)
 - quality record preparation (no QRVs or incorrect QRVs)
 - receipt control and inspection (no formal transmittals, incomplete documents)
 - storage and maintenance (no standard filing system, no comprehensive logs)
 - control of dual storage (inconsistencies in BDM's files and informal transfer controls)
 - correction handling (incomplete document not replaced)
- d. Adequate protection of quality records is not ensured by the present storage system. The quality records storage systems that are in place are being managed in such an informal fashion that the integrity of the files cannot be verified.
- e. A comprehensive inventory of EM-343 quality records that have been generated and are being maintained does not exist. Without a set of logs or indexes to identify records and their storage locations, retrieval of quality records from the system is not verifiable.
- f. Responsibilities for implementing quality records management activities at EM-343 are not clearly assigned. A Quality Records Coordinator has not been assigned to receive, process, and maintain quality records. As a consequence, while the procedures may exist that describe a records system, the activities described by the procedure are not being performed.

3.2 Observations

3.2.1 Temporary/Dual Storage

The surveillance team is concerned that EM-343 has misinterpreted DOE/RW-0214 QARD requirements (ASME NQA-1, Supplement 17S-1, Part 4) for temporary storage and dual storage of records. Due to this misinterpretation, EM-343 procedures describe a quality records management program in a way that is not consistent with the normal records management processes.

EM-343 needs to rethink its records management system and should consider revising its entire records management process. The reasons for this observation follow. SPP 7.02, Section 4 states that

...quality records are accumulated within the HLW Program in a way which meets the requirements of temporary storage. During temporary storage, a dual record system is established by requiring the originator to keep a copy and also forward a copy as directed by the DOE-HLW Program. Quality records are copied and indexed. The copies and index are then transferred to a Federal Records Center or a facility that meets the dual facility requirements within two years of the start of temporary storage...

First, the DOE/RW-0214 QARD/NQA-1 requirement provides for either (a) one facility for records storage or (b) dual facilities for records storage, each with its own set of requirements. EM-343 has stated that dual facility storage for quality records is required and has attempted to implement dual storage. Thus, dual facility quality records storage would satisfy the RW records management requirement.

Second, temporary storage as addressed in NQA-1 Supplement 17S-1 Paragraph 4.4.3 has nothing to do with the establishment of a single facility or dual facilities for permanent quality records storage. The NQA-1 temporary storage requirements are appropriate only for processing or using the records outside of the established permanent records storage facility or dual facilities. There are unique requirements for records storage if records are in temporary storage.

Third, a dual record system that requires the originator to maintain a copy of the quality records package for at least two years logically appears to have a high probability of failure due to personnel turnover and generally poor personal record keeping practices. Also, the SPPs in the Section 5 Procedure sections and the sections addressing quality records preparation do not require the originator to maintain a copy of the quality records packages much less maintain a copy for two years.

3.2.2 Lack of Coordination/Centralization

EM-343 records activities are currently being implemented by each organization that generates documents identified to become quality records. No one organization has been assigned to collect and maintain records. The activities observed were performed to some extent according to the SPPs, but there is no evidence of consistency or integration among the various locations and little oversight from DOE HQ in this area. There is no mechanism by which to identify what records have been completed by whom and where they may be found. Because storage locations are scattered, there is no focal point for retrieval of quality records.

3.2.3 Training Concerns

Only orientation training for SPP 7.01 and SPP 7.02 was provided to the EM-343 staff and some direct-support contractors while other direct-support contractors had not received any training on the procedures but were still implementing the procedural requirements. The poor procedural implementation effectiveness found during the surveillance raises concerns that the training given was inadequate or ineffective or both. Also, the fact that some personnel were performing work without training in the appropriate procedures raises further concerns regarding the effectiveness of the EM-343 training program and quality assurance program. This area is outside of the scope of this surveillance and was not further pursued. However, these findings have been provided to the audit team members who are performing the review of EM-343's training program during Audit HQ-91-003 to be performed during the final week of August 1991.

3.2.4 Lack of Control of Dual Storage

EM-343 has established that quality records will be stored using dual storage. SPP 7.01 and SPP 7.02 do not directly address how records are to be controlled between the two storage places though tools that could be used for controlling quality records at the two facilities are provided for in the procedures. Also, the procedures do not address if each storage place is an independent facility for processing quality records or if one place is to be designated the primary facility for the handling of all initial quality record packages while the second place is only a storage facility for the backup of quality records packages. The lack of formal controls for the handling of records between the dual storage facilities is a major concern as the surveillance team has found that the EM-343 dual storage facilities reviewed do not represent dual storage for the quality records.

3.2.5 Turnover of Records to RW or A Local Records Center

The records management procedures currently defined by EM-343 do not address the identification, packaging, and transfer to RW of quality records packages. There is no specific method defined in the current procedures for EM-343 to provide permanent storage of those quality records identified as lifetime, or a plan for how EM-343 will collect, prepare, and turn over those records to the RW records system in accordance with the established requirements. Another issue is the need to consider the establishment of an EM local records center that meets the requirements of DOE/RW-0194, *Records Management Policies and Requirements*.

4.0 ATTACHMENTS

Attachment I - List of Requirements Documents

Attachment II - Attendance Record

Attachment III - Contents of EM-343 Identified Quality Records Files

Attachment IV- Draft Corrective Action Request HQ-SR-91-033

**ATTACHMENT I
REQUIREMENTS DOCUMENTS**

The surveillance team used the following documents in preparing for and conducting Surveillance HQ-SR-91-011: *01-*

DOE/RW-0214, *Quality Assurance Requirements Document, Revision 4*

DOE/EM/WO/02, *Quality Assurance Program Description for High-Level Waste Form Development and Qualification, Revision 0*

SPP 3.02, *Preparation and Conduct of Training, Indoctrination, and Orientation, Revision 0*

SPP 6.01, *Official HLW Office Files, Revision 0*

SPP 7.01, *Preparation, Transfer, and Receipt of Quality Records, Revision 0*

SPP 7.02, *Quality Records Management, Revision 0*

ATTACHMENT II

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

SHEET 1 OF 1
WBS NO. CA

ATTENDANCE RECORD

[] AUDIT
[✓] SURVEILLANCE
[] TRAINING/INDOCTRINATION

SUBJECT

Records Management

[] TEAM BRIEFING
[✓] PRE-CONFERENCE
[] POST-CONFERENCE

odw
AUDIT OR SURVEILLANCE LEADER/INSTRUCTOR(S)

Craig Glabbe
Cheryl Dye
Signature
Signature

DATE 8-6-91

CLASS LENGTH _____

BRIEF SUMMARY OF MATERIAL COVERED _____

Pre-Surveillance Briefing

NAME OF ATTENDEE PRINTED	SIGNATURE	ORGANIZATION/ COMPANY	POSITION/TITLE	PHONE NUMBER
<i>Olenna Trusket</i>	<i>Olenna Trusket</i>	<i>DOE HQ / EM-343</i>	<i>Tech Review Manager</i>	<i>301 353-7194</i>
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<i>Ken Chace</i>	<i>Ken Chace</i>	<i>DOE - EM-343</i>	<i>DR. CHIEF</i>	<i>301 353 7186</i>

Contents of EM-343 Identified Quality Records Files

<u>Record Folder</u>		<u>Records Found in File</u>
5720.31	Application Position (Gold Sheet)	None
5720.31.301	Prep. Maint. of Plans for Pers TI&O	None
5720.31.301.01	Assessment Plan & Schedule	None
5720.31.301.02	Needs Assessment Worksheets	Found Worksheets for Hennessey, Trice, Chacey, Truskett, Guttman, McIntosh, Walter, Carter, Nguyen
5720.31.301.03	TI&O Plan & Schedule	Memo and TI&O Plan & Schedule for VP Branch Rev. 0, 2-15-91
5720.31.302	Prep & Cond. of Pers TI&O	4 memos (1 was a copy of another) about when training is to be conducted
5720.31.302.01	Course Documentation	None
5720.31.302.01.01	Attendance Sheets	QA Orientation (10-15-90; 10-29-90) HLW 9002 QAMT Orientation to SPPs (10-16-90; 10-18-90; 12-12-90)
5720.31.302.01.02	Course Critiques	2 memos/several critiques
5720.31.302.01.03	Tests	One unused copy of the test and 5 completed QA orientation tests (with only one having a name on it)
5720.31.302.01.04	Critique and Course Summary	None
5720.31.302.01.05	Lesson Plans, Handouts and Visual Aids	I Outline (Misc) for HLW QAMT II EM-343 QA Orientation Course - 03.901.024.01 III Documentation on EM-343 QA Orientation Course IV Documentation on SPP Orientation Course V Notes on IV VI Leaders Guide for IV

Contents of EM-343 Identified Quality Records Files (Con't)

<u>Record Folder</u>		<u>Records Found in File</u>
5720.31.302.02	Personnel Training File	Guttman/Chacey - 1 memo Trice - Attendance Sheet/1 memo Pircarella/Carter - 1 attendance sheet each Hennessey - Attendance sheet, ATL course, Hazardous Waste Certificate McIntosh, Walter, Curtiss, Nguyen, Walton, Allison, Sands.
5720.31.302.02.01	Completed copies of TI&O Records	BDM Training Status Report for EM-343 dated 4/26/91
5720.31.302.02.02	Organizational Plan & Function Statements	None
5720.31.305	Admin of Pers. Cert & Qual. Records	None
5720.31.305.01	Pers. Qual. Files (tabbed) Wkg	None
5720.31.305.01.01	Resume	None
5720.31.305.01.02	Training Documentation	None
5720.31.305.01.03	Audit/Surveil. Participation Records	None
5720.31.305.01.04	Verif of Education Document	None
5720.31.305.01.05	Job Description/Task Qualif. Requirements	None
5720.31.305.01.06	Physical Ability	None
5720.31.305.02	Pers. Qual. Files (tabbed) Received	None
5720.31.305.02.01	Resume	None
5720.31.305.02.02	Training Documentation	None
5720.31.305.02.03	Audit/Surveil. Participation Records	None
5720.31.305.02.04	Verif of Education Document	None
5720.31.305.02.05	Job Description/Task Qualif. Requirements	None
5720.31.305.02.06	Physical Ability	None

Contents of EM-343 Identified Quality Records Files (Con't)

<u>Record Folder</u>		<u>Records Found in File</u>
5720.31.411	TRG and Technical Documents (TRGs); WCP; WQR Waste Acceptance Documents	List of addresses and numbers for WQR TRG members
5720.31.411.01	Waste Acceptance Documents (DWPF, HWVP, WVDP) (WCP&WQR)	DWPF list of WCP and WQR #1, 2, 3, 4 & 10 document titles, Rev. numbers, and File numbers; and WVDP list of WCP and WQR #1, 2, 3 document titles, Rev. No., and File numbers
5720.31.411.02	Safety Analysis Reports (PSAR/FSAR) (DWPF/HWVP/WVDP)	Sheet/List of: 1) DWPF FSAR Rev. 2 2) HWVP PSAR Rev. B 3) STS SAR Draft WVDP SMWS Addendum
5720.31.411.03	S/U Readiness Review Team (SRRT) (DWPF)	Copy of S/U Readiness Review Team File Classification System
5720.31.411.04	QA Activities (DWPF/HWVP/WVDP)	Copy of a list of existing QA manual documents and audit/surveil file with file numbers
5720.31.412	Review of Program Execution Guidance Document	Numerous PEGD and memos
5720.31.412.01	Review File for Each Document	None
5720.31.412.01.01	DWPF	None
5720.31.413	Participation in Evaluation Activities led by External Organization	None
5720.31.413.01	External Evaluation Participation Records	1) Audit 91-15-03-1012 2) Draft S/U Strategy Doc OPS-DPK-90-0013 3) 90-15-03-1006
5720.31.601	Official HLW Office Files	Index to Project Files 5/13/91
5720.31.601.01	File List	None
5720.31.601.02	Holding File for Docs to be Filed	None

Contents of EM-343 Identified Quality Records Files (Con't)

<u>Record Folder</u>		<u>Records Found in File</u>
5720.31.602	Preparation of Correspondence	None
5720.31.602.01	Reading File	None
5720.31.603	Incoming Mail	None
5720.31.603.01	Incoming Mail Routing and Handling Matrix	None
5720.31.603.02	Incoming Mail Log	None
5720.31.604	Commitment Control	None
5720.31.604.01	Commitment Log	Commitment Summary Log for 1, 4, 5-8/91
5720.31.604.02	Status of Commitment	None
5720.31.605	Controlled Documents	None
5720.31.605.01	Controlled Document Master List	Controlled Documents Master Listings 1/3/91 Chacey, Guttman, Walter, McIntosh, Trice CDML 7/29/91 Olenna Tuskett plus a dist. list with 5 other names.
5720.31.605.02	C.D. Acknowledgment Receipts	None
5720.31.605.03	C.D. File	None
5720.31.701	Preparation, Trans, Receipt of Quality Records	None
5720.31.701.01	QR Index	Rev. 0/Rev. 1
5720.31.701.01.01	Records Classification	None
5720.31.701.01.02	PM Approval	None
5720.31.701.01.03	Current Original	None

Contents of EM-343 Identified Quality Records Files (Con't)

<u>Record Folder</u>		<u>Records Found in File</u>
5720.31.701.01.04	Historical Revisions	None
5720.31.701.01.05	Transmittals	None
5720.31.701.02.01	Q Records File-1	None
5720.31.701.02.01.01	Q Record Verification Sheet	1 blank QRVS Form/Sheet
5720.31.701.02.01.02	Q Record Inventory List	1 blank QRIL Form/Sheet
5720.31.701.02.01.03	Q Record Original	None
5720.31.701.02.01.04	Unacceptable Records Return Correspondence	None
5720.31.701.02.01.05	Q Records Correction Correspondence	None
5720.31.701.02.02	Q Records File-2	None
5720.31.701.02.02.01	Q Record Verification Sheet	1 blank QRVS Form/Sheet
5720.31.701.02.02.02	Q Record Inventory List	1 blank QRIL Form/Sheet
5720.31.701.02.02.03	Q Record Original	None
5720.31.701.02.02.04	Unacceptable Records Return Correspondence	None
5720.31.701.02.02.05	Q Records Correction Correspondence	None
5720.31.702	Q Records Management	None
5720.31.702.01	RIDS	None
5720.31.702.01.01	QAS Concurrence	None
5720.31.702.01.02	PM Approval	None
5720.31.702.01.03	EM-343 Records Officer Approval	None
5720.31.702.02	Overall Filing System	SPP Filing List and memo from J. Hennessey that includes the list

Contents of EM-343 Identified Quality Records Files (Con't)

<u>Record Folder</u>		<u>Records Found in File</u>
5720.31.702.03	Disposition Instructions for Non-Record Material	None
5720.31.702.03.01	PM Concurrence	None
5720.31.702.04		None
5720.31.702.04.01		None
5720.31.702.05		None
5720.31.702.06		None
5720.31.702.07		None
5720.31.702.08		None
5720.31.702.09		None
5720.31.702.10	Authorized Records Access List	None
5720.31.702.11		None
5720.31.702.12		None
5720.31.702.13		None
5720.31.702.14		None
5720.31.702.15		None
5720.31.702.16		None
5720.31.702.17		None
5720.31.802		None

DRAFT

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

¹⁴ CAR NO. HQ-SR-91-033
 DATE: _____
 SHEET: 1 OF 2
 QA
 WBS NO.: 6.07

CORRECTIVE ACTION REQUEST

¹ Controlling Document DOE/EM/WO/02, Rev. 0, 10/09/90, Quality Assurance Program Description		² Related Report No. HQ-SR-91-016	
³ Responsible Organization EM-343		⁴ Discussed With Ken Chacey	
¹⁰ Response Due	¹¹ Responsibility for Corrective Action		¹² Stop Work Order Y or N
⁵ Requirement: DOE/EM/WO/02, Rev. 0 states that EM-343 has established a "quality records system for collecting, storing, and maintaining Vitrification Projects Branch-prepared records."			
⁶ Adverse Condition: A Vitrification Projects Branch quality records system has not been established and implemented and objective evidence does not exist that an effective quality records system has been implemented for or by any contractor that is required to comply with Procedures SPP 7.01 and SPP 7.02. This finding is based on the following objective evidence: 1. Not one total quality records package meeting all requirements of SPP 7.01 and SPP 7.02 was found during the surveillance of EM-343 and two direct-support contractors (BDM/SAIC and PDC). <div align="right">(continued on following page)</div>			
⁷ Recommended Action(s): 1) Evaluate the current status of the quality records system for EM-343 and its direct-support contractors and determine if one records center with dual storage is implementable. If so, centralize the handling of quality records by assigning the responsibility to a specific person or group. <div align="right">(continued on following page)</div>			
⁸ Initiator Craig Walenga	Date: 8/20/91	⁹ Severity Level - 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	¹³ Approved by OQA _____ Date: _____
¹⁵ Verification of Corrective Action: 			
¹⁶ Corrective Action Completed and Accepted: OAR _____ Date _____		¹⁷ Closure Approved By: OQA _____	

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

CAR NO. HO-88-91-033

DATE: _____

SHEET: 2 OF 2

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

6 Adverse Condition: (continued)

- 2) Implementation of SPP 7.01 and SPP 7.02 was either not apparent or inadequate for every procedural requirement except for development of a Quality Records Index.
- 3) Some support contractors had not been trained on the implementation of SPP 7.01 and SPP 7.02. The only training given to EM-343 staff and some support contractors was "orientation training" on SPPs. The inadequate implementation of SPP 7.01 and 7.02 indicate that this training was insufficient or inadequate or both. In one case, an untrained contractor employee, responsible for the contractor's quality records, stated that procedures did not have to be followed.
- 4) Project managers could not provide a list or a set of lists that identified the quality records that exist for EM-343 nor could they identify how the dual storage system was implemented for any specific contractor.
- 5) The dual storage record systems for EM-343/BDM-SAIC and for PDC were so informally controlled that the duplicity of records between individual storage areas was unverifiable.
- 6) Specific responsibility for the implementation of the records management program had not been assigned by EM-343.

7 Recommended Action(s): (continued)

- 2) Once the specific quality records system has been established, develop functional training for implementing the system. Ensure that all direct-support contractors and EM-343 staff are trained in accordance with the quality records system requirements.
- 3) Establish an audit and surveillance schedule that overviews the implementation of the quality records system on a quarterly basis for the next twelve months or until effective implementation of the program can be verified.
- 4) Identify the cause of the condition adverse to quality and determine the actions necessary to prevent recurrence.

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CRITERION 1: ORGANIZATION

1.a <u>General:</u>	WMM
1.b. <u>SPP 10.03 - Differing Staff</u> <u>Opinions and Allegations:</u>	WMM
1.c <u>SPP 5.03 - Stop Work Orders:</u>	WMM
1.d <u>Requirements of Field Offices:</u>	WMM

CRITERION 2: QUALITY ASSURANCE PROGRAM

2.a <u>General:</u>	WMM
2.b <u>Independence of Personnel Performing</u> <u>Verification Activities:</u>	WMM
2.c <u>Planning:</u>	WMM
2.d <u>SPP 4.01 - Planning and Scheduling of</u> <u>Evaluation and Assessment Activities:</u>	WMM
2.e <u>Indoctrination and Training - General</u> <u>(including SPPs 3.01, 3.02, and 3.05):</u>	WMM
2.f <u>SPP 3.03 - Qualification of QA Audit Personnel:</u>	PSS
2.g <u>OAP-EM-1-2.1 - Qualification and Certification</u> <u>of EM Audit and Appraisal Personnel:</u>	PSS
2.h <u>SPP 3.04 - Documentation of Surveillance</u> <u>Personnel Qualifications:</u>	PSS

2.i	<u>SPP 3.05 - Administration of Personnel Certification, Qualification, and Training Records:</u>	WMM
2.j	<u>SPP 8.02 - Annual Assessment of the OA Program</u>	WMM
2.k	<u>SPP 8.03 - OA Program Progress and Status Reports:</u>	WMM
2.l	<u>Overview and Requirements of Field Offices:</u>	WMM
2.m	<u>SPP 2.01 - Standard Practice Procedures:</u>	GSB
2.n	<u>SPP 2.03 - Quality Assurance Program Description:</u>	GSB
2.o	<u>SPP 4.04 - Administration and Conduct of Surveillance:</u>	PSS
2.p	<u>EM-343 OAPD Section 2.1.4 - Graded OA Program:</u>	GSB

CRITERION 3: DESIGN CONTROL

3.a	<u>Section 3 of the EM OAPD:</u>	GSB
3.b	<u>SPP 4.08 - Administration and Conduct of Peer Reviews:</u>	GSB
3.c	<u>SPP 4.15 - Administration and Performance of Technical Reviews:</u>	GSB

CRITERION 4: PROCUREMENT DOCUMENT CONTROL

4.a	<u>Section 4 of the EM OAPD:</u>	PSS
4.b	<u>SPP 4.12 - Quality Assurance Input to the Program Execution Guidance Documents:</u>	PSS

CRITERION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.a Section 5 of the EM QAPD:

GSB

CRITERION 6: DOCUMENT CONTROL

6.a Section 6 of the EM QAPD:

GSB

6.b SPP 6.05 - Controlled Documents:

GSB

CRITERION 7: CONTROL OF PURCHASED ITEMS AND SERVICES

7.a Section 7 of the EM QAPD:

PSS

CRITERION 15: CONTROL OF NONCONFORMING ITEMS

15.a Section 15 of the EM QAPD:

CRM

15.b SPP 5.01 - Deviations and Corrective Actions
(addressed in Criterion 16, below; the
checklist will not be repeated here)

CRITERION 16: CORRECTIVE ACTION

- 16.a Section 16 of the EM OAPD: CRM
- 16.b SPP 5.01 - Deviations and Corrective Actions: CRM
- 16.c SPP 5.07 - Evaluation and Assessment Commitment Tracking and Reporting System: CRM
- 16.d SPP 10.01 - Analysis of Adverse Quality Trends: CRM
-

CRITERION 17: QUALITY ASSURANCE RECORDS

- 17.a Section 17 of the EM OAPD: CRM
- 17.b SPP 7.01 - Preparation, Transfer, and Receipt of Quality Records: CRM
- 17.c SPP 7.02 - Quality Records Management: CRM
-

CRITERION 18: AUDITS

- 18.a Section 18 of the EM OAPD: PSS
- 18.b SPP 4.02 - Administration and Conduct of Quality Assurance Audits: PSS
- 18.c SPP 4.13 - Observation of Evaluation Activities Led by External Organizations: PSS
-

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CRITERION 1: ORGANIZATION

1.a <u>General:</u>	WMM
1.b. <u>SPP 10.03 - Differing Staff</u> <u>Opinions and Allegations:</u>	WMM
1.c <u>SPP 5.03 - Stop Work Orders:</u>	WMM
1.d <u>Requirements of Field Offices:</u>	WMM

Quality Assurance Audit Checklist

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Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 1 Of 7	
Organization Evaluated: DOE EM-343 VPD		Audit Subject: Criterion 1		Prepared By: T. Colandrea <i>[Signature]</i> <small>Audit Team Leader</small>		Date: 7/17/92
Date(s) Of Evaluation: July 20-24, 1992		Type Of Audit: QA Program Effectiveness		Approved By: J. T. Conway <i>[Signature]</i> <small>QA Program Manager</small>		Date: 7/17/92
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
<p>CRITERION 1: ORGANIZATION</p> <p>1.a General:</p> <p>1. Per Sect. 1 of the EM-343 QAPD, the 10/30/91 MOA states that RW-3 will interface directly with the Director, EM-343, for planning and coordinating the High-Level Waste QA Program. The MOA, per Para. 1.1.4 provides for coordination of resolution of nonconformances to RW requirements or resolution of quality problems. Examine the MOA and discuss this aspect of the QA Program with the involved managers to determine if adequate provisions for resolution of disagreements are provided.</p>		<p>EM-343 QAPD, Rev. 1, EM/WO/02, Section 1 and Para. 1.1.4</p>				

Quality Assurance Audit Checklist

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1.a

Audit I. D. No.: **92EA-VP-AU-001**

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No.	Description				
2.	Determine the extent to which the functional responsibilities and levels of authority of the Program Managers are documented as required by BR-1 of NQA-1, which is invoked by RW-0214.	EM-343 QAPD, Rev. 1, EM/WO/02, Section 1			

Quality Assurance Audit Checklist

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1.a

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No.	Description				
3.	Para. 1.1.4 of the EM-343 QAPD notes that the QA Program Manager (a) assists and serves as a staff advisor for determining the QA controls to be applied and (b) manages the QA Program. Verify that these statements do not conflict and that the QA Program Manager serves both as a staff advisor and also fills the "QA management position" as specified in RW-0214.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.1.4			

Quality Assurance Audit Checklist

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No.	Description				
4.	Through discussions with the QA Program Manager and review of his PD, verify that the QA Program Manager has no other duties or responsibilities that could compromise the independence required in managing the EM-343 QA Program.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.1.4			

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Audit I. D. No.: **92EA-VP-AU-001**

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No.	Description				
5.	Para. 1.4 of the QAPD states that the QA Program Manager has access to senior management to identify and resolve unresolved quality concerns. Evaluate the extent to which the QA Program Manager has such access. Determine the extent to which this authority has been documented in implementing procedures. Does this documented authority include access to "senior management and management at the next higher program organizational level" as required by RW-0214, Para. 1.1.f? Determine whether the QA Program Manager has had to use this access to resolve quality concerns and evaluate the effectiveness of the established provisions.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.1.4			

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1.a

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No.	Description				
6.	Evaluate whether sufficient staffing resources are allocated to the EM-343 QA Program Manager for carrying out his assigned responsibilities in an effective manner, including the surveillances, audits, and reviews to ensure that the QA Programs of the DOE field offices and their M&O contractor organizations are adequate and effectively implemented.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.1.4			

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1.a

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Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
7.	Examine the reporting relationship between the QA Specialists and the QA Program Manager versus the management direction from the individual Program Managers to the Specialists. Although Fig. 1.3 shows the QA Specialists under the Program Managers, both Fig. 1.3 and Para. 1.1.4 indicate they receive direction not from their assigned Program Managers but from the QA Program Manager. Evaluate the effectiveness of this relationship. Many of the EM-343 SPPs assign specific responsibilities to a QA Specialist without specifying which specialist. Determine how the individual QA Specialists know which specialist is assigned the responsibility for a specific SPP and evaluate the effectiveness of this arrangement.	EM-343 QAPD, Rev. 1, EM/WO/02, Fig. 1.3 and Para. 1.1.4			

Quality Assurance Audit Checklist

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Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 1 Of 5	
Organization Evaluated: DOE EM-343 VPD		Audit Subject: Criterion 1		Prepared By: T. Colandrea <i>T. Colandrea</i>	Date: 7/17/92	
Date(s) Of Evaluation: July 20-24, 1992		Type Of Audit: QA Program Effectiveness		Approved By: J. T. Conway <i>J. T. Conway</i>	Date: 7/17/92	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
	1.b <u>SPP 10.03 - Differing Staff Opinions and Allegations:</u> 1. If there are any, review* the completed "Employee Differing Staff Opinion/Allegation Form" to verify that the procedure established in SPP 10.03 is effective in handling disputes, allegations and concerns without fear of reprisal to the concerned individual.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.3 and 1.4, SPP 10.03, Rev. 1, Section 3.a.				
* To maintain proper confidentiality, it may be necessary for EM-343 to mask off any indication as to who the "concerned individual" is prior to review of the form(s) by the audit team.						

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1.b

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Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	Para. 1.4 of the QAPD states that each allegation concerning inadequate quality will be investigated by personnel who are independent of the affected activity. Since this provision has apparently not been incorporated into SPP 10.03, determine whether it has been incorporated into any other EM-343 implementing procedure.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.4 and SPP 10.03, Rev. 1			

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1.b

Audit I. D. No.: **92EA-VP-AU-001**

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Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	Determine why, if the completed "Employee Differing Staff Opinion/Allegation Form" is considered significant enough to be maintained in the quality records system per SPP 10.03, the EM-343 Division Director is not required to review or even receive a copy of the completed form [i.e., he only receives the form if the originator of the form is unhappy with the Program Manager's proposed resolution...Section 4.b.(5)].	SPP 10.03, Rev. 1, Section 4.c.			

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1.b

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No.	Description					
4.	Check whether a conflict exists between Para. 1.3 of the QAPD, which requires that differences of opinion involving QA matters be brought to the Director, EM-343, for resolution, and SPP 10.03, which requires that differing opinions (including those relating to QA matters) be documented and submitted to his or her manager for resolution. For those cases where the matter is resolved between the concerned individual and the Program Manager, the Division Director is not even informed, per Section 4.b.(4) of SPP 10.03.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.3, SPP 10.03, Rev. 1				

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1.b

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No.	Description				
5.	Evaluate whether SPP 10.03 is adequate to cover the situations when the concerned individual is a program manager in EM-343. Also check to determine who processes the records generated per SPP 10.03 when the concerned individual works for the Systems Engineering Program Manager, who doesn't appear to have an assigned QA Specialist.	SPP 10.03, Rev. 1			

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Date(s) Of Evaluation: July 20-24, 1992		Type Of Audit: QA Program Effectiveness		Approved By: J. T. Conway <i>J. T. Conway</i> QA Program Manager	Date: 7/17/92
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
1.c SPP 5.03 - Stop Work Orders:					
1.	Review the Stop Work Orders and Stop Work Order Releases, if any, that have been issued or processed during the past 12 months in accordance with SPP 5.03 and the associated Deviation and Corrective Action Report to determine whether (a) the information specified in Attachment B and C of SPP 5.03 were provided, and (b) the procedures have been effective in stopping work and lifting stop work orders, when necessary, and exactly defining the work being stopped.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.5 and SPP 5.03, Rev. 1			

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1.c

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No.	Description				
2.	Para. 1.5 of the QAPD requires that the stop work process be delineated in approved procedures which include, among other items, the criteria for stopping work and for lifting stop work orders/requests. Determine the extent to which such criteria are adequately provided in the implementing procedure (SPP 5.03) and, when such criteria are met, the stop work process is required to be initiated.	EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.5 and SPP 5.03, Rev. 1			

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1.c

Audit I. D. No.: **92EA-VP-AU-001**

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No.	Description				
3.	<p>Section 4.a.(2)(a) of SPP 5.03 states that the QA Program Manager "verbally notifies the Director and obtains his verbal <u>concurrence</u> that stop work should be issued." (emphasis added) ASME NQA-1-1989 Edition states that the QA organization "shall have <u>sufficient authority</u>, access to work areas, and organizational freedom to.... (4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred." (emphasis added) Determine if the QA Program Manager has "sufficient authority" to stop work if he must first obtain the concurrence of the Director before doing so. What recourse does the QA Program Manager have if the Director does not concur in the stop work or refuses to sign the Stop Work Order?</p>	<p>SPP 5.03, Revision 1, Section 4.a.(2)(a) SPP 5.03, Revision 1, Section 4.a.(3)</p>			

Quality Assurance Audit Checklist

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Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	Check whether the QA specialist responsible for processing the Stop Work records is adequately identified in SPP 5.03.	SPP 5.03, Rev. 1			

Quality Assurance Audit Checklist

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Organization Evaluated: DOE EM-343 VPD		Audit Subject: Criterion 1		Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>	Date: 7/17/92	
Date(s) Of Evaluation: July 20-24, 1992		Type Of Audit: QA Program Effectiveness		Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>	Date: 7/17/92	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
1.d Requirements of Field Offices: 1. Determine the extent to and manner in which the requirements of the field offices, described in Para. 1.6 of the QAPD, are effectively communicated to the field offices.			EM-343 QAPD, Rev. 1, EM/WO/02, Para. 1.6			