

United States Government

Department of Energy

memorandum

MARCH 10. 1994

DATE:

REPLY TO: RW-3.1
ATTN OF:

SUBJECT: Office of Radioactive Waste Management (OCRWM) Quality Assurance (QA)
Surveillance HQ-SR-94-03 of EM-343 Implementation and Effectiveness of
Remedial Actions

TO: Ralph Erickson, Director, Vitrification Projects Division (EM-343)

Please be advised that a team from OCRWM, Office of Quality Assurance (OQA), will conduct a QA surveillance of the EM-343 implementation and effectiveness of remedial actions and recommendations identified by OCRWM audits, surveillances, and observations during the period of March 14-16, 1994. The surveillance team will hold a brief pre-surveillance meeting on Monday, March 14, 1994, beginning at 9:30 a.m. at the EM-343 Offices. Please arrange for the appropriate personnel to attend this meeting. The post-surveillance meeting is tentatively scheduled for 3:00 p.m. on Wednesday, March 16, 1994.

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



Donald G. Horton, Director
Office of Quality Assurance

Attachment

cc:

T. Johnson, RW-3.1
S. Broccoum, RW-22
D. Spence, RW-3.2
D. Shelor, RW-30
J. Conway, EM-343
K. Grisham, EM-343
M. Horseman, QATSS-HQ

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WM-11 PDR

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

QUALITY ASSURANCE SURVEILLANCE RECORD

¹ ORGANIZATION/LOCATION: EM-343, Germantown, MD		² SUBJECT: Implementation and Effectiveness of Remedial Actions		³ DATE: 3/14-16/94	
⁴ SURVEILLANCE OBJECTIVE: To verify that Remedial Actions continue to be effective for identified deficient areas of QA Program.					
⁵ SURVEILLANCE SCOPE: Surveillance evaluation to include: Remedial actions to deficient areas corrected during verification activities and other appropriate actions to address OCRWM recommendations, identified by audit HQ-93-02; surveillance HQ-SR-93-01; and observations 94EA-VP-S-05/20, 94EA-WV-AU-01, 94EA-AN-S-01.				⁶ SURVEILLANCE TEAM: Team Leader: Tom Swift Additional Team Members: Fred Bearham Conrad Coulombe	
⁷ PREPARED BY: Thomas R. Swift Surveillance Team Leader		3/7/94 Date		⁸ CONCURRENCE: R.W. Culp QA Division Director 3/9/94 Date	
SURVEILLANCE RESULTS					
⁹ BASIS OF EVALUATION / DESCRIPTION OF OBSERVATIONS:					
¹⁰ SURVEILLANCE CONCLUSIONS:					
¹¹ COMPLETED BY: Surveillance Team Leader			¹² APPROVED BY: QA Division Director		
Date			Date		

**SURVEILLANCE HQ-SR-94-03
SCHEDULE OF EM-343 SURVEILLANCE ACTIVITIES**

MON. 3/14/94	TUES 3/15/94	WED. 3/16/94	THUR. 3/17/94	FRI. 3/18/95
9:30 ENTRANCE MEETING Team A: Organization & Program (1,2) Team B: Document Control (6) Team C: Audits, Corrective Action (18, 16)	9:00 MANAGEMENT MEETING Team A : (1, 2) Team B: WQR, TRG (2) Team C: (16, 18)	9:00 MANAGEMENT MEETING Team B: (6) Team C: (17)	N/A	N/A
LUNCH 11:30 -12:30	LUNCH 11:30 - 12:30	LUNCH 11:30 - 12:30	N/A	N/A
Team A: Organization & Program (1,2) Team B: WAPs (2) Team C: Audits, Corrective Action (18, 16) 16:00 TEAM MEETING	Team A: (1, 2) Team B: (2) Team C: Records (17) 16:00 TEAM MEETING	15:00 POST MEETING	N/A	N/A

TEAM A: Tom Swift, CER/QATSS, Elements 1, 2

TEAM B: Fred Bearham, CER/QATSS, EM-WAPs, WQR, TRG, Elements 2, 5, 6, 17

TEAM C: Conrad Coulombe, CER/QATSS, Elements 16, 17, 18

Belemeade Bldg #3 (Pink Palace)
Room 272 (if problem contact Bob Toro)
Entrance Meeting

SURVEILLANCE HQ-SR-94-03
SCHEDULE OF EM-343 SURVEILLANCE ACTIVITIES

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LUNCH 11:30 -12:30 Team A: Organization & Program (1,2) Team B: WAPs (2) Team C: Audits, Corrective Action (18, 16)	LUNCH 11:30 - 12:30 Team A: (1, 2) Team B: (2) Team C: Records (17)	LUNCH 11:30 - 12:30 15:00 POST MEETING	N/A	N/A
16:00 TEAM MEETING	16:00 TEAM MEETING			

TEAM A: Tom Swift, CER/QATSS, Elements 1, 2

TEAM B: Fred Bearham, CER/QATSS, EM-WAPs, WQR, TRG, Elements 2, 5, 6, 17

TEAM C: Conrad Coulombe, CER/QATSS, Elements 16, 17, 18

PAGE 1 OF 5
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

1 ORGANIZATION EVALUATED EM-343		2 <input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL		3 <input type="checkbox"/> AUDIT <input checked="" type="checkbox"/> SURVEILLANCE		4 PREPARED BY <u>Thomas R. Swift</u> Tom Swift		DATE <u>3/9/94</u>	
5 DATES OF EVALUATION 3/14-16/94		6 CONTROLLING DOCUMENT (Title, Number, Revision) DOE/EM/VO/SPP 1.02, Rev. 0				7 ACTIVITY EVALUATED Elements 1 and 2 Organization, Program			
8 ITEM NO.	9 CHARACTERISTICS TO BE EVALUATED				10 REMARKS			11 RESULTS	
1.	Review the EM Organization Chart (Recommendation HQ-93-02) (SPP 1.02) A) Verify organization is current 1. Review QA functions of Richland office 2. Review Memorandum of Agreement dated October 30, 1991 status for RW-3 and EM responsibilities 3. Review QA program responsibilities for the Status Tank Waste Remediation System Division (EM-361) B) Verify reporting relationship between DWPD and EM-343 is only for the Waste Acceptance Process.								

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SHEET 2 OF 5
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2.	<p>QA Status Report (Recommendation HQ-93-02, HQ-91-02)</p> <p>A) Verify Quarterly QA program report sent by all required groups to the Program Managers/EM-343 QA Manager.</p> <p>B) Verify Quarterly QA status report prepared by EM-343 QA Manager</p> <p>1. Sent to Director, EM-343 2. Copy sent to RW-3</p> <p>C) Verify reports issued on a timely basis.</p>		

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SHEET 3 OF 5
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3.	<p>Verify Management Assessment performed in FY-93 (Recommendation HQ-93-02) (Note not done in FY 92 due to major changes in Program)</p> <p>A) Responsibility of Division Director to arrange (SPP 1.02, Para. 4.d)</p> <p>B) Review recommendations, findings, observations for proper assignment of responsibility, resolution, and close-out.</p>		

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SHEET 4 OF 5
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
4.	Verify issuance of Program Execution Guidance (PEG) Document: A. FY-1993 B. FY-1994		

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SHEET 5 OF 5
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5.	Verify training performed for SPPs such as 7.0, (Rev. 5) and 7.02 (Rev. 3) (Quality Records Management) (Observation HQ-SR-91-16)		

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AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST

* ORGANIZATION EVALUATED EM-343	2	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	3 <input type="checkbox"/> AUDIT <input checked="" type="checkbox"/> SURVEILLANCE	4 PREPARED BY <u>Conrad Coulombe</u> <i>[Signature]</i> DATE <u>3/7/94</u>	
* DATES OF EVALUATION 3/14-16/94					
* CONTROLLING DOCUMENT (Title, Number, Revision) DOE/EM/WO/SPP 4.01, Rev. 3				* ACTIVITY EVALUATED Evaluation Activities	
* ITEM NO.	* CHARACTERISTICS TO BE EVALUATED			* REMARKS	* RESULTS
1.	Verify, FY94 15-month and Quarterly Evaluation Schedules prepared by EM-343: A. Verify with QA Specialist/QA Program Manager planning for schedule included use of applicable documents (Recommendation 93-02) 1. Program/Project plans, PEG, Quarterly Reports 2. Operations Offices, QA Program Evaluation and Assessment Schedules B. Verify that schedule(s) includes status updates - completed verification, delays, slippages.				

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SHEET 2 OF 4
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2	<p>Verify that deviations identified in Audits and Surveillances are evaluated and controlled under the Corrective Action process and program controls (93EA Observation).</p> <p>A. Review Audits and Surveillances and Commitment Tracking and Reporting Report (SPP 5.07) deviations and observations to evaluate the correct category</p> <p>B. Review various (6) DCARs for current processing, compliance with remedial action, root cause analysis, corrective action, and follow-up closure. Verify with A, above.</p>		

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SHEET 3 OF 4
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	<p>Verify that for Audits, Surveillance, and Technical Reviews, the personnel identified on the team have valid qualifications records in the QA records packages.</p> <p>A. Review several 1993/94 audit, surveillance, and/or Technical review packages for personnel list.</p> <p>B. Review Associated record packages for verification of qualifications and maintenance of qualification.</p> <p>(HQ-93-02) Quality Record of ORR</p>		

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SHEET 4 OF 4
AUDIT/SURVEILLANCE
NO. HQ-SR-84-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
4	<p>Verify that Records Packages are assembled in logical order and Quality Records Package Content Sheet is accurate.</p> <p>A. Review Records Packages for TRG Activities - Work Plan VQ/TRG-0294 and TRG-1162 or other Work Plan.</p> <p>B. Review Records Package for 2 Audits.</p> <p>C. Review Records Package for 2 Surveillance.</p> <p>HQ-SR-93-02 (6.1)</p>		

PAGE 1 OF 3
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

1 ORGANIZATION EVALUATED EM-343		2 <input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL		3 <input type="checkbox"/> AUDIT <input checked="" type="checkbox"/> SURVEILLANCE		4 PREPARED BY <u>Fred Bearham</u> <u>SR Smith</u> DATE <u>5/9/94</u>	
5 DATES OF EVALUATION 3/14-16/94				6 CONTROLLING DOCUMENT (Title, Number, Revision) SPP 6.05 Rev. 3 Controlled Documents			
7 ACTIVITY EVALUATED Document Control							
8 ITEM NO.	9 CHARACTERISTICS TO BE EVALUATED			10 REMARKS		11 RESULTS	
1.	Verify, through review of master document control list or similar document, that distribution of controlled document is adequate. Verify that manual holders receive and acknowledge revised procedures. a) review the status and distribution of the EM-QAPD, which has not been revised to comply with DOE/RW/0333P b) Review the control and distribution of SPPs c) Review the change control process d) Review the process for transmitting final records from PDC to BDM						
2.	a) Review the status of the EM WAPs EM categorized the WAPs as a Specification and RW categorized the WAPs as a guidance document. b) Review Memorandum of Agreement between EM & RW regarding WAPs c) Verify that the interface between EM & RW is clearly defined. d) Review MOA dated 10/30/91 regarding SPP 1.02						

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SHEET 2 OF 3
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3.	Determine the status of the process for qualification of input data for WQRs. This has been identified as an observation in HQ-SR-91-11 and TRG meetings. (Observation HQ-SR-91-11) A. Savannah River B. West Valley		
4.	Review activities by EM-343 as a result of the observations regarding Technical Reviews and approval of WQRs. (HQ-SR-91-11) A. Audits B. Surv. C. Meetings D. Tech. review		

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SHEET 3 OF 3
AUDIT/SURVEILLANCE
NO. HQ-SR-94-03

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5.	Review the TRG membership list and verify that a QA representative is appointed. Review any recent changes to the membership for selection process and assignment. (Recommendation HQ-93-02) A. Attendance at meetings B. Comments provided including resolution		
6.	Review the response and rationale for the recommendation to conducting a formal SPP 4.15 technical review of the EM WAPs. (Recommendation HQ-93-02)		

ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM
HQ-91-03	02	REC	EM-343	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 procedure 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)"
HQ-91-03	02	REC	EM-343	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.
HQ-93-02	02	REC	EM-343	Expedite the issuance of the 1993 Program Execution Guidance (PEG) Document to Replace the memo concerning the QA requirements for the FY93 PEG, issued December 21, 1992 by Ralph E. Erickson.
HQ-93-02	02	REC	EM-343	Add to DOE/EM/WO/02, Section 1.0, Fig. 1.1, Organization Chart, a footnote clarifying that the depicted reporting relationship between the DWPD and EM-343 is for Waste Acceptance Process activities only.
HQ-93-02	02	REC	EM-343	A FY92 Management Assessment was not conducted due to the major changes made to the EM-343 QA Program. Since the intent of a management assessment is to provide information to management for program improvement, EM-343 should perform a management assessment as early in FY93 as is practical.
HQ-93-02	02	REC	EM-343	Include RW-3 on distribution for the Quarterly Vitrification Project Division Quarterly QA Programs and Status Report.

5/7/94

ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM
HQ-93-02	02	REC	EM-343	EM-343 should consistently use the field office monthly progress status reports as an input to the Evaluation and Assessment Plan and Schedules.
HQ-93-02	02	REC	EM-343	EM-343 has initiated a revision to Evaluation and Assessment (E&A) Schedule format. This revision should indicate completed verifications as well as slippage and deletions.
HQ-SR-91-14	02	CON	EM-343	<p>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:</p> <p>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.</p> <p>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.</p>

ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM
HQ-SR-91-16	02	OBS	EM-343	<p>TRAINING CONCERNS</p> <p>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 procedure 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 member 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.</p>
HQ-SR-91-11	03	OBS	EM-343	<p>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 audits. Once procurement documents are revised and material traceability is established, manufacturing will resume. The surveillance team recommends that manufacturing not resume until:</p> <ul style="list-style-type: none"> a) <u>Approvals</u> 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) <u>Readiness Review</u> EM-343 should conduct a readiness review prior to allowing the resumption of canister manufacturing. c) <u>Unqualified Data</u> 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.

ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM																											
HQ-SR-91-11	04	OBS	EM-343	<p>DATA IN WASTE FORM QUALIFICATION REPORTS (WQRs)</p> <p>Work is moving forward in Savannah River and West Valley based on unapproved <i>Waste Form Compliance Plans</i>. Additionally, preparation of the Waste Form Compliance Plans themselves were initiated based on unapproved QA programs. Finally, none of the following <i>WQR Packages</i>, issued for ME-343 review, have been approved by EM-343:</p> <table><tr><th><u>Project</u></th><th><u>WQR Package</u></th><th><u>EM-343 Review Status</u></th></tr><tr><td>Savannah River</td><td>1</td><td>Review completed 12/18/89</td></tr><tr><td>" "</td><td>2</td><td>Review completed 10/26/89</td></tr><tr><td>" "</td><td>3</td><td>Review in progress</td></tr><tr><td>" "</td><td>4</td><td>Review completed 12/21/90</td></tr><tr><td>West Valley</td><td>1</td><td>Review completed 08/20/90</td></tr><tr><td>" "</td><td>2</td><td>Review in progress</td></tr><tr><td>" "</td><td>3</td><td>Review in progress</td></tr><tr><td>" "</td><td>4</td><td>Review completed 08/20/90</td></tr></table> <p>For the most part, the above <i>WQR Packages</i> were developed while working to an unapproved QA Program and unapproved <i>Waste Form Compliance Plan</i>. Thus, <i>WQRs</i> contain unqualified data. Nothing in the <i>WQRs</i> 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, at present, there is no budget for qualifying unqualified data. Specific recommendations are as follows:</p> <p>a) <u>Rules</u> 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 <i>QAPD</i> should state, at what point in the waste acceptance process, unqualified data must be qualified. Waste forms cannot be qualified using unqualified data.</p>	<u>Project</u>	<u>WQR Package</u>	<u>EM-343 Review Status</u>	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
<u>Project</u>	<u>WQR Package</u>	<u>EM-343 Review Status</u>																													
Savannah River	1	Review completed 12/18/89																													
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" "	4	Review completed 12/21/90																													
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ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM
HQ-SR-91-11	04	OBS	EM-343	<p>b) <u>Technical Reviews</u> 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.</p> <p>c) <u>Approvals</u> If and when EM-343 approves the above <i>WQRs</i>, 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.</p>

ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM
HQ-SR-91-11	04	OBS	EM-343	<p>TECHNICAL REVIEW PROCEDURES</p> <p>The surveillance team is concerned that EM-343's two principal technical review procedures may be inadequate. These two procedures are SPP 4.06, <i>Conduct of Technical Reviews</i>, and 4.11, <i>Review of Waste Acceptance Process Technical Documents</i>. SPP 4.06 is supported by a closely related procedure, SPP 4.05, <i>Administration of Technical Reviews</i>.</p> <p>SPP 4.11 is being used to review project office SARs (<i>Safety Analysis Reports</i>). 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.</p> <p>Specific concerns are as follows:</p> <p>a) <u>Applicability</u> 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.</p> <p>b) <u>Background Information</u> 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.</p> <p>c) <u>Review Criteria</u> 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</p>

ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM
HQ-SR-91-11	04	OBS	EM-343	<p>TECHNICAL REVIEW PROCEDURES (continued)</p> <p>c) 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.</p> <p>d) <u>Review Teams</u> Page 8 of SPP 4.05 lists the composition of a group of five course members on review teams, called the <i>TRG (Technical Review Group)</i> 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."</p> <p>To date, the TRG Chairman has been an off-site contractor and the Review Coordinator and EM-343 project manager. The review of the Savannah River WCP had a core group of four versus five members. Their expertise was in was 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.</p>
HQ-91-03	06	REC	EM-343	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.
HQ-93-02	06	REC	EM-343	Consideration should be given to providing QA representation on the TRG.
HQ-93-02	06	REC	EM-343	Since it represents the highest level technical baseline document within the EM-343 document hierarchy, consideration should be given to conducting a formal SPP 4.15 technical review of the draft EM WAPS.

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HQ-93-02	06	REC	EM-343	There appears to be some minor problems or confusion with document distribution lists, assignment of manuals, and receipt acknowledgements. This should be resolved when BDM/SAIC completes the processing of final records transmitted to them by PDC. It is recommended that a follow-up surveillance be conducted to address these concerns.
HQ-SR-93-01	06	REC	EM-343	The status of the EM WAPS should be resolved. The surveillance team recommends that the Memorandum of Agreement (MOA) between EM-343 and RW, which is currently in draft form, be used to resolve this issue.
HQ-91-03	16	REC	EM-343	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.
HQ-91-03	16	REC	EM-343	The procedures for corrective action, including the Deviation and Corrective Action Report (DCAR), quality improvements, an trending systems should be evaluated for unnecessary overlap of system function and definition of applicability. Consolidation of procedures with significant overlap is recommended.
HQ-91-03	16	REC	EM-343	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 mad to obtain responses from Savanna River, but the audit team also recognizes that the responsibility rests with EM-343 for timeliness and for adequacy of responses.

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OBSERVATION 93EA-SR-AU-01	16	OBS	EM-343	<p>During both EM Audits 93EA-WV-AU-01 and 93EA-SR-AU-01, the decision of DCAR versus Observation was based solely on a consensus between the Auditor, ATL, and Audit Manager rather than upon procedural requirements. When challenged, the Observers were told that this practice was based upon past precedence and that there would be no further discussion.</p> <p>As reported in OCRWM observer reports of previous EM-343 audits, violations of QA Program requirements are not consistently documented on Deviation and Corrective Action Reports (DCARs) as required by Vitrification Projects Division, EM-343, implementing procedures. Specifically, Standard Practice Procedure (SPP) 4.02, <i>Administration and Conduct of Quality Assurance Audits</i>, Rev. 3, Paragraph 4.c(4) requires that audit team members record adverse findings on a DCAR in accordance with SPP 5.01, <i>Deviations and Corrective Actions</i>. In addition, SPP 5.01, Paragraph 3.a, states in part "...A DCAR shall be initiated to define a deviation and to request corrective action by the responsible organization. The DCAR form is utilized to document the entire process of finding and correcting a deviation....Deviations identified during an audit require corrective action and action to prevent recurrence." SPP 5.01 goes on to define a "Deviation" as a Condition Adverse to Quality that is a departure from specified requirements. A "DCAR" is defined as a report to document and track deviations and corrective actions. (See OBS Report for examples, Sect. 5.4).</p>
HQ-91-03	17	REC	EM-343	<p>The audit team was informed that 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:</p> <ul style="list-style-type: none"> • 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. <p>The audit team recognizes that EM is now in the process of completing the working files.</p>
HQ-93-02	17	DCR	EM-343	<p>During the audit, missing qualification records for several ORR team members were located and placed in appropriate QA records packages.</p>

ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM
HQ-SR-91-11	17	OBS	EM-343	<p>RECORDS SYSTEM</p> <p>The surveillance team is concerned that EM-343's reliance on off-site contractors to conduct technical reviews, perform audits and surveillances of these review, 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.</p> <p>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.</p>

ACTIVITY NO.	CRIT.	TYPE	PARTICIPANT	DESCRIPTION OF PROBLEM
HQ-SR-91-16	17	OBS	EM-343	<p>TEMPORARY/DUAL STORAGE</p> <p>The surveillance team is concerned that EM-343 has misinterpreted DOE/RW-0214 QARD requirements (ASME NQA-1, Supplement 17S-1, Par 4) for <i>temporary storage</i> and <i>dual storage</i> of records.</p> <p>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:</p> <p><i>...quality records are accumulated within the HLW Program in a way which meets the requirement 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...</i></p> <p>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.</p> <p>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 requirement for records storage if records are in temporary storage.</p> <p>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</p>

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HQ-SR-91-16	17	OBS	EM-343	<p>LACK OF COORDINATION/CENTRALIZATION</p> <p>EM-343 record activities are currently been 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 not 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.</p>
HQ-SR-91-16	17	OBS	EM-343	<p>TURNOVER OF RECORDS TO RW OR A LOCAL RECORDS CENTER</p> <p>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 not 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, <i>Records Management Policies and Requirements</i>.</p>
HQ-SR-91-16	17	OBS	EM-343	<p>LACK OF CONTROL OF DUAL STORAGE</p> <p>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 through 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 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.</p>

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HQ-SR-93-01	17	REC	EM-343	SPP 7.01, <i>Preparation, Transfer, and Receipt of Quality Records</i> should include requirements to file records in a logical sequence and to number each page of the record. This recommendation is based on SPP 7.01, paragraph 4.a(3) which identifies the responsibility of the Quality Assurance Specialist to "ensure that documents arecomplete and identifiable to the item or activity".
HQ-91-03	18	REC	EM-343	The qualifications of two technical specialists used on audit 91-EA-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.